



# Text Book of Public Health and Community Medicine



*Chief Editor: RajVir Bhalwar*

*Editors: Rajesh Vaidya, Rina Tilak, Rajul Gupta, Renuka Kunte*

Published by  
**Department of Community Medicine**  
Armed Forces Medical College, Pune

In Collaboration with  
**World Health Organization**  
India Office, New Delhi



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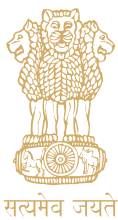


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महानिदेशक सशस्त्र चिकित्सा सेवा एवं वरिष्ठ कर्नल कमान्डेन्ट

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## FOREWORD

The need for a comprehensive textbook covering the vast and closely related subjects of Public Health and Community Medicine in the Indian context has been felt by all concerned in the medical field in India. The health scenario in our country is rapidly changing, both in terms of the public health challenges that we face as well as our response to these challenges. As India becomes more and more developed and we have greater means at our disposal, our response to our health challenges must reflect our changing health and socio-economic status. It is, indeed, time for a quality textbook to clearly bring before our scientists and health practitioners, the actual health situation in our country and guide their responses to these challenges.

It gives me immense pleasure to learn that the Department of Community Medicine, Armed Forces Medical College, Pune has endeavored to author a textbook on 'Public Health & Community Medicine' to encompass the rapid changes in the field of Public Health and Community Medicine, while preserving the basic contents of the subject, for the benefit of medical students and the practitioners of public health.

The book is comprehensive and complete in its content and aims to reflect the current medical knowledge on the topics presented. A unique feature of this book is that several new chapters have been included which would be difficult to find in any standard textbook at one place. Besides, all chapters have been provided with summary and relevant questions to make learning more comprehensive. All chapters in the book have detailed references and suggested readings which will guide readers towards further reading, thereby making it an ideal resource book for students undergoing training in the speciality of Community Medicine / Public Health, including those preparing for entry into these specialities.

This textbook will indeed occupy a niche in the shelves of library of graduate and post-graduate medical students, practitioners of public health, as well as various Institutes of Public Health and Community Medicine in our country. I implore all to ensure that this book is updated at regular intervals.

I acknowledge and appreciate the perseverance and dedication shown by the team of Authors and Editors led by Col RajVir Bhalwar, Professor & Head and the faculty at the Department of Community Medicine, Armed Forces Medical College. I congratulate them all for this commendable effort and wish them all success.

New Delhi

  
(Yogendra Singh)  
Lieutenant General







### MESSAGE

Today, public health is poised at a critical juncture in terms of its further development in India. There exists a need to review the current medical education curricula and provide a meaningful public health orientation. Public health training requires to be re-gearred to address the needs of the community. There is a need to broaden the concept of public health to include community-focused health services. While institutional care is necessary, community public health problems cannot be addressed only by health care facilities. An important challenge today, is to link institutional service delivery with national public health programmes and community-oriented services.

Concurrently, globally, there is a widespread recognition of the complex social determinants of health. Influences on human health have acquired a global dimension. In face of rapid global ization, emerging global health threats, and environmental challenges, greater integration of public health with other disciplines is needed. Multi-sectoral actions and multi-disciplinary approaches are required to achieve public health goals.

Public health is a diverse and growing field of study in India. While education in public health is vital, there needs to be equal emphasis on public health practice, with a clear vision of reaching the un-reached. In this context, the preparation of this document titled 'Textbook of Public Health and Community Medicine' is an important input to the field of public health in India. This document is a timely and valuable resource for public health practitioners, experts, and programme managers. We hope that the textbook would provide major inputs to students pursuing studies in public health.

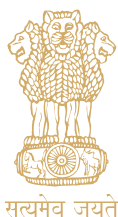
The WHO is pleased to support this commendable initiative undertaken by the Armed Forces Medical College (AFMC), Pune. It is hoped that this comprehensive work would contribute towards further development of public health education and practice in India.

A handwritten signature in blue ink, appearing to read 'Habayeb'.

Dr S. J. Habayeb  
WHO Representative to India







*Brig Raj Vir Bhalwar*

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### From The Chief Editor's Desk

There is widespread recognition of the fact that the health status of the population at large in our country leaves much to be desired, despite having a well-developed administrative system, good technical skills in many fields, and an extensive network of public health institutions for research, training, and diagnostics. The acceptance of this yawning gap between our capabilities and the actual reality of the health situation in India has focused the attention of governmental and non – governmental bodies on the twin disciplines of Community Medicine and Public Health.


As a consequence, Community Medicine and Public health are expanding rapidly in India. After relative inactivity for several years, they have now moved to the centre stage of health related activities. The emergence of new infections like HIV/ AIDS, re-emergence of a number of infections like pandemic influenza and dengue fever, and enormous increases in lifestyle related diseases in India have refocused the limelight on preventive rather than curative medicine. A number of large scale government initiatives like the National Rural Health Mission are a direct offshoot of the inequities in health care delivery.

This increased attention on public health in the country has brought out the stark reality of a massive shortage of public health professionals in the country. Running the Public Health agenda of our country needs not only medical doctors, but professionals from diverse fields, particularly various Biomedical disciplines, management and finance. Public health professionals try to prevent problems from happening or re-occurring through implementing educational programs, developing policies, administering services, and conducting research. It is also a field that is concerned with limiting health disparities and a large part of public health is the fight for health care equity, quality, and accessibility. Overall, Community Medicine and Public Health are concerned with protecting the health of entire populations. These populations can be as small as a village, or as large as an entire country.

To fulfill the enormous demand for health professionals in the field of Community Medicine, in addition to the academic departments of Community Medicine / PSM in various medical colleges, a number of public health schools have opened across the country with several more in the pipeline. These schools offer degrees of varying names and with varied course content. Most of these courses including several Masters of Public Health (MPH) courses are still not recognized by any statutory academic body. The curriculum of these courses is not standardized. There is no prescribed course book for these courses. Most of these schools of public health accept medical as well as non-medical personnel as students. Different schools have courses of different durations (One / two years) and appear to follow varied syllabi.

The currently available textbooks in our country, on undergraduate (or even postgraduate) teaching in public health and preventive medicine are aimed only at medical professionals. Against this backdrop, this textbook has been developed with a view to address a wide variety of target audience. The selection of topics covered, the depth and extent of coverage, and the structure of the book have been designed for three categories of users. This book should, firstly, fulfill the needs of undergraduate and postgraduate students of Community Medicine. Secondly, it should be able to be used by students undergoing MPH courses, whether they are medical doctors or non medical professionals. Thirdly, this book should be able to provide guidance to both medical and non medical professionals who are active in the field of public health in India. The book is also intended to be prescribed reading for training courses. Towards this end, each chapter has been provided with a summary, self assessment Multiple Choice Questions (MCQs) and short and long questions.

Any effort can be improved upon. This first edition of the book will, without doubt, have errors and shortcomings. We intend to improve the book as it evolves over the years. Feedback from the readers is the most important instrument for improvement and we earnestly solicit it from all our readers.

  
(Brig RajVir Bhalwar)



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# 1

## **Introduction and General Concepts in Public Health, Community Medicine & Preventive Medicine**





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The last two decades of the 20<sup>th</sup> century saw a renewal of the world population's interest in public health, in disease prevention, communicable and chronic disease control, health protection and health promotion. Not that public health is a new concept; great public health movements had already started in mid-nineteenth century by Edwin Chadwick in UK (report on an inquiry into the sanitary conditions of the labouring population in great Britain, 1842) and around the same time in USA in 1850 by Lemuel Shattuck (Report of the sanitary commission of Massachusetts) (1,2). These two reports initiated that brilliant movement - now known as public health, of which preventive medicine is an essential component and which has been responsible for saving billions of human lives and reducing human suffering during the last 100 years. The recent increasing interest in public health shown by nearly all governments, whether from developed or developing countries has been, therefore, due to the realization of the fact that continued investment in clinical care brings diminishing returns, while the gains can be maximized by resorting to methods of health promotion and disease prevention among populations at large.

The handicap that public health and preventive medicine always face is that its predominant focus on prevention makes it more abstract than curative medicine and its achievements are therefore more difficult to recognize. The doctor who cures a patient has achieved a real, recognizable benefit and the patient, as well as her near ones and even the community members, are all grateful. On the other hand, public health cannot point to the people who have been spared of illness by its efforts. As the famous quote goes "---- If we had but the gift of second sight to transmute abstract figures into flesh and blood, so that as we walk along the street, we could say, "that man would have been dead of typhoid fever", "that woman would have succumbed to anaemia of pregnancy", "that rosy infant would have been in its coffin because of diarrhoea and dehydration", -then only would we have a faint conception of the silent victories of public health-----". In fact, it is this "silence" that accounts, in large part, for the lack of attention paid to public health by those who are in a position to mobilize community opinion or take public decisions. In developing countries not even one percent of the total national budget is spent on public health; the situation, even in the developed countries is no better. For example, even in USA, just about 1% of the nation's total health spendings go towards public health. In 1992, when the average cost of medical treatment was \$3,007 for each American, the amount spent on public health was only \$ 34 per person (3) !

Despite the above-mentioned difficulties that public health including preventive medicine, as a concept and as a science, is faced with, it has undoubtedly been a major force in furthering the cause of human health and development. Indeed, during

the 20<sup>th</sup> century, many times more lives have been saved and diseases prevented by simple public health measures as safe water supply, sanitary excreta disposal, vaccination and insect-vector-control measures, than would have been saved by all the dazzling advancements of curatives and diagnostics put together! For instance, as per a report, the life expectancy in USA increased from 45 years in beginning of 20<sup>th</sup> century to over 75 years in the next 100 years and only 5 out of these 30 years increase can be attributed to the work of curative medical care system, while the large majority of this gain has come from improvements in public health, broadly defined to include better housing, nutrition, sanitation, immunization and occupational safety (4).

## Definitions & Basic Concepts

At the outset it would be worth-while to review the meanings of some terms in common use in the disciplines of public health, preventive medicine & community medicine. In fact, meanings change with time. Terms which have been long in use acquire extended meanings (a case in point is the term "Preventive Medicine" itself), while new terms are coined to signal a new emphasis. The meanings of some terms may overlap and different shades of meanings may be associated with use of the same term. In fact, Public Health, Preventive Medicine and Community Medicine contain very overlapping ideas as would be evident throughout this book; accordingly, their definitions are quite likely to overlap.

### Health

There are many views as to what constitutes "health". One view puts it as "absence of disease", i.e. there are no impediments to an individual's functioning or survival. This view is reflected by Oxford English Dictionary (5) which defines health as the state of being free from illness or injury. Implicit in this view is a set of abilities that favours growth and development and the efficient performance of bodily function in the face of changing environmental conditions, a capability known as "adaptability". As a corollary, disease corresponds to failures or disturbances in growth, development, function and adjustments of the organism, as a whole or any of its systems (6).

The problem inherent in the "absence of disease" definition is that it focuses only on disease. However, there is, in every disease, a long phase of transition from actual health to the overt disease process, as will be appreciated when one goes through the chapter on "natural history of disease and levels of prevention" in this book. Hence, health is something much more than the mere absence of disease.

The above ethos is echoed in the widely used definition of health by WHO, which states "Health is a state of complete physical, mental and social well being and not merely the absence of disease or infirmity (7). This definition is commonly seen as the statement of an "ideal" towards which nations should aspire, rather than as a practical working definition. For this reason, an "operational" definition of health, one drawn from the above "ideal" definition, has been forwarded, by a technical study group of WHO (8). According to this definition, the concept of health is viewed as being of two orders - first, in a broad sense, health can be seen as a condition or quality of the human organism in given conditions : genetic and

environmental. Secondly, in a narrow sense, more useful for working purposes, health means :

There is no obvious evidence of diseases and that the person is functioning “normally”, i.e. conforming within normal limits of variations to the standards of health criteria, generally accepted for one’s age, sex, community and geographic region and,

That various organs of the body are functioning adequately in themselves and in relation to one another, which implies a kind of equilibrium or homeostasis.

### **Medicine**

The noted medical historian Henry Sigerist (9) defined medicine as “Medicine, by providing health and preventing illness, endeavours to keep individuals adjusted to their environment as useful and contented members of society; or by restoring health and rehabilitating the former patient, it endeavours to readjust individuals to their environment.

It is clear from the above-mentioned, widely accepted definition, that “Medicine” as a discipline, has two clear components - firstly the “promotive and preventive” component, which is mainly the purview of preventive medicine; and the other, a “restorative and rehabilitative” component, which is the main purview of curative medicine. However, there is no such sacrosanct dividing line in practice, since very often, a clinician may also adopt ways and means of primary and secondary prevention, while a preventive medicine practitioner may very often focus on basic clinical care or rehabilitation. Finally, public health, as a discipline, keeps a focus on both the components, i.e. health promotive / preventive as well as restorative / rehabilitative, but distinguishes itself from curative or specific preventive medicine in two very special facets - that in public health, the focus is on the “Public” (i.e. a community or a population) and not on any individual and that the approach utilizes “organised community efforts”, as we shall appreciate a little later.

### **Preventive Medicine**

Preventive Medicine is that branch of medicine which deals with promoting health and preventing disease. The cardinal goal of preventive medicine is to avert the occurrence of disease. Achievement of this goal requires that actions be directed at the earliest stage of the natural history of disease, i.e. stage of susceptibility, using the methods of health promotion and specific protection; and to some extent, methods of secondary prevention by early detection of disease when it may be otherwise not detected using usual methods of diagnosis, often by screening followed by appropriate intervention. However, in a broader sense, preventive medicine refers to “limiting” the progression of disease at any stage of its course. Thus, when a clinician, using the approach of curative medicine, diagnosis and treats a patient of pulmonary tuberculosis, she is practicing preventive medicine too, since she is “preventing” the progress of the disease from the mild / uncomplicated phase to one of complications and more disability. Similarly, when we “treat” a patient of Colle’s fracture, by closed reduction and plaster cast, we are actually limiting the progress of a disease to a more severe form which would have complications like mal-union; thus we are practicing preventive medicine (preventing disability).

To understand as to what preventive medicine has come to represent as a movement within medical theory and practice, it is necessary to follow historically the application of the concept and its interaction with other movements. As said earlier, preventive medicine, in its modern form, is not the same as the older discipline of public health, although the principles and techniques of prevention are also widely applied by public health professionals. Initially, preventive medicine was identified with its most outstanding activity, i.e. contributing to the control of communicable diseases. In fact, in its early years, preventive medicine was equated with infectious disease control. Subsequently, by applying specific measures, as demonstrated by the continuing emergence of “Epidemiology” (one of the most important tools of preventive medicine & public health), the preventability of non-communicable diseases was demonstrated as well, with health education and counselling for behaviour change being added on to the armamentarium of preventive medicine.

### **Public Health**

The perspective of public health is captured in statements contained in the report on “Higher Education for Public Health” of the Milbank memorial commission (10). In public health, problems are named within the context of the community as a whole rather than occurring in a series of individuals. This view leads to the establishment of priorities and permits rational choices on the use of resources. From this view also comes a commitment that is communal rather than personal, one in favour of solving problems for the benefit of the health of the population as a whole. Over the years, the unique feature of public health has been acknowledged to be “Organized Community Effort” and “Systematic Social Action” and the classical definition of public health, which has stood the test of time, is the one forwarded by CEA Winslow (11) as :

“The science and art of preventing disease, prolonging life and promoting physical health and efficiency through organized community efforts for the sanitation of the environment, the control of community infections, the education of the individual in principles of personal hygiene, the organization of medical and nursing services for the early diagnosis and preventive treatment of diseases and the development of social machinery which will ensure to every individual, in the community, a standard of living adequate for maintenance of health”.

Thus public health is best identified as a social movement concerned with protecting and promoting the collective health of the community. This is its origin and this is its accomplishment. Thus, the province of public health is by no means limited to prevention. While mostly public health activities are funded and regulated by the Governments (National or State), the work of voluntary health agencies is also very much part of public health activities since they represent an organized community effort and systematic social action. In fact, even a small movement by a small village to purify their drinking water source or to stop alcohol drinking is also very much a public health activity. As has been very aptly stated by Mustard “A health problem becomes a public health responsibility if, or when, it is of such character or extent as to be amenable to solution only through systematized social action” (12).

## Preventive Medicine versus Public Health

The dividing line between preventive medicine and public health is actually a very thin, rather hazy one. Preventive medicine is an overall science, public health is an approach within this science. When preventive medicine starts focusing on population groups rather than individuals and utilises the approach of 'organised community efforts' it takes the shape of public health.

The other approach of using preventive medicine is the "individualized" preventive medicine, for instance, immunising an otherwise healthy child, or the "clinical" preventive medicine, which can be very effectively practiced in clinical settings; for example, a doctor who educates her ante-natal case about breast feeding or a doctor who takes a pap smear from her patients who are attending a family planning clinic is actually practicing individualized or clinical preventive medicine, but, may be, not public health. On the other hand when the government or even a Non Governmental Organization (NGO) working with community members in a village, organises a health education program in breast feeding for expectant mothers, or organises a cervical cancer screening camp, the approach becomes that of public health.

## Social Medicine

The concepts of social medicine were formulated by some very eminent physicians like Rudolph Virchow, Grotjahn and Rene Sand, besides others. The fact that man is a social animal, it is apparent that any effort at preventing or curing the disease or making an assessment of the health problems has to take social factors into account. This is, in essence, the concept of social medicine. Subsequently, the concepts of social medicine merged with preventive medicine, to form the specialty of preventive & social medicine (see later).

## Preventive & Social Medicine

Beginning from somewhere around the mid twentieth century, it was realized that the art and science of preventive disease and promoting health should be taught as an independent subject in the curricula of medical schools. Till then, most of the medical colleges were conducting such training for graduate level students under the subject nomenclature "Hygiene" usually as a part of General Medicine curriculum. It was also realized that every human disease has deep rooted social causes and not simply a result of an infectious agent. For example, everybody does not get infected with tubercle bacilli; and even out of those who get infected, only a small proportion develop the actual disease. Who gets the infection and who gets the disease is actually decided by a wide array of social factors as poverty, ignorance, overcrowding, malnutrition and so on. The considered decision was that preventive medicine should essentially combine the social aspects of health and disease in its theory, practice and teaching. This led to the birth of academic departments and the specialty of Preventive & Social Medicine (PSM) or Social & Preventive Medicine (SPM).

## Socialized Medicine

Socialized Medicine is different from Social Medicine. It refers to the policy of providing complete medical care, preventive and curative, to all members of a society (usually a nation) as

a governmental commitment and out of governmental (public) finances, as is the policy in Russia.

## Community Medicine

As a professional movement, Community medicine (or Community Health) is the most recent of the three fields to emerge in medical education and medical practice. As a discipline, it is defined as that branch of medicine, which addresses certain selected aspects of health promotion, disease prevention, health restoration (by curative steps) and rehabilitation of the former patients, in the community, usually, from an "Institutional Community Base" which is usually either an Academic Department in a medical college or through a curative centre. Community medicine, as an approach, has borrowed heavily from the concepts, methods and approaches of its two elder sisters, viz. public health and preventive medicine.

Community medicine is one pathway for representing an institution's commitment to improving health of its immediate (or adopted) community - generally a medical college, hospital or a clinical department serve as the base. The health task is to define the health problems, propose solutions, maintain surveillance, evaluate progress and monitor the use of resources. The approaches employed range from tools of epidemiology to the social skills, necessary for involvement with the community. Central to the approach of community medicine, whether in academia or in practice, is the promise that the main factors that determine a community's health are to be found within the community itself - in its social, cultural or biological features, or in its environment - natural and man made.

An understanding of the ways in which these factors interact to cause disease or promote health in different communities, is basic to the decisions to be made in the care and protection of the community (13). For these reasons, community medicine must be concerned with and relate to, the community behaviour and its environment and not solely restrict itself to the health services, which, very frequently, is otherwise the principal interest of the Institutional unit responsible.

As a professional movement, in USA, community medicine first appeared when some medical schools began to establish a new department (or rename an existing Dept of Preventive Medicine) and to charge it with functions of defining the health problems of a community (in the vicinity of the college, or an adopted community) and to suggest solutions, maintain surveillance and monitor progress. Many hospitals also established department of community medicine to bring together responsibility for the professional direction and coordination of a range of ambulatory programs in OPD and emergency, personal health, outreach satellite elements and other services. In UK, community medicine essentially includes Epidemiology and Medical Administration and has been seen as a successor to public health, providing information and advise on the health status and the services to the community and to the local Self Govt / community organizations, as well as performing other planning and management functions. Thus, in UK, the community medicine specialist is trained to function as Medical Officer of Health (MOH).



## Evolution of Contemporary Public Health

### From Shattuck and Chadwick in Mid-Nineteenth Century to Twenty-First Century (14, 15)

In the late nineteenth and early twentieth century, concern with control of epidemics was at the centre of medical and public attention. Measures for protection of the community through “environmental health” appeared first and with the establishment of effective sanitary services, the modern era of public health was born. Later, towards end of nineteenth century, microbiology expanded greatly and laid down new and scientific basis of infectious disease control. When it became clear that an “organized effort” to apply these sanitary and bacteriologic techniques was needed, the responsibility of governmental health departments, to control the communicable diseases, was given the status of law; and since treatment of infected individuals was also a part of control of infectious diseases, this also became a responsibility of public health. Later public health responsibility was further extended for organized maternal and child health services, thus extending public responsibility into the realm of personal care of individuals. As a result, organized “programs” for prevention (usually public funded but often by voluntary, non govt. organizations) became more visibly identified.

In the first half of the 20th century, personal preventive services in large numbers began to be publicly financed, while the personal curative services, for the most part, remained privately supported. As a result the personal health services became compartmentalized into two different medical practice settings - one largely preventive and the other largely curative. However, later on, as the concept of “comprehensive health care” came in, the traditional dichotomy between preventive and curative medicine became less and less differentiable.

One way of coping with the compartmentalization of activities into the two practice settings (preventive & curative) is to rationalize their inter-relationships. For example, the concept of prevention has been, in recent times, extended into curative settings in the form of “secondary prevention”, as one form of response to the rising frequency of chronic, non-communicable diseases and diseases of special groups (mothers, children, old people and industrial workers). Under this new strategy, clinicians are being urged to think more regularly about preventive management in diseases and to incorporate more of a preventive outlook in their daily practice. Similarly, public health physicians are being invited to move from their preoccupation with primary prevention, to undertake administrative involvement in health care systems. By doing so, they could relate to the total range of health care and take part in the planning, operation and evaluation of any or all of the health services. In fact, according to one of the contemporary views, “Medical Care Administration” has been advocated as a legitimate concern of public health authorities. While mostly public health activities are funded and regulated by the Govt. (National or State) the work of voluntary health agencies is also very much part of public health activities since they represent an organized community effort and systematic social action.

### Contemporary Views on the Definition, Role, Principles, Core Activities and Components of Public Health

**Definition :** The Definition of Public health, as enunciated by Winslow (11) and which has been presented earlier, though more than 80 years old now, has stood the test of time and is very well accepted among the public health fraternity as the most standard definition. Another definition given by the Institute of Medicine (USA) also echoes the same ethos : “Public Health is a mission for the fulfillment of society’s interest in assuring the conditions in which people can be healthy, through organised community efforts aimed at the prevention of disease and the promotion of health, using activities undertaken within the formal structure of government as well as the associated efforts of private and voluntary organizations and individuals” (16).

**Role of Public Health (16) :** As per international consensus, the role of public health is to contribute to the health of the public (community) through :

**Assessment of Health Status & Health Needs :** For making assessments of health status and health needs and to reach a “community diagnosis”, with the ultimate objective of formulating health policies and planning appropriate health services, public health specialists draw heavily from the “quantitative sciences” (Epidemiology, Research Methodology, Bio-statistics, Information Technology); from “Environmental Sciences”; from “Socio-Behavioural & Communication Sciences”; and, from “Bio-Medical Sciences”.

**Development of Health Policies :** For this purpose the public health specialist will need a good knowledge of Quantitative Sciences; Managerial Sciences; and of Socio-Behavioural & Communication Sciences.

**Assurance of the Availability and Quality of Health Services:** To fulfill this role, sound knowledge of Basic Clinical Skills, Managerial Sciences, Bio-Medical Sciences and Quantitative Sciences would be an essential requirement.

In fact, the present text-book has been organized addressing, in a section-wise manner, the various core-competencies as enlisted above. These major sciences required for the practice of public health can be grouped into five major core competency areas, viz. Quantitative Sciences, Environmental Sciences, Socio-Behavioural and Communication Sciences, Biological Sciences and Managerial Sciences. The details of these core areas are given in Table - 1.

**Core Principles Underlying Public health Practice:** Contemporary thinking indicates that the principles underpinning the concepts of public health are as follows and the public health specialist must develop the mental attitude to adopt these core principles in her activities (17) :

- The emphasis on collective responsibility for health.
- An envisaged major role of the state in protecting and promoting the public's health.
- A focus on whole populations and not on individuals.
- An emphasis on prevention, especially primary prevention, while not losing track of the importance of curative medicine also.



**Table - 1 : Core-Competency Areas in Public Health Training & Practice**

<b>(a) Quantitative and Analytical Sciences</b>	
<ul style="list-style-type: none"> <li>• General Epidemiology</li> <li>• Field Epidemiology, including outbreak investigations and public health surveillance systems</li> <li>• Bio-statistics including statistical software</li> <li>• Health Research Methodology</li> <li>• Database Management and other core issues of Information Technology</li> </ul>	
<b>(b) Environmental Sciences</b>	
<ul style="list-style-type: none"> <li>• Water and Food Safety</li> <li>• Sanitation and Disposal of Wastes</li> <li>• Environmental heat, cold &amp; altitude and related aspects of shelter &amp; clothing</li> <li>• Air, Soil and Noise Pollution</li> <li>• Nuclear &amp; Chemical Pollution</li> </ul>	
<b>(c) Socio-Behavioural &amp; Communication Sciences</b>	
<ul style="list-style-type: none"> <li>• Sociology in Health</li> <li>• Life Style &amp; diseases of the lifestyle</li> <li>• Health Education, Information, Education &amp; Communication (IEC)</li> </ul>	
<b>(d) Biological Sciences</b>	
<ul style="list-style-type: none"> <li>• Clinical Sciences (basic diagnostics and therapeutics for common and important health problems in the Community)</li> <li>• Microbiology &amp; Pathology</li> <li>• Infectious and Non-Communicable Diseases : Epidemiology, prevention and Control</li> <li>• Entomology</li> </ul>	
<b>(e) Managerial Sciences</b>	
<ul style="list-style-type: none"> <li>• General Principles of Management &amp; application in Health care</li> <li>• Health policies &amp; programmes, including policy / programme management</li> <li>• Legal issues in Health care</li> <li>• Health systems and Organization of health care delivery at various levels</li> <li>• Personnel, Financial and Equipment Management</li> <li>• Management of Hospitals &amp; other Health Care Facilities</li> <li>• Medical Care Administration at Primary, Secondary &amp; Tertiary level</li> <li>• Management of Health Care for Special Groups (Women, Children, Workers, old people, the “challenged” and the socio-economically disadvantaged)</li> <li>• Health Care Management during Disasters</li> </ul>	

- A concern for underlying socio-economic determinants of health and disease as well as more proximal determinants, such as health care.
- A multi-disciplinary basis; the readiness to work, in a team, with different and diverging disciplines concerned with human health and development.
- Attitude to incorporate qualitative and quantitative methods, as appropriate, in the area of work.

- Readiness to undertake partnership with populations being served.

**The “Dozen” Core Activities of Public Health** : In 1995, the US Health and Human Services department identified ten core activities of public health (18). In our national context, we can think of the “One Dozen” core activities of public health, as follows :

- 1) Protecting the environment, food and water.
- 2) Promoting healthy behaviour through information, education and communication.
- 3) Assessing needs, making community diagnosis and monitoring the health status of the population/ community being served.
- 4) Leading to the development of sound health policy and planning.
- 5) Health programme management and management of other medical & health care systems (health care system includes the triad of personal medical care, public health care and other inter-sectoral initiatives related to health).
- 6) Preventing and investigating epidemics and maintaining surveillance on important diseases, to provide early warning.
- 7) Promoting the health and efficiency of the “workers” and protecting the “work-environment”.
- 8) Effectively responding to disasters.
- 9) Mobilizing community action.
- 10) Research to develop new insights and innovative solutions for relevant community health problems.
- 11) Reaching out to link the health services with the high risk, disadvantaged and hard to reach people (socio-economically weaker sections, hilly, tribal and inaccessible areas), or those requiring special attention (women, children and old people).
- 12) Assuring the availability, accessibility, quality and accountability of medical care.

### **Bridging the Gap between Theory and Practice in Public Health and Community Medicine**

A very peculiar situation which all specialists in public health and community medicine realize after just a few years of practice, is the wide gap between “theory” and actual “practice” in this specialty. Such gaps occur in all other medical specialties too, but only to a limited extent - a patient of typhoid or one with ante-partum haemorrhage will show variations as regards clinical presentation and response to treatment when compared to what is written in the standard textbooks, but only to a limited, understandable extent. In public health practice, the practitioner is faced, everyday, with challenging situations, for addressing which she has to work out innovative solutions, which may not be at all described in her standard textbooks (in fact, that is why it is difficult to have a “standard textbook” in public health; one could only have guidelines!). The reason is that in community medicine and public health, we do not deal with a patient; we rather deal with human groups, who are apparently healthy (at least that is the way they feel themselves to be). Human groups or communities have their own attitudes and practices and their own diverse ways of assessing and responding to situations.

For the aforesaid reasons, the author would, based on own

experience and the shared experience with colleagues, like to narrate, certain “rules of the game”, which are otherwise not formally written down in any textbook. It is felt that putting these guiding principles into day to day practice may help bridging the gap between theory and practice, thereby deriving more satisfaction out of our specialty work. A dozen of such guiding principles are as follows :

**1. Learn how to take insults, be tenacious** : Remember that public health / community medicine with its focus on prevention, is more abstract than curative medicine and its achievements are therefore more difficult to recognize. The Doctor who cures such a person has achieved a real, recognizable benefit and the patient is grateful; public health cannot point to the people who have been spared illness by its efforts. Public health and preventive medicine lead to silent, unrecognized victories. This “silence” accounts in large parts, for the relative lack of attention paid to public health by decision makers and the general public (in comparison to the attention paid to medical care).

So, remember, that while Public health may not be as glamorous a specialty as Cardiac Surgery or Imaging, it has tremendous potential to improve the quality of life of innumerable human beings - to give you a proof, the major improvements in health and quality of human life during the last one century have actually come from clean food and water, sanitary housing and immunization rather than all the other “glamorous” medical specialties put together. Despite this, preventive medicine and public health is often at the receiving end of insults as “Sewer drain doctors” “insect catchers” or “people who could never make it to the clinical world”. You have to learn how to bear with such humiliations, but do not lose heart - be tenacious, keep moving forward - you have indeed selected the most humane specialty.

**2. Stick to the facts - preferably based on quantitative evidence** : Public health, with its very important tools of epidemiology and statistics, is an evidence based specialty and is dependant on collecting, analyzing and interpreting the data in a valid manner and making use of good quantitative and qualitative evidence. Good public health practitioners should collect good knowledge about topics they are dealing with, whether it is the incidence of ARI among children in their area of jurisdiction or it is concerning the amount of risk that tobacco carries for IHD. Good amount of reading into latest journals, reports or text books and discussion with experts is a must for public health practitioners.

**3. Develop the art of communicating** : Remember that unless “data” are turned into “stories” which are understood by all, people would not show concern for your reasoning. Having command on communication skills, both verbal and written, is an art which is a compulsory requirement for public health practitioners and this art should be developed very diligently and methodically.

**4. Walk well and talk well** : A successful public health specialist is one who changes shoes every month or two, since constant walking, seeing for herself and making assessments of environment and the community’s conditions, tears off the shoe - sole very fast. This is the typical shoe - leather epidemiology. So keep moving in your area, talk to the community members

about their health problems and make assessment of their behaviours, beliefs, lifestyle and the environment they live in.

**5. Develop “Multi - Disciplinary Team” approach** : Always remember that in public health, you have to build an effective team, comprising of people from various disciplines - Statisticians, Clinicians, Social Scientists, Entomologists, Pathologists, Civil Engineers, Management experts, Administrators, Politicians and so on. No public health specialist can be successful by working in isolation. Learn how to form an effective team; have respect for others, listen to their advice and take decisions in consultation with them after logical reasoning and not by arguing or bulldozing. In fact, be proactive in seeking out allies from these various specialties / walks of life.

**6. Always prepare very well before you meet people** : Whenever you go to attend a conference, be it of administrators and specialists from allied specialties, or else a focus group discussion with school - teachers, make sure to always read the agenda and its details very well. Apply your thought to the issues under discussion, think what do you want to achieve and how you will be best placed to do so, with those present.

**7. Focus on “long term” but take action on “short term” also** : The objectives of public health (whether through an immunization program or purification of community water supply, etc.) are achieved over the longer time period of decades or generations. However, Governments are generally reluctant to think further ahead of the 5 year term of parliament / assembly. They would, naturally, like to demonstrate some results within the limited span of a couple of years. Hence, in public health practice, while gaining support for achieving the long term goals should be definitely an objective, it is equally essential to have some very readily identifiable strategies to demonstrate progress towards these long term goals, in a shorter period of time - the so called strategy of “Early Victories”.

**8. Understand the “Politics”** : Very often we find public health specialists talking about ways of influencing “Policy Makers”. This means getting to know your chief administrative boss (and other influential people) and how he or she works. When you are, as a public health management manager, confronted to a one of senior politicians or bureaucrat, the first things you should do is to set to know what makes him or her “tick” and do things in a way that merges with his / her line of thinking.

Public health specialists should also keep themselves well aware of the “political climate” - not only international and national but, also the “local” politics and even the political climate in their own office. It is essential, in public health, to have good political antennae. Moreover, in any organization or office, it is essential to understand as to who wields the power - this may not only be the chief executive, but may be some lower level staff officer also. It is also very paying to have good relationships with colleagues.

**9. Don’t take on too much** : Failure to deliver is one of the biggest potential risks for public health and you should remember that one important reason for landing in this pitfall is when you take on too many jobs, well beyond your capabilities. You should learn how to say “No” to tasks which you feel are getting on too much; or else, if it is something that has to be done, then decide what is going to be dropped off your agenda.

Next, once you take on a job, then keep track of its progress.

**10. Develop Your Staff :** A clinician may still do well without improving his staff and without delegating; conversely, in public health practice you must constantly endeavour to develop your staff and subordinates as regards their technical and managerial competence. Secondly, analyze their capabilities and learn how to delegate responsibilities / tasks to your subordinates. If you try to do everything yourself, in public health practice, you will get bogged down and become inefficient pretty soon.

**11. Always Know of Specialists who can do the Jobs :** The wide activity of public health inevitably means that you will not be able to retain all the necessary skills at any one time, though you may have been trained to some extent in all these disciplines (as entomology, epidemiology, statistics, database management, etc.). Therefore, maintaining networks with others who have the skills & expertise in that area, is vital.

**12. Always Be There :** Though stated in the last, this twelfth golden principle is one of the most important. Remember that the world is run by people who are physically there at the place of action; the first rule of politics is to “be there”. It is surprising how scant attention is paid to this very simple dictum. So, for being a successful public health specialist, never miss a meeting, a workshop, any function, a sports meet or even any street play to which you have been invited.

And, finally, keep the highest regards for your specialty - it is the biggest asset you have in the changing fortunes of time; Keep perseverance and faith alive, for, despite all it's drudgery and sham, it is still a beautiful world -----.

## Summary

The last two decades of the 20<sup>th</sup> century saw a renewal of the world population's interest in public health, in disease prevention, communicable and chronic disease control, health protection and health promotion. The two reports in mid-nineteenth century by Edwin Chadwick in UK & Lemuel Shattuck in USA initiated the genesis of public health & preventive medicine. During the 20<sup>th</sup> century, many lives have been saved and diseases prevented by simple public health measures as safe water supply, sanitary excreta disposal, vaccination and insect-vector-control measures.

Widely used definition of health by WHO states that “Health is a state of complete physical, mental and social well being and not merely the absence of disease or infirmity. This definition is commonly seen as the statement of an “ideal” towards which nations should aspire. “Operational” definition of health, one drawn from the above “ideal” definition, has been forwarded, by a technical study group of WHO. This concept of health is viewed as being of two orders - first, in a broad sense, health can be seen as a condition or quality of the human organism in given conditions : Genetic and environmental. Secondly, in a narrow sense, more useful for working purposes which includes no obvious evidence of diseases and that the person is functioning “normally” & various organs of the body are functioning adequately in themselves and in relation to one another.

A widely accepted definition of medicine by Henry Sigerist defines medicine as “Medicine, by providing health and

preventing illness, endeavours to keep individuals adjusted to their environment as useful and contented members of society; or by restoring health and rehabilitating the former patient, it endeavours to readjust individuals to their environment”. Preventive Medicine is that branch of medicine which deals with promoting health and preventing disease. The cardinal goal of preventive medicine is to avert the occurrence of disease. The field of Epidemiology has emerged as one of the most important tools in preventive medicine & public health. CEA Winslow gave the most comprehensive & widely accepted definition for public health which states as “The science and art of preventing disease, prolonging life and promoting physical health and efficiency through organized community efforts for the sanitation of the environment, the control of community infections, the education of the individual in principles of personal hygiene, the organization of medical and nursing services for the early diagnosis and preventive treatment of diseases and the development of social machinery which will ensure to every individual, in the community, a standard of living adequate for maintenance of health”. The two unique feature of public health are acknowledged as “Organized Community Effort” and “Systematic Social Action”. Preventive Medicine is a branch of medicine which deals with promoting health and preventing disease. When preventive medicine starts focusing on population groups rather than individuals and utilises the approach of “organised community efforts” it takes the shape of public health. The integration of the social aspects of health and disease in theory, practice and teaching led to the birth of Preventive & Social Medicine (PSM) or Social & Preventive Medicine (SPM). Community Medicine is a branch of medicine, which addresses certain selected aspects of health promotion, disease prevention, health restoration (by curative steps) and rehabilitation of the former patients, in the community, usually, from an “Institutional Community Base” which is usually either an Academic Department in a medical college or through a curative centre.

Public health plays a very important role in contributing to the health of the public (community) through assessment of Health Status & Health Needs, development of Health Policies, assurance of the availability and quality of Health Services. Major sciences required for the practice of public health can be grouped into five major core competency areas, viz. Quantitative Sciences, Environmental Sciences, Socio-Behavioural and Communication Sciences, Biological Sciences and Managerial Sciences.

Core Activities of Public Health include protecting the environment, food and water, promoting healthy behaviour through IEC, assessing needs, making community diagnosis and monitoring the health status of the community being served, development of sound health policy and planning, health programme management and management of other medical & health care systems, preventing and investigating epidemics and maintaining surveillance on important diseases, to provide early warning, promoting the health and efficiency of the “workers” and protecting the “work-environment”, effectively responding to disasters, mobilizing community action, research to develop new insights and innovative solutions for relevant community health problems, reaching out to link the health services with the high risk, disadvantaged and hard to reach



people, or those requiring special attention, assuring the availability, accessibility, quality and accountability of medical care.

## Study Exercises

**Short Notes :** (1) Definition of health (2) Definition of public health (3) Community Medicine - definition and scope (4) Core activities of public health

### MCQs & Exercises

#### Fill in the Blanks

1. Movement - now known as public health were initiated in nineteenth century by ----- & ----- in their reports on sanitary conditions of the labouring population in Great Britain & sanitary commission of Massachusetts.
2. Health is a state of complete -----, ----- and ----- well being and not merely the absence of ----- or ----- . This was the definition given by -----.
3. "Operational" definition of health view's health as being ----- in broader sense & -----, ----- in narrower sense.
4. Two unique features of public health are ----- and -----.
5. When preventive medicine starts focusing on population groups rather than individuals and utilises the approach of ----- it takes the shape of-----.
6. ----- is the branch of medicine which deals with promoting health and preventing disease.

#### Match the Following

- |                    |   |
|--------------------|---|
| 1. CEA Winslow     | a. Sanitary commission of Massachusetts |
| 2. Henry Sigerist  | b. Social medicine                      |
| 3. Rudolph Virchow | c. Definition of Medicine               |
| 4. Grotjahn        | d. Definition of Public health          |
| 5. Lemuel Shattuck | e. Virchows triad                       |

#### Answers :

**Fill in the Blanks :** (1) Edwin Chadwick; Lemuel Shattuck (2) Physical; Mental ; Social; Disease; Infirmary; WHO

(3) Condition or quality of the human organism in given conditions : genetic and environmental; Within normal limits of variations to the standards of health criteria; various organs of the body in a state of equilibrium or homeostasis (4) Organized Community Effort; Systematic Social Action (5) Organised community efforts; Public health (6) Preventive Medicine.

**Match the Following :** 1-d; 2-c; 3-e; 4-b; 5-a.

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## 2

## History of Public Health

Leo S. Vaz

During the ancient Egyptian period developments such as toilets and bathing were introduced, but this was on a private level. While Egyptian religious beliefs encouraged washing the body, thereby improving the health of the population, this was not part of a public health programme. The Greeks encouraged

healthy living and pursued regimens of exercise and hygiene such as those prescribed by Hippocrates in his Regimen and Regimen in Acute Diseases (4th century BC). Patients visiting the temples of the god of healing, Aesculapius, were encouraged to take part in exercise, but the temples were, again, not part of a public health system. There was some development of public health by the Minoans, a Mediterranean civilization that flourished on Crete about 3000-1050 BC. The Minoans built baths and constructed channels to supply clean water and remove waste. However, these facilities were lost when the Minoan civilization collapsed and their palaces and towns

were destroyed by natural disasters and invading Greek forces. Aqueducts (bridges carrying water) were also constructed; one of the first great aqueducts was built in 691 BC to carry water for 80km to Ninevah, capital of the ancient Assyrian Empire. However, the scale of the public health system introduced by the Roman Empire from around 300 BC was without precedent in the Western world.

### **Ancient India and Public Health**

Ancient Indian thoughts, philosophy developed on concepts of spirituality. Ayurveda is the ancient science of life. It lays down the principles of management in health and disease and the code of conduct for the physician. Charaka has described the objective of medicine as two fold; preservation of good health and combating disease. Ayurveda emphasised the need for healthy lifestyle, including cleanliness and purity, good diet, proper behaviour and mental and physical discipline. Purity and cleanliness were to be observed in everything : jalasuddi (pure water), aharasuddi (clean food), dehasuddi (clean body), manasuddi (pure mind) and desasuddi (clean environment).

Ayurveda calls upon the physician to treat the patient as a whole: *'Dividho jayate vyadhih, Sariro manasasthatha, Parasparanz tavorjanma, Nirdvadvam nopalahhyate'*. Diseases occur both physically and mentally and even though each part might be dominant, they cannot be compartmentalized. Ayurveda treats man as a whole body, mind and what is beyond mind. The earliest protagonists of Indian Medicine, such as Atreya, Kashyapa, Bhela, Charaka and Susruta have based their writings on the foundations of spiritual philosophy and ethics. Charaka Samhita prescribes an elaborate code of conduct.

The ruins of ancient civilizations like Mohenjodaro and Harrappa show intricate water and sullage disposal systems. It can hence be assumed that sanitation played a major part in planning of these cities.

### **Greco-Roman Era**

This period focused on personal hygiene. Governmental public health practices were effected to augment the prevailing religious attitude. Medical care hospitals, staffed with public physicians and programs in environmental sanitation (water supply and sewage) were developed. These measures which placed a high priority on a clean mind and body were developed for the upper classes. The Romans were able to implement public health measures as they had an organized, centralized government and the money to pay for the work. Such a vast system of public health was unprecedented in history and made the Romans a much healthier people. The Romans did not know about bacteria and the true causes of disease, but they observed that swamps caused illness and that a lack of fresh water was damaging to health. By the end of the Roman Empire in AD 476, the Roman public health system was more advanced than any system of public health would be in Europe for the next 1,400 years or so.

### **Middle Ages**

This is considered as a period identified as an era of paganism, barbarism and anti-intellectualism. When Christianity became the official religion of the Roman Empire, the poor and afflicted were given status and recognition. Society was given an obligatory responsibility for care and treatment of the sick.

During the Middle Ages (5th-15th centuries) in Europe, public health systems collapsed and became virtually non-existent, particularly during the period known as the Dark Ages (around 500-1000 AD). The towns and cities of the Romans were often abandoned and the aqueducts, sewers and baths were allowed to fall into disrepair. Medieval governments and wealthy people in society no longer felt the responsibility or need to provide public health. Money was not spent on providing fresh, clean water or removing waste, but on more pressing concerns, such as the provision of armies and defences for the almost continuous wars that raged throughout the period. Various diseases (leprosy, consumption, typhoid fever and the black death) fatally affected approximately one-third of the population living in middle and southern Europe. In the Middle Ages, commerce and industry developed which were based on economic theory involving exchange of goods and services. Through the accumulation of wealth, individuals and nations became powerful. Because of such affluence, concern developed for labour as it related to productivity.

Streets were often used as dumping grounds for slaughterhouse waste or the contents of chamber pots from people's houses. Action was only taken during outbreaks of disease such as the Black Death, an epidemic of bubonic plague that swept across Europe in the mid-14th century, killing between one-third and half of the population. When the plague arrived in England in 1348, Edward III ordered the lord mayor of London to clean up the streets of the capital and keep animals and slaughterhouses out of the city. Public toilets were to be introduced and the dumping of waste in the streets was forbidden. The improvements continued until the end of the 14th century, but the measures were often poorly enforced and had little effect on the overcrowding and lack of cleanliness that was rife in the larger towns and cities. Few hospitals existed and doctors were far too expensive for the poor to consult, so ill health and disease were unchecked and spread rapidly.

### **18th-19th Centuries (Europe)**

This was the period of the industrial revolution and cholera epidemics. The industrial revolution brought about the need for increased manpower and massive use of labouring classes. The life expectancy rate based on social class was : gentry, 35 years; tradesmen, 22 years; and labourers, 15 years. Approximately one-half of the children of the working classes died before age of five.

William Farr, the keeper of abstracts at the Registrar General Office in 1836 was convinced that mortality increased with density of population. From 1839 William Farr collected statistics from parish registers on births and deaths. He was able to show the impact of poor living conditions on life expectancy and the differences between different areas. The Victorian middle class believed that the overcrowding resulted in immorality, drunkenness, crime, incest and destroyed the sanctity of homes. This resulted in moralistic theories being projected all over Britain & Europe as a cure of most evils including disease.

The poor engaged in agriculture went through a series of bad harvests at the end of the eighteenth century and by 1795 the farmers had fewer & fewer resources to pay their labourers. An allowance system was then started and administrated



through the Poor Law. A study of Poverty was carried out by two assistants of Central Poor Law Commission an economist and lawyer Nassau Senior and upwardly mobile lawyer Edwin Chadwick. They concluded that the allowance system was a threat to the free market economy. The Poor Law Amendment 1834 which Chadwick wrote deprived the paupers of his liberty and put them into workhouses.

The cholera Epidemic of 1832 highlighted the problem of disease. In 1837 Chadwick appointed doctors to investigate the London districts with high typhus mortality. The report highlighted the squalor of the inhabitants and the insanitary conditions. Chadwick compiled a survey of "Sanitary condition of labouring classes of great Britain" in 1842 in which he recommended the "Sanitary Idea" with creation of a public health authority to provide drainage, potable water, sanitation, regulation of buildings etc. He believed in the 'miasmatic' theory of disease origin where gaseous contamination of atmosphere due to putrefaction of organic matter was the cause of disease.

The first British Public health Act was passed in 1848 creating a General Board of health with Southwood Smith as its medical advisor and Chadwick its only salaried member. The city of London also had its own private Sewers Act 1848. Internal conflicts in the Metropolitan Sewers Commission resulted in removal of Chadwick in 1849.

A shift from "Sanitary idea" to medical managed took place when Chadwick was succeeded as Britain's chief health administrator by Dr John Simon. The new concept was of "State Medicine" He had been credited to having laid the foundation of subsequent British health policy. He followed a comprehensive approach to disease prevention and set up investigations into a wide range of issues from regulation of food contamination & drug adulteration to hygiene standards of environmental planning. Simon's most significant legislation was the Sanitary Act 1866. In 1856 Dr Henry Rumsey published a series of "Essays on state Medicine". He claimed that medical prevention would cover a broad range of causes of disease resulting in their elimination. In 1875 the Public Health Act was codified including all existing sanitary legislation. The prevailing social conditions in England resulted in an illustrative national survey, known as the Edwin Chadwick Report, which focused on the health of the labouring classes. The Chadwick Report affected sweeping reforms, such as the establishment of a National Board of Health, advances in environmental sanitation and hygiene, new legislation regulating factory management; child labour and welfare and care for the aged and mentally ill.

In 1864 the first contagious Disease Acts was passed which provided for compulsory examination of women believed to be "Common prostitutes" who were to be locked up for up to one year without right to habeas corpus if they were diagnosed to have sexually transmitted disease. The Act was approved by a large number of people including John Simon. The Act was repealed in 1886.

Free vaccination were made available through the Poor Law Medical Services in 1840. In 1853 vaccination was made compulsory for all children with the first year of life. In 1867 the new Vaccination Act imposed penalties on parents not vaccinating their children. A drive against compulsory

vaccination was started by John Gibbs which ultimately culminated in its modification in 1907.

### **Public Health in the United States**

In the 17th - 18th Centuries in Colonial America, life expectancy was less than in Central Europe. Towns and cities were generally unsanitary, contagious diseases were rampant and most physicians were self-designated and itinerant. In America the first colonist had found healthy land, clean water and fertile soil. However newer arrivals brought in scurvy, smallpox, cholera, measles, typhoid diphtheria and influenza. Small pox and measles contributed in large part to mortality. In the eighteenth century quarantine laws were passed in all major towns and pest-houses built for immigrants arriving on infected ships.

During the civil war a large number of soldiers died of Typhoid, Malaria, camp Diarrhoea and camp Measles. However, wherever the sanitary commission improved sanitary conditions, disease rates were found to be lower. Due to the industrial revolution cities grew and there was increase in number of disease. Due to a dedicated band of reformers, the Metropolitan Health Bill of 1866 was passed. In 1879 a large yellow fever epidemic swept Mississippi and New Orleans, resulting in the creation of the National Board of Health.

The Lemuel Shattuck Report encouraged social reform, including documentation of disease conditions and collection of vital statistics. Some pertinent recommendations of the Shattuck Report were establishment of sanitary inspection system, the collection and analysis of vital statistics, the promotion of health care, establishment of regulations to expose and eliminate quackery. Port cities such as Boston, Baltimore, New York and their respective states sought ordinances and legislation to reduce mortality, establish medical services for seamen and raise the professional status of physicians.

### **Sanitary Theory**

The theory of miasma, which said that disease is due to causes contained in bad air including the cosmic radiations, found much support during the 18<sup>th</sup> and 19<sup>th</sup> century. It made sense to the English Sanitary reformers of the mid-nineteenth century. Miasma explained why cholera and other diseases were epidemic in places where the water was un-drained and very foul-smelling. The theory led to improvements in the sanitation systems, which led to decreased episodes of cholera, which helped to support the theory. Even though the miasmatic theory has been dis-proven by the knowledge of viruses and bacteria, it made the connection between dirtiness and diseases. This caused public health reforms and encouraged cleanliness, even though some doctors still did not wash their hands between patients. They believed that the miasmata were only airborne and would not be stuck on the doctors' hands.

Chadwick has generally been considered to be the person who defined prevention of disease in "Sanitary" terms. However Edmund Parkes, the first British Professor of hygiene who was appointed to the Army Medical School at Netley believed that future of prevention lay in discovery of specific causes of individual diseases.

A shift in public health took place during the Edwardian period when individuals began to be categorized into "Risk

populations". These were on the basis of analysis of disease by Edmund Parkes. Soon thereafter came the germ theory which was based on the concept that specific microbes caused specific diseases. Developments in Bacteriology in 1880's were embraced by the preventive profession. A model was developed in which one agent was related to one disease (Robert Koch). This is discussed in subsequent chapters.

### Contemporary (19th and Early 20th Centuries) Public Health

During the 19th Century and the first half of the 20th century, the perception of public health was limited to prevention of communicable diseases through environmental sanitation. For example, a dramatic increase in industrialization in the late 19th century, coupled with urbanization, had profound effects on urban water supplies. There was pollution from human wastes from homes and the workplace disposed in the waterways. Effluents containing organic and inorganic toxic and non-toxic material were dumped into the same waterways. During this time medical theories were limited to bacteriological paradigms.

In 1898 when US sent troops into Cuba they lost 968 men in battle and 5438 due to infectious diseases. When yellow fever threatened troops in Cuba in 1900 an army commission under Walter Reed confirmed that the disease was transmitted by mosquito and eliminated the disease from Havana. The US Army in Philippines had to battle with malaria, dengue, dysentery and beriberi to continue to remain in the region.

The French attempt to build a canal across Panama was abandoned due to disease. The American attempt succeeded due to an intensive campaign against mosquitoes and hence reduction of yellow fever and malaria so as to prevent malaria in America troops. During World war II the Public Health service established the control of Malaria in war areas. After the war the organisation was converted into the Centres for Disease Control and Prevention.

In 1907 preventive medicine practitioners and town planners got together to bring about housing reforms. Simultaneously legislations were passed for free school meals, medical inspection of school children and antenatal care. These concerns were clubbed by society into "Endowment of motherhood" movement which included targeting of malnutrition and breaking habits of inefficient and unhygienic motherhood. A great emphasis was placed on health education. It was emphasised that infant morality was not a "Weeding Out" process of eugenic value as was earlier considered, but a preventable wastage of child life. Newsholm in 1910 introduced the concept of "Causal attack" upon disease after redefining the environment from a "Social Standpoint".

In Germany, Pettenkofer first calculated the financial returns on public health investments to prove the value of sanitary improvement in reducing death from typhoid.

Bacteriological analysis was used to determine the presence of coliform bacteria in municipal water supplies. Since coliform bacteria are present in great numbers in humans and animals but are not typical water organisms, their presence served as an indicator of fecal pollution and possible pathogenic organisms. Since industrial wastes did not contain these coliform

organisms, it was concluded that water sanitary hazards at industrial sites were generally remote with the exception of anthrax from tanneries and wool scouring facilities.

### Current Public Health

Classical infectious disease rates have declined while increased rates of so-called modern diseases (heart disease, cancer and immune deficiency diseases) are now being observed in epidemic proportions throughout the world. Classical public health organizations and systems are now in a state of flux because these structures were erected for classical communicable disease control. New problem-solving systems are needed in areas such as health care financing, medical care for the aged, environmental health protection and health care planning and administration.

### Founders of Modern Public Health, Community Medicine & Preventive Medicine

#### Edward Jenner (1749-1823)

Edward Jenner was born on May 17, 1749 in the small village in Gloucestershire. He had always been fascinated by the rural old wives tale that milkmaids could not get smallpox. He believed that there was a connection between the fact that milkmaids only got a weak version of smallpox - the non-life threatening cowpox - but did not get smallpox itself. Jenner decided to try out a theory he had developed. Jenner was given the opportunity on the 14 May 1796, when a young milkmaid called Sarah Nelmes came to see him with sores on her hands like blisters. He took some pus from cowpox blisters found on the hand of Sarah. She had milked a cow called Blossom and had developed the tell-tale blisters. Jenner 'injected' some of the pus into a young boy, James Phipps. This process he repeated over a number of days gradually increasing the amount of pus he put into the boy. He then deliberately injected Phipps with smallpox. James became ill but after a few days made a full recovery with no side effects. Jenner found a great deal of scepticism to his ideas and was subject to much ridicule. However, what he had discovered could not be denied and eventually his discovery had to be accepted - a discovery that was to eventually change the world. So successful was Jenner's discovery, that in 1840 the government of the day banned any other treatment for smallpox other than Jenner's. Jenner died in Berkeley on January 26, 1823 aged 74. The word vaccination comes from the Latin 'vacca' which means cow - in honour of the part played by Blossom and Sarah in Jenner's research. However, from the point of Jenner's demonstrations, it took the humanity almost two centuries to conquer small pox - In 1980, the World Health Organisation declared that smallpox was extinct throughout the world.

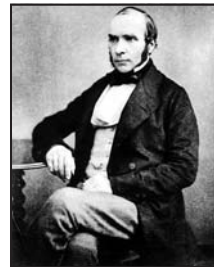


#### John Snow (1813 - 1858)

Snow was a British physician and also one of the founder fathers of the discipline of anaesthesiology, is also considered one of the founders of epidemiology for his work identifying the source of a cholera outbreak in 1854. He was born into a labourer's family on 15 March 1813 in York and at 14 was

apprenticed to a surgeon. At the time, it was assumed that cholera was airborne. However, Snow did not accept this 'miasma' (bad air) theory, arguing that in fact entered the body through the mouth.

He published his ideas in an essay 'On the Mode of Communication of Cholera' in 1849. A few years later, Snow was able to prove his theory in dramatic circumstances. In August 1854 a cholera outbreak occurred in Soho. It was common at the time to have a cesspit under most homes. Most families tried to have their raw sewage collected and dumped in the Thames to prevent their cesspit from filling faster than the sewage could decompose into



the soil. After careful investigation, including plotting cases of cholera on a map of the area, Snow was able to identify a water pump in Broad (now Broadwick) Street as the source of the disease. He had the handle of the pump removed and cases of cholera immediately began to diminish. Snow later used a spot map to illustrate how cases of cholera were centred around the pump. He showed that companies taking water from sewage-polluted sections of the Thames delivered water to homes with an increased incidence of cholera. Snow's study was a major event in the history of public health and can be regarded as the founding event of the science of epidemiology.

Snow was also a pioneer in the field of anaesthetics. In 1853 and 1857, he was responsible for giving chloroform to Queen Victoria at the birth of her son Leopold and daughter Beatrice. Snow died of a stroke on 16 June 1858.

### James Lind (1716 - 1794)

Lind was a Scottish doctor, a pioneer of naval hygiene and expert on the treatment of scurvy. James Lind was born in Edinburgh in 1716. In 1747, while serving as surgeon on HMS Salisbury, he carried out experiments to discover the cause of scurvy, the symptoms of which included loose teeth, bleeding gums and haemorrhages.

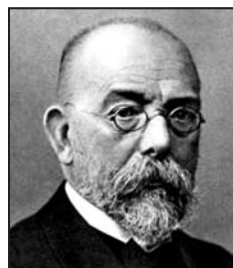


Lind selected 12 men from the ship, all suffering from scurvy and divided them into six pairs, giving each group different additions to their basic diet. Some were given cider, others seawater, others a mixture of garlic, mustard and horseradish. Another group of two were given spoonfuls of vinegar and the last two oranges and lemons. Those fed citrus fruits experienced a remarkable recovery. While there was nothing new about his discovery - the benefits of lime juice had been known for centuries - Lind had definitively established the superiority of citrus fruits above all other 'remedies'. In 1753, he published 'A Treatise of the Scurvy' and in 1757 'An Essay on the Most Effectual Means of Preserving the Health of Seamen in the Royal Navy', which threw much light on the appalling living conditions and diet of seamen. In 1763, Lind published work on typhus fever in ships and in the 1768 publication 'An Essay on Diseases Incidental to Europeans in Hot Climates' he summarised the prevalent diseases in each colony and gave advice on avoiding tropical

infections. Lind died in 1794 in Gosport.

### Robert Koch (1843 - 1910)

The French parasitologist Casimir-Joseph Davaine inspired by



the work of the French microbiologist Louis Pasteur had showed, in 1863, that anthrax in sheep was due to the presence of rod-like bodies in the blood. Koch announced that he had isolated and grown, the tubercle bacillus to the Physiological Society of Berlin on 24 March 1882. He believed this to be the cause of all forms of tuberculosis.

The outbreak of cholera in Egypt and the danger of it finding its way to Europe, caused Koch, as a member of the German government commission, to go to Egypt to investigate the disease. Although he was frustrated by the cessation of the epidemic, he was able to study the disease long enough to suspect a particular comma-shaped bacillus. Whilst there, however he was able to discover the cause of amoebic dysentery and the bacilli of two varieties of Egyptian conjunctivitis. He was able to complete his work on cholera by proceeding to India. He discovered the cholera organism and its transmission via drinking water, food and clothing. When he returned to Berlin Koch advised regular checks on the water supplies and recommendations regarding sewage disposal. He also organised courses in the recognition of cholera. Koch investigated the effect an injection of dead bacilli would have on a person who subsequently received a dose of living ones. He concluded that the local reaction produced might provide the means by which the disease could not only be diagnosed but, in the early stages, perhaps even cured. He used as the active agent a sterile liquid produced from cultures of the bacillus. As the liquid (tuberculin, 1890) proved disappointing as a curative agent its importance as a means of detecting a present or past tubercular state was not immediately recognised.

The result of Koch investigations into a bubonic plague epidemic in Calcutta in 1897 showed that rats were vectors of the disease. He also demonstrated that sleeping sickness is transmitted by the tsetse fly. Other studies by Koch included leprosy, surra, rinderpest, Texas fever and malaria. In 1905 Koch won the Nobel Prize for Physiology or Medicine for investigation and discoveries in relation to tuberculosis.

### Joseph Lister (1827-1912)

By the middle of the nineteenth century, post-operative sepsis



infection accounted for the death of almost half of the patients undergoing major surgery. A common report by surgeons was 'operation successful but the patient died'. Sepsis was considered as a kind of combustion caused by exposing moist body tissue to oxygen. It was therefore considered that the best prevention was to keep air away from wounds by means of plasters, collodion or resins.

Joseph Lister, a British surgeon, considered that infection was not due to bad air alone and that 'wound sepsis' was a form



of decomposition. In August 1861 he was appointed surgeon at the Glasgow Royal Infirmary and put in charge of its new surgical building. Lister reported that between 45 and 50 percent of his amputation cases died from sepsis between 1861 and 1865 in his Male Accident Ward. It was in this ward that Lister began his experimental work with antiseptics. Having tried methods to encourage clean healing, with little, or no success, He discarded the popular concept of direct infection by bad air and postulated that sepsis might be caused by a 'pollen-like dust'. When, In 1865, Louis Pasteur suggested that decay was caused by living organisms in the air, which on entering matter caused it to ferment, Lister made the connection with wound sepsis. He considered that microbes in the air were likely causing the putrefaction and had to be destroyed before they entered the wound. Lister had heard that 'carbolic acid' was being used to treat sewage in Carlisle and that fields treated with the effluent were freed of a parasite causing disease in cattle. Lister now began to clean wounds and dress them using a solution of carbolic acid. In 1867, he announced that his wards at the Glasgow Royal Infirmary had remained clear of sepsis for nine months. In 1870 Lister's antiseptic methods were used, by Germany, during the Franco-Prussian war saving many Prussian soldier's lives. Lister saw the culmination of his emphasis on the principle of preventive medicine with the opening of the Institute of Preventive Medicine in 1891. He died on the 10 February 1912 in Walmer, Kent.

#### **John Simon (1816-1904)**

An English physician, was appointed surgeon. He trained as a surgeon and lecturer in pathology at St. Thomas's Hospital in London in 1847. He was elected a Fellow of the Royal Society for his work on the comparative anatomy of the thyroid gland at the age of 29. When Parliament implemented the recommendations of the Royal Sanitary Commission and amalgamated the Poor Law Board, the Local Government Act Office and the Medical Department of the Privy Council to form the Local Government Board, Simon was appointed first Medical Officer of Health for London in 1848.

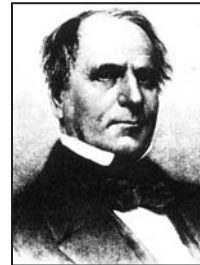
He soon discovered that, instead of his being given the free hand that he had expected, the Medical Department was subordinate to the Poor Law officers. His reports on the health problems of the city and the steps taken to deal with these problems, are regarded as models of preventive medicine and the administration of public health services. In 1858, Simon became medical officer to the Privy Council. Simon had overall responsibility for the organization and administration of national public health services. He oversaw the passage of the Public Health Act of 1875, but resigned the following year because of disagreements about implementing policies he advocated.

Simon's major achievements was his supervision of measures taken in 1866 to enhance public sanitation, including the provision of clean drinking water and safe sanitary disposal. He also established the General Medical Council, the licensing body for medical practitioners in the United Kingdom. His work on sanitary science and public health practice made Britain

the European (and world) leader in public health in the late nineteenth century. His books include two classics of public health, *Public Health Reports* (1887) and *English Sanitary Institutions* (1890). Simon was awarded a knighthood in 1897.

#### **Lemuel Shattuck(1793-1859)**

He was born in 1793 in Ashby, Massachusetts and he died in 1859 in Boston. He came to believe that he could enhance the ability of government to respond to social ills through the collection of statistics. In 1835, he gained attention for writing *A History of the Town of Concord*, which included a statistical analysis based on church and municipal records.



He became a bookseller and helped form the American Statistical Association.

After being elected to the Boston City Council in 1837, Shattuck was asked to create a report analyzing Boston's vital statistics from 1810 to 1841. In addition to his findings, which were published in the *American Journal of Medical Sciences*, Shattuck outlined a method for the systematic gathering of vital statistics and a plan for analyzing that data. Based on his suggestions, Massachusetts passed the Registration Act of 1842. Shattuck was also renowned for his 1850 survey of sanitary conditions throughout the state, the *Report of the Sanitary Conditions of Massachusetts*, which was commissioned by the state legislature. In this report, Shattuck proposed the creation of a permanent statewide public health infrastructure and he recommended establishing health offices at the state and local levels in order to gather statistical information on public health conditions. Although the legislature did not adopt his comprehensive plan, his specific proposals became routine public health activities over the course of the twentieth century.

#### **Edwin Chadwick(1800-1890)**

The son of a successful businessman, was born in Manchester on 24th January, 1800. Chadwick's father had progressive political views and encouraged his son to read books by radicals. In 1832, the Prime Minister, Earl Grey, initiated a Royal Commission of Enquiry on the Poor Laws. Chadwick was appointed as one of the assistant commissioners responsible for collecting information on the subject.



Edwin Chadwick soon emerged as one of the most important members of the investigation and he was eventually responsible for writing nearly a third of the published report. In the report published in 1834, the Commission made several recommendations to Parliament. As a result of the report, the Poor Law Amendment Act was passed. One of the suggestions accepted by Grey's government was that there should be a three man Central Poor Law Commission that would be responsible for supervising the working of the legislation. Chadwick was not appointed as a Commissioner but was offered the post as Secretary, with a promise that he would have the

power to make further recommendations on administering the Poor Law. During the economic depression of 1837, many working people were forced to enter the workhouse. Chadwick was identified as the man responsible for abolishing outdoor relief and during the 1837 General Election there were public demonstrations against him. After the influenza and typhoid epidemics in 1837 and 1838, Edwin Chadwick was asked by the government to carry out a new enquiry into sanitation. His report, *The Sanitary Conditions of the Labouring Population* was published in 1842. In the report Chadwick argued that disease was directly related to living conditions and that there was a desperate need for public health reform. However, it was only after the 1847 General Election, that new legislation was introduced. In 1848 Parliament passed a Public Health Act that provided for the formation of a Central Board of Health. This new body had powers to create local boards to oversee street cleansing, refuse collection, water supply and sewerage systems. Chadwick, who was appointed Sanitation Commissioner, had several ideas on how public health could be improved. This included a constant supply of fresh clean water, water closets in every house and a system of carrying sewage to outlying farms, where it would provide a cheap source of fertilizer. Attempts to introduce public health reforms were resisted successfully by people with vested interests, for example, landlords and water companies, in maintaining the present system.

In 1854 Chadwick was so unpopular it would be impossible to persuade the House of Commons to renew the powers of the Board of Health while he remained in charge of the organisation. In order to preserve the reforms that he had achieved, Chadwick agreed to resign. Although officially retired on a £1,000 a year pension, Chadwick continued to campaign for changes in the law. This included the reform of sanitation, education and transportation. Edwin Chadwick died on 6th July, 1890.

### **Sir Ronald Ross (1857 -1932)**



Ronald Ross was born in Almora, India. At the age of ten, Ross was sent to England for his education. Ross commenced his study of medicine at St. Bartholomew's Hospital in London and joined the Indian Medical Service in 1881. His first posting was in Madras. Ross studied malaria between 1881 and 1899. He worked on malaria in Calcutta at the Presidency General Hospital.

In 1883, Ross was posted as the Acting Garrison Surgeon at Bangalore during which time he noticed the possibility of controlling mosquitoes by controlling their access to water. In 1897, Ross was posted in Ooty and fell ill with malaria. After this he was transferred to Secunderabad, he discovered the presence of the malarial parasite within a specific species of mosquito, the *Anopheles*. He initially called them dapple-wings and following the hypothesis of Sir Patrick Manson that the agent that causes malaria was spread by the mosquito, he was able to find the malaria parasite in a mosquito that he artificially fed on a malaria patient named Hussain Khan. Later using birds that were sick with malaria, he was soon able to ascertain the entire life cycle of the malarial parasite, including its presence in the mosquito's salivary glands. He demonstrated that malaria is

transmitted from infected birds to healthy ones by the bite of a mosquito, a finding that suggested the disease's mode of transmission to humans. In 1902, Ross was awarded the Nobel Prize in Physiology / Medicine for his remarkable work on malaria.

During his active career Ross advocated the task of prevention of malaria in different countries. He also initiated organizations, which have proved to be well established, for the prevention of malaria within the planting industries of India and Ceylon. He made many contributions to the epidemiology of malaria and to methods of its survey and assessment, but perhaps his greatest contribution was the development of mathematical models for the study of its epidemiology, initiated in his report on Mauritius in 1908, elaborated in his *Prevention of malaria* in 1911.

### **William Farr (1807-1883)**

Farr was born in the village of Kenley, Shropshire, on 30 November 1807, the son of parents of modest means. At the age of two he went to live with Joseph Pryce, a local squire noted for his charitable works.



Pryce effectively adopted Farr and paid for his education. On his death in 1828 Pryce left Farr a legacy of 500 pounds which enabled him to pursue his studies in Paris and Switzerland.

He studied further at University College London, where he became a licentiate of the Society of Apothecaries, the only medical qualification he ever gained by study. In 1833 he set up as a practicing apothecary in Bloomsbury, London. From 1835 his earnings were supplemented by writings in early issues of the *Lancet*. In 1837, Farr contributed an article on "Vital statistics" for a volume entitled McCulloch's *Account of the British Empire*. Farr recognized that "Diseases are more easily prevented than cured and the first step to their prevention is the discovery of their exciting causes" and he set about establishing a firm foundation for his statistical work. He undertook a study of the bills of mortality, tabulating causes of death according to categories.

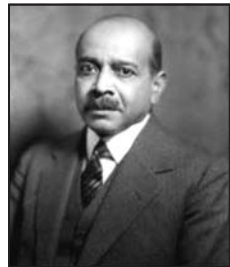
In 1838, the Office of the Registrar-General was established with the task of registering births, marriages and deaths. The dominant figure in the new service was William Farr, who was appointed as the first "compiler of abstracts" (chief statistician) to the new office. Farr remained in the post until his retirement in 1880 and used his position to become one of the leading figures in the sanitary movement, which campaigned for better sanitary conditions, especially in urban areas. Farr is often referred to as the father of modern epidemiological surveillance.

### **Sir Joseph William Bore (1878-1960)**

This Indian Civil Servant was responsible for the initial concepts of comprehensive health care. Bore committee was set up by the Government of India in 1943 to investigate and recommend improvements to the Indian Public Health system. Under the chairmanship of Sir Joseph William Bore the committee made many landmark recommendations in its final report in 1946.



The committee was instrumental in bringing about the public health reforms related to primary health centres in India. It said "If it were possible to evaluate the loss, which this country annually suffers through the avoidable waste of valuable human material and the lowering of human efficiency through malnutrition and preventable morbidity, we feel that the result would be so startling that the whole country would be aroused and



would not rest until a radical change had been brought about". Though most of the recommendations of the committee were not implemented at the time, the committee was a trigger to the reforms that followed. Even today, the primary health care infrastructure of our country is based on what the Bhore committee had recommended more than 60 years ago. Sir Bhore can be very rightly said to be the man who envisioned the primary health care component of public health in our country.

#### **Dr Sushila Nayyar (1914-2000)**

Dr Sushila Nayyar, was the younger sister of Pyarelal Nayyar, personal secretary to Mahatma Gandhi. She was born in 1914 in Kunjah, Punjab now in Pakistan and came to Delhi in her youth to study medicine at Lady Hardinge Medical College. In 1939 she came to Sevagram to join her brother and quickly became a close associate of Mahatma Gandhi.



Shortly after her arrival, cholera broke out in Wardha and the young medical graduate tackled the outbreak almost single-handedly. Gandhiji praised her fortitude and dedication to service and appointed her his personal physician. In 1942 she was awarded an MD and returned once more to Mahatma Gandhi's side, to take part in the Quit India Movement that was sweeping the country. That year she was imprisoned along with other prominent Gandhians at the Aga Khan's Palace. In 1944 she set up a small dispensary at Sevagram, but this soon grew so large that it disturbed the peace of the ashram and she shifted it to a guesthouse donated by the Birlas, in Wardha. In 1945 this clinic formally became the Kasturba Gandhi Memorial Hospital. After Mahatma Gandhi's assassination in 1948, Dr Sushila Nayyar went to the USA where she took two degrees in public health (M.P.H. and Dr PH) from Johns Hopkins University. Returning in 1950, she set up a tuberculosis sanatorium in Faridabad, the model township on the outskirts of Delhi. Dr. Nayyar also headed the Gandhi Memorial Leprosy Foundation.

Dr. Sushila Nayyar was deeply influenced by the Gandhian philosophy of hard work and abstinence. She felt strongly about the need for prohibition and linked this to the domestic concerns of poor women whose lives were often blighted by alcoholism in their husbands. She was also a staunch campaigner for family planning, once again seeing this as essential empowerment for women, especially poor women. She also believed, like Mahatma Gandhi that there was no

such thing as a dirty job and that medicine required hands-on involvement with patients and their ailments, regardless of feminine delicacy or upper caste squeamishness. In 1952 she entered politics and was elected to the Delhi State Assembly. From 1952 to 1955 she served as Health Minister in Pandit Nehru's cabinet. She was Speaker of the Delhi Vidhan Sabha from 1955 to 1956. In 1957 she was elected to the Lok Sabha and served till 1971. She was Union Health Minister again from 1962 to 1967. She retired from politics to devote herself to the Gandhian ideals. She had set up the Mahatma Gandhi Institute of Medical Sciences in Wardha, in 1969 and remained committed to confine her energies to developing and extending it. She passed away towards the end of 2000. Dr Nayyar has been very appropriately hailed as the leading light in the discipline of Community Medicine in our country.

#### **Alexander Duncan Langmuir(1910-1993)**

Alexander Duncan Langmuir was born on Sept. 22, 1910, in Santa Monica, California and grew up in New Jersey, died at the age of 83 in Baltimore of kidney cancer. He went to medical school, receiving a degree from Cornell and interning at the Boston City Hospital. His math training and a flair for statistics helped him earn a degree in public health from Johns Hopkins University.



His academic training led him into public health and he gained field experience working as a public health officer in New York State and as a member of the Armed Forces Epidemiological Board. He taught for three years at the Johns Hopkins University School of Hygiene and Public Health. In 1949, Dr. Langmuir created a corps of epidemiologists at the Federal Centers for Disease Control and Prevention in Atlanta. The corps was ready to fly anywhere immediately to investigate reports of an epidemic or an unusual cluster of cases. Known as the Epidemic Intelligence Service, the program played a crucial role in turning what was then an obscure and fledgling operation into a large Federal agency. From 1949 to 1970, Dr. Langmuir was the disease centers' chief epidemiologist. As the Government's chief disease detective, he created the concept of surveillance for infectious diseases. The agency used it to track dozens of diseases and to analyze patterns to take steps to prevent clusters and outbreaks from becoming epidemics. The agency also responded to requests from state health departments to investigate unusual cases and clusters. When the possibility of biological warfare was raised during the Korean War, scientists looked to epidemiology as the first line of defense. Dr. Langmuir seized the opportunity to strengthen disease surveillance and his program. Dr. Langmuir taught what he called "shoe leather epidemiology," stressing that investigators go into the field to collect their own data and view directly the locale of the public health problem they were investigating. His graduates wore lapel pins of a shoe with a hole in the sole. Upon retirement from the CDC, Langmuir served as a visiting professor at both the Harvard University School of Public Health and Johns Hopkins. He is rightly known as the founder of 20th century epidemiological and public health surveillance.

## Summary

The History of Public health dates back to Greco-Roman Era period, when Romans were able to implement public health measures and by the end of the Roman Empire in AD 476, the Roman public health system was well advanced comparatively in Europe. During the Middle Ages (5th-15th centuries) in Europe, public health systems collapsed, particularly during the period known as the Dark Ages (around 500-1000 AD). Action was only taken during outbreaks of disease such as the Black Death, an epidemic of bubonic plague that swept across Europe in the mid-14th century, killing between one-third and half of the population. Public toilets were to be introduced and the dumping of waste in the streets was forbidden.

In 1836, William Farr showed the impact of poor living conditions on life expectancy and the differences between different areas. In 1837 Chadwick compiled a survey of "Sanitary condition of labouring classes of Great Britain". In 1842 he recommended the "Sanitary Idea" with creation of a public health authority to provide drainage, potable water, sanitation, regulation of buildings etc. The first British Public health Act was passed in 1848. Chadwick then shifted the "Sanitary idea" to a new concept "State Medicine". He laid the foundation of subsequent British health policy and followed a comprehensive approach to disease prevention. In 1875 the Public Health Act was codified including all existing sanitary legislation.

In 1864 the first contagious Disease Acts was passed which provided for compulsory examination of women believed to be "Common prostitutes". Free vaccination was made available through the Poor Law Medical Services in 1840. In 1853 vaccination was made compulsory for all children with the first year of life. The Lemuel Shattuck Report encouraged social reform, including documentation of disease conditions and collection of vital statistics. The theory of miasma, which said that disease is due to causes contained in bad air, led to improvements in the sanitation systems, which led to decreased episodes of cholera. This caused public health reforms and encouraged cleanliness.

During the 19th Century and the first half of the 20th century, the perception of public health was limited to prevention of communicable diseases through environmental sanitation. During World war II the Public Health service established the control of Malaria in war areas. In 1907 preventive medicine practitioners and town planners got together to bring about housing reforms. Simultaneously legislations were passed for free school meals, medical inspection of school children and antenatal care.

In Germany, Pettenkofer first calculated the financial returns on public health investments to prove the value of sanitary

improvement in reducing death from typhoid. Bacteriological analysis was used to determine the presence of coliform bacteria in municipal water supplies. Currently, Classical infectious disease rates have declined while increased rates of non communicable diseases are now being observed in epidemic proportions throughout the world. New problem-solving systems are needed in areas such as health care financing, medical care for the aged, environmental health protection and health care planning and administration. Some of the pioneers and founders of Modern Public Health, Community Medicine & Preventive Medicine are Edward Jenner, John Snow, James Lind, Robert Koch, Joseph Lister, John Simmon, Lemuel Shattuck, Edwin Chadwick, Sir Ronald Ross, Sir Joseph William Bhole, Alexander Duncan Langmuir and Dr Sushila Nayyar.

## Study Exercises

**Short Notes :** (1) John Snow (2) Edwin Chadwick (3) Sir Ronald Ross (4) Public Health evolution

**MCQs & Exercises :**

- (1) The "Sanitary Idea", with creation of a public health authority to provide drainage, potable water, sanitation, regulation of buildings, was first recommended by (a) William Farr (b) John Snow (c) Edwin Chadwick (d) Pettenkofer.
- (2) 'On the Mode of Communication of Cholera' in 1849 was written by (a) William Farr (b) John Snow (c) Edwin Chadwick (d) Pettenkofer.
- (3) 'A Treatise of the Scurvy' and 'An Essay on the Most Effectual Means of Preserving the Health of Seamen in the Royal Navy' were published by (a) William Farr (b) James Lind (c) Edwin Chadwick (d) Pettenkofer.
- (4) The father of modern epidemiological surveillance is (a) William Farr (b) James Lind (c) Edwin Chadwick (d) Pettenkofer.
- (5) The founder of 20<sup>th</sup> century epidemiological and public health surveillance is (a) Langmuir (b) James Lind (c) Edwin Chadwick (d) Pettenkofer.

**Answers :** (1) c; (2) b; (3) b; (4) a; (5) a.

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## Theories of Disease Causation

Since the primitive ages, man has been always concerned with disease and its possible determinants like etiology, risk factors, preventive, diagnostic and therapeutic measures. As a result, various theoretical models to explain the causation of human disease have evolved.

### Theories in Primitive and Middle Ages

Since disease has always been a constant accompaniment of man, right from the pre-historic times onwards, he has been trying to find out the causes of disease. The various theories prevalent in different civilizations were “supernatural causes” (e.g. being possessed by evil spirits, wrath of gods, punishment for evil deeds during previous births and so on). Subsequently, as the middle ages came up, attempts were made to relate the human disease to “bad air” or to various forms of close contacts with diseased person (contagion theory). Even illustrious epidemiologists like William Farr were very inclined to the “miasma” theory which postulated that human diseases are due to bad clouds which are more dense at lower altitudes and hence diseases are more common among people who live nearer to the earth or sea level; in fact Farr tried to prove this by data taken from London cholera epidemic during mid-nineteenth century. These various theories had staunch supporters and backed up by strong religious and political sanctions to the extent that refuting such contemporary theories could mean facing severe forms of punishment.

### Germ Theory

It was in the second half of the 19th century that the golden era of medicine was heralded by the pioneering discoveries of bacteria as a cause of human disease, by Robert Koch and Louis Pasteur. The contributions of these discoveries to human health cannot be questioned. So tremendous was the impact that a tendency developed to relate every human disease to a specific microbe or “germ”, to the extent that the germ theory of the human disease emphasized that each and every human disease has to be caused by a microbe or germ, which is specific for that disease and one must be able to isolate the microbe from the diseased human being. This was the central philosophy of the famous Koch’s postulates, formulated by Robert Koch (now also known as Henle-Koch postulates) :

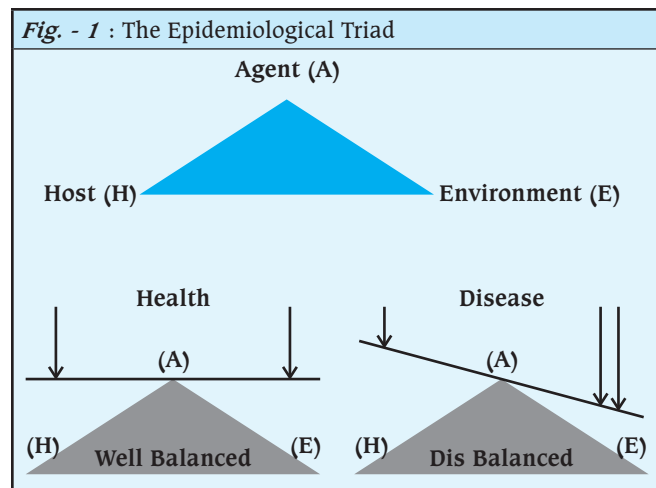
- 1) The disease agent occurs in every case of that disease and under circumstances which can account for the pathological changes and clinical course of the disease.
- 2) It occurs in no other disease as a non-pathogenic parasite.
- 3) After being fully isolated from the body and repeatedly grown in pure culture, it can induce the disease anew.

As the 20<sup>th</sup> century started rolling, it was realized that the germ theory really could not fully explain the causation of

human disease. The occurrence of tuberculosis in Western world fell down dramatically even without the availability of a specific vaccine (to specifically prevent infection) or a specific treatment (to specifically kill the tuberculosis “germ”). Simple facts like disease does not necessarily occur in everybody who has the tuberculosis germ in the body (i.e. infection does not necessarily lead to disease in Tuberculosis) started putting a question mark on the ability of the germ theory and Koch’s postulates, in completely explaining the causation of human disease.

### The Epidemiological Triad

Not refuting the importance of germ theory, thought processes were started to explain the role of other factors in accentuating or attenuating the effect of the “germ” or “agent” of disease. This finally culminated into an extremely important and widely used theory to explain causation of human disease-the “Epidemiological triad” (see Fig. - 1).



The epidemiological triad theory hypothesizes that there are 3 important determinants of the state of health or disease in a human being, namely :

**The agent factors :** Related to the various characteristics of the “agent” which causes the disease.

**The host factors :** Which relate to various characteristics of the human being himself.

**The environmental factors :** Which relate to the various characteristics of the environment in which the human being is living.

As per the theory, as long as a state of fine balance or equilibrium is maintained between the various agent, host and environmental factors, the person stays in a state of health. (Health has been defined by the World Health Organization as a state of perfect physical, mental and social well being and not merely an absence of disease or infirmity). On the other hand, the moment this fine balance is disturbed due to change in any one or more of the agent, host and environment related factors, a departure from the state of health occurs (though evidence of disease may still not occur because manifest evidence of disease may take sometime to develop; thus, the importance of the definition of health given by the WHO in that health is not simply absence of disease. This aspect will be explained

further, later in this chapter when we discuss the process of natural history of disease and levels of prevention).

To give an example, a person may have infection with *M tuberculosis* but may be perfectly healthy in terms of physical, mental and social well being (most of us in the developing countries are that way). He remains in the state of health because the agent, host and environmental factors are well balanced with each other. Now, let us say, some of the host factors change, e.g. the person because grossly malnourished due to severe measles; or becomes immuno-compromised due to HIV infection; or the environmental conditions lead to gross poverty, consequent to wars and famines. Any one or more of these changes will lead to a disturbance in the equilibrium that

was earlier maintained, thus leading to departure from the state of health.

The various factors related to agent, host and environment can fall into the following categories :

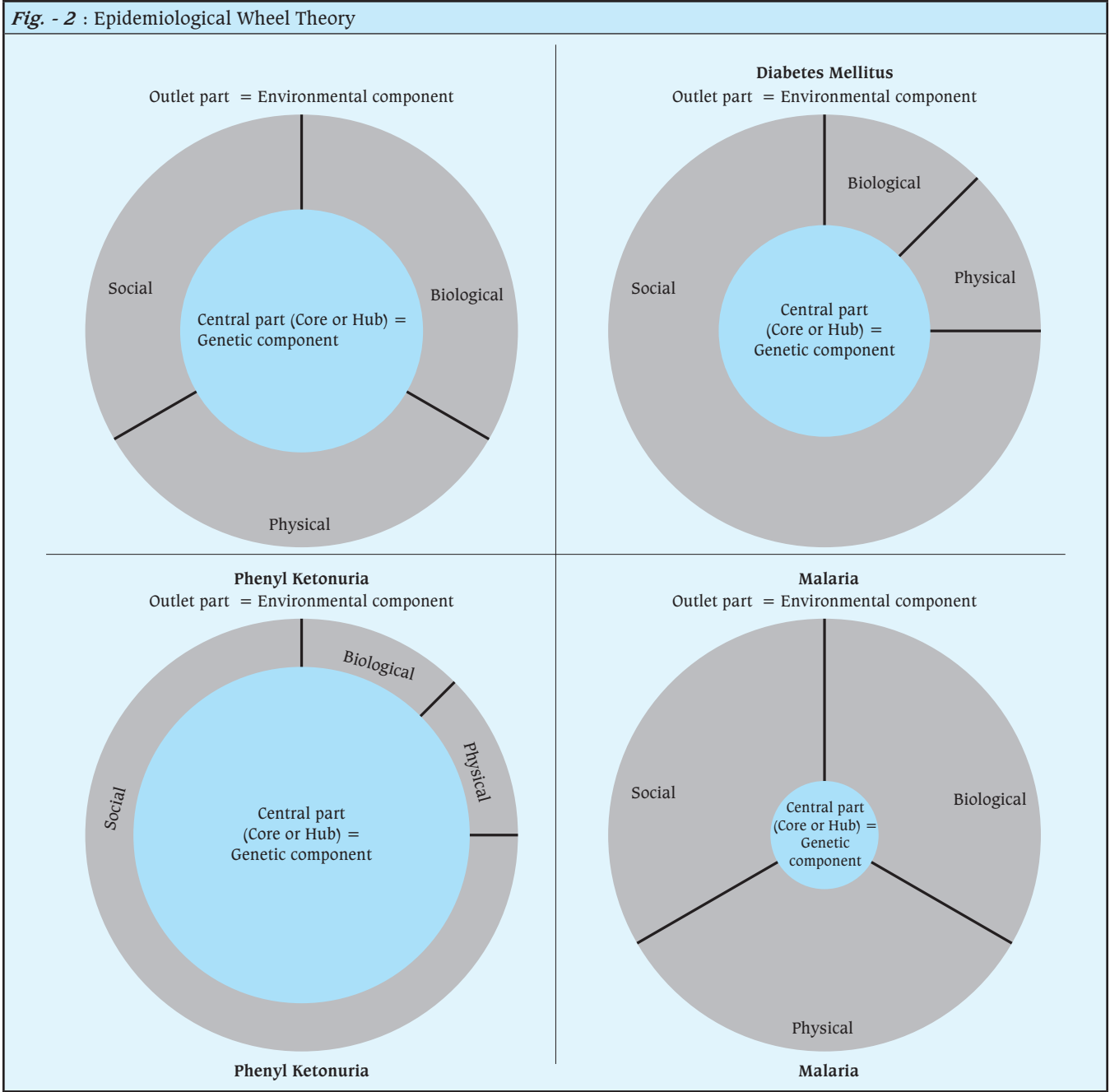
**Agent Factors**

**Physical Agents** : (as heat, cold, vibrations, electricity, mechanical forces etc.).

**Chemical Agents** : (as acids, alkalies, heavy metals, allergens, etc.).

**Biological Agents** : (as viruses, bacteria, parasites, etc.).

**Nutritional agents** : These are truly a part of chemical agents but often described as a separate category because of the





exclusive importance that nutrition has in human health. Both deficiencies as well as excess of nutrients cause diseases; in addition, specific food toxins cause a variety of diseases, which will be dealt with in the section on nutrition.

#### Host Factors

**Socio-demographic Factors** : Such as age, sex, occupation, education, marital status, etc.

**Psycho-social Factors** : Such as attitudes, practices, behavioural patterns, life style, etc.

**Intrinsic Characteristics** : Intrinsic Characteristics or the “biological, Immunological and Genetic factors” in a human being - e.g. genetic factors, HLA types, biochemical and physiological characteristics, etc.

#### Environmental Factors

**Physical Environment** : Such as seasons, climate, altitude, rainfall, etc.

**Biological Environment** : e.g. arthropod vectors of diseases like mosquitoes, animal reservoirs like canines and rodents, etc.

**Social Environment** : e.g. community attitudes, beliefs, practices and cultural factors affecting disease; level of socio-economic development; availability of health services, etc.

#### The “BEINGS” Model of Disease Causation

Another recent concept postulates that human disease and its consequences are caused by a complex interplay of nine different factors - *Biological factors* innate in a human being, *Behavioural factors* concerned with individual lifestyles, *Environmental factors* as physical, chemical and biological aspects of environment, *Immunological factors*, *Nutritional factors*, *Genetic factors*, *Social factors*, *Spiritual factors* and *Services factors*, related to the various aspects of health care services.

#### The Theory of “Web of Causation”

The “epidemiological triad theory” was very effectively used by Leavel and Clark in explaining the natural history of disease and levels of prevention for obviating such departures from the state of health, which have formed the basis of public health activities. However, difficulties come up when an attempt is made to explain the causation of non communicable diseases like IHD or road accidents on the basis of epidemiological triad. For example, no single agent can be ascribed for IHD; a wide variety of interacting factors like Hypercholesterolemia, hypertension, tobacco, obesity, physical inactivity, genetic background, age, sex, just to name a few, interact in various ways to finally lead to the pre-pathogenic changes of “plaque” formation, which finally progress to the pathogenic phase of full blown disease.

For explaining the causation of such non communicable diseases in particular, McMahon and Colleagues (McMahon and Pugh T. Epidemiology : Principle and methods 1<sup>st</sup> Ed, 1970) forwarded the theory of “epidemiological web of causation”, wherein the various factors (e.g. hypercholesterolemia, smoking, hypertension and so on) are like an interacting web of a spider. Each factor has its own relative importance in causing the final departure from the state of health, as well as

interacts with others, modifying the effect of each other. The web theory also postulates that for preventing a disease, it is not necessary to take action against all the factors - if we could identify a few “weakest links” in the inter-lacing webs, actions directed to these weakest links may be of considerable value in prevention.

#### Epidemiological Wheel Theory

As medical knowledge has advanced, the additional aspect which has been exciting interest is the comparative role of “genetic” and the “environmental” (i.e. extrinsic factors outside the host) factors in causation of disease. The “triad” as well as the “web” theory does not adequately cover up this differential. To explain such relative contribution of genetic and environmental factors, the “wheel” theory has been postulated. A graphical presentation of this theory is given in Fig. - 2.

The theory visualizes human disease in the form of a wheel, which has a central hub representing the genetic components and the peripheral portion representing the environmental component. Like any wheel, the outer part (environmental component) has spokes (3 in this model) and the environmental component is thus divided into 3 sub components, representing the social, biological and physical components of the environment. For every disease, the genetic, social, biological and physical environmental components take different sizes, which we shall clarify with three examples, depicted in Fig. 2.

For a disease like Diabetes Mellitus, the genetic as well as the overall environmental component have an equal contribution; and within the environmental component, the maximum role is of social environment (behavioural patterns related to diet, physical exercise, smoking and drinking and availability of health services). On the other hand, biological component has quite a small role (certain viruses like Mumps or Coxsackie’s being implicated) while physical environmental has hardly any contribution. The relative sizes of these various components are kept in proportion to their contribution to the disease of interest, as shown in Fig. - 2. For a disease like phenylketonuria the major role is played by the genetic factors and hence a large central part, while out of the three environmental factors, represented by the smaller peripheral part, the social component plays an important part, since, if the parents can be educated regarding the proper diet (and, of course, if they can economically afford it), still the symptoms of the disease can be prevented, despite the genetic background. Finally, in malaria, genetic factors have a small role and hence a small central hub, while out of the environmental factors, all the three components have a major and equal role (physical environment by way of producing malariogenic conditions by rainfall, humidity and water logging; biologic environment by way of affecting the breeding and bionomics of mosquitoes and the social environment by way of overall socio-economic development, housing conditions, availability of health services affecting the treatment and preventive programmes.) Thus, all the 3 components of environment are shown with equal share in the figure.

#### The Theory of “Necessary” and “Sufficient” cause

Way back, John Stuart Mill had defined “cause” as “The cause, then, philosophically speaking, is the sum total of the



conditions, positive and negative, taken together, the whole of the contingencies, of every description, which being realized, the consequent invariably follows". Thus, the "cause" of a particular human disease is like the constellation of various factors and when all of them come into play in an *optimum* combination, the pathological process which finally produces the disease gets initiated. The definition clearly underlines the "multifactorial" causation of disease rather than "unifactorial" causation that was thought of in the germ theory. Modern epidemiology therefore proceeds to identify "a cause" or "some of the causes" of a disease (rather than "the cause") and directs preventive action towards the one or few of the various factors which may form part of the contingency.

To explain in very general terms, if the "disease" was like the sweet melody which flows out of a concert, the various contingencies that combine to produce it are the violin, guitar, drums, accordion, musicians, electricity, etc. Once all these various contingencies come together in an *optimum* mix, the final melody flows out. Now for preventing the melody, it is not necessary to identify and take action against all the contingencies. Just cut off the electric wires of the guitar or make a hole in the drum and the melody is prevented! The definition of Mill was further expanded to the concept of web of causation by McMahon and colleagues. Subsequently, Rothman further dilated on this aspect and forwarded the concepts of "necessary" and "sufficient" cause. For example, there could be 3 different contingencies, all of which when present together in an "optimum mix" lead to Tubercular disease. In the first contingency, presence of infection with *M tuberculosis* (A) along with optimum amounts of overcrowding (B), poverty (C), malnutrition (D) and lack of BCG vaccination (E) will lead to tubercular disease. In the next situation, presence of infection (A), even in absence of B, C, D and E but in the presence of other factors, viz attack of severe measles (F) and possible racial or genetic predisposition (G) will also finally lead to disease. In the last situation, the presence of infection (A) simply along with HIV infection (H) would also cause the disease.

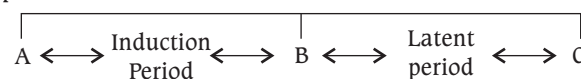
Interestingly, then, *M tuberculosis* (A) has to be present in all the contingencies for the tubercular disease to finally occur but alone, by itself, it will not necessarily cause the disease. Thus, *M tuberculosis* is a "necessary" cause of tuberculosis disease but NOT a "sufficient cause". On the other hand, (A, B, C, D, E) or (A, F, G) or (A, H) when they come together in "optimum mix" become "sufficient cause" for the disease to occur. Thus, a necessary cause is one whose presence is essential for disease causation, but which alone, by itself may or may not be able to finally cause the disease. Thus, disease may or may not occur in its presence but will not occur in its absence. At times, the necessary cause may by itself be a sufficient cause for the disease (e.g. infection with HIV is a "necessary" as well "sufficient" cause for AIDS). More often, however, in most of the infectious diseases, the necessary cause by itself may not be a sufficient cause (example of Tubercular disease given earlier). Finally in most of the non-communicable diseases one may not be able to identify any "necessary" cause at all; what is important in these diseases is whether the optimum mix of various factors has occurred in a way to produce the "sufficient cause". For example, for a non-communicable disease, like IHD, different factors may combine to form different "constellations"

of sufficient cause, e.g. :

(Genetic predisposition+smoking+middle age) >>>> IHD  
(Hypertension+central obesity+suppressed hostility) >> IHD  
(Hypercholesterolemia+DM+physical inactivity) >>>> IHD

### Induction and Latent Periods

The concept of "sufficient" cause has also brought about the interesting terms "Induction period" and "Latent period" in respect of non - communicable diseases.



A = Sufficient cause becomes operative.

B = Disease process (pathological changes) start in the human body.

C = Earliest point of detection of disease by available diagnostic methods.

Thus, induction period is the time interval that elapses between the point when "sufficient cause" becomes operative to the point when the first pathological changes of disease start in the body. On the other hand latent period is the time period that elapses between the initiation of pathological change till the point when the earliest diagnosis of the disease is possible with the currently available clinical and diagnostic armamentarium. The counterpart in infectious disease epidemiology is the "incubation period" which refers to the time period that elapses between the entry of the infectious agent into the body till the point the earliest manifestation of the disease are evident. The "generation time" on the other hand refers to the time between entry of the infectious agent into the body and the maximum infectivity of the human host.

### Predisposing, Enabling, Precipitating, Reinforcing and Risk Factors in Disease Causation

It is apparent from the foregoing discussion that in a "sufficient cause", besides the necessary cause, a large number of other factors are also present, based on whose optimum permutation and combination, the "sufficient cause" finally emerges. Experts have classified such factors into the following four types :

- Predisposing factors* are factors which create a state of susceptibility, so that the host becomes vulnerable to the agent or to necessary cause, e.g. age, sex, previous illness.
- Enabling factors* are those which assist in the development of (or in recovery from) the disease; e.g. housing conditions, socio-economic status.
- Precipitating factors* are those which are associated with immediate exposure to the disease agent or onset of disease, e.g. drinking contaminated water, close contact with open case of pulmonary TB.
- Reinforcing factors* are those which aggravate an already existing disease, e.g. malnutrition, repeated, exposures, etc.
- Risk factors* : A risk factor is defined as a condition, quality or attribute, the presence of which increases the chances of an individual to have, develop or be adversely affected by a disease process. A risk factor is thus not necessarily the cause of a disease but does increase the probability

that a person exposed to the factor may get the disease. For example, smoking is a risk factor for IHD; it increases the risk of developing IHD by about two times although it may not be an essential cause because many smokers may never develop IHD while many non-smokers may develop the same. Broadly, in public health approach, risk factors are classified as either modifiable or non-modifiable. The former includes those which cannot be changed, as age, sex, genetic background and racial background. The modifiable factors are those which can be modified or stopped, as smoking, lack of physical activity, dietary indiscretion, etc. While the non-modifiable factors cannot be changed, they are still quite important since if a person is having one or more non-modifiable factors, there is an even greater need for him or her to give up the modifiable risk factors.

- f) **Risk Marker** : There is a fine difference between a risk factor and a risk marker. A risk factor, once established by epidemiological studies, is directly involved in the chain of causation of the disease; any manipulation in the risk factor will also change the level of the disease. For example, if smoking is a risk factor for lung cancer, decrease or stoppage of smoking will decrease the chances of suffering from lung cancer and vice versa. However, a risk marker, on the other hand, is only a surrogate or a proxy indicator of the risk of the disease, mostly because of its association with another risk factor. For example, development of a transverse crease on the ear lobe has been shown, in many studies, to indicate an increased risk for IHD. However, even if we correct the ear lobe crease by a plastic surgery procedure, the risk of IHD will not reduce! However, risk markers are important in preventive and public health care, since one should get alert and vigorously enforce preventive procedures in those who have the risk marker.
- g) **Risk Groups and Risk Approach** : One of the important strategies in modern day public health is the “high risk approach”. A high risk group can be defined as a group of people or a subsection of the population, who, by virtue of certain characteristics, are likely to have a higher probability of suffering from one or more diseases or from general ill health. Such characteristics may be
- Innate, non-modifiable characteristic as age (infants and young children are more at risk for respiratory and gastro-intestinal infections), sex (males are more susceptible to IHD), or genetic background (children of both diabetic parents), or blood groups.
  - Modifiable Biological characteristics as obese people are at higher risk of developing IHD, hypertension and diabetes mellitus.
  - Socio-demographic and environmental characteristics: as low income, low education groups, slum dwellers, gender (females are more susceptible to complications of pregnancy, sexual exploitation and domestic violence) or geographical characteristics (people living in rural and remote hilly areas) or occupation (soldiers are more susceptible to injuries and adverse effects of hot, cold and high altitude environment).

Accordingly, the “high risk approach” has developed as an important strategy in public health. This is defined as a health care management strategy which endeavours to provide special care to those who are at higher risk of being affected by adverse health conditions, due to some identified characteristics, while, at the same time, providing optimum care to all other members of the community. Thus, the risk approach conceptualizes providing some basic level of care to all the members of the community and, in addition, providing special care to those who are more in need, being identified as being high risk. Risk approach has been most convincingly used in the field of mother and child health care, the details of which will be presented in the section of maternal and child health.

## Natural History of Disease

Next to searching and explaining the “causes” of diseases, another area which has been of great inquisitiveness to humans, is to study the “natural history” of diseases. This is defined as the “natural course that a disease would take when it has not been affected by any treatment or any other intervention. It is of much importance for all of us to understand the natural course of human diseases, since, as we shall see later in this chapter, the various modalities of disease prevention and control are dependant on such knowledge.

Let us take the example of a common disease like typhoid fever. After the infecting organism enters our body by way of food or drinks, there is an incubation period of about 14 days, after which we have clinical manifestations in the form of headache, remittent fever which rises in a step ladder pattern and initial constipation followed by pea-soup stools. The spleen is palpable and rash appears in the second week. Most of the individuals recover by the third week, though variable feeling of weakness may persist for a longer time. However, some patients may develop complications in the third week in the form of intestinal haemorrhage, perforation and peritonitis, with high mortality. Another small percentage may pass on to a chronic carrier state after an apparent clinical recovery.

Have you ever paused to think as to how the various textbooks describe the course of various human diseases? In fact, this is all based on the knowledge of epidemiology, as we shall describe later in the chapter on definition and uses of epidemiology.

Let's continue with our example of typhoid fever. If we ask you as to what is the cause of typhoid fever, you would be sure enough to reply “*Salmonella typhi*”. Very fine. But, is it the only cause? For example, if I gulp down a few salmonellae, will I certainly get typhoid fever. May be, not, because I may be already resistant to typhoid fever due to previous immunization. Therefore, another factor to be considered in development of human diseases is, besides the organism (agent), the human being himself too. Now, there is yet another factor which needs to be considered also. You would agree that the salmonella cannot just enter my mouth of its own accord! There should be water or food which should be contaminated with the faeces of a patient of typhoid fever. Therefore, the third thing, besides the microbial organism and the human being, which determines the disease, is the “environment”. This is known as the triad of agent, host and human factors. We have deliberated on these details earlier in this chapter.

You and me may not get typhoid fever, while many others around us would get it, because of various reasons like :

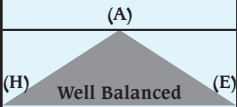
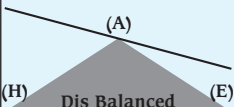
- Being public health trained persons, we know that typhoid bacillus is spread by contaminated food and water, so we will deliberately not consume such food and water about which we are suspicious, while an unaware human being may consume them because of ignorance.
- We won't be forced to consume contaminated food or water because of our better socio-economic status, while a poor person may not have any other alternative other than consuming unhygienic but cheaper food and water.
- Even if we consume such an infected food or water, being healthy and well nourished, possibly having been immunized against typhoid (being from public health services) and hence better immunity, we may not actually develop the disease as compared to a person who is sick, malnourished and not immunized.

We would therefore agree that the mere presence of agent, host and environment is not enough to cause the disease. As long as the agent, host and environment are in a state of equilibrium disease will not be initiated; the process of human disease would be initiated only if there is an appropriate interaction and a loss in equilibrium, between the agent, host and environment. For example, if we become malnourished due to an attack of severe measles or take on to heavy alcoholism, or become poor and hence forced to consume contaminated food or water, or are exposed to a very heavy dose of infection (for example, drinking raw water in a flood like situation), we would become "susceptible" to developing typhoid fever. Just note what we have said - we have become "susceptible" though still no pathological process of disease had started in our body.

The point which needs to be noted is that in any disease, there is a phase between the state of perfect health and the point from where actual pathological processes of the disease start. This phase is called as the phase of 'pre-pathogenesis' (since actual pathological processes have not started still) and also called as the phase of "susceptibility" (since the human being has become susceptible to developing the disease). This stage thus occurs even before the human being is actually involved with the disease process. This phase is important to be understood, since quite commonly, we tend to view health as a state of absence of disease. Factually speaking, then, health is not equivalent to an absence of disease, because in the phase of pre-pathogenesis or susceptibility, there is no disease, but the state of perfect health has also been compromised at the same time. This is also the ethos in the WHO definition of health which states that health is a state of perfect physical, social and mental well being and not merely an absence of disease or infirmity. Thus, people in the stage of susceptibility or the pre-pathogenesis stage are not in a state of health, though they may not be having any disease.

Now, let's see what happens after the disease agent enters the human host, i.e. the course of disease in man. Initially, there is a "silent period" during which the pathological processes keep developing inside the body but outwardly there is no sign or symptom; thus the person is not aware that he has some disease process developing inside the body, nor can any of the routinely used clinical or other diagnostic procedures detect the disease. For instance, the typhoid bacillus would settle down in the cells of RE system and multiply silently, during this phase. The pathogenesis period starts from this point and this phase is known as the "phase of early pathogenesis". While

**Fig - 3 : Natural History of Disease & Levels of Prevention**

		Stages of Pathogenesis			
Stage of Positive Health	Stages of Susceptibility (Pre Pathogenesis)	Asymptomatic (Early Pathogenesis)	Early, Discernible Disease	Full-Blown (Classical) Disease	Termination
		Pathological process has started. However, outwardly, there are no signs or symptoms what so ever. Detection is only possible by specialized pathological / investigative studies.	There are very mild or non-specific signs / symptoms which occur at a very early stage of clinical course; not easy to detect at this stage unless very fine clinical acumen and / or specialized equipment is used.	Full fledged disease in classical form; quite easy to diagnose.	<ul style="list-style-type: none"><li>- Complete Recovery</li><li>- Chronic Disease</li><li>- Life With Residual Disability</li><li>- Death</li></ul>
Agent, Host and Environmental factors are in perfect balance	Balance between Agent, Host and Environmental Factors is disturbed; conditions have been created for disease process to start; however pathological processes have still not started.				
Health Promotion	Specific Protection	Early Diagnosis and Prompt Treatment		Disability limitation	Rehabilitation
Primary Prevention		Secondary Prevention		Tertiary Prevention	
Levels of Prevention					



there are no signs or symptoms of the disease, still this phase is very important for two reasons. Firstly, the person, though undetectable, can still spread the disease; secondly, if we can use certain specialized procedures to detect the disease during this stage, we could treat it at this early stage and hence save from a lot of complications, which could occur if the disease is detected when it has become very advanced.

Now after this phase, the typhoid bacillus produces the typical manifestations of the disease. Initially, we have the stage of early, discernible lesions, which give us some indication that some disease, possibly typhoid fever, had occurred, as fever, headache, mild cough and constipation. Later, the disease presents with full fledged manifestations as remittent fever of step ladder pattern, rash, pea soup stools and splenomegaly. If allowed to progress further, some patients may pass on to complications as intestinal haemorrhage / perforation, toxemia and death, while some may develop long term disabilities as chronic typhoid carrier state. However, during this phase itself, the body also mounts the immunological response and most of the persons get cured by way of body's defence response overcoming the infective process.

Thus, the broad phase of "pathogenesis" has four sub-phases, namely, phase of early pathogenesis (also referred to as phase of asymptomatic disease), phase of early discernible lesions, phase of full blown disease and phase of termination; the last one (termination) has a wide spectrum ranging from full recovery at one end and death at the other and various grades of residual disability / chronicity in between.

These stages in the natural history of disease are not only for infectious diseases as typhoid fever but is true for non communicable diseases like IHD also. In IHD, there is no single "agent" (as typhoid bacillus in enteric fever) but multiple, interacting agents as tobacco smoking, saturated fats and cholesterol in diet, physical inactivity, raised blood pressure and so on. Let's take the example of a young boy who doesn't smoke, is physically active, eats a diet primarily of cereals, pulses and vegetables and has little stresses of life excepting for his studies. From this state of perfect health, suppose he gets a highly paid job, with prolonged working hours. Apparently, he starts driving to his office, starts eating fat-rich junk food available in a nearby restaurant, gets little time for physical exercise and games and starts smoking due to stressful office jobs. At this stage, while the pathological process of atherosclerosis may have still not started inside his body, so that he is still not "diseased", however, he is not in a state of perfect health but rather in the phase of susceptibility. Now, if this situation continues, the process of atherosclerosis will start off in its most initial forms of atheromatous plaque and increasing obliteration of coronaries. At present, this person won't have any outward sign or symptom of IHD but would now be considered in the "phase of pathogenesis" since the pathological processes have, in any case started. More specifically, he would be considered to be in the phase of asymptomatic disease since he does not have any symptoms and cannot be detected by routine clinical and diagnostic procedures but can be detected using some very specialized procedures as stress ECG test. The disease would now progress to the phase of early discernible lesions, in which the person

would start having symptoms of effort intolerance or angina; a good clinician with a good diagnostic level of suspicion would be able to diagnose and treat him. The disease would further progress to one of full blown disease, manifesting as acute myocardial infarction and thereafter would progress on to termination, either as death, or full recovery or else life with residual disability.

Now, what is the importance of understanding these sequences of action in the natural history of a disease? The importance is that it serves as the basis of planning the preventive activities. In fact, we take preventive actions throughout the entire sequence of the natural history of the disease, as shown in Fig. - 3.

## Levels of Prevention

In general, there are three major levels of prevention, depending on the phase of the natural history of the disease :

### Primary Prevention

These are all measures of prevention that are undertaken during the phase of pre-pathogenesis (phase of susceptibility), before the disease process has had onset. Primary prevention involves two types of sub-steps, as follows :

**Health Promotion** : These include all steps undertaken to improve the level of general health and well being so that conditions for initiation of disease process are prevented. However, these steps are not specific for any disease or a group of diseases. These actions include improvement in the overall socio-economic status of the population, health education, feeding programmes for mothers and children, promotion of breast feeding, promotion of small family norms, education and motivation for healthy lifestyle and such similar measures.

**Specific Protection** : These include measures to prevent the initiation of specific diseases or a group of diseases. Examples include immunization to protect against specific diseases, fortification of foods with specific nutrients (as salt with iodine), use of condoms to protect against sexually transmitted diseases (STDs), use of chemoprophylactic drugs to protect against particular diseases (as malaria, meningococcal meningitis, plague, tuberculosis, leptospirosis, etc), use of helmets to protect against head injuries, etc.

The difference between health promotion and specific protection should be clearly understood. Both are a type of "primary preventive" strategy, undertaken during the stage of susceptibility (pre-pathogenesis), with a view to obviate the very initiation of the disease process. However, health promotional approach improves the general health so that a number of diseases are aimed at, from preventive point of view and not a single disease. For example, when we promote breast feeding among children, we are trying to prevent general malnutrition, vitamin A deficiency, providing antibodies against various diseases, preventing diarrhoeal diseases (because artificial feeding carries the risk of infection) and so on. On the other hand when condom is used, it is for a very specific group of diseases i.e. STDs; when measles vaccine is given it is for a specific disease viz. measles.

In addition, there is also an increasing role of "primordial prevention" being recognized in contemporary public health.

Primordial prevention is different from primary prevention. Primary prevention focuses on steps so that the disease process is not initiated, i.e. the stage of pre-pathogenesis is not crossed, though the adverse agent, host and environmental factors may be present. For instance, in the example of the natural history of IHD given above, if we educate and motivate the young man not to start smoking, despite the fact that cigarettes are available, we are practicing primary prevention. On the other hand, primordial prevention endeavours to prevent the very creation of such environment or the establishment of such conditions, that are conducive to the development of the disease. For example, if we create conditions in which cigarettes are not available or even tobacco is not produced, then we are preventing the development of those very conditions which lead to the state of pre-pathogenesis; hence this would be primordial prevention.

### Secondary Prevention

These include all actions undertaken at the stage of early pathogenesis (asymptomatic disease) with a view to halt the progress of disease at its earliest, incipient stage, by "early diagnosis and prompt treatment". It is like stamping off a fire when it has just started rather than call the fire brigade after the fire has become voluminous. The person is not aware of any signs or symptoms and the routine clinical methods also may not be able to detect a disease at this stage, since the disease process is in the very preliminary stage. However, by using special procedures we can uncover a disease in such early stages. The classical example of this level of prevention is "screening for disease" as for breast cancer (using mammography) and cervical cancer (using pap smear). Various types of medical examinations as those of school children, infants and young children, of industrial workers and various disease screening camps are all examples of this level of prevention.

### Tertiary Prevention

These include all measures undertaken when the disease has become clinically manifest or advanced, with a view to prevent or delay death, reduce or limit the impairments and disabilities, minimize suffering and to promote the subject's adjustment to irremediable conditions. Tertiary prevention has two types of approaches inbuilt into it, viz. disability limitation and rehabilitation.

**Disability Limitation** : These include all measures to prevent the occurrence of further complications, impairments, disabilities and handicaps or even death. For example :

When we apply plaster cast to a patient who has suffered Colle's fracture, we are actually trying to prevent complications and further disability like mal-union or non-union.

When we give complete rest, morphine, oxygen and streptokinase to a patient of Acute MI, we are actually trying to prevent death or complications like arrhythmias / CHF.

The sequence with which a disease turns into a handicap is as follows :

**Disease** : This is a pathological process and its manifestations which indicate a departure from the state of perfect health.

**Impairment** : This is the actual loss or damage of a part of body anatomy or an aberration of the physiological functions

that occurs consequent to a disease.

**Disability** : This is defined as the inability to carry out certain functions or activities which are otherwise expected for that age / sex, as a result of the impairment.

**Handicap** : This is the final disadvantage in life which occurs consequent to an impairment or disability, which limits the fulfillment of the role a person is required to play in life.

For example, let us say an agricultural worker gets acute myocardial infarction. This is the disease. Because of this disease, he would have necrosis of a part of the myocardium, inadequate perfusion of the myocardium and inadequacy in the pumping action of the heart with a compromise in the oxygenation of the blood. These are the "impairments" due to the disease. Due to these impairments he will not be able to undertake hard manual labour, which an otherwise healthy male of his age would have undertaken - this is the disability, resultant to the impairment. Finally because of this disability, he will lose his job of an agricultural worker and hence not able to earn adequate livelihood - this is the handicap, consequent to the disability.

**Rehabilitation** : This is the second component of tertiary prevention. Rehabilitation stands for the combined and coordinated usage of all the available medical, social, educational and vocational measures, for training and retraining the person to the highest level of functional ability.

Rehabilitation emphasizes on the fact that the duty and obligation of a Doctor who cares for a patient does not end simply by curing the patient of his / her symptoms. It is also an obligation to assist the patient in getting rehabilitated so that he / she gets fully adjusted in the family and social milieu and lives a happy and productive life. When you treat a patient of Hansen's disease, it is not simply enough to treat the patient with the recommended antibiotic regime and then forget about the patient. A lot still has to be done. The patient would be having claw hand and would need the hands to be made as near normal as possible by corrective surgery, so that he can work productively as well as undertake the daily activities of life. The patient also needs to be trained in some vocation so that he can make a living. The patient's family and the society has to be educated to accept this patient as a normal human being and not one who has been cursed by the Gods. The patient himself would be emotionally weak and labile and would need to be emotionally supported. These all activities come under the purview of "Rehabilitation" (Re = restore into, habitat = the original home or environment of the person). Accordingly, rehabilitation is undertaken at four dimensions :

**Medical rehabilitation** : This is done through medical / surgical procedures to restore the anatomy, anatomical functions and physiological functions to as near normal as possible.

**Vocational rehabilitation** : This includes steps involving training and education so as to enable the person to earn a livelihood.

**Social rehabilitation** : This involves steps for restoration of the family and social relationships.

**Emotional and Psychological rehabilitation** : This involves steps to restore the confidence, personal dignity and



confidence.

### The Iceberg Phenomena in Human Diseases

Measurement of the level of health and disease is a major issue in public health. One way is to measure the magnitude of sickness that has come to the notice of health care providers. For instance, if we want to estimate the load of hypertension in our community, we may work out the details of cases of hypertension admitted to all the government hospitals and private nursing homes as also seen at the OPDs, dispensaries and by the GPs, during the entire year and develop our estimates. We are quite likely to grossly under-estimate the magnitude of the problem, if we take such a recourse, for we would be missing out a very large number of cases who are present in the population with undetected hypertension and those with mild disease who never reported to a health care provider. This is what is referred to as the “iceberg” phenomena in human diseases - the magnitude of disease that is apparent clinically is a small fraction of the entire load; the major part of the load is not clinically apparent (lies below the clinical horizon) and hence lies hidden in the community. This is in the same way that the part of an iceberg which lies above the surface of water is actually a very small part of the total iceberg which lies submerged beneath the water surface.

In the past, many accidents have happened among ships that could not appreciate this iceberg phenomena and, underestimating the actual bulk of the iceberg, crashed and sank in the sea. Similarly, public health professionals should be careful while making an assessment of the load of diseases and their associated risk factors in the community, remembering that the real load lies hidden in the community and is not clinically apparent. This will help preventing failures which may otherwise occur consequent to inadequate planning due to underestimation, in public health programmes.

### Summary

Right from the pre-historic times onwards, man has been trying to find out the causes of disease from “supernatural causes”, “bad air” and the “miasma” theory by Farr. It was in the second half of the 19th century that the germ theory of the human disease was put forth which was the central philosophy of the famous Koch’s postulates, formulated by Robert Koch (now also known as Henle-Koch postulates). Later, thought processes were started to explain the role of other factors in accentuating or attenuating the effect of the “germ” or “agent” of disease which finally culminated into the “Epidemiological triad”. This theory hypothesizes that there are 3 important determinants of the state of health or disease in a human being, namely the agent factors, host factors and the environmental factors. As long as a state of fine balance or equilibrium is maintained between these factors, the person stays in a state of health and the moment this fine balance is disturbed, a departure from the state of health occurs. The “BEINGS” model of disease causation postulates that human disease and its consequences are caused by a complex interplay of nine different factors - Biological factors innate in a human being, Behavioural factors concerned with individual lifestyles, Environmental factors as physical, chemical and biological aspects of environment, Immunological factors, Nutritional factors, Genetic factors,

Social factors, Spiritual factors and Services factors, related to the various aspects of health care services. The Theory of “Web of Causation” was postulated by McMahon and Colleagues to explain the occurrence of non-communicable diseases like IHD, wherein the various factors are like an interacting web of a spider. Each factor has its own relative importance in causing the final departure from the state of health, as well as interacts with others, modifying the effect of each other. For preventing a disease, it is not necessary to take action against all the factors - if we could identify a few “weakest links” in the inter-lacing webs, actions directed to these may be of considerable value in prevention. The “wheel” theory visualizes human disease in the form of a wheel, which has a central hub representing the genetic components and the peripheral portion representing the environmental component that has spokes (3 in this model) representing the social, biological and physical components of the environment.

*The theory of “necessary” and “sufficient” cause* : A necessary cause is one whose presence is essential for disease causation, but which alone, by itself may or may not be able to finally cause the disease. Disease may or may not occur in its presence but will not occur in its absence. At times, necessary cause may by itself be a sufficient cause for the disease (e.g. infection with HIV is a “necessary” as well “sufficient” cause for AIDS).

Induction period is the time interval that elapses between the point when “sufficient cause” becomes operative to the point when the first pathological changes of disease start in the body. On the other hand latent period is the time period that elapses between the initiation of pathological change till the point when the earliest diagnosis of the disease is possible with the currently available clinical and diagnostic armamentarium. The counterpart in infectious disease epidemiology is the “incubation period” which refers to the time period that elapses between the entry of the infectious agent into the body till the point the earliest manifestation of the disease are evident. The “generation time” on the other hand refers to the time between entry of the infectious agent into the body and the maximum infectivity of the human host.

A large number of other factors present, based on whose optimum permutation and combination, the “sufficient cause” finally emerges, are classified into : Predisposing factors (which create a state of susceptibility, so that the host becomes vulnerable to the agent or to necessary cause, e.g. age, sex, previous illness), Enabling factors (those which assist in the development of or in recovery from the disease; e.g. housing conditions, socio-economic status), Precipitating factors (those which are associated with immediate exposure to the disease agent or onset of disease, e.g. drinking contaminated water, close contact with open case of pulmonary TB), Reinforcing factors (those which aggravate an already existing disease, e.g. malnutrition, repeated, exposures, etc), Risk factors (defined as a condition, quality or attribute, the presence of which increases the chances of an individual to have, develop or be adversely affected by a disease process; a risk factor is thus not necessarily the cause of a disease but does increase the probability that a person exposed to the factor may get the disease; may be modifiable or non-modifiable), Risk Marker (is only a surrogate or a proxy indicator of the risk of the disease,

mostly because of its association with another risk factor) and Risk Groups and Risk Approach (a high risk group can be defined as a group of people or a subsection of the population, who, by virtue of certain characteristics, are likely to have a higher probability of suffering from one or more diseases or from general ill health). The “high risk approach” is defined as a health care management strategy which endeavours to provide special care to those who are at higher risk of being affected by adverse health conditions, due to some identified characteristics, while, at the same time, providing optimum care to all other members of the community.

Natural History of Disease is defined as the “natural course that a disease would take when it has not been affected by any treatment or any other intervention. The broad phase of “pathogenesis” has four sub-phases, namely, phase of early pathogenesis or phase of asymptomatic disease, phase of early discernible lesions, phase of full blown disease and phase of termination; the last one (termination) has a wide spectrum ranging from full recovery at one end and death at the other and various grades of residual disability / chronicity in between.

In general, there are three major levels of prevention, depending on the phase of the natural history of the disease : Primary Prevention (all measures of prevention that are undertaken during the phase of pre-pathogenesis or phase of susceptibility, before the disease process has had onset and involves two types of sub-steps : Health Promotion - which includes all steps undertaken to improve the level of general health and well being so that conditions for initiation of disease process are prevented; Specific Protection - includes measures to prevent the initiation of specific diseases or a group of diseases.), Primordial prevention (which endeavours to prevent the very creation of such environment or the establishment of such conditions, that are conducive to the development of the disease), Secondary Prevention (which includes all actions undertaken at the stage of early pathogenesis or asymptomatic disease with a view to halt the progress of disease at its earliest, incipient stage, by “early diagnosis and prompt treatment”) and Tertiary Prevention (which includes all measures undertaken when the disease has become clinically manifest or advanced, with a view to prevent or delay death, reduce or limit the impairments and disabilities, minimize suffering and to promote the subject's adjustment to irremediable conditions; it includes disability limitation rehabilitation. The iceberg phenomena in human diseases describes that the magnitude of disease that is apparent clinically is a small fraction of the entire load; the major part of the load is not clinically apparent (lies below the clinical horizon) and hence lies hidden in the community.

## Study Exercises

**Long Question :** Describe the natural history of disease, taking tuberculosis as an example.

**Short Notes :** (1) Theories of disease causation (2) Phases in the natural history of disease (3) Levels of prevention.

### MCQs & Exercises

- 1) Human diseases are due to bad clouds was a part of which theory? : (a) Supernatural causes (b) “Miasma” theory (c) Germ theory (d) Epidemiological triad
- 2) The “BEINGS” model of disease causation postulates that

human disease and its consequences are caused by a complex interplay of how many different factors ? : (a) 3 (b) 6 (c) 9 (d) 10

- 3) The theory of “epidemiological web of causation” was forwarded by : (a) Robert Koch and Louis Pasteur (b) McMahon and Colleagues (c) Henle-Koch (d) John Stuart Mill
- 4) Epidemiological Wheel Theory visualizes human disease in the form of a wheel, which has : (a) a central hub representing the genetic components and the peripheral portion representing the environmental component (b) a central hub representing the environmental component and the peripheral portion representing the genetic components (c) interplay of nine different factors in causation of disease (d) various factors like an interacting web of a spider with each factor having its own relative importance in causation.
- 5) According to the Epidemiological Wheel Theory, in malaria, there is : (a) a large central hub, while out of the environmental factors, all the three components have unequal roles (b) a large central hub, while out of the environmental factors, all the three components have a major and equal role (c) a small central hub, while out of the environmental factors, all the three components have unequal roles (d) a small central hub, while out of the environmental factors, all the three components have a major and equal role
- 6) The time interval that elapses between the point when “sufficient cause” becomes operative to the point when the first pathological changes of disease start in the body is : (a) generation time (b) induction period (c) Latent period (d) lag phase
- 7) A condition, quality or attribute, the presence of which increases the chances of an individual to have, develop or be adversely affected by a disease process is known as : (a) Predisposing factor (b) Risk factor (c) Precipitating factors (d) Risk Marker
- 8) Education and motivation for healthy lifestyle is : (a) Primordial prevention (b) Secondary prevention (c) Health Promotion (d) Specific Protection
- 9) The inability to carry out certain function or activity which is otherwise expected for that age / sex is known as : (a) Disease (b) Impairment (c) Disability (d) Handicap
- 10) Disability Limitation is part of : (a) Primordial prevention (b) Primary prevention (c) Secondary prevention (d) Tertiary Prevention
- 11) Screening for breast cancer using mammography is : (a) Primordial prevention (b) Primary prevention (c) Secondary prevention (d) Tertiary Prevention
- 12) Fortification of foods with specific nutrients as salt with iodine, is an example of : (a) Primordial prevention (b) Primary prevention (c) Secondary prevention (d) Tertiary Prevention
- 13) Primary Preventive measure can be applied at which stage of the natural history of disease : (a) stage of positive health (b) asymptomatic (early pathogenesis) (c) early, discernible disease (d) full - blown (classical) disease
- 14) Use of chemoprophylactic drugs to protect against malaria is : (a) Primordial prevention (b) Primary prevention

- (c) Secondary prevention (d) Tertiary Prevention
- 15) Measures that can be applied at the stage of early, discernible disease include : (a) Primordial and Primary prevention (b) Primary and Secondary prevention (c) Secondary and tertiary prevention (d) Primary, secondary and tertiary prevention

**Match the Following :**

1. An agricultural worker gets acute myocardial infarction  
 2. Necrosis of a part of the myocardium and inadequate perfusion  
 3. Not be able to undertake hard manual labour  
 4. Lose his job and hence not able to earn adequate livelihood
- a. Disease; b. Disability; c. Impairment; d. Handicap

**Fill in the Blanks :**

1. \_\_\_\_\_ is the theory which postulated that human diseases are due to bad clouds.  
 2. Koch's postulates, formulated by Robert Koch, later came to be known as \_\_\_\_\_

3. "BEINGS" model of disease causation postulates that human disease and its consequences are caused by a complex interplay of nine different factors which are \_\_\_\_\_  
 4. According to the Epidemiological Wheel Theory, in phenylketonuria the major role is played by \_\_\_\_\_ factors  
 5. Measures adopted to prevent the initiation of specific diseases or a group of diseases is known as \_\_\_\_\_ .

**Answers :**

**MCQs :** (1) b; (2) c; (3) b; (4) a; (5) d; (6) b; (7) b; (8) c; (9) c; (10) d; (11) c; (12) b; (13) a; (14) b; (15) c.

**Match the Following :** 1-a; 2-c; 3-b; 4-d.

**Fill in the Blanks :** 1. Miasma theory; 2. Henle-Koch postulates; 3. Biological factors, Behavioural factors, Environmental factors, Immunological factors, Nutritional factors, Genetic factors, Social factors, Spiritual factors and Services factors. 4. Genetic factors; 5. Specific Protection.

**4**

**Measuring the Level of Health in a Population : Epidemiological Measures (Indicators) of Health and Disease in a Community**

*RajVir Bhalwar*

"----- For the health administrator, nothing could be more valuable than to have, at his command, one or more measuring rods to help him in his task and also in assessing his specific problems relating to the health of the people, in designing his plans to deal with these, in guiding his administration and in evaluating his schemes ----- " (WHO).

In the previous chapter, we discussed the "summary measures" in epidemiology i.e. incidence rate, prevalence, etc. In real health care practice, these measures are actually expressed in terms of indicators which provide a quick idea of the status of health, disease and health related conditions in the community. These measures (also called as "Indicators") can be grouped as:

**Health Status Indicators**

These include Measures of Mortality and Morbidity.

**Indicators of Health Care**

These include measures of Health Infrastructure; Human Resources in health; Health Finance indicators; and Indicators of accessibility & utilization of health care services.

**Indicators of "Quality of Life"**

These include such measures as disability days, bed days, limited activity days, days on which activities of daily living

are compromised and days requiring "aids" for walking or such other routine activities of life.

**Demographic Indicators**

These include measures of fertility and population distribution.

**Socio-economic and Human Development Indicators related to Health**

These include measures of literacy, income, accessibility to safe water supply and sanitary excreta disposal facilities, etc.

**Other Indirect Indicators related to Health**

These are measures as nutritional status, child development, environmental indicators, etc.

**Summary Measures of Population Health (SMPH)**

These summarise, in a single numerical figure the level of health in a large population of country, as HALE, DALY, PYLL, etc.

**Measures of Mortality**

Measures of mortality in community health practice could be either Crude indicators or standardized indicators, or else Specific indicators. The commonly used ones are :

**Crude Mortality Rate :** The Crude Mortality Rate, also known as Crude Death Rate (CDR), gives the number of deaths in a defined community in a year per 1000 population in the middle of year (i.e. on 1st July).

$$\text{CDR} = \frac{\text{Total deaths in a defined community OR defined area in a year}}{\text{Mid-Year population (01 July) of that community OR defined area}} \times 1000$$



The CDR is useful for making “quick” comparisons regarding death rates between two population groups and for making a quick estimates of load of mortality in a given population. However comparison of CDRs between two populations may differ from each other because of confounding factors (e.g. the observed differences in the CDRs of 2 populations may be because of the different age-structure of the 2 populations). Therefore, “adjustments” for such factors are made by the procedure of “standardization”, to calculate “Standardized Mortality rates”, by statistical methods of Direct or by Indirect Standardization. The methods of direct and indirect standardization are dealt in detail in another chapter in the section on Biostatistics, Secondly, the CDR does not define as to which particular “subgroups” are most affected or what are the important causes of mortality. For this reason, “specific rates” are computed.

**Specific Morality Rates** : Specific mortality rates provide more meaningful information as compared to CDR, by identifying the “risk of death” in different subgroups or risk of death due to specific diseases. The commonly used specific mortality rates are :

**(a) Age Specific Mortality Rates (ASMR)** : This is calculated as the No. of deaths in a particular age group in a defined area over a defined time period per 1000 “mid-point” population of that particular age group in that defined area. For example, the ASMR for school age group children (5 to 14 years) in Delhi, in 2007 will be calculated as

$$\text{ASMR} = \frac{\text{Total deaths among children in the age group 5 to 14 Years in Delhi, during 2007}}{\text{Population of children in the age group 5 to 14 Years in Delhi, as on 01 July, 2007}} \times 1000$$

**(b) Sex Specific Mortality Rate (SSMR)** : This is calculated as the No. of deaths occurring in a particular sex group in a defined area and defined period of time (usually 1 year) per 1000 Mid-point population (usually mid year population) of that particular sex in that area. For example, the SSMR for women in Delhi, in 2007 will be calculated as

$$\text{SSMR} = \frac{\text{Total deaths among women in Delhi, during 2007}}{\text{Population of women in Delhi, as on 01 July 2007}} \times 1000$$

**(c) Cause Specific Mortality Rate (CSMR)** : The CSMR is calculated as No. of deaths occurring in a defined area due to a particular disease, in a defined period of time (usually 1 year) for every 1000 Mid point (usually mid year) population in the defined area. The CSMR gives the risk of death due to that disease, in the defined population, over the period of interest. It also gives the relative importance of the disease as a cause of mortality in the community. e.g. the CSMR due to pulmonary tuberculosis for a ten year period of 1st January 1991 to 31st December 2000 in entire India would be calculated as

$$\text{CSMR} = \frac{\text{Total deaths due to Pulmonary Tuberculosis, in India during 01 Jan 1991 to 31 Dec 2000}}{\text{Population of India as on 01 Jan 1996}} \times 1000$$

**(d) Cross combination of Age, Sex, Cause etc.** : Depending on the requirements, further combinations of age, sex, cause, occupation etc. (as relevant) may be made to further enquire and identify special risk groups. For example, we can make the cause specific (Lung CA) death rate in a specific age group (40 to 60 years) and in a specific sex (males) working in a specific occupation (Asbestos industry) in a city (Pune) during 2007 would be calculated as :

$$\frac{\text{No. of deaths due to Lung CA among male asbestos workers, of the age group 40 - 60 Years in Pune during 2007}}{\text{Population of all 40- 60 Years old male asbestos workers in Pune as on 01 Jul 2007}} \times 1000$$

**(e) Case Fatality Rate (CFR)** : The CFR is calculated as No. of persons, dying due to a particular disease, during a defined time period, in a defined area per 1000 persons in that area, having that particular disease. For example, the CFR due to rabies in Mumbai during the year 2007 would be calculated as:

$$\frac{\text{Total deaths due to Rabies in Mumbai, during 2007}}{\text{Total cases of Rabies in Mumbai during 2007}} \times 1000$$

The CFR does not give the risk of dying due to the given disease which a person in the defined community has or the importance of the disease as a leading cause of mortality in the community at large (that is given by cause specific mortality rate); it rather gives the “killing power” of the disease; e.g. the CFR for Rabies is very high (100%); for acute MI and Japanese encephalitis it is quite high (30-40%) while it is very low for common cold (almost 0%).

**(f) Proportionate Mortality ratio (PMR)** : This gives the proportion of total deaths that are due to a given cause, out of the total deaths. It is calculated as Total deaths due to the particular disease in a defined area over the given time divided by the total deaths (due to all causes) in that area during that time and multiplying the result by 100 to get it as a %. Thus, PMR for Acute MI in Lucknow during 2007 will be calculated as:

$$\frac{\text{Total deaths due to acute MI in Lucknow District during 2007}}{\text{Total deaths (due to All Causes) in Lucknow District during 2007}} \times 1000$$

### Cautions to be Observed while Interpreting the Various Measures of Mortality

While interpreting the various types of measures of mortality, the epidemiologist should be careful about certain “biases” that may occur. Such biases can occur in two ways :

**(a) Errors in the numerator** : This can occur because of inaccurate or incomplete reporting of the various causes of death in large population groups; e.g. in a developing country, road accident deaths may be diagnosed, recorded and reported more accurately as compared to deaths due to various neoplasms.

**(b) Errors in the denominator** : This may occur because of inadequate or incorrect enumeration of either the “population”



or the deaths, depending on which one of the two is in the denominator.

### Special Mortality Indices used in Maternal and Child Health Care

In maternal and child health care, certain measures of mortality are commonly used, as follows :

**(a) Infant Mortality Rate (IMR) :** This is calculated as the No. of deaths among children less than 1 year age in a year for every 1000 live births in the same year in the same area. The IMR is one of the most sensitive indicators of the health and socioeconomic conditions of a community, since it is affected by diseases that directly cause infant deaths (Acute Respiratory Infections, Diarrhoeal diseases etc), by the availability and utilization of health care services and by various social factors like income, family size, customs, beliefs etc.

**(b) Maternal Mortality Rate (MMR) :** It is calculated as the No. of deaths due to “maternal causes” in a given community, in a year per 1000 live births in the same year in the same area. (Maternal death is defined as death occurring to woman, while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of pregnancy, from any cause related to or aggravated by pregnancy, but not from accidental or incidental causes). Similarly, the MMR is another very sensitive indicator of the health status of women in the reproductive age group, as well as of the obstetric services. Truly speaking, the MMR is not really a rate, as it is commonly referred to but rather a ratio, since the numerator is not a part of the denominator.

**(c) Neonatal Mortality Rate (NMR) :** This is calculated as the deaths in a year, in a defined area, among children upto (and including) 28 days age per 1000 live births in the same year in the same area. (Note that in IMR, MMR and NMR, the denominator is the ‘total live births’ and not the mid point population of that particular group). Thus, the component of Infant mortality rate which occurs after neonatal period is also often referred to as “Post-Neonatal Mortality”.

**(d) Perinatal Mortality Rate (PMR) :** This is defined as the No. of foetal deaths of > 28 weeks gestation plus infant deaths of < 7 days age in a defined area in one year per 1000 “live births plus foetal deaths” of > 28 weeks gestation (i.e. total live and still births) in the same area and in the same year.

The point to be noted is that as overall socioeconomic conditions and health care systems improve, the IMR may decrease quite fast but the NMR, especially PMR, may not decline so fast. This is because most of the causes of “Post-Neonatal Mortality” (i.e. deaths between 1 month to 12 months age) are amenable to good health care in the form of immunization of children, early diagnosis and treatment of acute respiratory infections / diarrhoeal diseases and nutritional care. However, the causes of NMR (and especially PMR) are less amenable to such improvements in health care delivery, being often related to causes like congenital malformations.

It also stands to reasoning that, since MMR, IMR and other indicators are all closely related, if health care is improving, all of them should show decline. A decline in one without a proportionate decline in the others should initiate a search for a possible “disproportionate” development of health services.

For example, a decline in MMR, without a corresponding decline in IMR may be because of much improvement in obstetric care to the community without simultaneous improvement in childhood immunization or early treatment of acute infections among infants.

### Measures of Morbidity

While mortality indicators are, by and large, “incidence measures” (since they are nearly always related to some period of time over which the “follow up” has been done), morbidity measures can be either in the form of incidence or prevalence and are calculated as counterparts of “mortality measures”, as Crude Morbidity Rate, Age or cause specific Morbidity, etc. For example, the “annual incidence”, or else the “prevalence” of HIV infection in a community will be worked out as

$$\text{Incidence} = \frac{\begin{array}{c} \text{Total new cases of HIV occurring} \\ \text{in a year in a community,} \\ \text{out of those initially sero -Negative} \end{array}}{\begin{array}{c} \text{Total persons who were 'At Risk' of} \\ \text{developing HIV at the start of follow up} \end{array}} \times 1000$$

$$\text{Prevalence} = \frac{\begin{array}{c} \text{Total persons in a community found to be} \\ \text{having HIV positivity at the} \\ \text{time of the survey} \end{array}}{\begin{array}{c} \text{Total persons in the community who were} \\ \text{examined} \end{array}} \times 1000$$

### Interpreting the Various Indicators of Morbidity and Mortality

While interpreting the various morbidity rates (incidence or prevalence) the epidemiologist should again be cautious of the errors that can occur either in the numerator or else in the denominator, as we have already explained in indicators of mortality.

### Errors in Numerator may Occur due to the following Important Reasons

**Inadequate reporting of the disease :** Inadequate reporting of the disease in a particular area or community due to inadequate diagnostic facilities; inadequate training of physicians in recognizing the disease; low index of diagnostic suspicion about the disease since the disease is uncommon in that region; or due to poor coverage by the health care facilities (due to poor facilities, poor accessibility, adverse behaviour of health care providers, etc), leading to a section of the population not being covered by the health workers or by the reporting hospital. It may also occur because for certain particular diseases, the community may be seeking care from the practitioners of Indigenous systems of medicine and hence the disease may not be completely reported; or else due to possible stigma related to the disease and hence either the physicians may not report the disease or the persons may not come forward to get themselves tested.

**Over-reporting of the disease :** Over-reporting of the disease in a particular area or community because of very fine diagnostic facilities or the particular health care facility may be specializing in that disease; due to vague case definitions so that many other diseases may be included (as “viral fever”

may actually include a number of cases of malaria, dengue, etc); or because the disease has been newly discovered or has re-appeared in that area after a long time (as plague) and hence medical personnel are over-enthusiastic about the disease.

**Cross-reporting of the disease** : Cross-reporting of the disease in a particular area or community; for example, some of the patients with that particular disease may actually report and seek treatment from a health centre of another district and hence will be reflected in the other district while the population base from where they come, will be taken in the numerator of their parent district.

**Changes in diagnostic criteria** : Changes in diagnostic criteria over time, due to Changes in International Classification of Diseases (ICD) criteria or changes in the diagnostic criteria or case definition of the disease, by expert bodies, over time; or else due to availability of better diagnostic facilities over time, even in the same community or nation.

**Similarly, errors in denominator may occur because of :**

- Inadequate enumeration of total population, as in countries with inadequate census facilities.
- The enumeration of total population may suddenly improve and hence it may be erroneous to compare the current rates with previous rates.

Once the epidemiologist has undertaken a logical reasoning about the apparent mortality or morbidity rates and has satisfied herself that there are no errors in the numerator or denominator, then only she should proceed to analyse as to why the disease is posing a health problem and how best can we tackle it.

## Measures of Fertility

Epidemiologic measures of fertility are extensively used in fields of demography, family planning and health administration. The selected indices are :

**Crude Birth Rate** : It is calculated as number of live births in an area during one year per 1000 mid year population. The CBR has the advantage of ease of compilation. However, the denominator in CBR is total population; on the other hand, the real contribution to the births in a population comes from the females in the reproductive age group (15 to 44 years age). This deficit of CBR is overcome in General Fertility Rate (GFR).

**General Fertility Rate (GFR)** : It is defined as Number of live births in a given area during a year per 1000 mid year population of females in the reproductive age groups (15 to 44 years) in that area, during that year.

While GFR is definitely an improvement over CBR, comparisons

between two populations based on GFR may not be accurate because the populations structure of ladies within the category of 15 to 45 years age may be quite different between the two population (for example, one population may have much higher proportion of females aged 15 to 30 years, while the other population may have higher proportion of females aged 30 to 45 years). Secondly, the GFR does not allow for identifying the “high risk” age group of females, as far as conception is concerned, so that family planning activities can be directed towards such high risk groups. This difficulty is overcome by computing the Age Specific Fertility Rates (ASFR).

**ASFR** : It helps in identifying the age groups of women having the highest reproductive potential, so that family planning measures can be directed towards such groups. It is calculated as Number of live births to women in a specified age group (e.g. 20 to 25 years age group) in a given area and in a given year per 1000 mid year population of females in the same age group (e.g. 20 to 25 years) in that area during that year.

**Total Fertility Rate (TFR)** : This gives the estimated number of children which a group of 1000 women would bear, if they were to start their reproductive life at a common point of life and were to pass through their entire reproductive span, subject to the current age-specific fertility rates. This measure is calculated by summing up the ASFRs for the different age groups and multiplying such sum by the class - interval on which the age groups have been formed; e.g. if we have made the age groups as 15-19, 20-24 years and so on (thus the class interval being 5 years), the ASFRs would be summed up and multiplied by 5 to get the TFR. The TFR is quite an accurate epidemiological measure of fertility and provides valid answer to the issue “How many children would a woman have, on an average?” (or, in case the ASFR have been calculated as “per 1000”, it will tell us how many children 1000 women are likely to have).

**Gross Reproductive Rate (GRR)** : This is a measure of the average number of female live births that would occur to a female new born, growing up and passing her entire reproductive age, if the current fertility rate were to apply. The GFR assumes that these women will not die before completing their childbearing age, which is more of a hypothetical assumption and this drawback is overcome through compilation of Net Reproductive Rate (NRR). The GRR is thus equivalent to TFR for female children only.

**Net Reproductive Rate (NRR)** : The NRR is a measure of the average number of female live births that will occur to a newborn female as she grows up and passes through her

**Table - 1 : Calculation of the Human development indices**

Index	Measure	Minimum value	Maximum value	Formula
Longevity	Life expectancy at birth (LE)	25 yrs	85 yrs	$L = \frac{LE-25}{60}$
Education	Literacy rate (LR)	0%	100%	$E = \frac{2LR + CGER}{3}$
	Combined gross enrollment ratio (CGER)	0%	100%	
GDP	GDP per capita (PPP)	100 US Dollars	40,000 US Dollars	$E = \frac{\log_{10} GDP_{pc} - 2}{2.60206}$

entire reproductive age group, provided she was subjected to the current rates of fertility as well as mortality. Thus, the NRR is similar to GRR, but, in addition, also caters to the fact that some women will die before completing the child bearing age, while making the calculations. The NRR is a sensitive indicator of population growth. If the NRR is 1.00, it indicates that each generation of mothers is being replaced by an exactly equal number of daughters; in other words, the female population is “maintaining itself”. India, as well as a large number of other developing countries have kept a target of achieving a NRR equal to 1.00, as a part of their family welfare programmes.

**Population Growth Rate** : This is also known as the natural rate of population increase. It is calculated as the difference between CBR and CDR. For example, if the CBR in a country is 21 per 1000 while the CDR is 9, the population growth rate would be 12 per 1000 or 1.2%.

**Dependency Ratio** : The dependency ratio is calculated as the ratio between (Population < 20 years age + population > 65 years) divided by the population in the age groups 20 to 64 years. Higher the dependency ratio, lower is the productive work-force in that community or country. Ideally, this ratio should be 1.00 or lesser.

#### Indicators related to “Health Services”

These are indicators which either measure the “availability” (as, Doctor - Population ratio, Population served by each Health centre, Population - hospital bed ratio); or, “expenditure on health care” (as, percentage of national budget earmarked for health sector, Average finances spent per person on health care); or, “health coverage” (e.g. percentage of children fully immunized, deliveries conducted by trained birth attendants, % of cases of pulmonary TB brought under ATT, % of houses that were adequately sprayed with an insecticide, etc.); or “accessibility” (e.g. Mean distance in Kms required to be traveled in a village to reach the health centre); or, “utilization” (e.g. % of women who availed of cervical cancer screening camp out of those who were eligible); or, finally, the “policy” (e.g. availability of a stated health policy and enunciated targets).

These indicators are discussed in more detail in the section on health management.

#### Socio-Economic Indicators

As has been explained in the opening chapters of this book, health is the result of a complex interplay between the human beings and their environment, including the various array of socio-economic factors. Hence, in the process of measuring the health of a community, the epidemiologist cannot do without various socio-economic indicators. The major indicators as relevant to health care are :

**Life Expectancy** : Life expectancy at birth is a commonly used summary measure of the health status of a population. It is defined as the average number of years in a population (or a nation) that an individual is expected to live from birth onwards, if the current mortality rates continue. Another variant is “life expectancy at 1 year age”. Life expectancy at birth, 1 year age or at any other age is calculated through “life tables”, the discussion on which is made in another chapter. Comparisons based on life expectancy may be made between two countries or else may be made for different periods of time for the same country.

**Indicators of overall development** : The Human Development Index (HDI) is an index combining normalized measures of life expectancy, literacy, educational attainment and GDP per capita for countries, worldwide. It is claimed as a standard means of measuring human development, according to the United Nations Development Program (UNDP). The HDI combines three basic dimensions, viz. Life expectancy at birth, as an index of population health and longevity; secondly, Knowledge and education, as measured by the adult literacy rate (with two-thirds weighting) and the combined primary, secondary and tertiary gross enrollment ratio (with one-third weighting) and, thirdly, the standard of living, as measured by the natural logarithm of Gross Domestic Product (GDP) per capita at Purchasing Power Parity (PPP) in US Dollars. The Human Development Index (HDI) thus represents the average of these

**Table - 2 : Road traffic accidents (RTAs)**

Age Group (years)	Mid point of the age group	Population	Deaths due to RTA in one year	YPLL (65 minus mid point of age)	Age specific YPLL (Coln 4X Coln 5)
(1)	(2)	(3)	(4)	(5)	(6)
0-4	2.5	18252000	1190	62.5	74375
5-14	10	34146000	2397	55	131835
15-24	20	38252000	14447	45	650115
25-34	30	43315000	10467	35	366345
35-44	40	34305000	5938	25	148450
45-54	50	23276000	3576	15	53640
55-64	60	22019000	3445	5	17225
65-74	70	17668000	3277	Not applicable	Not applicable
75-84	80	9301000	2726	Not applicable	Not applicable
>=85	90	2867000	778	Not applicable	Not applicable
Total		213565000	41460		1441985



three general indices as shown in Table 1.

The HDI is finally calculated as  $(L + E + G) / 3$ . An index of below 0.5 indicates poor development, while an index of 0.8 and above indicates good development of a country. Reviews in 2007 indicate that India, with an Index of approximately 0.6 is progressing but has still a long way to go. Countries like Norway, Canada and Japan have been often taking the first place.

**Percentage of Population Living below Poverty Line** : This is another very commonly used index of overall standard of living and economic status of a country. Poverty line actually means inability to buy adequate food calories which is equivalent of 2400 Kcal per day in rural and 2100 Kcal per day in urban areas. It is also taken as equivalent of a family income of less than Rs. 1,500/= per month. In India, about one-fourth (26.1%) of the population is still living below poverty line.

As per the Government of India, poverty line for the urban areas is Rs. 296 per month and for rural areas Rs. 276 per month. As per GOI, this amount will buy food equivalent to 2400 Calories per day. This actually translates to Rs. 3552 and Rs. 3312 per capita per year for urban and rural areas respectively. According to the Planning commission, the poverty line for all India is rural Rs. 356.30 and urban Rs. 538.60 per capita per month. However, these levels are for overall all India guidelines; individual states have different levels. The World Bank's definition of the poverty line, for underdeveloped countries like India, is US\$ 1/day/person or US\$ 365 / year/ Person. As per this definition, more than 75% of all Indians are below the poverty line.

**Percentage of population in different socio-economic classes**: Various scales of measuring socio-economic status are being used in public health care. The commonly used ones in India are the Prasad's Modified Scale and the Kuppaswamy's scale, which takes into consideration the combined effect of Income, Education and Occupation. Details are given in the section of sociology.

**Indicators of educational Levels** : The simplest and widely used indicators in public health work are the "Adult Literacy rate" and the "School Enrolment rate".

**Indicators of "Empowerment of Women"** : Percentage of women employed in industry, or executive jobs and in government jobs and the Adult literacy rate among women/ School enrolment rate among girls are used as surrogate indicators of empowerment of women in a society.

### **Summary Measures of Population Health (SMPH) : An Emerging Concept in Public Health Practice**

Regular assessment of population health is a key component of public health policy development. So far we have seen indicators of morbidity, mortality and health states. These are useful for planning, evaluating, etc. However, if these different indicators are to be used for making comparisons of health status between 200 countries, a vast array of indicators would need to be generated and their interpretation would become extremely challenging. It would become even more unwieldy if a large number of diseases are being compared over time, across population groups, or else before and after some intervention.

Therefore some indicator is needed, which can combine information of mortality as well as non-fatal outcomes, so as to measure the population health level in a single number. Such "summary figures" are called as "Summary Measures of Population Health" (SMPH). SMPH do not replace the more detailed reporting of data on specific aspects of health and disease (discussed so far). They supplement this data with more comprehensive indicators that can be used to monitor trends and make wider comparisons. The important uses of SMPH are :

- To make comparisons of the average health levels in different population subgroups or in the same population over time.
- Assessment of the relative contribution of two different diseases, injuries or risk factors, to overall population health.
- Identifying and quantifying overall health inequalities within a population, thus identifying the "at risk" or vulnerable groups, needing greater services.
- Provide inputs for short-listing of national health priorities for national health planning.

### **Types of SMPH**

Broadly, there are two categories of SMPH

**a) Summary Measures of Health "Expectancies"** : The common ones are Healthy Life Expectancy (HALE), Active Life Expectancy (ALE), Disability Free Life Expectancy (DFLE) and Quality Adjusted Life Expectancy (QALE).

**b) Summary Measures of Health "Gaps"** : The commonly used are Years of Potential Life Lost (YPLL) and Disability Adjusted Life Years (DALY).

A detailed description of some of the important SMPH us as follows :

**Years of Potential Life Lost (YPLL)** : This is defined as the years of potential life lost due to premature death. In contrast to other mortality measures, YPLL emphasizes the processes underlying premature mortality in a population. By this method, deaths occurring at younger ages accrue more years of life lost than deaths at later ages.

An illustration is given in Table-2 below which shows the hypothetical details of deaths due to Road Traffic Accidents (RTAs).

The last 3 age groups have been shown as strike-through, since they have not been used in analysis; as the analysis in YPLL only involves age groups upto 65 years. From Table-2, the YPLL due to road traffic accidents, for this population are 14,41,985 years. To calculate the YPLL rate per 1000 this formula can be used :

$$\text{YPLL Rate (Per 1000)} = \frac{\text{YPLL}}{\text{Population under age of 65 years}} \times 1000$$

Here, it can be calculated as  $(1441985 \times 1000) / 213565000 = 6.8$  YPLL per 1000 population below the age of 65 years.

**Disability Adjusted Life Year (DALYs)** : This is a health gap measure that extends the concept of "Potential Years of Life Lost" (PYLL) due to premature death, It also includes equivalent



“Years of Life Lost due to Disability” (YLD) by virtue of being in states of poor health. The DALY combines, in one measure, the time lived with disability and the time lost due to premature mortality. One DALY can be thought of as one lost year of ‘healthy’ life and the burden of disease as a measurement of the gap between current health status and an ideal situation where everyone lives into old age free of disease and disability. Thus, DALY = YLL + YLD.

**Physical Quality of Life Index (PQLI)** : This index combines three measures into a single indicator. These are Literacy status, Infant Mortality rate (IMR) and Expectation of life at 1 year of age. Each of the three components is marked on a scale of 0 (absolutely hopeless state) to 100 (absolutely best state). An average of the 3 components, with equal weight to each is calculated, which again would range from 0 to 100. PQLI has been often used in making international comparisons.

**Sullivan's Indicator** : Sullivan's indicator is a health state measure of a group of persons which is independent of its age structure. It offers a possibility to compare health states of the entire population between two dates in spite of a modification of its age composition (provided that the sizes of the age groups are not too large). The comparability is also increased by the calculation of this indicator separately for males and females.

### Some Facts & Figures for India in respect of Important Measures of Health

The current levels and our targets to be achieved in national context, in respect of some important measures of morbidity,

mortality, fertility and health care are given in Table - 3.

### Summary

During epidemiological and medical research studies, a large amount of data is collected in respect of various variables, for a large number of subjects who have been studied in the study. To make sensible interpretations from this large collection of data, it has to be reduced to certain summary figures, namely, means, or medians or proportions, which facilitates quick understanding of the magnitude of the problem as well as in making comparisons. Most often, these summary figures are either the incidence or else the prevalence of the condition of interest in the study.

In actual epidemiological practice, there are various types of diseases and other outcomes which are to be studied. Hence, these incidence and prevalence measures are actually worked out in the form of “indicators” which summarise the health status of the population. These indicators of health and disease are of the following categories :

Health Status Indicators include various measures of mortality and morbidity. Mortality indicators include crude death rates, specific death rates and standardized death rates. Important specific death rate indicators are age and sex specific death rates, cause specific death rates, case fatality rate and proportional mortality ratio. Special indicators of mortality pertaining to maternal and child health care are Infant Mortality rate and Maternal Mortality rate. Morbidity indicators are broadly either incidence rates or else prevalences of specific

**Table - 3 : Some facts & Figures for India in Respect of Important Measures of Health**

Health Indicators in Indian Context	Current (Figures)	Goals
Crude Birth Rate (CBR)	24.1(SRS, 2004)	21 (NPP- 2010)
Crude Death Rate (CDR)	7.5 (SRS, 2004)	9 (NPP- 2010)
Total Fertility Rate (TFR)	2.7 (NFHS-3, 2006)	2.1 (NPP- 2010)
Net Reproductive Rate (NRR)	1.5 (1990)	1 (NPP- 2010)
Couple Protection Rate (CPR)	56.3 (NFHS-3, 2006)	60 (NPP- 2010)
Infant Mortality Rate (IMR)	57 (NFHS-3, 2006)	<30 (NPP- 2010)
Under five Mortality	74 (UNICEF, 2005)	41 MDG (2015)
Neonatal Mortality Rate	43 (WHO Report, 2005)	----
Maternal Mortality Ratio (MMR)	3.01 (SRS, 2003)	<1 (NPP- 2010)
Institutional Deliveries	40.7% (NFHS-3, 2006)	80% (NPP- 2010)
Delivery by Trained personnel	48.3% (NFHS-3, 2006)	100% (NPP- 2010)
Tuberculosis Mortality (per lakh)	30 (WHO Report, 2006)	----
Children 12-23 months fully immunized	43.5 (NFHS-3, 2006)	100% (NPP- 2010)
Children 12-23 months who have received BCG (%)	78.2 (NFHS-3, 2006)	100% (NPP- 2010)
Children 12-23 months who have received 3 doses of polio vaccine (%)	78.2 (NFHS-3, 2006)	100% (NPP- 2010)
Children 12-23 months who have received 3 doses of DPT vaccine (%)	55.3 (NFHS-3, 2006)	100% (NPP- 2010)
Children 12-23 months who have received measles vaccine (%)	58.8 (NFHS-3, 2006)	100% (NPP- 2010)

(NFHS : National Family Health Survey; NHP : National Health Policy; NPP : National Population Project; SRS : Sample Registration Scheme; MDG : Millennium Development Goals)

diseases. Indicators of health care includes the measures of Health Infrastructure; Human Resources in health; Health Finance indicators; and Indicators of accessibility & utilization of health care services. Indicators of "Quality of Life" include such measures as disability days, bed days, limited activity days, days on which activities of daily living are compromised and days requiring "aids" for walking or such other routine activities of life. Demographic Indicators include measures of fertility and population distribution, as crude birth rate, General fertility rate, Age Specific fertility rate, Total fertility rate, gross reproduction rate and Net reproduction rate. Socio-economic and Human Development indicators related to health include measures of literacy, income, accessibility to safe water supply and sanitary excreta disposal facilities, etc. Other Indirect Indicators related to health are nutritional status, child development, environmental indicators, etc. Summary Measures of Population Health (SMPH) summarise, in a single numerical figure the level of health in a large population of country, as HALE, DALY, PYLL, etc.

## Study Exercises

**Long Question :** Classify the various measures of health of a population in public health work. Discuss the merits and demerits of the various measures of mortality.

**Short Notes :** (1) Potential errors in interpretation of indicators of morbidity (2) Human development index (3) Maternal Mortality rate (4) Goals and present situation regarding important indicators of fertility and demography in the Indian context (5) SMPH

### MCQs & Exercises

- Calculate the HDI for a hypothetical nation having average expectancy of life at birth as 65 years, Adult literacy rate of 55%, Combined gross enrolment ratio of 60% and with a GDP of 2000 US dollars per capita per year. ( $\log_{10}$  2000 is 3.301).
- In a community development block area with population of one lac, there were 500 cases of TB and 5 cases of rabies during 2006. During the same year there were a total of 250 deaths, out of which 5 were due to rabies and 50 due to TB. Calculate the CDR. Also calculate, separately for TB and rabies, the cause-specific mortality rate (CSMR), CFR and PMR.
- In a township with population of 1 lac, the following are the statistics for the year 2007. From the table, calculate the CBR, GFR, ASFRs for the 6 age groups, TFR and GRR (all rates to be calculated per 1000).
- In a state during 2007, approximately 10% of all deaths in age group 0 to 14 years were due to accidents and injuries, while in the age group 15 to 35 years, 20% of all deaths were due to accidents and injuries. How many times is the risk of dying due to accidents and injuries among 15 to 35 years as compared to 0 - 14 years? (a) 2 (b) 0.5 (c) 1 (d) 4 (e) cannot be concluded from the data.
- If, in the computation of GFR, women who have undergone hysterectomy are not considered, the GFR will : (a) Increase (b) Decrease (c) will not be affected (d) None.
- The population of District 'X' as on 01 July 2006 was 2 lac. As per the Dist. TB control programme register, there were 186 active cases of Pulmonary TB on this date, while 12 new cases of active pulm TB occurred between 1<sup>st</sup> January to 30<sup>th</sup> June 2006. With the above information, answer the following (a) The incidence rate of active pulm TB for the six month period was (i) 6 per 100,000 (ii) 12 per 100,000 (iii) 0.60 per 1000 (iv) cannot be calculated (b) The prevalence of active pulm TB as on 01 July 2006 was : (i) 372 per lac (ii) 93 per lac (iii) 0.93 per 1000 (iv) None.
- Lung cancer is a highly fatal disease and patients die in a very short duration after onset of disease. Which of the following statements is correct for this disease : (a) Incidence and mortality rates will be almost similar in a year (b) Mortality rates will be higher than incidence rate (c) Incidence rates will be higher (d) There will be no relation between the two.

**Answers :** (1) HDI = 0.578 (L = 0.667, E = 0.567, G = 0.50). (2) CDR = 2.5 per 1000; CSMR : TB - 0.5 / 1000, rabies - 0.05 / 1000; CFR : TB - 10%, rabies 100%; PMR : TB - 20%, rabies 2%. (3) CBR = 30; GFR = 120; ASFRs respectively 80, 140, 175, 125, 100, 100; TFR 3600 (or 3.6 per woman); GRR 1740.65 (or, 1.7 per woman). (4) The correct answer is (e). The % of deaths are actually PMRs (proportional mortality ratios) for the two age groups. The PMR gives up the proportion of deaths that are due to a given cause out of the total deaths but does not give us the risk of dying due to that disease. The risk of death due to accidents and injuries in a particular age group would be given by the age and cause specific mortality rate (5) (a) (because the denominator will decrease due to removal of women having hysterectomy, but the numerator will not change since these women do not contribute to child births). (6) (a) : (i); 6 (b) : (ii) and (iii) both are correct; (7) a.

Age Group	Mid-year population of females	Births in the year	
		Total Live Births	Total female live births
15-19	5000	400	192
20-24	5000	700	347
25-29	4000	700	331
30-34	4000	500	240
35-39	4000	400	189
40-44	3000	300	151
Total	25000	3000	1450

Vijay K. Bhatti

We may define classification of diseases as a system of categories to which morbid entities can be assigned in accordance with certain established criteria. In epidemiological practice, a basic requirement is to identify the disease. The simplest way is to develop "case definitions". However, there will be a need to standardize the case definitions, do as to bring about uniformity, while making comparisons between two different places or over periods of time, as regards differences in disease frequency. To ensure such standardization, it is necessary that a system of disease classification be worked out so that each and every disease can be allocated a particular "code", which should be followed by all health care persons / institutions all over the world.

One of the most standard and time tested means to obtain this end is through the International Statistical Classification of Diseases and Related Health Problems, commonly known by the abbreviation ICD (International Classification of Diseases). ICD is a part of the WHO Family of International Classifications (WHO-FIC).

The ICD is used to classify diseases and other health problems recorded on many types of health and vital records including death certificates and health records. In addition to enabling the storage and retrieval of diagnostic information for clinical, epidemiological and quality purposes, these records also provide the basis for the compilation of national mortality and morbidity statistics by WHO Member States. ICD is published by the World Health Organisation. It assigns a unique category and a code upto six digit characters long to classify diseases and a wide variety of signs, symptoms, abnormal findings, complaints, social circumstances and external causes of injury or disease. Every health condition can be assigned to a unique category & given a code, up to six characters long. ICD is revised periodically and is currently in its tenth edition i.e. ICD-10.

### Historical Evolution of ICD

François Bossier de Lacroix (1706-1777), better known as Sauvages, is credited with the first attempt to classify diseases systematically. His comprehensive treatise was published under the title *Nosologia methodica*. At the beginning of the 19th century, the classification of disease in most general use was one by William Cullen (1710-1790), of Edinburgh, which was published in 1785 under the title *Synopsis nosologiae methodicae*.

For all practical purposes, however, the statistical study of disease began with the work of John Graunt on the London Bills of Mortality. He attempted to estimate the proportion of liveborn children who died before reaching the age of six years, no records of age at death being available. He took all deaths classed as thrush, convulsions, rickets, teeth and worms, abortives, chrysomes, infants, livergrown and overlaid and added to them half the deaths classed as smallpox, swinepox, measles and worms without convulsions. Despite the crudity of this classification his estimate of a 36 % mortality before the

age of six years appears from later evidence to have been a good one. In 1837, the General Register Office of England and Wales, William Farr (1807-1883) laboured to perfect classifications of disease available at the time and tried to secure better classifications and international uniformity in their use.

The International Statistical Institute, in Vienna in 1891, constituted a committee, chaired by French man Jacques Bertillon (1851-1922), with the preparation of a classification of causes of death. The report of this committee was presented by Bertillon at the meeting of the International Statistical Institute in Chicago in 1893 and adopted by it. In 1898, the American Public Health Association (APHA) recommended that the registrars of Canada, Mexico and the United States also adopt it. The APHA also recommended revising the system every ten years to ensure the system remained current with medical practice advances.

The French Government therefore convoked in Paris, in August 1900, the first International Conference for the Revision of the Bertillon or International List of Causes of Death. Delegates from 26 countries attended this Conference. A detailed classification of causes of death consisting of 179 groups and an abridged classification of 35 groups were adopted on 21 August 1900. The desirability of decennial revisions was recognized and the French Government was requested to call the next meeting in 1910. Similar subsequently revisions occurred every 10 years to reach the current version of ICD 10. The revisions that followed contained minor changes, until the sixth revision of the classification system. With the sixth revision, the classification system expanded to two volumes. The sixth revision included morbidity and mortality conditions and its title was modified to reflect the changes : Manual of International Statistical Classification of Diseases, Injuries and Causes of Death (ICD). Prior to the sixth revision, responsibility for ICD revisions fell to the Mixed Commission, a group composed of representatives from the International Statistical Institute and the Health Organization of the League of Nations. In 1948, the World health Organisation (WHO) assumed responsibility for preparing and publishing the revisions to the ICD every ten years. Only the time lag between ICD 9 (promulgated in 1979) and 10 (promulgated in 1999) was 20 years.

### Types of WHO - FIC Classifications

The WHO-FIC is comprised of three types of classifications, the Reference Classifications, the Derived Classifications and the Related Classifications.

**1. Reference Classifications** : These are the main classifications on basic parameters of health. They are categorized into three heads :

- (a) International Classification of Diseases (ICD)
- (b) International Classification of Functioning, Disability and Health (ICF)
- (c) International Classification of Health Interventions (ICHI)

**2. Derived classifications** : Derived classifications are based on the reference classifications (i.e. ICD and ICF). Derived classifications are prepared either by adopting the reference classification structure and categories, providing additional detail beyond that provided by the reference classification or they may be prepared through rearrangement or aggregation



of items from one or more reference classifications. Derived classifications in the WHO-FIC are :

- (a) International Classification of Diseases for Oncology, Third Edition (ICD-O-3)
- (b) The ICD-10 Classification of Mental and Behavioural Disorders
- (c) Application of the ICD to Dentistry and Stomatology, Third Edition (ICD-DA)
- (d) Application of the ICD to Neurology (ICD-10-NA)
- (e) ICF Version for Children and Youth (ICF-CY)

**3. Related Classifications** : Related classifications are those that partially refer to reference classifications, or are associated with the reference classification at specific levels of structure only. Related classifications in the WHO-FIC are :

- (a) International Classification of Primary Care (ICPC)
- (b) International Classification of External Causes of Injury (ICECI)
- (c) The Anatomical, Therapeutic, Chemical (ATC) classification system with Defined Daily Doses (DDD)
- (d) Technical aids for persons with disabilities : Classification and terminology (ISO 9999)

### Basic Structure and Principles of Classification of the ICD

The structure of present day ICD has developed out of the one proposed by William Farr. William Farr had proposed that for all practical purposes statistical data on diseases should be grouped in the following way :

- (a) Epidemic diseases
- (b) Constitutional diseases or general diseases
- (c) Local diseases arranged by site
- (d) Developmental diseases
- (e) Injuries

This is the pattern that is seen in ICD-10. The basic ICD is a single coded list of three - character categories, each one of which can be further subdivided into up to ten four character subcategories. In place of the purely previous numeric coding system the tenth revision uses an alphanumeric code with a letter in the first position and a number in the second, third and fourth positions. The fourth character follows a decimal point. Possible code numbers therefore range from A00.0 to Z99.9. The letter 'U' is not used.

### Organisation of ICD-10

It consists of three volumes. Volume 1 contains the main classifications; volume two provides the guidance to the use of ICD; and volume three is the alphabetical list to the classification. Most of volume 1 has the main classification consisting of the three character categories and the tabular list of inclusions and four letter sub categories. The "core" classification - list of three character categories in volume 1 is the mandatory level for reporting to the WHO mortality database and for general international comparisons. The tabular list is the one which gives the full details of the four character level and is divided into 21 chapters. Volume 1 also contains the following -

- (a) Morphology of neoplasm
- (b) Special tabulation lists - 4 such lists are present in the Volume 1, list 1 and 2 are on general mortality and lists 3 and 4 are for infant and child mortality (0-4yrs)

- (c) Definitions
- (d) Nomenclature regulations

### Chapters

The classification is divided into 21 chapters, the first character of the ICD code is a letter and each letter is associated with a particular chapter except for the letter D and H. Letter D is used in chapter II (Neoplasms) and chapter III (diseases of the blood and blood forming organs and certain disorders involving the immune mechanism). The letter H is used in both chapter VII (diseases of the eye and adnexa) and chapter VIII (diseases of the ear and mastoid process). Four chapters (I, II, XIX and XX) use more than one letter in the first position of their codes.

Not all codes in a chapter are used - some are left blank for future revision and expansion. Chapters I to XVII relate to diseases and other morbid conditions. Chapter XIX deals with injuries, poisoning and certain other consequences of external causes. Chapter XVIII contains symptoms, signs and abnormal clinical and lab findings not classified elsewhere. Chapter XX covers external causes for morbidity and mortality. Chapter XXI covers the factors influencing health status and contact with health services.

### Block Categories

Each chapter is divided into homogenous blocks of three character categories. The range of categories is given parentheses after each block title.

**Three -Character categories** : In each block some of the three character categories are for single conditions while other are for groups of diseases with some common characteristics.

**Four - character subcategories** : Most of the three character categories are subdivided by means of a fourth numeric character after a decimal point, allowing upto 10 subcategories. Where a three character category is not subdivided it is recommended to use letter "X" at the fourth place so that codes are of standard length for data processing. The four character subcategory is usually used in whatever way is most appropriate, identifying, for example, different sites or varieties if the three category code is for a single disease, or for individual diseases if the three character category is for a group of diseases.

**Supplementary subdivisions for use at the fifth or subsequent character level** : The fifth and subsequent character levels are usually sub-classifications along a different axis from the fourth character. They are found in Chapter XIII (sub divisions by anatomical site), Chapter XIX (subdivisions to indicate open and closed fractures as well as intra-cranial, intra-thoracic and intra-abdominal injuries with and without open injuries) and chapter XX (subdivisions to indicate the type of activity being undertaken at the time of the event).

**The unused "U" codes** : The codes U00-U49 are to be used for the provisional assignment of new diseases of uncertain aetiology. Codes U50-U99 may be used in research, e.g. when testing an alternative sub classification for a special project.

**International Classification of Functioning, Disability and Health (ICF - 2001)** : It belongs to a family of classifications developed by the WHO for applications in various aspects of health care. In WHO's family of international classifications, health conditions are classified mainly in ICD - 10, which



basically provides an etiological framework. On the other hand, ICF aims to provide a unified and standard language and framework for the description of health and health related states. The health states associated with diseases, disorders or other health conditions are classified in ICF. The ICD - 10 and ICF are therefore complementary. ICD - 10 provides a “diagnosis” and this information is enriched by the additional information given by ICF. Together, information on diagnosis and functioning provides a broader and more meaningful picture that describes the health of individuals or populations. ICF - 2001 has moved away from its earlier version, namely the International Classification of Impairments, Disabilities and Handicaps (ICIDH - 1980) to a “components of health” classification. ICF organises the information in 3 components:

- The Body Construct comprises two classifications, one for functions of the body system (physiology and psychology, as vision) and one for body structure (anatomy, as eyes). The chapters of both these classifications are organised as per body systems.
- The Activities and Participation Constructs cover the complete range of domains denoting aspects of functioning from both an individual and societal perspective. These are listed in a single common list, which covers the full range of life areas (as basic learning and watching to more composite ones as social tasks). Each of these two domains are qualified by two basic qualifiers, viz, performance and capacity.
- A list of Environmental factors also forms part of the classification. Environmental factors have an impact on all the three construct and are organised from the individual's most immediate environment to the general environment.

The ICF codes are only complete by the presence of at least one qualifier which denotes the magnitude of the level of health (e.g. severity of the problem) either in terms of “performance” or “capacity”. Qualifiers are coded as one or two numbers after a decimal point. Use of any code should be accompanied by at least one qualifier. Without qualifiers, codes have no meaning.

## Summary

ICD is a commonly used abbreviation for International Statistical Classification of Diseases and Related Health Problems. ICD is published by the World Health Organisation. The ICD is used world-wide for morbidity and mortality statistics, reimbursement systems and automated decision support in medicine. This system is designed to promote international comparability in the collection, processing, classification and presentation of these statistics. William Farr had proposed that for all practical purposes in ICD statistical data on diseases should be grouped into Epidemic diseases, Constitutional diseases or general diseases, Local diseases arranged by site, Developmental diseases and Injuries.

The ICD is a core classification of the WHO Family of International Classifications (WHO-FIC). ICD assigns a unique category and a code to classify diseases and a wide variety of signs, symptoms,

abnormal findings, complaints, social circumstances and external causes of injury or disease. ICD 10 is contained in three volumes. Volume 1 contains the main classifications; volume two provides the guidance to the use of ICD; and volume three is the alphabetical list to the classification. The basic ICD is a single coded list of three -character categories, each one of which can be further subdivided into up to ten four character subcategories. In place of the purely previous numeric coding system the tenth revision uses an alphanumeric code with a letter in the first position and a number in the second, third and fourth positions. The fourth character follows a decimal point. Possible code numbers therefore range from A00.0 to Z99.9. U codes are left unused for use for provisional new diseases and research.

International Classification of Functioning, Disability and Health (ICF - 2001) belongs to a family of classifications developed by the WHO for applications in various aspects of health care. ICF aims to provide a unified and standard language and framework for the description of health and health related states. The health states associated with diseases, disorders or other health conditions are classified in ICF. The ICD - 10 and ICF are therefore complementary.

## Study Exercises

**Short Notes :** (1) Basic structure and principles of classification of the ICD (2) International Classification of Functioning, Disability and Health.

### MCQs

- 1) The structure of present day ICD has developed out of the one proposed by (a) John Gruant (b) William Farr (c) Langmuir (d) John Last
- 2) The number of characters in main categories of the basic ICD is (a) Three (b) Four (c) Five (d) Six
- 3) The number of volumes in ICD-10 (a) 2 (b) 3 (c) 4 (d) 5
- 4) In ICD-10, the letter which is not used for coding is (a) i (b) u (c) x (d) o
- 5) In 1948, the World health Organisation (WHO) assumed responsibility for preparing and publishing the revisions to the ICD every (a) 10 years (b) 9 (c) 20 (d) 15
- 6) The time lag between ICD 9 (promulgated in 1979) and 10 (promulgated in 1999) was (a) 10 years (b) 9 (c) 20 (d) 15

**Answers :** (1) b; (2) a; (3) b; (4) b; (5) a; (6) c

## References

1. International classification of diseases for oncology (ICD-O), second ed. Geneva, World Health Organization, 1990.
2. The ICD-10 classification of mental and behavioural disorders : clinical descriptions and diagnostic guidelines. Geneva, World Health Organization, 1992.
3. International classification of impairments, disabilities and handicaps. A manual of classification relating to the consequences of disease. Geneva, World Health Organization, 1980.
4. Bertillon J. Classification of the causes of death (abstract). In : Transactions of the 15th International Congress on Hygiene Demography. Washington, 1912.
5. International statistical classification of diseases and related health problems Volume 1, Volume 2 and volume 3 Geneva, World Health Organization, 1993.

*Leo S. Vaz, Sunil Agrawal & Rajvir Bhalwar*

Universal health care is the provision of health care at all levels and available to all members of the community. The well-off, both in relatively wealthy industrialized countries and in the poorer developing world, may be able to get health care including clinical services from sources they prefer and can pay for in the private sector. The vast majority of people in most countries, however, are dependent in various ways upon health services provided by the state, to which they may contribute comparatively little or, in the case of poor countries, nothing at all.

### Health for all

In developed countries the rate of infectious diseases decreased through the 20th century largely due to broad public access to water and sewage systems, sanitation, immunizations and economic prosperity. Public health then began to put more focus on chronic diseases such as cancer and heart disease. However, in developing countries people remain plagued by largely preventable infectious diseases, exacerbated by malnutrition and poverty. More than a billion people lack access to clean drinking water and over 2.4 billion lack access to proper sanitary facilities. There are more people in the world's hospitals today suffering from water-borne diseases than any other ailment. Poor nutrition contributes to 1 out of 2 deaths (53%) associated with infectious diseases among children under the age of five in developing countries. Under-nutrition among pregnant women in developing countries leads to 1 out of 6 infants born with low birth weight. Keeping this in view, the WHO propounded a new theory for providing the basic minimal health facilities to the maximum populace.

### WHO Declaration of Alma-Ata

In 1977, the Director General of WHO called for a new strategy, acknowledging that although the health care strategies of the industrialized world—that of big hospitals, drugs and curative medicine—had been exported to developing countries for thirty years, the health of the world had not improved. The International Conference on Primary Health Care was convened in Alma-Ata, Kazakhstan, in 1978 and was attended by virtually all the member nations of the World Health Organization (WHO) and UNICEF. 134 governments ratified the WHO Declaration of Alma-Ata, asserting that :

- (a) Health for all could be achieved by 2000.
- (b) Governments have a responsibility for the health of their people that can be fulfilled only by the provision of adequate health and social measures.
- (c) Primary health care is the key to attaining a level of health that will permit their citizens to lead a socially and economically productive life.

The Alma-Ata Declaration of 1978 emerged as a major

milestone of the twentieth century in the field of public health and it identified Primary Health Care (PHC) as the key to the attainment of the goal of Health for All (HFA). Following are excerpts from the declaration :

- The Conference strongly reaffirmed that health, which is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important worldwide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector.
- The existing gross inequality in the health status of the people, particularly between developed and developing countries as well as within countries, is politically, socially and economically unacceptable and of common concern to all countries.
- The people have a right and duty to participate individually and collectively in the planning and implementation of their health care.
- An acceptable level of health for all the people of the world by the year 2000 can be attained through a fuller and better use of the world's resources, a considerable part of which is now spent on armaments and military conflicts. A genuine policy of independence, peace, détente and disarmament could and should release additional resources that could well be devoted to peaceful aims and in particular to the acceleration of social and economic development of which primary health care, as an essential part, should be allotted its proper share.
- All this could be achieved by provision of Primary Health Care.

### Definition of “Health For All (HFA)”

HFA is defined as “the attainment by all peoples of the world by a particular date (kept at that time as the year 2000), of a level of health that will permit them to lead a socially and economically productive life”. It does not imply that by that date, everybody in the world will have the most state of the art health care but that by that date, everybody in the world will attain a level of health so as to enable him or her to lead a physically, mentally, socially and economically fulfilling life and contribute fully, depending on his / her capabilities, towards the socio-economic development of the community and nation. The Global Strategy for Health for All by the Year 2000 (HFA2000) set the following guiding targets to be achieved by year 2000 :

- Life expectancy at birth above 60 years
- Infant mortality rate below 50 per 1000 live births
- Under-5 mortality rate below 70 per 1000 live births.

### Health for All in the 21st Century

In May 1998, the World Health Organisation adopted a resolution in support of the new global Health for All policy. The new policy, Health for All in the 21st Century, succeeds the Health for All by the Year 2000 strategy launched in 1977. In the new policy, the worldwide call for social justice is elaborated in key values, goals, objectives and targets. The 10 global health targets are the most concrete end points to be pursued. They can be divided into three subgroups, viz. health outcome targets (total four targets), targets on determinants

of health (two) and targets on health policies and sustainable health systems (four targets).

## Global Health Targets

### Health Outcome

**1. Health equity** : Childhood stunting—By 2005, health equity indices will be used within and between countries as a basis for promoting and monitoring equity in health. Initially, equity will be assessed on the basis of a measure of child growth.

**2. Survival** : Maternal mortality rates, child mortality rates, life expectancy—By 2020, the targets agreed at world conferences for maternal mortality rates (<100/100 000 live births), under 5 years or child mortality rates (<45/1000 live births) and life expectancy (>70 years) will be met.

**3. Reverse global trends of five major pandemics** : By 2020, the worldwide burden of disease will be reduced substantially. This will be achieved by implementing sound disease control programmes aimed at reversing the current trends of increasing incidence and disability caused by tuberculosis, HIV/AIDS, malaria, diseases related to tobacco and violence or trauma.

**4. Eradicate and eliminate certain diseases** : Measles will be eradicated by 2020. Lymphatic filariasis will be eliminated by the year 2020. The transmission of Chagas' disease will be interrupted by 2010. Leprosy will be eliminated by 2010 and trachoma will be eliminated by 2020. In addition, vitamin A and iodine deficiencies will be eliminated before 2020.

### Determinants of Health

**5. Improve access to water, sanitation, food and shelter** : By 2020, all countries, through intersectoral action, will have made major progress in making available safe drinking water, adequate sanitation and food and shelter in sufficient quantity and quality and in managing risks to health from major environmental determinants, including chemical, biological and physical agents.

**6. Measures to promote help** : By 2020, all countries will have introduced and be actively managing and monitoring, strategies that strengthen health enhancing lifestyles and weaken health damaging ones through a combination of regulatory, economic, educational, organisational and community based programmes.

### Health Policies and Sustainable Health Systems

**7. Develop, implement and monitor national Health for All policies** : By 2005, all member states will have operational mechanisms for developing, implementing and monitoring policies that are consistent with this Health for All policy.

**8. Improve access to comprehensive essential health care**: By 2010, all people will have access throughout their lives to comprehensive, essential, quality health care, supported by essential public health functions.

**9. Implement global and national health information and surveillance systems** : By 2010, appropriate global and national health information, surveillance and alert systems will be established.

**10. Support research for health** : By 2010, research policies and institutional mechanisms will be operational at global,

regional and country levels.

The Member States of WHO have to translate the Regional Health Policy into realistic national policies backed up by appropriate implementation plans. WHO, on its part, will provide support to the Member States based on countries' realities and needs, especially community health problems, the strengthening of health systems and services and the mobilization of countries and the international community for concerted action in the harmonization of national policies with regional and global policies.

## Primary Health Care

Primary health care is defined as "essential health care based on practical, scientifically sound and socially acceptable methods and technology, made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination". It forms an integral part both of the country's health system, of which it is the central function and main focus and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work and constitutes the first elements of a continuing health care process. Primary Health Care was identified as the key measure through which HFA was envisaged to be achieved.

In India the first National Health Policy in 1983 aimed to achieve the goal of 'Health for All' by 2000 AD, through the provision of comprehensive primary healthcare services. It stressed the creation of an infrastructure for primary healthcare; close co-ordination with health related services and activities (like nutrition, drinking water supply and sanitation); active involvement and participation of voluntary organisations; provision of essential drugs and vaccines; qualitative improvement in health and family planning services; provision of adequate training; and medical research aimed at the common health problems of the people.

### The "Graded (3-Tier)" System of Health Care

In the curative domain there are various forms of medical practice. They may be thought of generally as forming a pyramidal structure, with three tiers representing increasing degrees of specialization and technical sophistication but catering to diminishing numbers of patients as they are filtered out of the system at a lower level. Only those patients who require special attention either for diagnosis or treatment should reach the second (advisory) or third (specialized treatment) tiers where the cost per item of service becomes increasingly higher. The first level represents primary health care, or first contact care, at which patients have their initial contact with the health-care system.

**Primary health care** : It is an integral part of a country's health maintenance system, of which it forms the largest and most important part. It deals with the entire gamut of the community at the grass-root level. Primary health care is a comprehensive team-work between medically qualified



physician as well as a wide range of nursing and paramedical personnel. Quite often, primary health care systems are further subdivided into three levels - the most peripheral level which is in direct contact with the community and is usually managed by one or more members from within the community who are trained and equipped in preventive and Promotive health care as well as in the most basic clinical and emergency care. The next higher level is managed by one or more nursing / paramedical workers, while the highest level within primary health care is managed by a medical person along with his team of nursing and paramedical persons. In our country, these 3 levels correspond to the ASHA / VHGs, MPWs at subcentres and the Primary Health centre, respectively.

**Secondary health care** : The vast majority of patients can be fully dealt with at the primary level. Those who cannot are referred to the second tier for the opinion of a specialist. Secondary health care often requires the technology offered by a local or regional hospital.

**Tertiary health care** : The third tier of health care, employing super specialist services, is offered by institutions such as teaching hospitals and units devoted to the care of particular groups. The dramatic differences in the cost of treatment at the various levels is a matter of particular importance in developing countries, where the cost of treatment for patients at the primary level is usually only a small fraction of that at the third level.

### Characteristics of Primary Health Care

These are :

- (a) Stresses prevention rather than cure.
- (b) Relies on home self-help, community participation and technology that the people find acceptable, appropriate and affordable.
- (c) Combines modern, scientific knowledge and feasible health technology with acceptable, effective traditional healing practices.
- (d) Should be shaped around the life patterns of the population.
- (e) Should both meet the needs of the local community and be an integral part of the national health care system.
- (f) Should be formulated and implemented with involvement of the local population.

### Components of Primary Health Care

There are eight essential components :

- (a) Education about common health problems and what can be done to prevent and control them;
- (b) Maternal and child health care, including family planning;
- (c) Promotion of proper nutrition;
- (d) Immunization against major infectious diseases;
- (e) An adequate supply of safe water;
- (f) Basic sanitation;
- (g) Prevention and control of locally endemic diseases;
- (h) Appropriate treatment for common diseases and injuries.

### The Four Pillars of Primary Health Care

Primary health care is not simply treating patients or immunizing children and so on. It is an ethos, a concept, which

is built up as a system. For this concept to be successful, it should employ the following four essential principles :

**Community Participation** : While most of the efforts in providing health care come from the state, the system of primary health care should be based on full participation and involvement of the community. It is akin to placing people's health in people's hands. In our country, the concepts of ASHA, VHGs, TBAs are all examples of community participation.

**Appropriate Technology** : Appropriate technology is one which is scientifically sound, adapted to local needs, acceptable to those who apply it and to those on whom it is applied and which can be maintained by the people, as a part of self reliance and within the resources which can be afforded by the community and the nation. Outstanding examples of appropriate technology are the use of coloured tapes / bangles for measuring mid-upper arm circumference and use of coconut water for oral rehydration.

**Inter-Sectoral Coordination** : Health care, especially primary health care's preventive and Promotive functions can not be executed in isolation by health sector alone. A large number of other sectors concerned with human development will need to function in close cooperation and tandem. These include health, education, legal, urban / rural development, agriculture, industrial and such other sectors. Even at the grass root level, health care functionaries cannot function in isolation but will need to function with various other functionaries for obtaining best results. An outstanding example of inter-sectoral coordination at the grass root level is that of the Anganwadi, as a part of ICDS programme.

**Equitable Distribution** : Health services should be available to each and every one in the community and not depend on one's capability to pay for the services. In fact, those who are not in a position to pay are the one's who are in most need of health care. Similarly, disadvantaged groups within the homes / society (as women in a household or persons belonging to Scheduled Castes / Scheduled Tribes in the community) should have equal access and right to provision of health care, for it to be successful.

### Millennium Development Goals (MDGs)

The Millennium Development Goals derive out of the eight chapters of the United Nations Millennium Declaration, which were officially established at the Millennium Summit in September 2000, where 189 world leaders adopted the United Nations Millennium Declaration. These are intended for the Member Countries to take efforts in the fight against poverty, illiteracy, hunger, lack of education, gender inequality, infant and maternal mortality, diseases and environmental degradation. The Millennium Declaration adopted 8 development goals, 18 time-bound targets and 48 indicators to be achieved by 2015. Three of the 8 goals, 8 of the 18 targets and 18 of the 48 indicators are related to health. The various health related goals and targets are :

#### Goal 1. Eradicate extreme poverty and hunger

**Target 1** : Reduce by half the proportion of people living on less than a dollar a day

**Target 2** : Reduce by half the proportion of people who suffer



from hunger

## **Goal 2. Achieve universal primary education**

**Target 3 :** Ensure that all boys and girls complete a full course of primary schooling

## **Goal 3. Promote gender equality and empower women**

**Target 4 :** Eliminate gender disparity in primary and secondary education preferably by 2005 and at all levels by 2015

## **Goal 4. Reduce child mortality**

**Target 5 :** Reduce by two thirds the mortality rate among children under five

## **Goal 5. Improve maternal health**

**Target 6 :** Reduce by three quarters the maternal mortality ratio

## **Goal 6. Combat HIV/AIDS, malaria and other diseases**

**Target 7 :** Halt and begin to reverse the spread of HIV/AIDS

**Target 8 :** Halt and begin to reverse the incidence of malaria and other major diseases

## **Goal 7. Ensure environmental sustainability**

**Target 9 :** Integrate the principles of sustainable development into country policies and programmes; reverse loss of environmental resources

**Target 10 :** Reduce by half the proportion of people without sustainable access to safe drinking water

**Target 11 :** Achieve significant improvement in lives of at least 100 million slum dwellers, by 2020

## **Goal 8. Develop a global partnership for development**

**Target 12 :** Develop further an open, rule-based, predictable, non-discriminatory trading and financial system Includes a commitment to good governance, development and poverty reduction - both nationally and internationally

**Target 13 :** Address the special needs of the least developed countries Includes : tariff and quota free access for least developed countries' exports; enhanced programme of debt relief for HIPC and cancellation of official bilateral debt; and more generous ODA for countries committed to poverty reduction

**Target 14 :** Address the special needs of landlocked countries and small island developing States

**Target 15 :** Deal comprehensively with the debt problems of developing countries through national and international measures in order to make debt sustainable in the long term.

**Target 16 :** In cooperation with developing countries, develop and implement strategies for decent and productive work for youth.

**Target 17 :** In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries

**Target 18 :** In cooperation with the private sector, make available the benefits of new technologies, especially information and communications.

## **Summary**

The International Conference on Primary Health Care was convened in Alma-Ata, Kazakhstan, in 1978 and was attended by virtually all the member nations of the World Health Organization (WHO) and UNICEF. 134 governments ratified the WHO Declaration of Alma-Ata, asserting that Health for all could be achieved by 2000, Governments have a responsibility for the health of their people that can be fulfilled only by the provision of adequate health and social measures; and Primary health care is the key to attain a level of health that will permit their citizens to lead a socially and economically productive life. The Alma-Ata Declaration of 1978 emerged as a major milestone of the twentieth century in the field of public health and it identified primary health care (PHC) as the key to the attainment of the goal of Health for All (HFA). HFA is defined as "the attainment by all peoples of the world by a particular date (kept at that time as the year 2000), of a level of health that will permit them to lead a socially and economically productive life". The new policy, Health for All in the 21st Century, succeeds the Health for All by the Year 2000 strategy launched in 1977. In the new policy, the worldwide call for social justice is elaborated in key values, goals, objectives and targets. The 10 global health targets are the most concrete end points to be pursued, which are divided into three subgroups, viz. health outcome targets (total four targets), targets on determinants of health (two) and targets on health policies and sustainable health systems (four targets).

Primary health care is defined as "essential health care based on practical, scientifically sound and socially acceptable methods and technology, made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination". It forms an integral part both of the country's health system, of which it is the central function and main focus and of the overall social and economic development of the community. Primary Health Care was identified as the key measure through which HFA was envisaged to be achieved. Health care System forms a pyramidal structure, with three tiers representing increasing degrees of specialization and technical sophistication. There are eight essential components of PHC a) Health education b) MCH including family planning c) promotion of proper nutrition d) immunization e) an adequate supply of safe water f) basic sanitation g) prevention and control of locally endemic diseases h) appropriate treatment for common diseases and injuries. The four essential principles: Community Participation, Appropriate Technology, Inter-Sectoral Coordination and Equitable Distribution.

The Millennium Development Goals derive out of the eight chapters of the United Nations Millennium Declaration, which were officially established at the Millennium Summit in September 2000, where 189 world leaders adopted the United Nations Millennium Declaration. These are intended for the Member Countries to take efforts in the fight against poverty, illiteracy, hunger, lack of education, gender inequality, infant and maternal mortality, diseases and environmental degradation. The Millennium Declaration adopted 8 development goals, 18 time-bound targets and 48 indicators to be achieved by 2015.

Three of the 8 goals, 8 of the 18 targets and 18 of the 48 indicators are related to health.

### Study Exercises

**Long Questions :** (1) Discuss the characteristics, Components and Principles of Primary Health Care. Describe briefly 3-tier Health care System in India. (2) Enumerate the eight goals in Millennium Declaration. Discuss in detail the Health related goals with respective targets.

**Short Notes :** (1) Alma-Ata Declaration of 1978 (2) Components of Primary Health Care (3) Principles of Primary Health Care (4) Health related MDG goals.

#### MCQs :

1. Alma-Ata Declaration was held in (a) 1976 (b) 1977 (c) 1978 (d) 1980
2. The Global Strategy for Health for All by the Year 2000 (HFA2000) set the following guiding targets to be achieved by year 2000 except (a) Life expectancy at birth above 60 years (b) Infant mortality rate below 50 per 1000 live births (c) Under-5 mortality rate below 70 per 1000 live births (d) MMR below 301/lakh
3. The Millennium Development Goals which were derive out of the eight chapters of the United Nations Millennium Declaration was held in the year (a) 1999 (b) 1978 (c) 2000 (d) 2001
4. The health related targets in MDGs are (a) 8 (b) 18 (c) 48 (d) 3
5. The health related indicators in MDGs are (a) 8 (b) 18 (c) 48 (d) 3
6. The MDG goal related to reducing the Child mortality is (a) 3rd (b) 4th (c) 5th (d) 6th
7. The MDG goal related to improving the maternal health is (a) 3rd (b) 4th (c) 5th (d) 6th
8. The MDG goal number 7 deals with (a) lack of education (b) gender inequality (c) infant and maternal mortality (d) environmental degradation
9. Target 6 of MDG-5 aims at reducing the maternal mortality ratio by (a) three quarters (b) half (c) one-fourth (d) two thirds.
10. Target 5 of MDG-4 aims at reducing the mortality rate among children under five by (a) three quarters (b) half (c) one-fourth (d) two thirds

**Answers :** (1) c; (2) d; (3) c; (4) a; (5) b; (6) b; (7) c; (8) d; (9) a; (10) d.

### Further Suggested Reading

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2. Government of India (ICMR and ICSSR). Health For All by the year 2000. An alternative strategy, 1980.
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4. UNDP(2003). Human Development Report 2003, Millennium Development Goals : A compact among nations to end poverty.

## 7

### Public Health in Developing Countries and Countries with Transitional Economies - History, Development & Policies

*Amitava Datta*

Historically, especially in resource poor countries, public health was synonymous with health development efforts undertaken by government agencies. Public health action was seen also as various health interventions aimed at groups of individuals and included efforts to provide community hygiene, sanitation, safe water supply, health education, maternal and child health care and disease control activities. These activities were provided by specially trained workers who were known as public health workers. The spectrum of public health activities covered preventive, promotive, curative and rehabilitative measures. With time the concept of public health evolved to include the involvement of people together with the government in provisioning of health activities. This helped in increasing the acceptance and utilization of the health facilities by the

targeted community. This concept of a wider public role in health development has become more prevalent today when both non-communicable diseases as well as communicable diseases are simultaneously present in the country in significant numbers.

Health of the people has always been one of the prime concerns of democratically elected governments. With more and more states becoming independent from their colonial masters, the clamour for improving the health status of their people had increased in the later parts of the 20<sup>th</sup> century. Increasing globalization had also increased international concerns on prevailing poor state of health of a large number of the developing countries. It was also realized that health status of people living in the developed countries could not be assured without upliftment of health in the vast numbers of developing countries. The increased cooperation between developed and developing countries in the field of health specially under the aegis of different organs of the United Nations specially World Health Organisation has been the hallmark of public health activities during the later part of the 20<sup>th</sup> century.

The historical development of public health in the developing countries can be better appreciated if viewed in four parts - first, ancient public health; second, the development of public

health under the colonial structure; third, the efforts made by the countries as soon as they attained independence; fourth, the change in concept of public health from narrow disease control interventions to multi sectoral approaches. Today, developing countries except those ravaged by bitter sectoral war or dispute are moving towards an era of public health development with twin problems - infectious diseases as well as chronic problems. The health system of these countries are functioning with limited local resources but also obtaining resources from the international society to provide the best possible health for their citizens.

### **Ancient Public Health**

Since ancient times, human life has been threatened with diseases of all kinds. The teachings of Lord Buddha as well as the Bible and Koran covered various aspects of personal hygiene and other public health practices. Royal decrees were used to ensure sanitation measures for the common good of the country. Heavy punishments were used to prevent food adulteration or littering of streets. Quarantine or prohibition were major measures used historically to protect against transmission of diseases within a country as well as from one country to another. However, very few records of public health in developing countries exist for the ancient ages till the 18<sup>th</sup> century.

### **Colonial Public Health**

Massive shifts of native populations were indulged by the ruling powers to work on plantations, construction sites, mines or industries mainly from Asia and Africa. The colonials established their own administrative, legal and medical care systems with varying degrees of autonomy and authority. To protect the health of their own people and the workers, colonial rulers established laws similar to those in their home countries. Specific public health legislation varied with each colonial power of which some have still remained in place today in many countries in Asia, Americas and Africa. The public health measures made a great impact in these countries. Some colonial powers introduced their social and cultural identity, mainly through religious groups and their educational systems. European and American religious missionaries also embarked on expeditions around the world. Many of them established medical care institutions as well as general educational systems. Introduction of the "Western" system of medicare in some of these countries of Asia and Africa was the first exposure and increasing access by the people in these countries to so called "Western medical care".

The late 18<sup>th</sup> century saw an increasing momentum in public health education with establishment of undergraduate and post-graduate courses at first in the home countries and then in the colonies. Some of these public health educational and research institutions in India such as the "School of Tropical Medicine and Hygiene" and the "All India Institute of Hygiene and Public Health" both located in Kolkata, were established in British India in the early 1920s. The "Haffkine Institute" in Mumbai, "King's Institute of Preventive Medicine" in Chennai, "Central Vaccine Research Institute" at Kasauli, "National Institute of Communicable Diseases" (earlier known as Malaria Institute of India), "Indian Research Fund Association" (later known as Indian Council of Medical Research) and the National

Institute of Nutrition were the exemplary research and teaching institutions established at that time. Similar institutions were established in Thailand, Philippines, Malaysia, Singapore, Hong Kong, Indonesia, Sri Lanka (earlier Ceylon), Ghana, Nigeria, South Africa, Mexico, Brazil and so on.

However the actual development of public health and medical care services for the general public remained rudimentary in these former colonial countries and territories. Infectious diseases posed formidable obstacles to attainment of good health in these areas. Developments in science and technology in the early 20<sup>th</sup> century led to an explosion in applications in public health practices. Improved communications by radio and telephone speeded up communications among people. International concerns lead to the major public health initiative in prevention and control of smallpox through vaccination. Pilot disease control projects under Rockefeller foundation also demonstrated means to control prevailing diseases in some developing countries which could be replicated in other countries as well.

### **Public Health in Immediate Post-Independence period**

With the end of the Second World War, the spirit of solidarity, peace, security and tranquility lead to the creation of inter governmental institutions like United Nations and its specialized agencies like World Health Organisation (WHO). The main functions of WHO are directing and coordinating international health development. Former colonial countries saw Second World War as the beginning of the end of colonial rule. Within a few years many countries achieved independence. After gaining independence, many countries adopted ambitious plans for socio-economic development, including health. The health care facilities were however non-existent. Many countries thus initiated reviews of their national health situations and formulated long term development plans. In India, the Bore Committee was established in 1945 to review the health situation and to recommend improvements in the Indian health system. In Myanmar (earlier Burma), the Sorrento Villa Plan in 1947 and the Pyidawtha Plan in 1950 were drawn up for achieving rapid socio-economic growth, including the expansion of health and education. Similar socio-economic plans were initiated by other developing countries. Most developing countries in the post Second World War period followed the advice and support of WHO and other international agencies to improve their health systems infrastructure based on the western system of hospitals and health centres. Health workers who had only undergone minimal training ran these centres in rural areas. National projects on maternal and child health, school health, etc were established to expand the basic services. Health care services were mainly provided "free" but were few and mainly concentrated in towns and cities. These were mainly those existing during the colonial period. Training of different categories of health auxiliaries, such as health assistants, medical assistants, sanitary workers, community educators, laboratory technicians, etc was initiated by the establishment of paramedical training institutes. These workers were deployed to serve at the various health institutions, especially those established in the rural areas. A number of rural health development and demonstration centres were also



established in many countries. The Kalutara rural health project in Sri Lanka, the pilot project Aung San demonstration rural health unit in Myanmar and the Singur rural health project in India were a few of them. The development of human resources for health especially by creating medical, nursing and other paramedical schools was more intense between the 1950s and 1970s.

### Change in Concepts of Public Health

The International Rural Health Conference held at New Delhi, India in 1953 under the aegis of WHO reviewed the concepts of rural health services and use of multi purpose village health workers for delivering comprehensive rural health services. It recommended that rural health centres were the basic units through which comprehensive health care could be provided to the rural areas. Simultaneously under the guidance of WHO and UNICEF, governments were encouraged to focus on provision of maternal and child health services as a means to reduce the unduly high maternal and infant mortality. The initial vertical approach of provision of maternal and child health services had to be soon reviewed as they did not produce the necessary impact. Countries recognized the need to provide comprehensive basic health services while focusing on the problems of mothers and children. The relatively high levels of maternal and child mortality and morbidity compounded with a rapid growth in population adversely affected the social and economic development in the developing countries. Since the early 1960s, most developing countries started adopting population policies in which family planning was the main strategy. In spite of availability of technology the utilization of contraceptive services in these countries continued to be comparatively low, thus hastening the increasing population. The "Green Revolution" of the 1960s had a positive impact in better availability of food and nutrition. The initial focus of the "Green Revolution" was on cereals rather than on pulses and vegetables. Vitamin A deficiency was thus widespread in Asia. Although the proportion of population with inadequate nutrition steadily decreased, however the increasing population ensured that hunger and malnutrition continued to be the most devastating problems in the developing countries.

Promotion of environmental sanitation was also given a high priority along with provision of basic health services. This was based on the experience of the developed countries through the 18<sup>th</sup> and 19<sup>th</sup> centuries. Promoting the provision of safe drinking water and adequate sanitation specially in rural areas were key initiatives. However progress was hindered due to insufficient financial resources, inappropriate application of technology and lack of community participation. Large scale migrations in search of work started occurring from the rural areas to urban areas as the agriculture based economy could not support the increasing population. Industrialisation also hastened migration. The sanitary infrastructure already inadequate in the towns and cities became overloaded and slums developed in the peripheries as well as within towns. A WHO survey carried out in 1970 in 91 developing countries showed that only 29% of the total population had access to safe drinking water and only 50% of the urban population had access to safe water. The access to safe sanitation facilities was

even worse. Considerable attention thus started being given to care for these under developed urban clusters which were developing in a completely unplanned manner.

Most governments invested large amounts of funds and human resources in the prevention and control of Malaria. During the early 1950s, WHO demonstrated in various pilot projects that residual spraying of human dwellings with DDT and the effective treatment of Malaria cases, with 4-amino quinolones could interrupt the transmission of malaria effectively and efficiently. Erratic availability of DDT despite efforts of WHO and inadequate planning and supervision of spraying operations led to increasing resistance among malaria vectors. Still there were drastic reductions of malaria as well as collateral benefit in reduction of visceral Leishmaniasis. Leprosy, the oldest and widely prevalent disease in developing countries was the focus of public health action. Availability of dapsone provided a welcome boost to the leprosy control activities which were based on early case detection through mass screening and treatment with dapsone, together with health education. Millions of leprosy cases were detected and provided with long term dapsone therapy. Effective treatment with long lasting penicillin in 1948 changed the control measures against sexually transmitted diseases in Europe. Few pilot projects on venereal disease control were initiated in developing countries in 1950s to identify appropriate community intervention strategies. These included early case detection, effective contact tracing, early treatment, continuous surveillance and health education. Availability of effective treatment conveyed a false sense of public health security which ignored the increasing prevalence of prostitution, promiscuity and homosexuality besides rapid urbanization, industrialization and migration of labourers - thus promoting syphilis and other STDs.

Control on the spread of an acute bacterial disease, cholera, could be achieved in western countries with the provision of adequate sanitation and safe drinking water assisted by quarantine measures. Development of a cholera vaccine in the 1950's, also helped to arrest the further spread of cholera. A new cholera biotype, eltor, appeared in 1965 in Indonesia and invaded all of Asia, creating waves of epidemics. The eltor epidemic took thousands of lives and affected millions of people for more than two decades. It also spread to Africa and Americas and caused major public health crisis. *Vibrio cholerae* 0139, a new bacterial strain has been identified in India and other parts of Asia and has spread slowly to other parts of the world.

However, all was not gloomy in the public health picture in developing countries. Assistance of international agencies like WHO, UNICEF besides philanthropic institutions like Rockefeller foundation promoted global disease control campaigns against major communicable diseases. Demonstration projects were established in different countries to identify appropriate country specific disease prevention and control strategies. Many educational and research institutions were established which provided the much needed pool of trained manpower. Spectacular success was achieved in the field of Yaws control, reduction in morbidity and mortality due to malaria, leprosy, sexually transmitted diseases, cholera and smallpox.



## Public Health Successes and Failures

The greatest success achieved by the developing countries in the twentieth century was the prevention and control as well as ultimate eradication of small pox. Although vaccination had been introduced in the developing countries by their colonial masters, however, control could not be achieved due to technical reasons. With the coordinated efforts of WHO, this dreaded disease could be eradicated through a mixed approach of mass vaccination, special searches for cases and providing rewards for reporting of cases.

Efforts by governments had reduced the burden of epidemic and endemic diseases. With the assistance of international organizations, the health care delivery systems were also strengthened. However, in 1975 more than two-thirds of the population of developing countries still did not have reasonable access to permanent form of health care. Health care facilities were mainly in urban areas. Professional and paramedical workers were disinclined to work in rural areas which contributed to the disparity between the different parts of the country. Much of the health planning was done at central level without closer involvement of the people responsible for the implementation. Life expectancy was far lower in Africa and Asia as compared to Europe. Infant mortality was 10-15 times higher than in the developed world. Proportion of GDP spent on health was 1-6 percent in many developing countries as compared to more than 10 percent in the developed world. Traditional systems of medicine like Ayurveda, Siddha, Unani-Tibb, Chinese, Tibetan and others had almost been abandoned by governments during and immediately after the colonial days. These systems again started being promoted in the developing countries.

The 1970s and 1980s were economically and politically unstable decades. Armed conflicts in various parts of the world had serious consequences on world economy. Problems of high morbidity and mortality due to maternal and childhood diseases, infectious diseases and malnutrition were compounded by rapidly increasing population. Too much focus on technological advancements and dominance of biomedical science approach without adequate focus on community led to failure of many mass control programs. Health planners came to believe that in view of political needs and demands of the community, the widening gaps between health needs and available resources require fitting clinical medicine into a social context. The value of health as a fundamental human right and its attainment as an essential social goal were firmly recognized. These debates led to the World Health Assembly adopting the historical resolution on "Health for All by the year 2000". It was expected that governments would use better approaches for preventing and controlling diseases and alleviating illness and disability. The obstacles for attaining the goals for Health for All led to the "Alma Ata declaration" which called for protecting and promoting the health of all the people using the primary health care approach.

Developing countries saw the Alma Ata primary health care conference as an opportunity for restructuring their health systems to reach the goal of Health for All by year 2000. They formulated new health policies and strategies as well as plans

of action to launch and sustain primary health care. With international assistance, these countries attempted to organize and manage comprehensive national health systems within the primary health care framework. Accessibility to primary health care elements rose to more than 80 percent in most countries. However, shortcomings in provision of maternal and child health care as well as safe water and sanitation remained. Use of community health volunteers, after minimal initial training, to support the existing health care workers in provision of many public health interventions like immunization, maternal and child health care, environmental health promotion, etc was successfully implemented by many countries.

The successful implementation of the Expanded program of Immunisation to protect all children against the main vaccine preventable diseases is another major public health success in the developing countries. It is estimated that approximately 2 million children were saved by this program.

Developing countries participated in several disease elimination/eradication programs. The polio eradication program has had mixed success despite use of innovative strategies. The concept of national immunization days for mass immunization has successfully eliminated polio from many countries. However, cases of wild polio continue to occur in some of the countries like India, Afghanistan, Pakistan and Nigeria. Leprosy elimination with use of multi drug therapy has become a possibility even in the previously hyper endemic countries like India. Dracunculosis (Guinea worm disease) which afflicted annually more than 10 million cases in Africa and South Asia before the 1980s has been drastically reduced with many countries claiming eradication including Pakistan(1997) and India(2000). Onchocerciasis (River Blindness), which afflicts people in tropical Africa, Latin America and Arabian Peninsula has also been targeted for control using better case management and an effective drug (Ivermectin). Sustained program with strong international support should lead to global elimination of Onchocerciasis in the near future. There has however been emergence of a disease which threatens to wipe out the gains of the 20<sup>th</sup> century - HIV / AIDS. In the absence of an effective vaccine, this disease which is mainly transmitted by sexual route is planned to be controlled by political advocacy, mass education (including sex education), behavioural intervention and social mobilization. Other diseases like malaria, viral hepatitis B, yellow fever, plague and tuberculosis have reappeared in increasing numbers leading to considerable morbidity and also mortality. WHO promoted the use of "Directly Observed Treatment Short Course" (DOTS) strategy for effective management of infectious tuberculosis cases. The malaria situation in Asia especially due to chloroquine resistant *Plasmodium falciparum* is serious. WHO initiated program "Roll Back Malaria" in 1998 in the developing countries with multi-pronged interventions and well coordinated strategies.

Developing countries had adopted prevention and control of diarrhoeal diseases and respiratory infections as part of major health interventions. Training of basic health workers on Integrated Management of Childhood Illnesses (IMCI), using easy to use algorithms for management of these two groups of killer disease is considered very effective. Unfortunately, only one-third of the families know about it and have access to it.

Non-communicable diseases have witnessed a sharp increase due to improved longevity, changes in lifestyle and diets, besides increased use of tobacco and alcohol. Diabetes mellitus, cardio-vascular diseases and cancers are showing a rapid rise for which the developing countries are inadequately prepared. This double burden of disease (tackling existing and re-emerging communicable diseases along with the rising non-communicable diseases) has made it difficult for health planners, policy makers and administrators to decide on equitable allocation of scarce resources. This epidemiological transition may be the biggest challenge for public health at the start of the new century in developing countries. Globalisation has however shrunk the world in terms of relative distances. Local control of outbreaks of diseases has become a global struggle. The increasing opportunities in developing countries and numbers of international travelers pose threat of rapid spread of diseases.

### The Road Ahead

It is however a stark fact that more than a quarter of the developing world's people still live in poverty as measured by the human poverty index (a composite measure including life expectancy, basic education and access to public and private resources). Around 2.5 billion people live on less than \$2 a day (40% of the world's population) and 1 billion live on less than \$1 a day. Not only is health a long recognized human right, but improving health is associated with a decrease in poverty by securing better livelihoods. WHO estimates that in 2015 in developing countries, the burden of disease (DALYs) and death rates will be slightly higher for chronic diseases (including smoking-related disorders) than for communicable, maternal and nutritional disorders combined. The prevention of chronic diseases in low and middle income countries is now a priority. Heart disease, diabetes and cancers are increasingly affecting poor people in developing countries. The costs of treating them are high and contribute to household poverty. WHO's stated goal is to work with the developing countries to focus global efforts to build healthy populations and communities. The efforts of national and international communities should aim at promoting healthy living, reducing the double burden of disease and making essential health care accessible to all. To tackle this massive agenda clear targets are required to provide milestones against which progress can be measured. These are based on recent UN Conventions and Resolutions including setting of Millennium Development Goals (MDGs). The four key areas for health gain suggested are Infant and child mortality, Maternal mortality, Reproductive health and control of HIV, Tuberculosis, malaria and other communicable diseases. As is however very clear from the MDGs, improved health will only be possible through inter-sectoral coordination to simultaneously eliminate extreme hunger and poverty, provide education to all, enable empowerment of women, besides protection and better management of the natural and physical environment. The goals, targets and their indicators have been enunciated for action by all countries. MDGs will however only be successful if there is the political will to address international cooperation and involvement of both poorer and richer countries in this gigantic task.

### Summary

Historically, in resource poor countries, public health had been synonymous with health development efforts taken by Government agencies. Very few records of public health in developing countries exist for ancient ages. With the start of the 18<sup>th</sup> century, Colonials (Americans and Europeans) established their own administrative, legal and medical care with varying degree of autonomy. The late 18<sup>th</sup> century saw an increased momentum in public health education first in home countries then in colonial countries. However, the actual development of public health and medical care services for the general public remained rudimentary in these colonies. Development in science and technology in the early 20<sup>th</sup> century led to explosion in the application in public health practices. Public health in immediate post independence period evolved with the creation of inter Government institutions like United Nations and its specialized agencies like World Health Organization. Most developing countries in the post Second world war period followed the advice and support of WHO and other international agencies to improve their health systems-National health programmes were started; health care services were provided free; training of health workers initiated and development of human resources for health was focused. The initial vertical approach of provisioning of health services was reviewed to provide comprehensive basic health services. Promotion of environmental sanitation - provision of safe drinking water, adequate sanitation etc was also given high priority. Shift from agriculture based economy to industrial economy posed additional burden of these facilities and simultaneously increasing incidence of communicable and non communicable diseases. Assistance of international agencies promoted global disease control campaigns. Demonstration projects were established in different countries to identify country specific disease prevention and control strategies. Spectacular success was achieved in the field of Yaws control, reduction in morbidity and mortality due to malaria, leprosy, sexually transmitted diseases, cholera and smallpox. The prevention of chronic disease in low and middle income countries is now the priority. Efforts are now directed against promoting healthy living, reducing the double burden of disease, making health care accessible to all - all included in the Millennium Development Goals.

### Study Exercises

#### MCQs & Exercises

- (1) The "School of Tropical Medicine & Hygiene" is located in: (a) Delhi (b) Mumbai (c) Kolkata (d) Chennai
- (2) The "All India Institute of Hygiene & Public health" is located in : (a) Delhi (b) Mumbai (c) Kolkata (d) Chennai
- (3) The "Haffkine Institute" is located in : (a) Delhi (b) Mumbai (c) Kolkata (d) Chennai
- (4) The "Central Vaccine Research Institute" is located in : (a) Delhi (b) Mumbai (c) Bangalore (d) Kasauli
- (5) The "National Institute of Communicable Diseases" was earlier known as \_\_\_\_\_
- (6) The "Indian Research Fund Association" was later known as \_\_\_\_\_
- (7) The International Rural Health Conference in 1953

- was held at : (a) New Delhi (b) Mumbai (c) Kolkata (d) Chennai
- (8) The initial focus of the 'Green Revolution' was on : (a) Pulses (b) Cereals (c) Vitamins (d) Minerals
- (9) In 1950s, spraying of DDT for Malaria, had a collateral benefit in reduction of : (a) JE (b) Dengue (c) Kala-Azar (d) Chikungunya
- (10) The oldest & widely prevalent disease in the developing countries was : (a) TB (b) Malaria (c) Kala-azar (d) Leprosy
- (11) A new cholera biotype, Eltor, appeared in 1965 in : (a) India (b) Indonesia (c) Sri Lanka (d) Burma

- (12) The drug used for treatment of Onchocerciasis is : (a) Chloroquine (b) Doxycyclin (c) Ivermectin (d) Artesunate

**Answers :** (1) c; (2) c; (3) b; (4) d; (5) Malaria Institute of India; (6) ICMR; (7) a; (8) b; (9) c; (10) d; (11) b; (12) c.

### Further Suggested Reading

1. Public health in poorer countries. Nicholas Banatvala and Jenny Amery in Oxford Handbook of Public Health Practice. 2nd ed, 2007. 292-300
2. The history and development of public health in developing countries. Than sein and Uton Muchtar Rafei in Oxford Textbook of Public Health. 4th ed, 2002. 39-62.

## 8

### Public Health in Developed Countries

*Amitava Datta*

Public health today is really a reflection of history of the developed world. People today live longer, fewer parents experience death of young children, fewer adults die of communicable diseases like tuberculosis and are less likely to experience periodic famines or epidemics. People are less likely to experience chronic pains or deformities from which only death provides a merciful release. An expectation of health and a pre-occupation with it are the hall marks of modern society. Public health in the modern era, which took roots in the developed world mainly in the 19<sup>th</sup> century, reflects in the way they collect and evaluate demographic data, keep cities clean and provide the means to the public to ensure their health. There have always been controversies in the aspect of definition of health and the role played by the public which invariably affect their health. Measures to be adopted by the state to preserve or promote the health of their citizens have also been dominated by politics. Even when there arose widely accepted reasons of state intervention and agendas of state responsibility for actions to ensure the health of their citizens, not every state was in a position to act on them. The responsibility of action was often unclear or overlapping.

#### Evolution of Concepts of Public Health

The combating of infectious diseases has often seemed the core of public health to be provided by the state. The levels and kind of physical and mental well being which should be guaranteed by the state has often been seriously debated. The problems posed in the actual causation of diseases based on personal, social, cultural, political, economic and biological considerations provides adequate reason for differing opinions regarding actions needed to be initiated to prevent or contain these diseases. The increasing concern for equity in ensuring public health based on principles of non-discrimination has

been increasing. Health status of certain groups was considered as a threat to others and therefore actions aimed at such groups were initiated to improve their health with a broader view to ensure the health of the benefactors themselves. The responses to disease in these groups range from calls to advice or aid them to the extremes of planning to imprison, banish or even kill them. The aspects of public health which have become refined are :

- Clear differentiation of aspects considered to be clearly the responsibility of the state or community vis-à-vis those which were clearly the responsibility of the individual.
- Application of concepts of inter-sectoral coordination with greater appreciation of fields other than medicine like engineering, social sciences, economics, religion, etc in their contribution to provision of health and prevention of disease.
- Provision of public health services considered to be above politics with claims of high moral ground by the proponents of public health action.

In the developed countries of the world, public health therefore revolved around three main aspects :

- Response to an epidemic situation
- As a regulatory or 'police'
- As a means to provide improvement or better life

The initial public health actions revealed mainly a reactive mechanism in response to outbreaks of epidemics of communicable diseases in neighbouring countries or within the country itself. Closing of borders or ports, instituting prophylactic measures like fumigation of ships and aircraft are clearly examples of this response mechanism to protect themselves. Like in the evolution of community living, regulation of aspects considered as threats to health of the members became part and parcel of the public health initiatives of countries. Control of food adulteration, prostitution, concern over substance abuse and smoking became the responsibility of public health providers. The political vision to provide improvement in health for all was last to arise in the field of public health. These were made possible by technological



achievements, like better vaccines, better diagnostic facilities, better demographic information and an optimistic view of possibility for progress in human life and not accept aspects like infant mortality as inevitable.

**Public health aspects of epidemic response** : The public health actions to meet an epidemic stemmed from the realisation that something could be done in these circumstances by the public. In some cases the replacement of supernatural explanation for causation of diseases like in small pox also occurred but not necessarily coincided with start of public action. The containment of plague epidemics in Europe started the public health movement in those regions. The Italians included development of 40 day hold on ships or other traffic coming from potentially infected areas, isolation of victims and numerous means like burning sulfur, burning clothes and bedding and washing surfaces with lime or vinegar. Plague control required officials to oversee quarantine or isolation procedures, staff to disinfect and a structure for gathering health information. Response to yellow fever and malaria consisted of flight and abandonment of cities by those who could afford it. The response to syphilis was variable among different countries. Mainly the state approach shifted from cure to prevention by aiming to regulate prostitutes, who were considered reservoirs of the disease. The efforts to contain epidemic diseases did not reflect any sense of obligation to individuals. At stake were mainly the military, commercial and cultural welfare of the state and individual's welfare was only incidental. The typhoid, typhus, relapsing fever and yellow fever were tackled by public action to improve the living conditions comprehensively to provide the physical and social changes that would produce a sound human being.

#### **Public health aspects of 'police' action**

Regulation of communities for common good was practiced by western nations. By the eighteenth century they were broadly being called 'police' action. The police functions included the following :

- Enforcing basic rules of sanitation, building construction and public morality
- Caring for poor and orphans
- Regulation of modes of work and work hours
- Regulation of markets and sale of commodities
- Marriage and midwifery practices
- Travel regulations and restrictions
- Maintaining population statistics
- Regulating medical practice

The business of public 'police' in the 18<sup>th</sup> and 19<sup>th</sup> century Europe did affect health in many ways. It also covered much of what would later belong to the domain of public health. Mainly however the concern was with amenity, morality and public order. The concept of medical 'police' arose first in Germany and Austria, to be followed by Scotland, Scandinavia, Italy and Spain. The importance of regulating personal behaviour to improve the health of soldiers and sailors was gaining recognition. Hence the idea emerged of trying the same on the rest of society among some rulers of countries in Europe. In America and England the 'police' concept did not really catch on. Modern public health may be considered to approach the domain of comprehensive 'police'. It recognizes that a wide

range of factors are implicated in health conditions including current concerns like effects of violent entertainment, prevention of gun violence and the conditions of the workplace. Modern liberal democracies today however consider these concepts as deeply problematic and are uncomfortable with infringing on personal liberties of their citizens.

**Public health aspects of provision of better life** : Public health emerged in the western countries as not something which was only reactive. It took upon itself the goal of reduction of morbidity and mortality. Originating in the 18<sup>th</sup> century, this aspect of public health had complex causes. Public health developed the ability to compare morbidity and mortality profiles of different population groups. Technological advances started to provide for means for prevention of diseases like vaccines besides diagnostic tests for diseases and carrier status. Armed with these information, public officials like John Simon in England, argued with towns with poor morbidity and mortality statistics to analyse the reasons and take appropriate action. The gathering and analysis of health data has become a central part of modern public health. However, new medical knowledge and technological advances did not necessarily precede the determination to improve the health for all. The sanitary campaigns against urban filth, which were based on a vague, flexible and erroneous concept of pathogenic miasmas, is the best example of the determination to improve the living conditions as a means of provision of better and healthier life. There was also greater resistance to accepting differential morbidity and mortality in disadvantaged population groups and need to initiate appropriate action. It needed two centuries to evolve to the present modern concept which admits no justifiable reason other than climatic and biological factors for differential morbidity and mortality figures among different groups, communities or nations - the concept of health equity.

#### **Phases of Public Health**

The available literature clearly brings out the changes which public health has undergone in the developed countries over a period of time, mainly the last two centuries. It would be appropriate to divide these into three phases to under the evolution of the concepts.

**Age of liberalism (1790-1880)** : The concepts of equity in health started with this age. John Simon pioneered work with English state medicine to change to the concept that the best policies were those that maximized human worth and welfare. The recognition of Human rights was still not transcribed in terms of health. Concern with public health arose accidentally and at different times in different countries of the developed world. Revolutionary France wished to abolish medical licensing and other aspects which were associated with 'police' functioning. These were quickly given up once the state interest was realized. States like Sweden and France weakened with depopulation due to disease focused attention on health and welfare of individuals. Edwin Chadwick developed "the Sanitary Idea" in 1830s. Only USA propagated the idea that individual's health was a private matter. All countries of Europe were strong proponents of need for state enforcement of sanitation policies and practices.

**Golden age of public Health (1880-1970)** : During this period European nations, America and later Japan, competed for



colonies and international influence. Realisation of weakness of its citizens forced action by powerful states like Britain to provide expanded public health services. Development of diagnostic facilities lead to diagnosis of diseases and containment measures. Persistently high infant mortality even in relatively well sanitized country like England lead to concern for containment of this avoidable loss of life. Concern for health conditions of women and of workers mainly in factories began to attract attention as never before, reflecting commercial and other interests. Public health measures, which could address the concern for reducing the high morbidity and mortality were sought, in spite of they infringing on an individual's life in all aspects like home, work, family relations, recreation, etc. The germ theory of disease matured in France and lead to concern for the human body as a harbour of germs. This was especially so in diseases like typhoid, tuberculosis and syphilis where it was recognized that the human body could harbour the disease in spite of not manifesting disease. Inspection and regulation were the public health strategies suggested as an outcome of the germ theory. The example of 'Typhoid Mary' who was incarcerated for 26 years by the city of New York, is an extreme example of this intervention. The legal limits and cultural sensibilities could be however be worked out over a period of time as a compromise between public health and civil liberties.

The emerging science of heredity was a contemporary of the 'germ theory'. The concept of eugenics as a hope for the improvement of health of people exercised the minds of many involved with public health. The extreme application occurred during Nazi Germany's attempt to exterminate Jews and other 'races' regarded as inferior. Negative eugenics was also practiced through American laws which prevented reproduction by those considered 'unfit'. Proponents of eugenics focused attention on human genome and urged public health to take cognizance of heredity as a basis for disease causation.

Nutritional sciences also developed leading to association of pellagra with over dependence on maize in southern parts of America and role of vitamin D and sunlight in prevention of rickets. Diet like genes, loomed large in the minds of the public as the cause of all troubles and provided a source of hope. Public health included attention to a varied diet which ensured adequate vitamins. People thus learnt to fear three entities-invisible germs of disease, mysterious genes and peculiar set of trace nutrients missing in their diets

**Return to liberalism (1970 onwards)** : Post second world war, threats posed by most of the known infectious diseases receded with better focus on public health. Pro-active actions of World Health Organisation ensured internationalization of public health and preventive action. The mission statement of WHO, that health was the birthright of all persons, emphasized the liberal attitudes of international community. However, the failure to combat chronic diseases by countries became highlighted in the absence of significant infectious diseases. Deadly effect of good living including smoking and a rich diet was brought sharply into focus. A new set of actions focusing on personal discipline emerged to control lifestyle diseases and accidents. Public health institutions and the people were increasingly at loggerheads over differing perceptions of role

of regulatory agencies in protecting environment and health of people. Even aspects of lifestyle could be attributed to the broader social environment. People smoked tobacco, drank alcohol, used narcotic drugs, ate too much or too little, failed to practice safe sex and spent hours in front of televisions and personal computers. They also beat up their spouses or children, fought with their co-workers and used readily available firearms to shoot themselves or others as they were unable to cope with the stresses of day to day living. Analyses of these events were however not conducive to solutions in view of the existence of serious vested interests. Arising of many widespread cancers and debility associated with ageing populations started focusing attention on the need for public health to also focus on these issues. The newly emerging diseases were not infectious and could be suffered by individuals privately without disturbing the community. However these certainly impacted on the fulfillment of human potential and could therefore justify the demands for action by the governments of these citizens. Efforts to expand state responsibility for health have generally worked when medical professionals have viewed them as personally advantageous. The relationship between expanded public health action and social welfare has however been problematic at other times. Suggestions for regulating human behaviour and lifestyle as a means of prevention of diseases associated with lifestyle have invariably drawn vociferous protests and lobbying actions. The context of tobacco control in several nations is an apt example of this dichotomy. The absurdity of the situation can be assessed when viewing that on the one hand countries and states were subsidizing tobacco production which was leading to addiction in other countries, while blaming their own citizens for smoking and damaging their health over a period of time. The relationship between the public health institutions and the citizens on whose behalf they claim to be working will remain one of the most serious challenges of the modern day public health.

### **The Way Forward - Need for Continued Public Health Action**

The momentous achievements of the 20th century revolutionised health and the consequent demographic transition, leading to new patterns of disease. There has been a major shift in causes of death and disability from infectious diseases to non-communicable diseases. Not only have the major causes of death changed but the average age of death has been steadily rising. There appears to be niggling doubts to the branding of the situation as a complete success story with the persistence of sub-populations of disadvantaged people. Reducing the burden of that inequity is a priority on the public health agenda. Health policy planners will need to deal with the twin problems of emerging and re-emerging infectious diseases compounded with the problems of non-communicable diseases. Mental depression and Injuries - both intentional and unintentional are fast emerging as leading causes of ill health. It is estimated that by 2020 injuries may rival infectious diseases worldwide in morbidity and mortality. Among infectious diseases malaria, HIV/AIDS and tuberculosis are diseases which continue to pose public health problems due to the microbial evolution - the growing resistance of the disease

producing organisms to anti-microbial drugs and other agents. Increase in international travel, trade (particularly food trade) and tourism mean that many of the deadly disease producing organisms can be rapidly transported from one continent to another. No region or country can therefore be considered safe and protected from infectious diseases. There is need to further strengthen the existing global surveillance and cooperation in the field of infectious diseases.

Even the wealthiest countries may not be able to provide entire populations with every intervention that has medical value. Priorities need to be debated, consensus generated and implemented in a manner conducive to universal access to affordable and effective health care. Priority setting varies from country to country. In Sweden, principles enunciated are human dignity irrespective of personal characteristics and social functions, need and solidarity and cost effectiveness. Innovations in health financing will be needed to achieve stated public health goals as costs of health care are beyond the capability of even wealthy countries. However, leaving the disadvantaged populations to fend for themselves even in capitalistic countries will deny the concepts of health equity which these countries propagate. Health research and development must also be prioritized in the scheme of public health actions planned to provide the means for transforming health concerns into actions. The critical gaps in knowledge and need for products have already been substantially identified. It may be necessary to provide incentives to individuals and institutions to focus research activities in the desired field of health research.

One of the ways of planning action for the future is to look to the past and consider what should have been done if only we could have had foresight. What do we wish that reasonable people had done in the past? When we look at the current conditions of rapid population expansion, environmental degradation, low birth weights, drug use, violence and a multitude of medical and social problems, it is tempted to wish that public health people of the past had acted differently. For example, what if public health people had taken a strong stand on tobacco when it first became obvious that this was a health problem? It was identified as a health problem in the 1930s. Even if America had waited until 1964, when the Surgeon General's report outlined strong proof regarding the role of tobacco in disease, 30 years of sustained effort would have put America in a situation quite different from the one it now finds itself. If decision-making had been based on public health evaluation, without the barriers of political decisions, the effects would have been completely different.

Similarly, there has always been suffering in the long run when public health officials took a local view of problems. Repeatedly reminders are required that public health must take a global perspective knowing that all things are interrelated and that health must be seen to involve all areas of life. Based of these experiences, it may be agreed that all future public health activities would be based on simple norms that programs would be planned from a global viewpoint, with the goal of providing what is best for the largest number of people and that programs would be planned with the longest time span possible.

What is the likely impact of a program on persons living hundreds of years in the future? What is the level of impact? These questions must be considered and rationally answered at the planning stage itself. For example, an episode of diarrhoea in an adult, while extremely annoying may have no long-term impact, whereas such an occurrence in a young child may be the pivotal event leading to death; the child's illness thus would assume greater priority. Similarly, vitamin A deficiency may lead to lifetime blindness, whereas the lack of education may lead to lifetime bondage; therefore, both must be viewed as being of concern. It must however be appreciated that some problems have an impact that can never be repaired. Population growth, the destruction of rain forests and depletion of ozone are examples of conditions that must be attended to no matter what the cost. The bottom line is that, while it would be great to see into the future, a rational step can be taken by looking at what was neglected in the past, to our current regret and making sure that these problems are not shared by the future. Population programs, anti-tobacco programs, alcohol control programs, the reduction of global weapons, the reduction of violence, adequate nutrition and primary education for all children, but especially for females, programs to reduce poverty and to control sexually transmitted diseases and other infectious diseases would be paramount.

It is possible to provide a new vision for public health, where truth and equity propel the decisions and common sense frames the priorities. Health would be seen to involve all aspects of the world. Interventions would benefit this generation as well as those to follow. We could be ideal ancestors while making relatively few changes in the way we operate.

## Summary

Public health today is a really a reflection of history of the developed world. An expectation of health & a pre-occupation with it are the hallmarks of modern society. Measures to be adopted by the state to preserve or promote the health of their citizens have also been dominated by politics. The combating of infectious diseases has often seemed the core of public health to be provided by the state. The actual causation of diseases based on personal, social, cultural, political, economic & biological considerations provides reason for differing opinions regarding actions to prevent them. There is an increasing concern for equity in ensuring public health. The public health aspects in terms of clear differentiation of areas which are the responsibility of state/community, application of the concept of inter-sectoral co-ordination & provision of public health services have been refined.

In the developed countries, public health revolves around three main aspects viz. response to an epidemic situation, as a regulatory or 'police' & as a means to provide improvement or better life.

The public health actions to meet an epidemic stemmed from the realization that something could be done under these circumstances by the public. The efforts to contain epidemic diseases did not reflect any sense of obligation to individuals. At stake were mainly the military, commercial & cultural welfares of the state & individuals welfare was only incidental. Regulation of communities for common good, practiced by

western nations were broadly called 'police' action. The concept arose first in Germany & Austria. The gathering & analysis of health data has become a central part of modern public health. New medical knowledge & technological advances didn't necessarily precede the determination to improve the health for all.

Public health has undergone changes in the developed countries mainly in the last two centuries. These can be divided into three phases under the evolution of concepts into :

- Age of liberalism (1790 - 1880)
- Golden age of Public health (1880 - 1970)
- Return to liberalism (1970 onwards)

The achievements of the 20<sup>th</sup> century revolutionized health & the consequent demographic transition, leading to new patterns of disease. Reducing the burden of inequity is a priority on the public health agenda. Health policy planners need to deal with twin problems of emerging & re-emerging infectious diseases compounded with the problems of non-communicable diseases. Even the wealthiest countries may not be able to provide entire populations with every intervention that has medical value. Priorities need to be set & consensus implemented, to ensure universal access to affordable & effective health care. It is possible to provide a new vision for public health, where truth & equity propel the decisions, & common sense frames the priorities. With relatively few changes in the way we operate, we could benefit both the present & future generations.

## Study Exercises

### MCQs and Exercises

- (1) The public health aspects in terms of clear differentiation of areas which are the responsibility of state/community have not been refined : True/False
- (2) In the developed countries, public health revolves around the aspects of all except : (a) Response to an epidemic (b) Regulatory or 'police' (c) provide improvement or better life (d) None
- (3) The public health actions to meet an epidemic stemmed from the realization that something could be done under these circumstances by the public : True/False
- (4) Regulation of modes of work & work hours, form part of the 'Police' action. True/False
- (5) Maintaining population statistics doesn't form part of the 'Police' action : True/False
- (6) The concept of medical 'Police' arose first in (a) Germany (b) Scotland (c) Scandinavia (d) Italy
- (7) The Golden age of Public health is : (a) 1790-1840 (b) 1840-1880 (c) 1880-1970 (d) 1970-2000
- (8) By 2020, injuries may rival infectious diseases worldwide in morbidity & mortality : True/False

**Answers :** (1) False; (2) d; (3) True; (4) True; (5) False; (6) (a); (7) c; (8) True.

### Further Suggested Readings

1. The history and development of public health in developed countries. Christopher Hamlin in Oxford Textbook of Public Health. 4th ed, 2002. 21-38.
2. The American Health Care System : Structure and Function. F. Douglas Scutchfield and Steven J Williams in Maxcy-Rosenau-Last. Public Health & Preventive Medicine. Appleton & Lange. 14th ed, 1998. 1115-1130

## 9

### State of Health in the World : Disparities and Divides

*Sunil Agrawal*

Within the various regions and continents of the world, there is persistence of extreme inequality and disparity both in terms of access to care as well as health outcomes. There are large within country differences in the coverage gap between the poorest and wealthiest population quintiles. In India and Phillipines, the wealthiest groups are three times more likely to receive care than the poorest. In terms of absolute difference, Nigeria has the largest inequity in coverage : the difference between maximum and actual coverage is 45 percentage points larger for the poorest than for the best off population quintile. Some countries, including the formerly socialist Azerbaijan and Turkmenistan, have remarkably small differences by

wealth quintile. Inequalities between population groups are particularly high for maternal and neonatal care, which includes antenatal care and the presence of a skilled attendant at delivery. The difference is smallest for the treatment of sick children and family planning. Global deaths and DALYs figures in 2000 are given in Table - 1.

The Americas, Europeans and western pacific region's life-expectancy at birth is about 23 years more than that of Africa region. IMRs in Africa region is about five times that of America, Europe or Western pacific region. MMR in Africa region is more than ten times that of America and western pacific region where it is about 30 times that of European region. The MMR of south East Asia and eastern Mediterranean region is also about five times that of America, European and western pacific region. Infant Mortality rates among regions also reveal wide variations. This high degree of variation of health indices is itself a reflection of the high variance in the availability of health services in different countries of the region.



**Table - 1 : Global deaths and DALYs (2000)**

WHO Region	Deaths All causes, 2000		DALYs from deaths, All causes 2000	
	Thousands	Percent	Thousands	Percent
African Region	10,681	18.9	357,884	24.4
Regions of Americas	5,911	10.5	145,217	9.9
South East Asia Region	14,467	25.6	418,844	28.5
European region	9,703	17.2	151,223	10.3
Eastern Mediterranean Region	4,156	7.3	136,221	9.3
Western Pacific region	11,636	20.6	257,868	17.6
Globally	56,554	100.0	1,467,257	100.0

## Demographic Indicators

### Population Statistics (2006)

The global population in the year 2006 was 6580 Million with median age of 28 years. The total population of South East Asia and Western pacific region are highest and more than double than any other region in the world. Global Population figures as on 2006 are given in Table - 2.

**Table - 2 : Global Population Statistics (2006)**

WHO Region	Total Population (000s)	Under 15 (%)	Over 60 (%)	Annual growth rate (%) 1996-2006	Popn in urban areas (%)
African Region	773,791	43	5	2.5	38
Regions of Americas	894,943	26	12	1.3	73
South East Asia Region	1721,049	31	8	1.6	32
European region	887,455	18	19	0.2	73
Eastern Mediterranean Region	540,284	35	6	2.0	49
Western Pacific region	1763,399	22	12	0.8	47

**Age Distribution** : Worldwide under 15 yrs population is 28% and about 10% population is of >60 yrs age group. However, annual growth worldwide has declined from 1.6 to 1.3 with decline in all the regions of WHO.

**Infant Mortality Rate (IMR)** : The global IMR is 49/1000 live births (Male-51, Female-47). For last two decades there is steady decline in IMR in all the regions of WHO. The major decline was seen in European region where it has declined from 81 to 14 per 1000 live births. It shows wide regional and inter country variation with countries like Afghanistan, Angola, Nigeria, Liberia, Sierra Leone having IMR of >150/1000 live births whereas, countries like Andorra, Cyprus, Czech republic, Denmark, Finland, Iceland, Italy, Japan, Luxembourg, Monaco, Norway, Portugal, San Marino, Singapore, Sweden have very low IMR of <=3/1000 live births. Neonatal mortality (at 28 per 1,000 live births) constitutes nearly 60%-65% of the IMR in various countries. Concerted efforts will be required under Home Based Neonatal Care (HBNC) to reduce the IMR and Neonatal Mortality Rate (NMR) further. Global statistics on IMR is given in Table - 3.

**Neonatal Mortality** : An estimated 4 million deaths occur during the first 28 days of life, accounting for 38% of all deaths of children under five. Causes include infections (36%), preterm birth (27%) and asphyxia (23%). Intensive care is not required to save most of the babies. Developed countries and some low income countries for e.g. Sri Lanka, have achieved neonatal mortality rates of 15 per 1000 without intensive care, which is less than a third of current neonatal mortality rates in Sub Saharan Africa.

Interventions like breast feeding, extra care of moderately small babies, cleanliness, warmth, community based management of acute respiratory and acute diarrhoeal diseases along with standard maternal and child health package is likely to be highly effective.

### Childhood Illnesses and Mortality among Children under Five

: Neonatal mortality rates and mortality rates for children under 5 can be reduced by large margins, at an affordable cost, by using interventions proven effective in low income settings. Improvements are likely to come from increasing the coverage of preventive measures, such as breast feeding and from expanding the scope of existing childhood vaccines beyond the traditional six antigens in areas where existing coverage is relatively high and where new antigens address diseases of significant burden, particularly pneumococcal vaccines. Curative interventions include case management of ARIs, malaria and acute diarrhoeal diseases which hold promise for lowering the 6 million preventable deaths each year in this age group. Global statistics on under 5 mortality rate is given in Table - 4.

**Maternal Mortality Ratio (MMR)** : The target for monitoring progress towards Millennium Development Goal 5 (MDG 5) (improve maternal health) is to reduce the maternal mortality ratio in all countries so that by 2015 it is one quarter of its 1990 level. The latest estimate is that 536000 women died in 2005 as a result of complications of pregnancy and child birth and that 400 mothers died for every 100 000 live births. The maternal mortality ratio was 9 in developed countries, 450 in developing countries and 900 in sub Saharan Africa.



**Table - 3 : Infant Mortality Rate (Per 1000 Live Births)**

WHO Region	Males			Females			Both Sexes		
	1990	2000	2006	1990	2000	2006	1990	2000	2006
African Region	116	106	100	100	92	87	108	100	94
Region of the Americas	37	25	19	30	21	16	34	23	18
South East Asia Region	81	62	52	78	60	51	79	61	52
European Region	87	21	15	74	17	12	81	19	14
Eastern Mediterranean Region	30	74	66	24	64	57	27	69	62
Western Pacific Region	32	25	18	40	32	22	36	28	20

**Table - 4 : Under 5 Mortality Rate (Per 1000 Live Births)**

WHO Region	Males			Females			Both Sexes		
	1990	2000	2006	1990	2000	2006	1990	2000	2006
African Region	190	174	164	174	160	150	182	167	157
Region of the Americas	46	30	23	39	25	19	42	28	21
South East Asia Region	110	80	66	116	85	71	113	82	69
European Region	113	25	18	107	20	14	110	22	16
Eastern Mediterranean Region	36	95	85	29	91	82	33	93	84
Western Pacific Region	42	32	22	50	39	25	46	35	24

**Table - 5 : Life expectancy at birth**

WHO Region	Males			Females			Both Sexes		
	1990	2000	2006	1990	2000	2006	1990	2000	2006
African Region	49	49	50	52	52	52	51	50	51
Region of the Americas	68	70	72	74	77	78	71	73	75
South East Asia Region	58	61	63	59	63	65	58	62	64
European Region	59	68	70	61	76	78	60	72	74
Eastern Mediterranean Region	67	61	63	74	64	66	70	63	64
Western Pacific Region	42	32	22	50	39	25	46	35	24

This means that 99% of the women who died in pregnancy and childbirth were from developing countries. Slightly more than half of these deaths occurred in sub Saharan Africa and about a third in southern Asia; together these regions accounted for over 85% of maternal deaths worldwide.

Meeting the MDG target for maternal mortality requires a decline in the maternal mortality ratio by around 5.5% each year. No region in the world has achieved this result. Globally the maternal mortality ratio showed a total fall of 5.4% in the 15 years between 1990 and 2005, an average reduction of 0.4% each year. The present MMR is 400 per 1,00,000 live births (2005) (WHS, 2008). Levels of maternal mortality vary greatly across the regions due to variation in access to emergency obstetrical care, prenatal care, anaemia rates among women,

education level of women and other factors. The MMR in regions like Africa, South East Asia and Eastern Mediterranean Region contribute maximum MMR of 900, 450 and 420 per 1,00,000 live births respectively. The maximum MMR is found in Sierra Leone, Afghanistan, Nigeria etc with around 2000 per 1,00,000 live births.

Total fertility rate (TFR), per women at Global level is 2.6, with high rates in Africa region (4.7) and Eastern Mediterranean region (3.5). However, there is constant decline in TFR all over world in last two decades.

**Life Expectancy at birth** : Average life expectancy in low and middle income countries increased dramatically in the past half century, while cross country health inequalities decreased. In the countries with the best health indicators, life expectancy

increased a substantial two and one half years per decade since 1960 and low and middle income countries on an average, had life expectancy gains of about five years per decade. Average life expectancy at birth 50 years ago was 38 years in sub Saharan Africa, 41 years in Asia, 45 years in the Middle East, 51 years in Latin America and the Caribbean and 60 years in Oceania. Over the following 50 years, average life expectancy at birth improved all over the world, increasing by almost 27 years in Asia, 23 years in the Middle East, 21 years in Latin America, 14 years in Oceania and 11 years in sub Saharan Africa.

Improvement in average income, education levels, generation and diffusion of new knowledge, low cost appropriate technologies etc contributed to these worldwide gains in health.

In SE Asian region both male and female Life Expectancy since 1990 has been steadily increasing, whereas, in eastern Mediterranean region it has actually declined. Increasing life expectancy is leading to increasing number of elderly persons in the population for which specific health facilities will need to be provided. Global statistics of life expectancy at birth is given in Table - 5.

## Socioeconomic Indicators

### Education

Literacy rate has increased by 10.6% during last decade (1990-2000). The global adult literacy rate is 78.4%. Many countries have Literacy rate above 95% like Bulgaria, Chile, Croatia, Cuba, Greece, Maldives, Mongolia, Ukraine while some countries like Mali, Nigeria, Afghanistan have literacy rate < 30% (Table-6).

**Table - 6 : Adult Literacy Rate (%)**

WHO Region	Adult Literacy Rate (%) 1990-1999	Adult Literacy Rate (%) 2000-2005
African Region	51.8	59.3
Region of the Americas	-	-
South East Asia Region	52.0	66.8
European Region	-	-
Eastern Mediterranean Region	53.4	64.4
Western Pacific Region	79.1	90.7

## Total Expenditure on Health as % of Gross Domestic Product

The various mortality and morbidity indicators are inversely proportional to the total expenditure on health as % of gross domestic product. The regions which have high expenditure show low levels of morbidity and mortality indicators (Table - 7).

**Table - 7 : Total expenditure on health as % of gross domestic product**

WHO Region	Total expenditure on health as % of gross domestic product 2000	Total expenditure on health as % of gross domestic product 2005
African Region	5.8	5.9
Region of the Americas	11.3	12.7
South East Asia Region	3.5	4.0
European Region	8.0	8.6
Eastern Mediterranean Region	4.5	4.9
Western Pacific Region	5.7	5.8

## Drinking Water and Sanitation

The percentage of population having access to safe drinking water facility and access to improved sanitation in both urban and rural areas are given in Table - 8.

Globally 86% of the population has access to improved drinking water whereas only 60% of population has access to improved sanitation. However, same has increased marginally in last two decades. Access to improved drinking water has increased from 95% to 96% in urban areas and from 62% to 78% in rural areas, whereas improved sanitation has increased from 76% to 78% in urban areas and from 34% to 44% in rural areas globally.

## Health Status Indicators

### Communicable Diseases Morbidity

**Tuberculosis** : Tuberculosis had an estimated 8.8 million new

**Table - 8 : Drinking Water and Sanitation**

WHO Region	Access to improved drinking water source (%)			Access to improved sanitation (%)		
	Urban	Rural	Total	Urban	Rural	Total
African Region	82	46	59	46	26	33
Region of the Americas	98	81	94	92	68	87
South East Asia Region	94	84	87	58	27	37
European Region	100	92	97	97	85	92
Eastern Mediterranean Region	93	75	82	85	43	60
Western Pacific Region	98	82	89	79	61	69

cases in 2003, fewer than half of which were reported to public health authorities and WHO. Approximately 3.9 million cases were sputum smear positive. The African region has the highest estimated incidence rate (345 per 1,00,000 population), but the most populous countries of Asia harbor the largest number of cases : Bangladesh, China, India, Indonesia and Pakistan together account for half the new cases arising each year.

Globally, 12 percent of new adult tuberculosis cases were infected with HIV in 2003, but there was marked variation among regions-from an estimated 33 percent in Sub Saharan Africa to 2 percent in East Asia and the Pacific. Approximately 1.7 million people died of TB in 2003, including 229,000 patients who were also infected with HIV.

**HIV/AIDS** : HIV/AIDS is one of the most urgent threats to global public health. The number of people living with HIV worldwide in 2007 was estimated at 33.2 million. Sub Saharan Africa continues to be the region most affected by HIV/AIDS. In 2007, one in every three people in the world living with HIV lived in sub Saharan Africa, a total of 22.5 million. Although other regions are less severely affected, 4 million people in South and South East Asia and 1.6 million in Eastern Europe and Central Asia were living with HIV/AIDS.

Although the total number of people living with HIV has increased significantly over the years, the proportion infected has not changed since the end of 1990s. In fact, the number of people who become infected every day (6800) is greater than the number who die of the disease (around 6000). Worldwide, 0.8% of the adult population (aged 15-49 years) is estimated to be infected with HIV, with a range of 0.7-0.9%. In sub Saharan Africa, the estimated proportion of the population infected has actually fallen steadily since 2000. Current data indicate that HIV prevalence reached a peak of nearly 6% around 2000 and fell to about 5% in 2007.

**Leprosy** : At the global level the prevalence rate of less than 1 per 10,000 has been achieved which were known as elimination levels for Leprosy. The number of cases registered for treatment worldwide fell from 5.4 million in 1985 to 460,000 by the end of 2003. Leprosy is reported from all regions of the world, but the burden of disease, which is estimated at 192,000 DALYs is concentrated in few countries. During 2003, 513,798 new cases were detected of which more than 80 percent were in Brazil, India, Madagascar, Mozambique, Nepal and Tanzania. India alone accounted for 75 percent of the new cases.

## Communicable Diseases Mortality

The maximum mortality due to HIV/AIDS was in African region, where HIV/AIDS is still one of the highest cause of mortality (203 deaths per lac population) whereas western pacific region had minimum mortality due to HIV/AIDS with 4 deaths per 1,00,000 population. However, deaths worldwide from HIV/AIDS are expected to rise from 2.2 million in 2008 to a maximum of 2.4 million in 2012 before declining to 1.2 million in 2030.

Malaria is endemic in many of the world's poorest countries. Malaria indicator surveys show important within country disparities showing that children living in wealthiest households are better protected by bed nets; they have a lower chance of carrying malaria parasite and when they fall sick they are more likely to be treated with antimalarial medication. Proportional Mortality Ratio among children aged < 5 years (%) is given in Table - 9.

## Non Communicable Diseases

**Cardiovascular disease (CVD)** : At the beginning of the 20<sup>th</sup> century, CVD was responsible for less than 10 percent of all deaths worldwide, but by 2001 that figure was 30 percent. About 80 percent of the global burden of CVD death occurs in low and middle income countries. Cardiovascular disease is the number one cause of death worldwide. CVD covers wide array of disorders, including diseases of the cardiac muscle and of the vascular system supplying the heart, brain and other vital organs.

Murray and Lopez (1996) predicted that CVD will be the leading cause of death and disability worldwide by 2020 mainly because it will increase in low and middle income countries.

**Cancer** : Globally, cancer is one of the top ten leading causes of death. It is estimated that 7.4 million people died of cancer in 2004 and, if current trends continue, 83.2 million more would have died by 2015. Among women, breast cancer is the most common cause of cancer mortality, accounting for 16% of cancer deaths in adult women. In developing countries, the top five female cancers in rank order of incidence are breast, cervical, stomach, lung and colorectal cancer and the top five male cancers are lung, stomach, liver, esophageal and colorectal cancer.

**Diabetes** : In 2003, the worldwide prevalence of diabetes was estimated at 5.1 percent among people aged 20 to 79. The prevalence of diabetes was higher in developed countries than

**Table - 9 : Proportional Mortality Ratio among children aged < 5 years (%).**

WHO Region	Neonatal causes	HIV/AIDS	Diarrhoea	Measles	Malaria	Pneumonia	Injuries	Others
African Region	26.2	6.8	16.6	4.3	17.5	21.1	1.9	5.6
Region of the Americas	43.7	1.4	10.1	0.1	0.4	11.6	4.9	27.9
South East Asia Region	44.4	0.6	20.1	3.5	1.1	18.1	2.3	9.9
European Region	44.3	0.2	10.2	0.1	0.5	13.1	6.2	25.4
Eastern Mediterranean Region	43.4	0.4	14.6	3.0	2.9	19.0	3.2	13.5
Western Pacific Region	47.0	0.3	12.0	0.8	0.4	13.8	7.3	18.4

in developing countries. In the developing world, the prevalence was highest in Europe and Central Asia and lowest in Sub Saharan Africa. In 2003, 194 million people worldwide aged 20-79 years had diabetes and by 2025 the number is projected to increase to 333 million, a 72 percent increase. During the same period, the number of people with diabetes is projected to double in three of the six developing regions : the Middle East and North Africa, South Asia and Sub Saharan Africa.

The WHO estimates that, in 2001, 959,000 deaths worldwide were caused by diabetes, accounting for 1.6 percent of all deaths and approximately 3 percent of all deaths were caused by non-communicable diseases. Also in 2001, diabetes resulted in 19,996,000 disability adjusted life years (DALYs) worldwide. More than 80 percent of the DALYs resulting from diabetes were in developing countries.

### Reproductive & Child Health

Globally 65% births were attended by skilled health personnel (Doctor/Nurse/Other health worker) in 2000-2006 which is marginally more than 61% during 1990-1999. The births attended by skilled health personnel were maximum in Regions of America, European region and western pacific region with >90% whereas African region and South East Asia region had only <50% births attended by skilled health personnel. This contributes immensely to high infant mortality rates and high maternal mortality rates in these regions. Similarly, there are wide variations in the nutritional status of children as given in Table - 10 :

Table - 10 : Nutritional status of children			
WHO Region	Low birth weight newborns (%) 2000-2002	Children aged <5 years (%) 2000-2006	
		Stunted for age	Underweight for age
African Region	14	43.3	23.0
Region of the Americas	9	13.7	3.9
South East Asia Region	26	42.0	32.8
European Region	8	-	-
Eastern Mediterranean Region	17	25.6	15.5
Western Pacific Region	8	15.3	6.7

**Contraceptive use** : Percentage of people using contraceptives in world is 63.3% in the year 2000-2006 using any contraceptive methods. There is a great variation in Contraceptive prevalence within the regions of WHO as per the Table -11.

**Child immunization coverage** : The immunization coverage among 1 year old was around 80% for both DPT and Measles in the year 2006 world wide. There were great regional differences with American region, European region and Western Pacific

region more than 90% whereas African region (73%) and South East Asia region (65%) had low immunization coverage. The immunization coverage of Eastern Mediterranean Region was around 86%. The immunization coverage in all the regions has shown an impressive improvement in last two decades, however, in South East Asia region the coverage has gone down for DPT from 70% in 1990 to 63% in 2006.

Table - 11 : Contraceptive Prevalence (%)	
WHO Region	Contraceptive Prevalence (%)
African Region	24.4
Region of the Americas	70.0
South East Asia Region	57.2
European Region	-
Eastern Mediterranean Region	43.0
Western Pacific Region	85.5

The immunization coverage is seen less than 50% in countries like Angola, Central African Republic, Nigeria and Somalia. The greatest burden of vaccine preventable diseases is in Sub Saharan Africa, which accounts for 58 percent of Pertussis deaths, 41 percent of Tetanus deaths, 59 percent of Measles deaths and 80 percent of Yellow Fever deaths. East Asia and the Pacific has the greatest burden from hepatitis B with 62 percent of deaths worldwide. South Asia also experienced a high disease burden, particularly from tetanus and measles.

**Risk Factors** : Tobacco use is the single largest cause of preventable death in the world today. Tobacco kills a third to a half of all those who use it. On average, every user of tobacco loses 15 years of life. Total tobacco attributable deaths from ischemic heart disease, cerebrovascular disease (stroke), chronic obstructive pulmonary disease and other diseases are projected to rise from 5.4 million in 2004 to 8.3 million in 2030, almost 10 percent of all deaths worldwide. More than 80 percent of these deaths will occur in developing countries.

Tobacco use is highly prevalent in many countries. According to estimates for 2005, 22 percent of adults worldwide currently smoke tobacco. Some 36 percent of men smoke compared to 8 percent of women. Over a third of adult men and women in eastern and central Europe currently smoke tobacco. Adult smoking prevalence is also high in South East Asia and northern and western parts of Europe. However, nearly 2/3<sup>rd</sup> of the worlds smokers live in just 10 countries : Bangladesh, Brazil, China, Germany, India, Indonesia, Japan, the Russian federation, Turkey and the United States, which collectively comprise about 58 percent of the global population (Table-12).

### Health System Resources

Globally, the density of physicians per 10,000 population is 13 whereas density for nurse and midwifery is 28 per 10,000 population. The density of dentistry personnel is 3, pharmaceutical personnel is 4, community & traditional health workers is 1, laboratory health workers is 3 and other health



service providers is 18 per 10,000 population (Table-13).

**Table - 12 : Alcohol and current tobacco use among adults aged ≥ 15 years**

WHO Region	Alcohol consumption adults aged ≥ 15 years (litres/person)	Prevalence of current tobacco use among adults aged ≥ 15 years (%)		
		Male	Female	Both sexes
African Region	4.09	17.3	2.8	10.1
Region of the Americas	6.66	30.1	18.7	24.6
South East Asia Region	0.51	39.1	4.6	21.9
European Region	8.84	44.4	23.2	34.1
Eastern Mediterranean Region	0.19	32.7	4.5	18.4
Western Pacific Region	5.18	55.7	5.0	30.5

**Table - 13 : Health workforce and hospital beds (per 10,000 population)**

WHO Region	Health Workforce		Hospital Beds
	Physicians density	Nurse density	
African Region	2	11	9
Region of the Americas	19	49	24
South East Asia Region	5	12	-
European Region	32	78	63
Eastern Mediterranean Region	10	15	14
Western Pacific Region	14	20	33

### Health Service Coverage

Coverage is defined as the percentage of people receiving a specific intervention among those who need it, is a key health system output and an essential indicator for monitoring health service performance. The coverage gap is an aggregate index of the difference between observed and 'ideal' or universal coverage in four intervention areas : family planning, maternal and neonatal care, immunization and treatment of sick children. Estimates from the most recent surveys showed that the mean overall gap across all 54 countries was 43%, with values for individual countries ranging from more than 70% in Chad and Ethiopia to less than 20% in Peru and Turkmenistan. In 18 of the 54 countries, the gap was 50% or more; it was between 30% and 49% in 29 countries and less than 30% in the remaining 7

countries.

The percentage of births attended by skilled health personnel is highest in European region with 96% whereas, in African and South East Asia region it is less than 50%. Globally 65% of births are attended by skilled health personnel which are 4% more than 1990-1999 figures (Table - 14).

**Table - 14 : Global situation of attended births and protection against neonatal tetanus**

WHO Region	Births attended by skilled health personnel (%) 2000-2006	Neonates protected at birth (PAB) against neonatal tetanus (%) 2006
African Region	44	74
Region of the Americas	92	83
South East Asia Region	48	86
European Region	96	68
Eastern Mediterranean Region	63	82
Western Pacific Region	92	75

Worldwide, percentage of neonates protected at birth against neonatal tetanus is 81% which has increased by more than 10% in last 15 years. Surprisingly, the percentage of children protected at birth against neonatal tetanus is lowest in European region.

In view of modern pandemic of HIV and Tuberculosis, another indicator of health services coverage is ART coverage and Tuberculosis detection rate and treatment success rate. Worldwide, only 22% of people with advanced HIV infection have access to anti retroviral therapy. This coverage is highest in America with 58% and lowest in eastern Mediterranean region with just 4%.

**Table - 15 : ART coverage, TB detection rate and TB treatment success under DOTS**

WHO Region	ART Coverage (%) of People with advanced HIV infections (2006)	TB detection rate under DOTS (%) 2006	TB treatment success under DOTS (%) 2005
African Region	21	46	76
Region of the Americas	58	69	78
South East Asia Region	17	67	87
European Region	13	52	70
Eastern Mediterranean Region	4	52	83
Western Pacific Region	23	77	92

The TB detection rate and treatment success under DOTS is about 61 percent and 85 percent respectively in the world. The TB detection rate under DOTS has drastically improved from 11 percent in 1995 to 28 percent in 2000 and now 61 percent in 2006. In spite of DOTS programme implemented more than a decade back the treatment success rate has marginally improved from 79 percent in 1995 to 85 percent in 2005 (Table-15).

## Summary

Within the various regions and continents of the world, there is persistence of extreme inequality and disparity both in terms of access to care as well as health outcomes. The global population in the year 2006 was 6580 Million with median age of 28 years. Worldwide under 15 yrs population is 28% and about 10% population is of >60 yrs age group. However, annual growth worldwide has declined from 1.6 to 1.3 with decline in all the regions of WHO. The global IMR is 49/1000 live births (Male-51, Female-47). An estimated 4 million deaths occur during the first 28 days of life, accounting for 38% of all deaths of children under five. Total fertility rate (TFR), per women at Global level is 2.6, with high rates in Africa region (4.7) and Eastern Mediterranean region (3.5). However, there is constant decline in TFR all over world in last two decades. Average life expectancy in low and middle income countries increased dramatically in the past half century, while cross country health inequalities decreased.

Literacy rate has increased by 10.6% during last decade (1990-2000). The global adult literacy rate is 78.4%. The various mortality and morbidity indicators are inversely proportional to the total expenditure on health as % of gross domestic product. In 2005, while the American region spends 12.7%, South-East Asia spends only 4%. Globally 86% of the population has access to improved drinking water whereas only 60% of population has access to improved sanitation. However, same has increased marginally in last two decades.

Tuberculosis had an estimated 8.8 million new cases in 2003, fewer than half of which were reported to public health authorities and WHO. Approximately 3.9 million cases were sputum smear positive. Approximately 1.7 million people died of TB in 2003, including 229,000 patients who were also infected with HIV. The number of people living with HIV worldwide in 2007 was estimated at 33.2 million. Worldwide, 0.8% of the adult population (aged 15-49 years) is estimated to be infected with HIV. HIV prevalence in Sub Saharan countries reached a peak of nearly 6% around 2000 and fell to about 5% in 2007. Deaths worldwide from HIV/AIDS are expected to rise from 2.2 million in 2008 to a maximum of 2.4 million in 2012 before declining to 1.2 million in 2030. At the global level the prevalence rate of Leprosy of less than 1 per 10,000 has been achieved which were known as elimination levels for Leprosy. Malaria is endemic in many of the world's poorest countries.

At the beginning of the 20th century, CVD was responsible for less than 10 percent of all deaths worldwide, but by 2001 that figure was 30 percent. Cardiovascular disease is the number one cause of death worldwide. Globally, cancer is one of the top ten leading causes of death. It is estimated that 7.4 million people died of cancer in 2004 and, if current trends continue, 83.2 million more would have died by 2015. In 2003, the worldwide prevalence of diabetes was estimated at 5.1 percent among people age 20 to 79. Tobacco use is highly prevalent in many countries. According to estimates for 2005, 22 percent of adults worldwide currently smoke tobacco. Some 36 percent of men smoke compared to 8 percent of women. Over a third of adult men and women in eastern and central Europe currently smoke tobacco.

Globally 65% births were attended by skilled health personnel in 2000-2006. Percentage of people using any contraceptives in world is 63.3% in the year 2000-2006. The immunization coverage among 1 year old was around 80% for both DPT and Measles in the year 2006 world wide. The immunization coverage in all the regions has shown an impressive improvement in last two decades, however, in South East Asia region the coverage has gone down for DPT from 70% in 1990 to 63% in 2006. Globally, the density of physicians per 10,000 population is 13 whereas density for nurse and midwifery is 28 per 10,000 population.

## Study Exercises

### MCQs

- Currently, the annual growth rate worldwide is (a) 1 (b) 1.3 (c) 1.9 (d) 2.
- The global IMR is (/1000 live births) (a) 40 (b) 49 (c) 59 (d) 39.
- Total fertility rate (TFR) per women at Global level is (a) 2.6 (b) 2 (c) 2.9 (d) 3.
- The global adult literacy rate is (a) 70.2% (b) 78.4% (c) 80.9% (d) 62.9%.
- Globally, the percentage of population having access to improved sanitation is (a) 60 (b) 80 (c) 86 (d) 72.
- In 2003, the worldwide prevalence of diabetes was estimated to be (a) 15% (b) 10.1% (c) 5.1% (d) 12%.
- HIV prevalence worldwide in 2007 is (a) 2% (b) 5% (c) 10% (d) 28%.
- The immunization coverage among 1 year old for both DPT and Measles in the year 2006 world wide was around (a) 60% (b) 70% (c) 80% (d) 92%.
- Globally, the density of physicians per 10,000 population is (a) 16 (b) 10 (c) 11 (d) 13.

**Answers :** (1) b; (2) b; (3) a; (4) b; (5) a; (6) c; (7) b; (8) c; (9) d.

## Further Suggested Readings

- Dean T J, Joel G B et al. Disease Control Priorities in Developing Countries, 2nd Ed, Oxford University Press, New York, 2006.
- World Health Statistics 2008. World Health Organisation, 2008.

Sunil Agrawal

India has 28 states and 7 Union Territories. There are 593 districts, 5470 sub districts and 5161 towns. There are 638588 villages. India is the second most populous country of the world after China and has changing socio-political-demographic and morbidity patterns that have been drawing global attention in recent years. Despite several growth-orientated policies adopted by the government, the widening economic, regional and gender disparities are posing challenges for the health sector. About 75% of health infrastructure, medical man power and other health resources are concentrated in urban areas where 27% of the population live.

## Disparities and Divides

### Interstate

Within the country, there is persistence of extreme inequality and disparity both in terms of access to care as well as health outcomes. Kerala's life-expectancy at birth is about 10 years more than that of Madhya Pradesh and Assam. IMRs in Madhya Pradesh and Orissa are more than five times that of Kerala. MMR in Uttar Pradesh is more than four times that of Kerala and more than three times that of Haryana. Crude death rates among states also reveal wide variations. Crude death rates in Orissa and Madhya Pradesh are more than twice the crude death rates in Delhi and Nagaland. This high degree of variation of health indices is itself a reflection of the high variance in the availability of health services in different parts of the country.

### Rural/Urban

Public health care system in rural areas in many states and regions leaves a lot to be desired. Extreme inequalities and disparities persist both in terms of access to health care as well as health outcomes (Table-1). This large disparity across India places the burden on the poor, especially women, scheduled castes, scheduled tribes and other tribal / disadvantaged groups. Inequity is also reflected in the availability of public resources between the advanced and less developed states.

Table - 1 : Urban/Rural Health Indicators

	Crude Birth Rate (per 1000)	Crude Death Rate (per 1000)	IMR (per 1000 live births)	Prevalence of Anaemia among Children (6-35 months) (%)	Prevalence of Anaemia among Pregnant Women (%)
Urban	19.1	6.0	40	72.7	54.6
Rural	25.6	8.1	64	81.2	59.0
Total	23.8	7.6	58	79.2	57.9

Source : Ministry of Health & Family Welfare (GOI), 2006 & NFHS 3, IIPS (2005-06).

The current available data regarding health status and health services in the country obtained from a range of reliable sources and surveys. The data can be grouped under the headings of Demographic, Socioeconomic, mortality, morbidity and other Health status indicators.

## Demographic Indicators

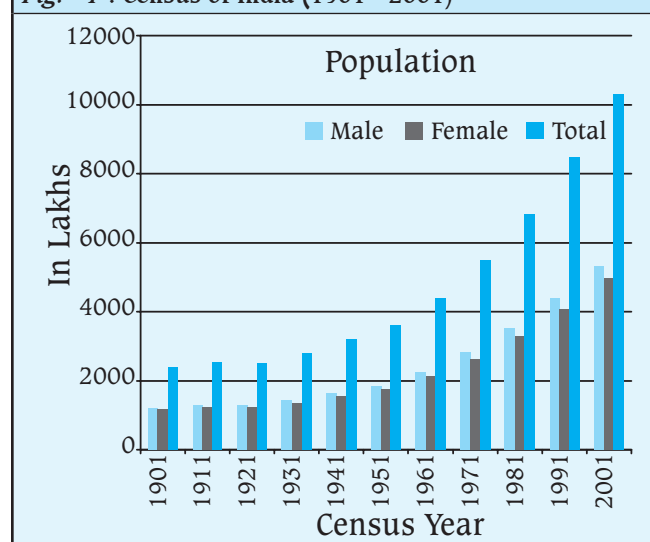
Demographic indicators will give an overview of country's population size, its composition, territorial distribution, changes therein and the components of changes such as natality, mortality and social mobility. Demographic indicators can be divided into two parts -

- Population statistics : Include indicators that measure the population size, sex ratio, density and dependency ratio.
- Vital statistics : Include indicators such as birth rate, death rate and natural growth rate, life expectancy at birth, mortality and fertility rates.

### Population Statistics (Census 2001)

India accounts for a meager 2.4% of the total world surface area, yet it supports and sustains 16.7% of the world population. India's population on 1st March 2001 (census of India) was 10286 lakhs (5322 lakhs males & 4964 lakhs females) which has increased from 8464.2 lakhs estimated during 1991 census (Fig. - 1). However, there is decrease in Decennial Change (%) & Average Annual Exponential Growth Rates compared to corresponding growth rates during previous decades. Projected population for 2016 is 12689.61 lakhs; a 40% of this increase will occur in four states mainly i.e. UP, Bihar, MP and Maharashtra.

Fig. - 1 : Census of India (1901 - 2001)



**Sex Ratio** : Sex Ratio is 933 female/1000 male [for last four decades it is around 930 (1971- 930, 1981- 934, 1999- 926, 2001- 933)]. It is lowest in Daman & Diu (710) followed by Chandigarh (770) & highest in Kerala (1058).

**Population Density** : Population Density is 325/sq.km. Urban Population is 27.8% of total population. Urban migration over last decade resulted in rapid growth of urban slums. It varies from 13/sq.km in Arunachal Pradesh to 903/sq.km in

West Bengal. UTs like Delhi (9340/sq.km) & Chandigarh (7900/sq.km) have highest population density.

**Age Distribution** : It is 34.2% in 0-14 age group & 7.5% in 60 plus age group. Kerala has got highest percentage of elderly people (11%) whereas Delhi has just 5% of its total population as elderly.

**Birth & Death Rates** : Overall UP has got highest birth rate (30). States like Goa & HP have lowest birth rate. MP has highest rural birth rate (31.2). Death Rate is highest in Orissa (9.3). It is higher in rural areas as compared to urban areas. Projected crude death rate is 7.2 / 1000 population. There is not going to be much change in death rate in next 20 years. The birth and death rates of India are given in Table - 2.

**Table - 2 : Birth & Death Rates**

	1993	2006 (Total)	2006 (Urban)	2006 (Rural)
Birth Rate	28.7	23.5	25.2	25.2
Death Rate	9.3	7.5	6.0	8.1
Growth Rate	19.4	16.0	12.8	17.2

**Life Expectancy at birth** : Female Life Expectancy in 1997-2001 was 63.6 then it decreased to 63.3 in 1998-2002 & from thereafter it is steadily increasing, whereas Male Life Expectancy is steadily increasing. Projected value for life expectancy for 2021-25 is 69.8 for males & 72.3 for females. Projected overall life expectancy is 69.8. Increasing life expectancy is leading to increasing numbers of elderly persons in the population for which specific health facilities will need to be provided. The life expectancy at birth is given in Table - 3.

**Table - 3 : Life Expectancy at birth**

	1991-95	2001-05
Males	59.7	62.3
Females	60.9	63.9

Source : Registrar General of India

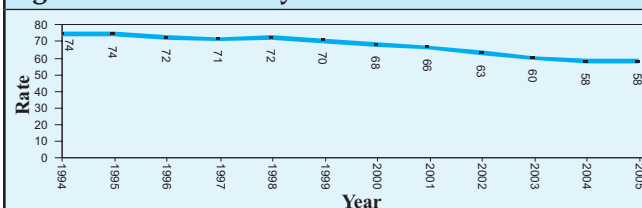
## Vital Statistics

**Infant Mortality Rate (IMR)** : IMR is 57/1000 live births (Rural-62, Urban-39). For last three years decline in IMR was minimal, whereas it had shown steady decline from 1998 till 2004. It shows wide inter-state variations, with states like Assam, Bihar, Chhattisgarh, MP, Orissa, Rajasthan & UP having high IMR. MP tops the list with 74 whereas minimum IMR of 11 is in Manipur. Neonatal mortality (at 37/1,000 live births) constitutes nearly 60-75% of the IMR in various states. Concerted efforts will be required under Home Based Neonatal Care (HBNC) to reduce the IMR & Neonatal Mortality Rate (NMR) further. The trends of IMR are shown in Fig. - 2.

**Maternal Mortality Ratio (MMR)** : The present MMR is 301 per 1,00,000 live births (2001-2003) (RGI, 2006). The trends are shown in Fig. - 3. Levels of maternal mortality vary greatly across the regions due to variation in access to emergency obstetrical care, prenatal care, anaemia rates among women, education level of women, and other factors. The MMR in states

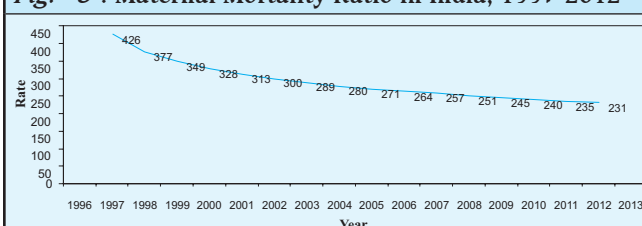
like UP, Rajasthan, Orissa, MP, Assam, Bihar are maximum and U.P. has contributed maximum MMR of 539 per 1,00,000 live births.

**Fig. - 2 : Infant Mortality Rate in India**



Source : SRS Bulletin, October 2006, RGI.

**Fig. - 3 : Maternal Mortality Ratio in India, 1997-2012**



Source : RGI, 2006

**Total Fertility Rate (TFR)** : TFR at national level is 2.9, Rural (3.2) and urban (2.1). Bihar (4.4 & 3.2), MP (4.2 & 2.5), Rajasthan (4.0 & 2.7) and UP (4.5 & 3.3) are states with high total fertility rate.

## Socioeconomic Indicators

Socioeconomic indicators provides data on education, gender, poverty, housing amenities, employment and other economic indicators which help in understanding the health scenario of a country.

### Literacy Rate

Literacy rate has increased by 13.86% during last decade (1991-2001) and it is 64.8% among population aged 7 yrs and above, according to census-2001. Literacy rate among males is 75.3% while among female it is 53.7%. Kerala and Mizoram have highest literacy rates of 90.9% and 88.8% respectively and Bihar and UP are least with 47% and 56% respectively (Fig. - 4).

### Mean Age at Marriage

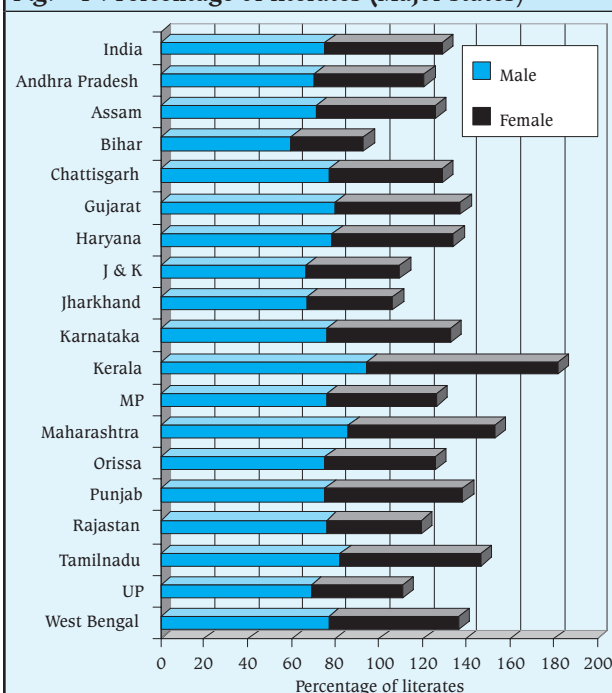
The mean age at effective marriage of females is 20.20 years. The break-up is 19.7 years in rural and 21.7 years in urban areas.

## India in the International Scenario

The comparative picture with regard to health indicators such as life expectancy, Total Fertility Rate (TFR), Infant Mortality Rate (IMR), and Maternal Mortality Ratio (MMR) points that countries placed in almost similar situation such as Indonesia, Sri Lanka, and China have performed much better than India. The health indicators among selected countries are given in Table - 4.



**Fig. - 4 : Percentage of literates (Major states)**



**Table - 4 : Health Indicators among Selected Countries**

Country	Infant Mortality (per 1000 live births)	Life Expectancy M/F	Maternal Mortality Ratio	Total Fertility Rate
India	58	63.9 / 66.9*	301	2.9
China	32	70.6 / 74.2	56	1.72
Japan	3	78.9 / 86.1	10	1.35
Republic of Korea	3	74.2 / 81.5	20	1.19
Indonesia	36	66.2 / 69.9	230	2.25
Malaysia	9	71.6 / 76.2	41	2.71
Vietnam	27	69.5 / 73.5	130	2.19
Bangladesh	52	63.3 / 65.1	380	3.04
Nepal	58	62.4 / 63.4	740	3.40
Pakistan	73	64.0 / 64.3	500	3.87
Sri Lanka	15	72.2 / 77.5	92	1.89

\*Projected (2001-06)

Source : India - RGI, Govt. of India (Latest Figures); Others - State of World Population, 2006.

## Economic Indicators

### Population Living Below Poverty Line (BPL)

The percentage of the population living below the poverty line decreased from 55% in 1973-74 to 36% in 1993-94. However, still there are 27.5% of population living below poverty line

in India in 2004-05. 28.3% of population in rural & 25.7% in urban areas live below poverty line according to planning commission estimates for the year 2004-2005. In Orissa 46.8% of population in rural area & 44.3% of population in urban area is BPL.

### Gross National Product (GNP)

GNP for the year 2006-07 was INR 37,60,285 crore at current price & Rs 28,45,155 crore at constant price.

### Employment

Total 26.5 million people are employed in organized sector, out of which 17.6 million in public and 8.8 million in private sector which is only 4.4% of population in age group 15-59. According to census 2001 there are total 40,22,34,724 workers i.e. 39% of total population.

### Housing and Amenities

According to 2001 census there are 19,19,63,935 households which gives average of 5.36 persons per households and out of which only 51.79% households are permanent. Total 55.85% of these houses have electricity (Rural 43.58%, Urban 87.58%). There is wide variation between states; Goa, HP, Punjab, Chandigarh, Daman & Diu and Lakshwadweep have electricity in more than 90% of houses whereas states like Bihar and Jharkhand have only 5.13% and 9.99% of houses having electricity in rural areas.

Most of the houses in rural areas have no drainage (14.26%-73.38%) and less than 5% of houses have got closed drainage in rural areas. The availability of sanitary toilet within the house is also a rare commodity with 79.5% of rural Orissa being without toilets. In urban areas the Union Territories like Pondicherry, Delhi, Chandigarh and states like Maharastra, Goa and Tamil Nadu do not have toilets in 15 to 25% of houses.

### Safe Drinking Water Facilities

The percentage of households having safe drinking water facility in India has improved over the last decade. States like Punjab and Haryana have more than 90% population having access to safe drinking water, both in urban as well as rural areas (Table - 5).

**Table - 5 : Safe drinking water facilities in India**

	1991	2001
Rural	55.5	73.2
Urban	81.4	90.0
Total	62.3	77.9

## Health Status Indicators

India is in the midst of an epidemiological and demographic transition with increasing burden of chronic diseases, decline in mortality and fertility rates, and ageing of the population. While communicable diseases as malaria, tuberculosis, HIV-AIDS, diarrhoeal diseases and ARIs are continuing to be major issues, Non-communicable diseases such as cardiovascular diseases, cancer, blindness, mental illness, etc. are also imposing increasing burden on the already over-stretched health care system of the country.

## Communicable Diseases

Among the various communicable diseases the following diseases accounted for the maximum number of cases during 2007 (Table - 6)

**Table - 6 : Major communicable diseases in India (No. of cases - 2007)**

Disease	No. of cases (2007)
Acute Respiratory Infections (ARI)	2,33,79,578
Acute Diarrhoeal Diseases (ADD)	94,78,813
Malaria	13,63,279
Pulm TB	7,20,395
Enteric Fever	6,94,862
Pneumonia	6,60,392
Gonococcal	1,53,050
Viral Hepatitis	97,827

Tuberculosis remains a public health problem, with India accounting for one-fifth of the world incidence. Every year 1.47 million people in India develop tuberculosis, of which 0.8 million are infectious smear positive cases. The emergence of HIV-TB co-infection and multi drug resistant tuberculosis has increased the severity and magnitude of the problem. Revised National Tuberculosis Control Programme (RNTCP) has achieved nation wide coverage in March 2006. Since the inception of the programme, over 6.3 million patients have been initiated on treatment.

National Vector Borne Disease Control Programme was initiated during 10<sup>th</sup> Plan with the convergence of on-going programmes on malaria, kala-azar, filariasis, Japanese encephalitis and dengue. Malaria cases in India declined from 3.04 in 1996 to 1.36 million cases in the year 2007. The number of *Plasmodium falciparum* (Pf) cases has also been decreasing. More than 80% of malaria cases and deaths are reported from North Eastern (NE) States, Chhattisgarh, Jharkhand, Madhya Pradesh, Orissa, Andhra Pradesh, Maharashtra, Gujarat, Rajasthan, West Bengal, and Karnataka. Under the Enhanced Malaria Control Project (EMCP), 100% support was provided in 100 districts of 8 states, predominantly inhabited by tribal population. These areas reported a 45% decline in malaria cases.

Dengue fever and Chikungunya are emerging as major threats in urban, peri-urban, and rural areas in many states/UTs. There were 56355 suspected cases out of which 1876 confirmed cases of Chikungunya in 2007 as compared to 13,90,322 suspected and 2001 confirmed cases in 2006.

AIDS is acquiring a female face, that is, gradually the gap between females and males is narrowing as far as number of cases and infections are concerned. The youth are becoming increasingly vulnerable. The prevalence rate of more than 1% amongst pregnant women was reported from four states, that is Andhra Pradesh, Karnataka, Manipur, and Mizoram. During 2007, a total of 1,99,453 cases of AIDS were reported. The risk of TB infection in HIV positive persons increased manifold. The HIV prevalence is stabilizing and States like Tamil Nadu,

Andhra Pradesh, Karnataka, Maharashtra, and Nagaland have started showing declining trends. The lessons learnt have been utilized in formulating NACP-III, which will be implemented in the country during the Eleventh Five Year Plan.

Morbidity trends over last eight years shows not much of change in incidence of ARI, ADD, Malaria, Pulm TB, Pneumonia, Gonococcal and Viral Hepatitis. However, it shows continuous increase in incidence of Enteric Fever for past four years. The number of cases and deaths due to important communicable diseases, during 2007 were as given in Tables - 7, 8 and 9.

**Table - 7 : Vaccine Preventable diseases**

Disease	Cases	Deaths
Tetanus	7005	272
Tetanus Neonatal	937	93
Diphtheria	3354	37
Whooping Cough	40729	15
Measles	36900	50

**Table - 8 : Malaria and other vector borne diseases**

Disease	Cases	Deaths
Malaria	1363279	1066
Kala Azar	44001	189
Japanese Encephalitis	4017	989
Dengue	5395	69

**Table -9 : Diarrhoeal and other water borne diseases**

Disease	Cases	Deaths
Cholera	2635	3
Acute Diarrhoeal Disease	9478813	2328
Enteric Fever	694862	393

**Other communicable diseases :** The goal of leprosy elimination at national level (<1 case/10,000 population) as set by National Health Policy (2002); was achieved in the month of December 2005. Even though the disease came down to a level of elimination, still it is prevalent with moderate endemicity in about 20% of the districts. During 2006-07, a total of 1.39 lakh new leprosy cases were detected with current prevalence rates of 0.72 per 10,000 population. The cases and deaths due to other major communicable diseases, during 2007, were as given in Table - 10.

**Table - 10 : Other major communicable diseases**

Disease	Cases	Deaths
Pulmonary Tuberculosis	720395	6037
Leprosy	139252	
AIDS	199453	
Rabies	221	

**Mortality** : Following communicable disease accounted for maximum no. of deaths, during 2007 : Pulmonary tuberculosis - 6037; ARIs - 4019; Pneumonia - 2865; malaria - 1066; JE - 989; Acute viral hepatitis - 480; Enteric fever - 393; tetanus (other than neonatal) - 272; tetanus (neonatal) - 93; meningococcal meningitis - 252; rabies - 221; kala azar - 189 (Table - 11).

**Table - 11 : Case fatality rate as reported during 2007 (except Rabies)**

Name of the Disease	Case Fatality Rate (%)
Japanese Encephalitis	24.62
Tetanus Neonatal	9.93
Meningococcal Meningitis	5.64
Tetanus other than Neonatal	3.88
Acute Poliomyelitis	1.68
Dengue	1.28
Diphtheria	1.10
Pulmonary Tuberculosis	0.84

Mortality trends in communicable diseases have remained same for most of the disease except Malaria, where there was increase in number of mortality cases in year 2006 (1704 deaths in 2006 as compared to 969 deaths in 2005). It has shown downwards trends in tetanus (neonatal and other than neonatal) and meningococcal meningitis. Orissa has noted maximum No. of deaths due to Malaria followed by Assam.

Annual cases and death due to Cholera in 1991 were 7088 and 150 respectively which now have reduced to 2635 and 3 respectively during the year 2007.

### Non Communicable Diseases

India is experiencing a rapid epidemiological transition, with a large and rising burden of chronic diseases, which were estimated to account for 53% of all deaths and 44% of Disability Adjusted life Years (DALYs) lost in 2005. Non-communicable diseases (NCDs), especially Diabetes Mellitus, cardiovascular diseases (CVD), cancer, stroke and chronic lung diseases have emerged as major public health problems due to an ageing population and environmentally-driven changes in behaviour.

The non communicable diseases take the major disease burden in India after communicable diseases. Morbidity indicators for non communicable diseases include incidence, prevalence, deaths and performance of disease control programme for Blindness, Cancers, Coronary Heart Disease and Diabetes. The number of cases of CHD was estimated to be nearly 3.6 crores for the year 2005, which is expected to reach 6.1crores in 2015. Cervix and breast cancers account for more than 36% of cancer incidence in the country. Estimated prevalence of blindness in 2004 was 11.2 (10.2 males and 12.2 females) per 1000 population and is expected to remain more or less same during the next two decade. There were 314704 accidental deaths reported in 2006.

Cancer has become an important public health problem in India with an estimated 7 to 9 lakh cases occurring every year. At any point of time, it is estimated that there are nearly 25 lakh

cases in the country. In India, tobacco related cancers account for about half the total cancers among men and 20% among women. About 1 million tobacco related deaths occur each year making tobacco related health issues a major public health concern.

In India, more than 12 million people are blind. Cataract (62.6%) is the main cause of blindness followed by Refractive Error (19.70%). There has been a significant increase in proportion of cataract surgeries during the past decade.

### Reproductive & Child Health

Mothers who had at least 3 antenatal care visits for their last births are 52% in the country. Goa, Kerala and TN report more than 90% coverage whereas states like Bihar and UP report coverage of 17.0% and 26.6% respectively for ANC. Mothers who consumed IFA for 90 days or more when they were pregnant with their last child are 23.1% nationally, whereas 76.3% pregnant women received at least two TT injections during pregnancy.

Nearly half (48.2%) births are attended by trained personnel (Doctor/Nurse/LHV/ANM/Other health worker) and two-fifths (40.7%) are institutional births in the country. Kerala has 99.7% births attended by trained personnel and 99.5% are institutional births whereas Bihar has 30.9% & 22% and UP has 29.2% & 22% respectively.

Percentage of people using contraceptives in India is 56.3% using any contraceptive methods and 48.5% of population is using any of the modern contraceptive methods. There is great variation in sterilization operations where females had 37.7% while only 1% male sterilization operations take place. NFHS - 3 data indicates that in 2005 - 06, 56% couples with wives in age group 16 to 49 years were effectively protected by contraceptive use (64% in urban and 53% in rural areas).

**Child immunization and Vit. 'A' supplementation** : The percentage of children aged 12-23 months who were fully immunized are approximately 43.5%. Goa, Kerala and TN have high coverage while Bihar, UP and northeast states have low coverage. Among children aged upto 3 years, 38.4% are stunted, 19.1% are wasted and 45.9% are underweight.

### Summary

In India, about 75% of health infrastructure, medical man power and other health resources are concentrated in urban areas where 27% of the population lives. Within the country, there is persistence of extreme inequality and disparity both in terms of access to care as well as health outcomes. The current available data regarding health status and health services is grouped under the headings of Demographic, Socioeconomic, Mortality, Morbidity and other Health status indicators.

Demographic indicators can be divided into two parts Population statistics and Vital statistics. India accounts for 16.7 % of the world population on 2.4% land. As per census, India's population on 1st March 2001 was 10286 lakhs. Sex Ratio is 933 female/ 1000 male but there is wide interstate variation. Population Density is 325/sq.km. Age Distribution is 34.2% in 0-14 age group & 7.5% in 60 plus age group. Birth rate, death rate and growth rate are 23.5, 7.5 and 16.0 respectively. Life expectancy at birth in 2001-05 was 62.3 for males and

63.9 for females. Vital Statistics : Infant Mortality Rate (IMR) is 57/1000 live births (Rural-62, Urban-39). The present MMR is 301 per 1, 00,000 live births (2001-2003). Total fertility rate (TFR), at national level is 2.9, Rural (3.2) and urban (2.1).

Socioeconomic indicators provides data on education, gender, poverty, housing amenities, employment and other economic indicators which help in understanding the health scenario of a country. Literacy rate has increased by 13.86% during last decade (1991-2001) and it is 64.8% among population aged 7 yrs and above, according to census-2001. Countries having similar socioeconomic status have performed better in health indicators like life expectancy, IMR, MMR etc.

Economic Indicators : There is 27.5% of population living below poverty line in India in 2004-05. 28.3% of population in rural & 25.7% in urban areas live below poverty line. Gross National Product for the year 2006-07 was INR 37,60,285 crore at current price & Rs 28,45,155 crore at constant price. According to census 2001 only 39% of total population is employed. The percentage of households having safe drinking water facility in India is 77.9 % (rural 73.2%, urban 90%).

Health status indicators : Tuberculosis remains a public health problem, with India accounting for one-fifth of the world incidence. Every year 1.47 million people in India develop tuberculosis, of which 0.8 million are infectious smear positive cases. Due to National Vector Borne Disease Control Programme (NVBDCP), initiated during the Tenth Plan malaria cases in India declined from 3.04 in 1996 to 1.36 million cases in the year 2007. However, dengue fever and chikungunya are emerging as major threats in urban, peri-urban, and rural areas in many states /UTs. There is continuous increase in incidence of Enteric Fever for past four years. The prevalence rate of HIV/AIDS of more than 1% amongst pregnant women was reported from four states, that is Andhra Pradesh, Karnataka, Manipur, and Mizoram. The goal of leprosy elimination at national level (<1 case/10,000 population) was achieved in the month of December 2005. The number of cases of CHD was estimated to be nearly 3.6 crores for the year 2005, which is expected to reach 6.1crores in 2015. Cancer has become an important public health problem in India with an estimated 7 to 9 lakh cases occurring every year. Estimated prevalence of blindness in 2004 was 11.2 (10.2 males and 12.2 females) per 1000

population. There were 314704 accidental deaths reported in 2006.

Reproductive & Child Health indicators : Nearly half (48.2%) births are attended by trained personnel (Doctor/Nurse/LHV/ANM/Other health worker) and two-fifths (40.7%) are institutional births in the country. Percentage of people using contraceptives in India is 56.3% using any contraceptive methods and 48.5% of population is using any of the modern contraceptive methods. The percentage of children aged 12-23 months who were fully immunized are approximately 43.5%. Among children aged upto 3 years, 38.4% are stunted, 19.1% are wasted and 45.9% are underweight.

## Study Exercises

**Long Question :** Describe in brief National Health Profile of India in 2007.

**Short Notes :** (1) Demographic indicators in India (2) Socio-economic indicators in India (3) RCH indicators in India (4) Health status indicators in India.

### MCQs

1. Sex ratio of India (2001 census) (a) 933 (b) 901 (c) 949 (d) 923
2. Communicable disease which accounted for the maximum number of deaths during 2007 (a) ARI (b) ADD (c) Malaria (d) Pulmonary TB
3. According to NFHS-3, Prevalence of Anaemia among pregnant women % (a) 58 (b) 69 (c) 47 (d) 52
4. Growth rate of India according to NFHS-3 (a) 16 (b) 18 (c) 21 (d) 14
5. Life expectancy of females (2001 census) (a) 63.9 (b) 61.6 (c) 65.1 (d) 60.8
6. According to NFHS-3, Prevalence of Anaemia among Children (6-35 months) (%) (a) 66 (b) 79 (c) 84 (d) 71
7. Communicable disease which accounted for the maximum number of cases during 2007 (a) ARI (b) ADD (c) Malaria (d) Pulmonary TB

**Answers :** (1) b; (2) a; (3) a; (4) a; (5) a; (6) a; (7) d.

## Further suggested reading

1. National Health Profile 2007. Central Bureau of Health Intelligence, Govt. of India, Director General Health Services, New Delhi.



# 2

## **Quantitative Sciences in Public Health & Community Medicine**

- 2a) Epidemiology & Research Methodology
- 2b) Statistics



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RajVir Bhalwar

The roots of "Epidemiology" can be traced back to somewhere around 400 BC, when Hippocrates had related the occurrence of human diseases to the environment in his treatise "On Airs, Waters and Places". (1). After a long lull for almost 2000 years John Graunt in 1662 and William Farr in the nineteenth century (2,3), revived the interest and laid the seeds of the modern epidemiological surveillance systems. These efforts were boosted by John Snow's field investigations of cholera epidemic in London in 1850s (4). However, it was only after 1940 that epidemiology really expanded as a modern science, with the initiation of cohort studies at Framingham, the clinical trials of anti - tubercular drugs, the preventive trial of injectable polio vaccine, the community intervention trials of fluoridation of water supplies, and the advent of Case - Control studies on smoking and lung cancer, by Sir Richard Doll and Sir AB Hill (5 - 7). By now, epidemiology has become an all pervasive science and a basic tool for understanding and practice of all specialties of medicine (8). In fact, the understanding of epidemiology involves two things - firstly, the knowledge of the principles of medicine; and, secondly, the knowledge of certain basic "principles" of epidemiology, which we shall endeavor to explain in this chapter.

For instance, if we, as medical person, or for that matter even an undergraduate medical student were asked to write a short essay on a common disease like malaria, the essay would read something like : " ..... Malaria is caused by a parasite called plasmodium. It is transmitted by the bite of female anopheles mosquito. It manifests as an acute febrile illness with chills and rigors. If untreated, many cases recover after a few febrile attacks but, in some, the disease may take a serious course and even some of those who recover may get a relapse. In our country out of every 1000 people, 2 to 3 are likely to get malaria every year. The disease is more common among the children, the poor people, among foreigner tourists, immuno - compromised persons, and among the agriculturists. It is commoner in North - Eastern states of our country, in rural areas and in urban slums but is not seen in highland areas. It is also much more common during and immediately after monsoons. Malaria can be prevented by spraying insecticides on water collections and on the walls of our dwellings. It can be diagnosed by a simple blood test and can be treated effectively by oral chloroquine and primaquin ....."

If we examine the above essay, we would appreciate that we have systematically covered certain facets, which are summarized in Table - 1. We would have covered up an essay in the same way for any other disease - IHD, HIV, Road Accidents or Neurosis.

The above facets, according to which we consider any disease, put together, are nothing but what we call "EPIDEMIOLOGY". Epidemiology is that branch of medicine which answers the issues related to all human health problems and diseases, the magnitude that they pose, their distribution according to persons, place and time, and the various factors which

determine the causation, risk, prognosis, management and prevention of the diseases.

**Table - 1 : Aspects covered in a hypothetical essay on malaria**

Facet	Example in our essay
What is the disease ( <i>Identification</i> )	Malaria, which presents with fever and chills
How much is the disease, i.e. how frequently does it occur ( <i>frequency</i> )	2 to 3 out of every 1000 people in our country
How is the disease distributed according to :	
Person characteristics (who are the persons affected)	Children, poor people
Place characteristics (where)	Rural areas, slums, NOT in highlands
Time characteristics (when)	During & immediately after monsoons
Why and How does it occur? (what are it's <i>determinants</i> )	
What is the cause (etiology)	Plasmodium
What are "risk factors" which predispose to this disease	Foreigner, agriculturist
What is it's natural history	Many recover, some relapse
What is it's prognosis	Untreated cases may turn serious, some die
What can be done about it? (How can it be prevented or mitigated?)	
How can it be diagnosed	Blood test
How can it be treated	Chloroquine, Primaquin
How can it be prevented	Insecticide spray, mosquito nets

### Definition

With the above background, we can define epidemiology as "*The study of the frequency, distribution and determinants of diseases and health - related states and events in human populations*" and the application of this knowledge in prevention, control and mitigation of these problems (9 - 12) . (Greek; Epi = upon, Demos = populations, Logos = scientific study). The major purpose of epidemiology is to obtain, interpret and use health information to promote health and reduce disease in a community.

### Historical evidence

How Epidemiology helped humanity even before scientific facts were discovered.

Epidemiology believes in promoting health, preventing ill health and mitigating disease and its effects. To achieve this purpose, epidemiology has, on a number of occasions, shown the way to

develop public health and clinical policy, much before the actual biological mechanisms became evident. This also goes on to prove that for implementing measures for health promotion and disease prevention among populations, epidemiological suggestions are enough to initiate action; one need not wait for final scientific proof of cause and effect relationship. Some of the notable instances are :

- In 1768, Edward Jenner, a British physician heard from a dairy maid "I won't get smallpox because I already had cow pox". It was just an observation, which Jenner followed up by administering the material from a cow pox lesion from a dairy maid (Sarah Nelmes) to a 8 year boy (James Phepps). After six weeks, he inoculated this boy with a material taken from an actual small pox lesion; the boy did not develop small pox. It would be appreciated that the variola virus and the theory of immunity were discovered many years later.
- In 1747, James Lind, a British Navy Surgeon, based on his observations and subsequent experiment on board the ship "Salisbury" observed that food consisting of lemon juice and fresh oranges could prevent / cure scurvy, a disease which was playing havoc among sailors at that time. 45 years later, the British navy accepted this and introduced lime juice and oranges as a part of naval rations (that is why British sailors were called "limeys") and virtually eradicated scurvy from their navy. The actual scientific process of the mechanism (involving Vitamin C) was however, discovered almost a century later.
- In mid - nineteenth century, Semmelweis, a surgeon, observed a high occurrence of puerperal fever among post partum cases. He attributed this to some 'contagion' which the medical students were possibly carrying on their hands (at that time, medical students used to attend obstetric clinics after attending autopsies). Semmelweis insisted that medical students should wash their hands after attending autopsies and before entering labour room. At that time, the opponents of the contagion theory rubbished him to the extent that he had to leave his practice and died a broken man. After half a century mankind got scientific confirmation that Semmelweis was absolutely correct!
- In the mid nineteenth century, London was being ravaged by an epidemic of cholera which had caused innumerable deaths. John Snow, an anaesthesiologist (famous for administering obstetric anaesthesia to Queen Victoria) undertook very systemic study of cholera cases, between 1848 - 49 and 1853 - 54, visiting each house, noting their source of water supply and deaths due to cholera. At that time, water supply in London was from two companies, namely, Southwark and Vauxhall company and Lambeth Company. Snow was severely criticized, among others, by none other than another famous epidemiologist, William Farr. Farr, as a proponent of the "miasma" theory (that cholera is caused by a cloud which contains disease and which is more dense near the surface of earth, so that the disease will be more common near the surface of earth) had shown that cholera cases actually declined as the altitude of residence from the Thames River increased. However, the evidence produced by Snow was so compelling that finally Farr also had to agree and had to issue an order asking

for households to give information regarding the company they were getting water from. One of the summary tables which Snow prepared was as follows (Table - 2) :

Table - 2			
Company supplying water	Population	No. of deaths from Cholera	Cholera death rate per 1000 population
Southwark and Vauxhall	167654	844	5.0
Lambeth	19133	18	0.9

John Snow thus clearly proved (and this had a major public policy implication in Britain at that time) that cholera is caused by polluted water; it is noteworthy that the actual organism was discovered by Robert Koch almost three decades later!

- In mid twentieth century, Doll and Hill, based on observational (case control) studies showed that smoking causes lung cancer. The actual harmful effects of tobacco were worked out much later but these epidemiological studies helped developing a public health policy regarding tobacco prevention well before that.
- In the early twentieth century, Goldberger (observations on pellagra) and Fletcher (observations on Beri Beri) clearly showed that these diseases were caused by maize diet and polished rice respectively. Preventive actions were thus formulated well in time, much before the actual discoveries of Niacin and Thiamin.
- More recently, early epidemiological observations on the transmission of HIV AIDS had put in place, preventive recommendations regarding promiscuity and needle sharing, well before the actual agent (HIV) was identified.

#### How does Epidemiology Differ from Clinical Practice:

Epidemiology uses the same tools and techniques as clinical medicine, excepting for the following major differences :

- In clinical practice the focus is on an individual, the patient; however, in epidemiology, the focus is on a group of human beings (patients or healthy people) which we refer to as "population" (13).
- In clinical practice there is no effort at "quantifying" by converting the findings into numbers, but epidemiology is essentially a "quantitative" science, in which the findings are analysed after converting them into "frequencies" which are numerical figures that "summarise" our findings.

### Uses of Epidemiology

There are a large number of uses of epidemiology (14), which can be broadly classified into 4 headings :

Principal Uses of Epidemiology
<ul style="list-style-type: none"> <li>• In Health Care Management</li> <li>• In Understanding the disease process</li> <li>• In Public Health Practice</li> <li>• In Clinical and preventive practice</li> </ul>

## Uses in Health Care Management

**(a) Making a Community Diagnosis :** In clinical settings, the clinician makes a clinical diagnosis before proceeding to manage the case. In health care of large community, the health provider must make a “Community Diagnosis” by epidemiological methods to obtain information on the important health problems and their associated socio - demographic characteristics, quantifying and summarizing them (15, 16) . Once a Community Diagnosis has been made, we can decide as to which programmes would be best for improving the health status of a community; only thereafter relevant health care for the community can be organized. This is in the same way as a clinician decides the best modality of management after she has made a clinical diagnosis.

**(b) Planning and Evaluation of Health Services :** Any planning process will need accurate information about the socio - demographic profile, the diseases, the health care facilities, communications, etc. Similarly, while evaluating a health programme, we will again need current information about various diseases and compare it with the “baseline” state that existed when we started the programme. This quantified and summarized information is available only through epidemiological steps (17).

**(c) Developing Health Policies :** Since Epidemiology is indispensable for making assessment of community “diagnosis” and “needs” and the fact that it provides “ evidence based” decisions about the risks for the individuals and communities, due to various exposures, makes it a key discipline for developing Public Health Policies (18). As will be illustrated with examples at the end of this chapter, the unique strength of epidemiology is that it leads to development of preventive and curative policies even well before the actual “cause” or the “modality of occurrence” of that disease has been scientifically proven.

## Uses in Understanding the Disease Process

**(a) Study of the Natural History of Diseases :** What we know today of the natural course of HIV or pulmonary TB or any human disease has been possible due to systematic observations on hundreds and thousands of patients and describing the summarized findings from the observations on these large number of patients, which is only possible by epidemiological methods.

**(b) Searching for the Causes and Risk Factors of Diseases:** How do we say that smoking is a cause of IHD? Or obesity is a risk factor for diabetes? It is by observing thousands of obese and non - obese people and following them forward to see what percentage in each group develops diabetes (cohort epidemiologic approach) or else by asking hundreds of IHD people compared to hundreds of healthy people about smoking history (case - control epidemiologic approach) (19, 20).

**(c) Historic study of rise and fall of diseases :** Small pox rose to its peak, killed millions and was finally eradicated; plague almost vanished after killing huge proportions of humanity and then again reappeared. Epidemiological studies of such rise and fall of diseases are essential to understand the various factors which can be effectively utilized in preventing

the occurrence or re - emergence of other diseases.

**(d) To Identify Syndromes :** The idea of “syndrome” is that two or more different medical phenomena (constellation of signs / symptoms) occur more frequently together than can be accounted for by simply a “chance” association. It is only after obtaining data on hundreds of patients from various countries about signs & symptoms of a related nature, through epidemiological methods, that we are able to put the pieces of information together and identify “syndromes” and their etiological factors. For instance, till 1920s, peptic ulcer was thought to be a single entity. Based on collection of large scale epidemiological data (from death certificates and surgical records) and its analysis according to sex, social class, anatomical site and time - related trends the two entities, viz, duodenal and peptic ulcer were clearly distinguished (22, 23). More recently, obesity, central obesity, raised blood pressure, impaired glucose tolerance and raised triglycerides / low HDL - Cholesterol were all identified individually as CHD risk factors; however, only after studying the data from large number of subjects, across various countries, in a consolidated manner, it was observed that these tend to cluster together more frequently than can be expected simply due to chance, as “Metabolic Syndrome X” (24, 25).

## Uses in Public Health practice

**(a) Investigations of Epidemics and Other Field Investigations :** While epidemiology, today, is involved in practically all aspects of medicine and health care, the fact remains that it originally started as the science dealing with investigations of epidemics (26) and even today, this remains one of the most important duties of the epidemiologists.

**(b) Surveillance for Diseases :** In addition to investigations of epidemics, disease surveillance was another important function for which epidemiology came into being. Surveillance essentially monitors trends in the occurrence of selected diseases, thereby giving early warning about increase in their occurrence so that early control measures can be instituted. Today, we have huge national & international surveillance systems which all essentially involve epidemiological principles of information generation, consolidation, analysis interpretation and feed - back of results.

**(c) Making Projections :** Quite often we hear that there will be so many million cases of IHD in our country by 2025 and so on! How are these projections made? They are actually mathematical models developed by epidemiologists after collecting data from large populations for the past many years and then developing the mathematical models to calculate what is likely to occur in future.

**(d) Assessing the Programmes for Mass Screening for Diseases :** Based on epidemiological principles of “diagnostic test assessment”, the mass screening programmes are planned and subsequently evaluated for their effectiveness in large population groups.

**(e) Assisting in formulating medical teaching curricula :** Today's medical teaching curriculum are often blamed for not being able to actually target the needs of the community, that the doctors and nurses trained by these medical schools would later serve. In fact, if we utilize the principles of epidemiology,



find out and quantify as to what are the priority health problems in a given state or district, and what are the available resources to tackle these problems, we could plan a very effective medical curriculum which would be very appropriate for teaching the would be doctors, nurses and paramedicals.

### Uses in Clinical and Individualized Preventive Practice

**(a) As the basic and indispensable science for clinical research :** The question that we may, quite intuitively, ask is that we are all very well qualified and experienced; we can conduct research pretty well, with the capability to execute research improving with increasing clinical experience. Why should we have text books or training curriculum in “Medical Research Methodology”. In Fact, medical research methodology is nothing but an extension of the wise clinician's intuitively explorative faculties. However, such an extension of this faculty (of educated thinking, observing, analyzing and reasoning) as well as the understanding of essential principles and methods of epidemiological research does not occur simultaneously and concurrent to the learning and practice of medicine. For instance, history of medicine is replete with examples, wherein results based on unscientifically conducted research (gastric freezing, blood letting, “tape - seton” and so on) have been applied, only to cause harm to the patients, just because they were based on unscientific research methods. It therefore needs, in addition to our qualifications and experience in medicine and public health, a working knowledge of the essential principles of epidemiology, research methodology and biostatistics, that need to be clearly understood by all medical persons who are interested in research (26 - 35).

**(b) Assessing the effectiveness of treatment and preventive modalities :** How can we conclude whether a newly formulated herbal antihypertensive drug which has been sponsored by a pharmaceutical agency is better than the standard treatment regime using a ACE - inhibitor? Any treatment modality, be it a drug, surgical intervention, or else any preventive modality (vaccine, immunoglobulin preparation, chemoprophylactic drug, lifestyle change, personal protective measure, etc.) has to be evaluated through the epidemiological approach of “Randomized Controlled Blinded Trial” (RCT or Clinical trial) before it can be taken up in clinical usage.

**(c) Assessing Prognosis :** Does appearance of flapping tremors indicate bad prognosis in the course of otherwise uncomplicated Viral Hepatitis A (VHA)? This issue can only be answered when we follow up a large group of patients with VHA with flapping tremors and another large group of VHA patients without flapping tremors and see how much mortality occurs in each group. Thus, epidemiological studies on a large sample of patients, using the “cohort” approach are essential for evaluating the role of a prognostic factor in predicting the outcome of a disease.

**(d) Assessing the effectiveness of diagnostic procedures :** Any new diagnostic procedure, as a new laboratory test or a radiological test or even a clinical algorithm has to be evaluated for its diagnostic accuracy as well as utility, by studying it on a adequately large sample of patients who are all also subjected to the gold - standard test, based on epidemiological principles

of “diagnostic test evaluation studies”.

**(e) Guiding Clinical decision :** If you see a five year old child with cervical lymphadenopathy and gradual loss of weight, you will, in India, make a diagnosis of “Tubercular Cervical Lymphadenitis”.

However, if you were in a developed country as USA, you would have made the diagnosis of lymphoma! Why is this difference in approach at two different places for the same presentation?

Summary Box : Definition & Uses
<b>Definition :</b> Study of Frequency, Distribution and determinants of diseases and health problems in human populations and it's application in prevention, control and mitigation of health problems.
<b>Uses</b>
1. In Health care management <ul style="list-style-type: none"> <li>• Making Community Diagnosis</li> <li>• Planning &amp; Evaluation of Health Services</li> <li>• Developing Health Policies</li> </ul>
2. Understanding Disease Process <ul style="list-style-type: none"> <li>• Studying natural history of diseases</li> <li>• Searching for Causes &amp; Risk factors</li> <li>• Historic studies of rise and fall of diseases</li> <li>• Identification of Syndromes</li> </ul>
3. Uses in Public health practice <ul style="list-style-type: none"> <li>• Investigations of Epidemics</li> <li>• Surveillance for Diseases</li> <li>• Making Projections for Future</li> <li>• Disease Screening Programmes</li> <li>• Formulating medical teaching curricula</li> </ul>
4. Assisting in Clinical Practice <ul style="list-style-type: none"> <li>• Assessing Effectiveness of Treatment Modalities</li> <li>• Assessing Effectiveness of Preventive modalities</li> <li>• Studying Prognostic factors</li> <li>• Studying Effectiveness of diagnostic Modalities</li> <li>• Assisting in Clinical decision making</li> <li>• Basic and Indispensable science for planning, conducting and analyzing clinical research</li> </ul>

It is because epidemiological information about the various diseases tells us as to what are the “common” diseases in a particular country or community. Even in the same country you may approach a disease in different manner at different times. If you have a young man with clinical presentation of pneumonia, you may routinely not ask about his occupation, but if epidemiological information has told you that bird flu case are being reported from that area recently, you would certainly ask about exposure to fowls and other birds. In addition, modern epidemiological methods as “clinical decision trees” are being increasingly used in clinical practice for taking decisions regarding optimum clinical management of individual patients.

### Study Exercises

**Long Questions :** (1) Define Epidemiology. Discuss its uses. (2) Epidemiology is a basic and indispensable science for public



health and community medicine. Discuss this statement, with common examples.

**Short Notes :** (1) Similarities and dissimilarities between epidemiology and clinical practice. (2) Epidemiological approach in planning and evaluation of health care. (3) Role of epidemiology in major clinical areas - diagnosis, risk evaluation, assessing prognosis, treatment and prevention. (4) How does epidemiology guide clinical decision - making ? (5) Community Diagnosis.

### MCQs & Exercises

1. Some situations / concepts in the field of medicine / health care are listed in column 'A'. Match each one of them with the most appropriate use of epidemiology as listed in column 'B' Refer to the table on previous page.

- The book "Airs, waters and Places" was compiled by : (a) John Graunt (b) William Farr (c) Hippocrates (d) Alexander Fleming
- Which of the following has been considered, sometimes or the other, as a part of definition of epidemiology : (a) Study of frequency, distribution and determinants of diseases (b) Study of epidemics (c) Study of mass phenomena of diseases (d) All of the above
- Epidemiology is different from clinical practice as regards all the following aspects, except : (a) Epidemiology focuses on a large number of subjects and not a single person (b) In epidemiology we 'quantify' the findings (c) In epidemiology, we do not use clinical skills (d) In epidemiology the focus is whether the subject being examined has the disease we are interested while in clinical practice our

Match the following (See Exercises - Q. 1 overleaf)			
A		B	
a	Among Indians, increased waist circumference, diabetes and raised blood pressure tend to occur together and greatly increase the risk of Ischaemic heart disease (IHD)	I	Making Community Diagnosis
b	Certain tribal populations in our country have been identified, who suffer from difficulty in geographical accessibility, leading to low education, high infant and maternal mortality and high occurrence of tuberculosis.	II	Planning & evaluation of health services
c	A Doctor who practiced for about 20 years in Bihar (India), moved on a 3 - year contract to Uganda. He saw a case of jaundice and thought of yellow fever as the first possibility	III	Developing health policies
d	The use of Rofecoxib, initially used as an excellent anti - inflammatory drug, was discontinued due to demonstration of adverse cardio - vascular effects	IV	Study of natural history of disease
e	It has been recently observed that people who have elevated levels of homocysteine in their blood have a higher chance of getting IHD	V	Searching for risk factors
f	In India, health workers visit every house in a fortnight and find out about the occurrence of any fever case. This information is regularly reported to the Primary health centre (PHC) and then to the District malaria Officer.	VI	Historic studies of rise & fall of diseases
g	One of the states in India have recommended to start a 3 - year medical degree in which training would be given about the major locally prevalent diseases and their treatment using locally available resources	VII	Identification of syndromes
h	A number of experts, after reviewing the national health scenario, have recommended that we should have a PHC for every 30,000 population rather than having super - specialty hospitals in urban areas	VIII	Investigations of epidemics
i	A combination of exercise - ECG and echocardiography has been found to be quite effective in diagnosing IHD	IX	Surveillance of diseases
j	A number of cases of eosinophilia - myalgia syndrome (EMS) were reported in a district over a short period of time. These cases were found to have used tryptophan, produced by a particular drug company, as a dietary supplement	X	Making projections for future
k	Tuberculosis, which was a major problem in USA and Europe, declined to a very low level at the start of 20th century, even before BCG and anti - tubercular drugs were discovered	XI	Disease screening programs
L	Community programmes using pap smear for cervical cancer are being widely used and found to be quite effective	XII	Formulating medical teaching
m	It is estimated that by the year 2020, the number of hypertensives in India may grow to 200 million.	XIII	Assessing effectiveness of treatment modalities
n	Earlier, the overall approach to family welfare program in our country was based on allotting 'targets' (e.g. vasectomies or tubectomies to be undertaken in a year). Since the year 2000, this type of approach has been discontinued.	XIV	Assessing effectiveness of preventive procedures
o	HIV infected persons who develop multidermatomal or recurrent herpes zoster are likely to die earlier	XV	Study of prognostic factors
p	The asymptomatic stage in HIV infection usually lasts for 8 years; thereafter, death is likely in the next 2 years.	XVI	Effectiveness of diagnostic procedures
q	Use of Insecticide Treated bed nets (ITBN) has been found to be quite helpful in preventing malaria in endemic areas.	XVII	Assisting in clinical decision making

focus is “which is the disease that the patient has”.

5. Community diagnosis means : (a) Quantifying and summarizing the important health problems and their associated socio - demographic characteristics in a community (b) Priority wise listing of the common diseases seen in a community (c) Summarising the standards of living and lifestyle factors in a community (d) None of the above

6. Which of the following function does not fall within the purview of “uses of epidemiology” (a) Deciding whether our community needs one PHC or 4 subcentres (b) Establishing the natural history of HIV infection (c) Training the medical students in conducting delivery (d) Investigating an outbreak of food poisoning

**Answers :** (1) a-vii; b-i; c-xvii; d-xiii; e-v; f-ix; g-xii; h-ii; i-xvi; j-viii; k-vi; l-xi; m-x; n-iii; o-xv; p-iv; q-xiv; (2) c; (3) d; (4) c; (5) a; (6) c.

## 12

### The Essential “Building Blocks” of Epidemiology and Research Methodology

*RajVir Bhalwar*

Since all of us are very well qualified and experienced, we feel that we can conduct research pretty well. Thus there is a question that we may quite intuitively ask. Why should we have text books or training curriculum in “Medical Research Methodology”? In fact, medical research methodology is nothing but an extension of the wise clinician's intuitively explorative faculties. Unfortunately, such an extension of this faculty (of educated thinking, observing, analyzing, reasoning and the understanding of principles and methods of epidemiological research) does not occur concurrently with the learning and practice of medicine. History of medicine is replete with examples, wherein results based on unscientifically conducted research (gastric freezing, blood letting, “tape - seton” etc.) have been applied, only to cause harm to the patients. A working knowledge of the essential principles of epidemiology, research methodology and biostatistics is therefore essential to conduct research. This chapter deals with these essential principles.

#### The First Building Block : The Research Question

Funny though it may sound but as per the collective opinion of a number of expert referees of some of the most esteemed international medical journals, in almost half of the research articles that they get for reviewing, the authors did not seem to be clear as to what they wanted to do! Therefore, the first stepping stone in any effective medical research is to develop a proper research question. An appropriate research question, developed after fair amount of academic reading and discussions, is an essential requirement (26). Developing an epidemiological or research question is essentially an academic exercise, consisting of a series of steps. They will be discussed in detail in the next chapter.

#### The Second Building Block : One Subject or Many ?

Let us look at an example drawn from a report in a reputed journal published in 1969 “..... a 58 year old woman

with moderately severe Parkinson's disease recounted to her family physician that 3 months ago, while taking amantadine hydrochloride 100 mg twice daily to prevent flu (then used as an anti - viral drug), she experienced a remarkable remission in her symptoms of rigidity, tremors and akinesia. These symptoms promptly returned on stopping the drug after six weeks .....”(27). The effect in the patient was striking. At that time, medical world was in desperate need of an effective drug for Parkinsonism. However, this report based on a single case could not lead to immediate change in clinical practice. Clinicians tried out Amantadine in a limited number of patients of Parkinsonism and observed beneficial effects in many of them. They, thereafter, tried out the drug in a standard clinical trial, randomly dividing a group of patients of Parkinsonism into two, giving Amantadine to one group and the existing standard therapy to the other and noticing the much larger beneficial effects in the Amantadine group. From the initial description in 1969, it took the medical fraternity a couple of years before introducing Amantadine into clinical practice as an anti - Parkinsonism drug.

There is reason for such delays, for no inferences regarding a risk factor or prospective marker, diagnostic agent, therapeutic procedure or preventive agent can be drawn from observations on only one or even a few patients or subjects. It is because, there is a well known natural phenomenon of variability - no two human beings are likely to be the same. Hence what happens in a single patient may be simply due to chance just because of this natural law of variability. It may be just because of chance that the first patient of lung cancer whom you see may not have even touched a cigarette over his lifetime but that does not mean that smoking is not a risk factor for lung cancer. Inferences about the role of smoking in causation of lung cancer were based on history taken from hundreds of patients of lung cancer and comparing them with hundreds of healthy persons (28, 29).

Thus, an important building block in research methodology is the concept that while clinical practice and research utilize exactly similar procedures, in clinical practice, our focus is on a single individual - the patient, but in clinical research, the interest is not on a single but large number of patients or subjects. And it is from here that many of the (apparent) difficulties of research methodology originate, because, in research, you have to study

a “large” number of patients (“subjects”) vis - à - vis only one patient in clinical practice.

### **Third Building Block : Ultimately, Research is the Relationship between “Variables”**

In the process of medical research, we decide the various headings under which we will make measurements on our subjects. For example in a trial of the efficacy of a new lipid lowering drug, we would note down the age, sex, blood pressure, blood glucose, total / LDL / HDL cholesterol, etc. We will note down whether the particular subject was given the standard lipid lowering drug or the new drug. Other relevant observations like the final level of lipids after, say, 6 months will be noted down. In research methodology, these various “headings” are called “Variables” (30). Thus, Age, Sex, name of the drug administered, LDL level, etc., are all “variables”. A variable is thus any quantity or quality of a subject which can be measured and which ‘varies’, i.e. likely to have a different value from one subject to another. Thus, sex is a “variable” since it is a “quality” which is likely to take some different value (either male or female) between two subjects. In fact, when reduced to the lowest terms, all epidemiological and medical research practice is simply the study of relationship between variables.

It becomes very important for the epidemiologist to specify as to what ‘variables’ will be studied and how the values of each of these, for the various subjects, will be recorded. We will make a detailed discussion regarding these aspects in a subsequent chapter.

### **Fourth Building Block : The “Data” Needs to be Summarised**

In the process of medical research, we would collect the information on a large number of variables as are relevant to our research work. However, this large collection of data does not convey any meaning. Hence, we need to summarize our data into “summary figures” which will convey, in one sight, what our data tends to convey. Depending on the way we have measured the various variables, these summary figures would be either “mean”, or “median” or more commonly, a proportion or a rate. In turn, a proportion is generally worked out as “prevalence” while a rate is worked out as “incidence”. We would further clarify these concepts in a subsequent chapter in this section.

### **Fifth Building Block : Whether to Study One Group or two Groups**

Have a look at the following results of a research study : “..... *Some strokes are caused by cerebral infarction in the area of brain distal to an obstructed segment of the internal carotid artery. It should be possible to prevent stroke in people with these lesions by bypassing the diseased segment so that blood can flow to the threatened area normally. Also, it is technically feasible to connect the superficial temporal artery to the internal carotid artery, distal to an obstruction. Because its value seemed self evident on anatomic and physiological grounds, the procedure was applied on a series of patients who were offered surgery, out of which quite a few showed improvement. With this background, as also the documented*

*success of another analogous procedure, the CABG, this new surgical procedure of extracranial - intracranial - arterial - bypass became widely used in 1970s & 1980s. (However it may be noted that no control group was studied at that time).....”*. In 1985, the EC/IC bypass study group conducted a randomized controlled trial in which patients with cerebral ischemia and an obstructed internal carotid artery were randomly allocated to surgical or medical treatment. In the surgical group, “*the operation was a technical success - 96% of the anastomoses were patent a year after surgery. However, surgery did not help the patients. Mortality and stroke rates after 6 years were, in fact, slightly higher in the surgically treated patients as compared to medically treated patients; Moreover, deaths had occurred earlier in the surgically treated patients .....*” (31).

An important building block of epidemiological research methodology is to realize the fact that final conclusion about the risk factors, therapy, prevention or prognosis can be drawn only after comparative research. While results derived from observations made on only one group of subjects may give valuable suggestions for further exploration, however, putting into action, conclusions based on only one group may be fallacious. Studies which describe certain phenomenon or clinical outcomes in only one group are called descriptive studies; they generate strong suggestions or hypothesis but certainly do not give us the final verdict. For getting the final verdict we have to do a comparative study in which a group having the factor of interest is compared with another group which does not have the factor. If the result is better in the group with the factor then only we can conclude that the particular factor really makes a difference. We will further deliberate on these issues in subsequent chapters.

### **Sixth Building Block : Quantifying the Exposure (Cause) - Outcome (Effect) Relationship**

The following is a hypothetical example : In the 1970s an issue in the treatment of pulmonary TB was that the patients who had been issued their medicines for the complete month (Domiciliary, self administered ATT) were not showing the desired cure rate despite the documented efficacy of multidrug regimen. It was felt that some form of directly observed intake of drugs, which ensures compliance, may be more effective. To test this question, 300 patients of Pulmonary Tuberculosis (Pul TB) were divided into 2 groups of 150 each. One group was managed with directly observed regimen while the other with the conventional, self administered regimen. Outcome criteria of cure were based on microbiological, clinical & radiological parameters after six months of treatment. The results were as shown in Table - 1.

It is clear that out of the 150 patients given the exposure, 121, i.e. 80% achieved the outcome (were cured) while 40% of the non exposed group achieved the outcome. These values of 80% and 40% are in technical language called the incidence of outcome in the exposed and the non exposed groups respectively. If we were to ask you whether DOTS was effective, you would immediately say yes. How many times is DOTS more effective than self administered treatment? : Two times. How did you work out this figure? : by dividing 80% by 40%. In epidemiological research practice, this value of “2

times more” is called the RR (Relative risk or Risk ratio) and we work it out by simply dividing the incidence of outcome in the exposed group with the incidence of outcome in the non exposed group.

**Table - 1**

Exposure (intervention modality)	Achieved outcome (cured)	Did not achieve outcome (not cured)	Total
Given Trial modality (DOTS)	121 (80 %)	29 (20%)	150 (100%)
Not given trial modality but given control modality	59 (40 %)	91 (60%)	150 (100%)
Total	180 (60%)	120 (40%)	300 (100%)

One of the key issues in understanding epidemiology and medical research methodology is to understand and be comfortable with the 2 X 2 table. It is a cross combination of exposure at 2 levels (given or not given) and the outcome also at 2 levels (achieved or not achieved)

These simple issues of describing the exposure - outcome relation and calculating the overall effect through the conventional 2x2 table are actually one of the most important building blocks in epidemiology and research methodology : We would have detailed deliberations on the mechanics of the 2X2 table in a later chapter.

### **Seventh Building Block : Concept of Population and Samples and External Validity**

In the second building block we had agreed that in medical research, to make any valid conclusion, we have to study not one, but many patients or subjects. But then, what do we mean by “many”. How many? Ten ? Thousand ? A million ? Or all the patients with that disease in this universe. One of the major considerations that crops up in epidemiology and research methodology is that we always study a “sample” and not the entire collection of patients in the world having that disease. The moment we do that, two issues become prominent. Firstly, the sample may not be representative of the total population, so that we may not be able to apply our findings from our study, to the total population; this is the problem of “external validity”. Secondly, the sample may be too small and hence our findings may not be precise. We will discuss these issues in a subsequent chapter.

### **Eighth Building Block : Concept of Random Error or Chance**

In the previous building block, we said that there are two major issues which come up when we study samples. First one is the issue of “representativeness” which affects the external validity. Which is the second issue? Now, in epidemiological research, the moment we start studying a sample, besides the issue of external validity due to a non representative sample, there is another major issue that needs to be addressed - that of Sampling error also called Random error Sample to Sample

error or more simply, Chance. This is an error which occurs because, as long as you are studying a sample, your results from the sample will be different from the actual reality that exists in the total population from which you have drawn the sample. This is a natural phenomena which will occur despite your most honest and meticulous efforts. For instance, if you are examining a sack of grain for presence of weevil (insects which infest the grain) and let's say that, in reality, every 100 grams of grain has 5 weevil in this bag, your one sample fistful of 100 grams may contain 4 or 6 or even 10 weevil; your next fistful may contain 1 or 5 or 11 weevil and not exactly 5 of them. Hence, as long as we are studying a sample and not the total population, which we would be doing any way, some error should always be accepted. But we can actually do two things about this error.

- Firstly, we can minimize this error by using an adequately large sample. Calculation of adequately large sample, using statistical procedures, is dealt later in the section on Biostatistics.
- Secondly, after the research is over, while analyzing the results we apply statistical procedures to calculate the probability by which our result may differ from the real value in the “total population”, because of random error. This is undertaken through various statistical procedures, which we would deliberate in detail in the section on biostatistics.

### **Ninth Building Block : Confounding : Compare Apples with Apples, Not with Oranges**

Well, while minimizing the random error by studying an adequately large and representative sample and calculation of the p - value which gives the probability of the random error is all very important, it is just one of the three major errors, that we have to guard against, in epidemiology and medical research (see Box - 1). In fact, it is more important to effectively neutralize the other two errors. These two errors are, firstly, confounding error and secondly, systematic error also called bias or loss of internal validity or error of measurement.

#### **Box - 1 : In medical research we should understand where all “errors” can occur :**

- Since we study a ‘sample’ from a “population”, error of loss of external validity may occur if representative sample is not taken
- Random error (sample to sample error or chance) will occur because we study samples from a population.
- Error will occur if our basic measurement process is wrong.
- If we systematically differentiate while comparing the two groups (Bias or systematic error or loss of internal validity)
- If the groups being compared are dissimilar in various other respects (Confounding error).

Let us take a hypothetical study which evaluated the risk factors of IHD by taking 100 cases of IHD and 100 comparable but perfectly healthy people and obtaining the history of various putative risk factors. One of the factors which the investigators considered was the history of habitual defecation in privies



versus open fields. The findings are displayed in Table - 2.

<b>Table - 2</b>			
<b>Exposure (defecation habit)</b>	<b>Outcome</b>		<b>Total</b>
	<b>O+ IHD cases</b>	<b>O - Healthy controls</b>	
E+ (Privy latrines)	70 (70%)	30 (30%)	100
E - (Open fields)	30 (30%)	70 (70%)	100
Total	100	100	200

It would be appreciated that 70% of the IHD patients gave history of defecation in proper latrines, while much less (30 %) of the healthy people gave this history, preferring the traditional “open air” practice. Going to the open fields apparently, seemed to be a great protective factor against IHD while sitting on the commode inside a privy increased the risk by more than two fold! The authors were thrilled about the scientific breakthrough they had made, when a scientist told them that something seemed to have gone wrong! What had actually gone wrong was the occurrence of a very common phenomenon which occurs in research : that of confounding. In this case there was another variable which created all the confusion - it was socioeconomic affluence, for the rich who used their privies and had more IHD not because of their hygienic habit but because of the affluent unhealthy lifestyle. This phenomenon occurred because this study did not follow the basic doctrine of research which says that two group being compared should be similar to each other in all other respects except for the factor being studied.

Never compare apples with oranges. In all correctness the authors should have selected the groups whose subjects should have been similar in all other respects like age, sex, race, family history and socioeconomic status except for that one group had IHD, and other did not. In confounding, an observed association between an exposure (e.g. defecation practice) and an outcome (e.g. IHD) is “explained away” by a “third” variable (e.g. ‘socio - economic status, in our example). This creates a ‘confusion’ or a nuisance (32 - 34). It is imperative for an epidemiologist and a medical researcher to always be on guard against this phenomenon of confounding, a detailed discussion about which will be made in a subsequent chapter.

#### **Tenth Building Block : Precautions against “Bias” (Syn : Systematic Error Measurement Error Misclassification, Lack of Internal Validity)**

Some trials undertaken earlier showed that patients with inguinal hernia who undergo laparoscopic repair seem to have less post operative pain and more rapid return to work than open conventional surgery. Is this result really correct or might be that laparoscopic repair may appear better because of certain bias. The following points need consideration :

- Perhaps laparoscopic repair is offered to patients who are in a better health or seen to have better tissue strength because of age or general health
- It may be possible that surgeons and patients are more inclined to think that this procedure should cause less

pain, because it is new.

- As the scar is smaller, the patients report less pain and the surgeons are less likely to ask for pain or record it in the case sheet
- Perhaps patients who get laparoscopic surgery return to work earlier, than those who get open surgery, because the surgeons have so guided them.

If any of the above reasons were true, the favorable result of laparoscopic repair may be related to systematic differences in how the patients are selected for laparoscopic procedure, how they report their symptoms or are asked about them, or how they were told what they can do rather than a true difference in the success rates. A clinical trial conducted after carefully taking care of these possible biases, found that patients given laparoscopic surgery in fact do experience less pain and a more rapid return to work, every thing else being equal (35).

One of the essential requirements in any scientific process is to measure correctly what we actually want to measure. In the above example, we had actually intended to measure “the relief in pain and rapidity of resuming normal day to day work” as brought about by laparoscopic versus conventional procedure. However, at a number of points we systematically departed from the correct state, making measures which were different than what we really intended to. It is a surprising and concerning fact, the central issue of measuring what we really intend to measure is lost in many a study. Any measurement must have the following two characteristics :

- It should have ‘reliability’ (Syn : precision, repeatability, replicability) - in that repeated measurements should give consistent results.
- It should be ‘valid’ (i.e. accurate) - It must measure what is really intended to be measured. Loss of validity (accuracy) occurs if a measurement process tends to produce results that depart systematically from the true value. (Bias) (36). Bias has to be visualized during the planning stage and steps taken to prevent it. It will be discussed in detail in later chapters.

#### **Eleventh Building Block : Selecting the Appropriate “Research Design”**

Selection of the correct design is a vital issue in epidemiologic research and depends on a thorough understanding of the research question. For a given research question there is one ‘most suited’ design. The various types of designs, viz., Descriptive, Analytic (Case - Control, Cohort, Cross - sectional), Experimental, and Diagnostic test studies are described in detail in subsequent chapters.

#### **Twelfth Building Block : No Epidemiologic Research is an End by Itself**

A well conducted study not only yields invaluable scientific data but also opens up other interesting issues that are worth pursuing further. Epidemiologic research is therefore an ongoing academic process wherein we critically review our work, ask further questions and try to solve them by further epidemiological research studies. The cycle is unending .....

### **Summary**

Epidemiology is the basic and essential science for the study of human health and disease. As a result, therefore, medical

research methodology is totally dependant on epidemiology and its sister science, biostatistics. This science is dependant on certain essential scientific considerations or “building blocks, as follows :

Any epidemiological or medical research study must start only after a proper question has been formulated after adequate amount of academic reading and discussions. While in clinical practice our focus is on a single individual (the patient), in epidemiology and medical research, our focus is on a large number of subjects or patients. It is only on the basis of information drawn from this large body of subjects that we can make conclusions about the health state of a population and about causes, risk factors, treatment, prognosis and prevention of a disease.

When we consider a large number of subjects for drawing conclusions, there are four types of potential and serious errors that can occur and which need to be prevented in our epidemiological studies :

We will always be studying a “sample” and making inferences about the large population from which the sample has been drawn. Now, the sample may not be representative of the population and hence we may not be able to “generalize” the results of our sample on to the population. This is the error of external validity or lack of generalizability. As a part of the natural phenomena of random error (syn. Chance, sampling error sample to sample error), our results from even a representative sample may not be exactly the same as the truth that is there in the large population. This error is prevented by studying an adequately large sample and by estimating the extent of “chance” through p - value calculated by statistical procedures after the study has been done. Our observed association from the study may be actually un - real, due to a third variable, which is acting indirectly. This is the error of confounding. Our basic measurement process may be wrong or we may be systematically differentiating between the two groups which we are comparing in our study. This is the error of measurement or systematic error or bias. Finally, we must

remember that no epidemiological study is an end in itself; it generates further questions which again need to be addressed by subsequent error - free studies. This is the epidemiological or research cycle.

## Study Exercises

**Long Question :** Discuss, with suitable examples, the essential building blocks of epidemiology & medical research methodology.

### MCQs

1. Any epidemiological study should start with a well formulated research question, developed by : (a) Discussions with colleagues and experts (b) Thorough academic reading (c) Our own clinical experiences (d) all of the above (e) none of the above.
2. The situation when an observed association between two variables is explained away by a third variable, due to indirect associations is known as (a) chance (b) Bias (c) Confounding (d) lack of generalizability.
3. While undertaking a study for the load of diabetes in a city, a sample of subjects was taken. All were asked if they saw ants being attracted to the place where they had passed urine; if the answer was yes, they were taken to be diabetics, otherwise not. Which of the following errors is potential in this case : (a) Error of Confounding (b) Error of measurement (c) Random Error (d) None of the above.
4. By random error we mean that : (a) No sample is likely to give us results which are exactly the same as the truth in the total population (b) No two samples drawn from the same population are likely to give us the same results (c) It will not occur if we study the entire population (d) all of the above (e) none of the above.
5. In an epidemiological study to find out whether smoking is related to laryngeal cancer, IHD is (a) Exposure variable (b) Outcome variable (c) Both exposure and outcome variable (d) confounding variable. (e) Secondary outcome variable.

**Answers :** (1) d; (2) c; (3) b; (4) d; (5) e.

13

## Developing the Correct Epidemiological (Research) Question

*RajVir Bhalwar*

For most of us, asking a epidemiological research question seems to be so simple and “taken for granted” that we often tend to overlook its importance. The results of such casual approach may be disastrous. It is ironical that a large number of workers when asked on the completion of their study, as to

what exactly was their research question are unable to clearly state the same. The entire planning, design, conduct and analysis of any research work, is dependant on the research question itself. A carelessly developed research question, therefore, leads to wastage of and adds another (un)scientific paper to the many that already exist !

### Steps in Developing a Research Question

Developing a research question is neither automatic nor haphazard. It involves a series of meticulously steps. The research question is the ultimate objective of the study. It often begins with a general concern which then should be narrowed down to a concrete, researchable issue. For example, consider

the question “Should middle aged adult men undertake more exercise?” This is a good point to begin, but we need to get more focused before we can start any worthwhile research. This involves breaking the question into specific components and concentrating on one or two of them. The components in this example could be :

- How often do people undertake physical exercise? What is the usual intensity and duration?
- Does regular moderate intensity physical exercise for 30 minutes a day reduce the risk of diabetes?
- Will jogging and weight training have the same effect as regards protection from diabetes?
- Will regular jogging carry an increased risk of osteoarthritis, sudden death and musculoskeletal injuries?
- Will postural “Yoga” exercises have the same protective effect on cardio - vascular health, as brisk walking?

The sequence of steps for proper development of a research question could be :

**Step 1 - Do not let the research question be forced upon you** : It is important to realize at the very outset one must conform to his interest. Very often a particular research work is forced upon us (peer group pressure, obtaining “funding” from an agency, etc.). It must be realized that if we take up a research work which does not genuinely interest us, we would not plan and design it properly, would conduct it half - heartedly and the end product would be an invalid, unattractive piece of work.

Sometimes initially you are not interested in a particular research area. However, before rejecting it, one may undertake some reading in the area. You may start getting interested in it. (In marriage, what is important is to fall in love, whether you fall in love and get married or else get married and then fall in love !).

**Step 2 - Find a general area of interest** : After having assured oneself of the ‘genuine interest’, find the “broad or general area”. This is a “broad field” in the particular area of medicine; e.g. “AIDS” or “Urinary Tract Calculi” or “Patellar Fractures”, etc. One should turn to various personal resources for identifying such broad field of interest, as :

- Our own intrinsic interests
- Clinical observations that accrue over the years of professional experience
- Deliberations made at medical conferences and clinical meetings
- Discussions with colleagues
- Questions asked by our students and subordinates

**Step 3 - Read “around” the topic** : Once a general area of interest has been identified, a “wide” (extensive) study is undertaken in that area. Care needs to be taken at this stage not to make the reading an “in - depth” (i.e. intensive) one. The purpose is achieved by a superficial “browsing” of books and going through abstracts of articles published during past 3 - 5 years. Make a list of relevant journals. Scan through index of these journals. Browse through their abstracts. If the abstract seems interesting, note the reference for getting back to the article later. Avoid reading the complete article at this juncture. Internet can be a useful tool.

**Step 4 - Identify an area of “specific” interest** : The superficial reading leads us to identify areas with certain gaps in the existing body of knowledge and that one can try to fill up. We thus, identify certain “specific” areas of interest within the “general” area of interest. For example, after a wide reading in the general area “urinary tract calculi”, we may get specifically interested in “risk factors for urinary calculus formation”.

**Step 5 - Read into the topic** : We must now do an “indepth” (intensive) study into this specific area (in contrast to the wide, extensive study of step - 3). This would involve detailed study of published articles, personal communications with experts who have worked in that particular specific area and computer based searches of medical literature, giving the carefully selected, relevant key words.

By now, the readers would be convinced that developing a research question needs a definite scholarly attitude and plenty of reading.

**Step 6 - Formulate a ‘tentative’ research question** : A specific item has now been identified, where some work has already been done but still certain gaps exist in its knowledge, which need to be investigated. We can thus write a statement indicating our “tentative guess” which we wish to prove (or disprove) in our proposed research work. This is what we call as our “tentative research question”. For example, after a thorough in - depth reading on “risk factors for urinary tract calculi” we develop an idea that “Will ensuring drinking at least 5 litres of water a day prevent urinary tract calculus formation in tropical areas?”. We would come to this conclusion after consideration of following facts

- Some amount of work has been done in this area
- There are, however, gaps in the body of existing knowledge that need to be filled up. For instance, while there may be some published evidence that adequate drinking water prevents urinary tract calculi in temperate climates, it may not be clear whether the same holds good for tropical climates also. Or else, there may be evidence regarding efficacy in overall population but not in certain specific populations as some particular industrial workers or sports persons or among soldiers.
- This has generated our interest in the issue.
- We must decide if we would be able to undertake this research, given our capabilities and facilities?

**Step 7 - Evaluate the tentative research question for its ‘suitability’** : The next step is to answer the issue “Whether it can be done by us?” We should note that the research question that we have developed by now is only a ‘tentative’ one. This tentative research question is to be tested for its ‘suitability’, before we proceed further. In other words we should evaluate it on the following parameters :

**(a) Is it “Do - Able? - Answer the following questions -**

- (i) Do we have the required technical support in terms of patients, hospital beds, laboratory support etc.? Will adequate number of patients (or healthy subjects) be available? Do we have the required diagnostic and therapeutic facilities?
- (ii) Do we have enough funds available to finance our research requirements ? Will some research body be ready to finance us?



- (iii) Are we professionally qualified to undertake this research work? If not, is professional support of qualified persons (co - guides / co - workers) available?

- (iv) Will we be able to muster the required administrative and logistic support in terms of administrative sanctions, manpower, vehicles, equipment etc.?

**(b) Is the research question 'pertinent' ?**

Does it have relevance to our specialty? For example, "attitudes regarding family planning in a rural community" may be a very good research question, but possibly not if a vascular surgeon working in a tertiary care hospital has to do it, since it neither has much relevance to his specialist fraternity (Vascular Surgeons) nor to his "usual" settings of medical practice.

**(c) Is it Ethical ?**

- (i) Does our proposed research work involve a breach on "confidentiality" of human subjects? Will we be able to keep the information obtained, confidential?
- (ii) Does our proposed research expose the subjects to a potentially hazardous agent?
- (iii) Does our proposed research has a likelihood of depriving the human subjects of a known or potentially useful agent?
- (iv) Will it be possible for us to develop a system of obtaining 'informed consent' from the subjects, if required?
- (v) Has the project been discussed in the "ethical committee".

**(d) Will our research question pass the "If so, so what" test, after the research has been completed?"**

- (i) Will the findings of our proposed research work benefit the medical fraternity in general, or our specialist fraternity in particular, in some way?
- (ii) Are the recommendations that may finally come out, likely to be "practicable"?
- (iii) Is something new likely to come out of the research work, thus, filling the gaps in the existing body of knowledge? Or is it, that we are finally going to draw the already well known conclusion like "cigarette smoking is injurious to health" !

The importance of step 7 (evaluation of a research question for its suitability) needs no emphasis. A research question may be technically very well developed, through meticulously following steps 1 to 6; however, if the various evaluation criteria mentioned in step 8 raise doubts about its suitability, it must be reconsidered.

**Step 8 - Make the "tentative research question" as specific as you can :** The more specific a research question is, the more fruitful would subsequent research be. We should examine our written statement at this point, to assess whether there is any element of vagueness or some "general" form of statement which can be made more "specific". As an example, in the above cited research work in the specific area of "adequate hydration for prevention of urinary calculi", a specific research question can be : "Can drinking 5 litres of water per day reduce the risk of renal stone formation by 25%, in young, physically active males, in tropical climate, after duly considering the confounding effects of primary renal disease, dietary factors, racial background, occupation, hypercalciuria, hyperoxaluria, and hyperuricosuria ?

Pragmatically, it may not be always possible to develop a fully

specific question. However, efforts should be made to develop as specific a question as possible. A well developed and specific research question will give us the following indications :

- (a) The suspected "exposure" or "cause" - e.g. "lack of drinking enough water" (5 litres per day) in the above mentioned research question.
- (b) The postulated "effect" or "outcome" - e.g. urinary tract calculi.
- (c) The "magnitude of the effort" - e.g. 25% reduction following removal of the risk factor / cause
- (d) The possible confounding factors - e.g. primary renal disease, dietary factors etc.
- (e) The general settings of the study - e.g. young, physically active males in tropical areas.

**A word about Research hypothesis and Null Hypothesis :**

The research question, when expressed in a statement form (rather than an interrogative form) becomes the research hypothesis, e.g. the research hypothesis in the above situation would be "Drinking 5 litres of water can reduce the risk of renal stone formation by 25% among young, physically active males, in tropical climate, after duly considering the confounding effects of primary renal disease, dietary factors, racial background, occupation, hypercalciuria, hyperoxaluria, and hyperuricosuria". The research hypothesis is a tentative guess which we wish to test and finally accept or reject in our proposed research work.

At this point let us also elaborate on the term "Null Hypothesis". The null hypothesis is nothing very special; it is simply the research hypothesis stated in a negative manner. For example, the null hypothesis for the above mentioned research hypothesis would be "Drinking of 5 litres water per day *does not have any effect* in reducing the risk of renal stones (by 25% at least) among young, physically active males, in tropical climate, after duly considering the confounding effects of primary renal disease, dietary factors, racial background, occupation, hypercalciuria, hyperoxaluria, and hyperuricosuria".

The finer aspects of the distinction between Null hypothesis and research hypothesis at this juncture, may not be immediately required to be understood. However, it is important to note, at this point, about these two forms of hypotheses, since (as we shall note subsequently in the sections on bio - statistics), that during the statistical analysis of our research data, we proceed to accept or reject the "Null hypothesis" and not the research hypothesis.

**Step 9 - Write down the research question and its significance :**

Quite often, we do not follow this step, but it will be a really gainful exercise to reduce the research question, once finalized, to writing in a sentence or two (as given in the example on urinary tract calculi in step 7 above). This would provide a permanent reference during the entire conduct of the study; in addition, it would be easier for us to further refine it.

In addition to writing down the research question, we should also write down its 'significance' in brief. The same would come very handy, for writing the "Introduction" of our research paper or thesis. In addition, it is an obligatory requirement of all the funding agencies. The significance of our research question should briefly bring out the following aspects :



- (a) The importance of the particular disease or health condition (on which the research work is proposed) for public health or clinical practice.
- (b) What is already known in this area, based on review of recent literature.
- (c) What are the potential gaps in the existing knowledge that need to be filled up.
- (d) How the findings of the present study are likely to resolve the present uncertainties in the area, and influence / improve clinical or public health practice / policy.
- (e) What are the potential problems in executing the proposed research work, in terms of feasibility, ethical issues and methodological issues and how they are proposed to be overcome.

## Summary

A well formulated research question ensures that half the job of research work is well completed. Developing a research question is a very scientific and deliberate process involving comprehensive academic inputs.

Developing a good research question involves the following steps

- Find a 'general' area of interest
- Read 'around' the topic - a wide and extensive study in that area
- Find a 'specific' area of interest
- Read 'into' the topic - an in - depth, intensive reading in the specific area
- Formulate a tentative research question
- Make the research question as 'specific' as possible - specify the exposure, outcome and confounding variables, the settings, the dose response relationship & the expected magnitude of effect
- Test the tentative question for feasibility, relevance, ethical angle, and novelty.
- Write down the final research question and its background significance in a page or two.

## Study Exercises

**Long Question :** Describe the steps in developing a research / epidemiological question

**Short Notes :** (1) Ethical considerations while developing a research question (2) Null Hypothesis (3) Considerations while making a research question as specific as possible.

## MCQs

1. Which of the following steps follows the step "find a general area" of interest, while developing a research question : (a) Read around the subject (b) read into the subject (c) Make the question as specific as possible (d) Find a specific area of interest.
2. The best way of selecting a research topic for your thesis / dissertation is by : (a) Looking at the list of topics which have been taken up for dissertation during past 5 years (b) Extensive academic reading in your areas of clinical or public health interest (c) Going through the details of the research project which your guide is undertaking at present (d) None of the above.
3. Detailed reading of the entire articles published in relevant journals will be undertaken during the stage of (a) making the research question as specific as possible (b) Read into the subject (c) read around the subject (d) All of the above stages.
4. Which of the following does not represent a "specific area of interest" : (a) Does regular, brisk walking have a protective effect against IHD (b) Is laparoscopic repair of inguinal hernia better than conventional open repair (c) What is the problem of marasmus in India (d) Does HRT prevent osteoporotic fractures among post - menopausal women ?
5. Once a research question has been developed, which of the following is NOT a criteria for assessing its suitability : (a) It should be feasible (b) It should be tailored according to budgetary allocation for research (c) It should be ethical (d) There should be something new in the proposed research.
6. For passing the 'if so, so what' test, a research work should be able to : (a) recommend practical suggestions for improving public health or patient care practices (b) get published in an international journal (c) Open up further research questions (d) bring out statistically significant results.
7. Specification of which of the following is NOT an essential requirement for making a research question "specific" : (a) cause (exposure) (b) magnitude of effect (c) general settings of the proposed work (d) cost of conducting the research.
8. Which of the following is not required to be included in the background significance of a proposed research work : (a) What is already known in that field (b) How the proposed research work will be conducted (c) how the results are likely to improve the health care practice (d) what are the potential gaps in the existing body of knowledge.

**Answers :** (1) a; (2) b; (3) b; (4) c; (5) b; (6) a; (7) d; (8) b.

RajVir Bhalwar

Epidemiology and medical research is one field where 'measurement' assumes paramount importance - the entire research depends on how correctly measurements have been planned, executed and recorded.

### The First Step in Epidemiologic Practice identifying the Disease and "Case Definition"

As we have seen in the previous chapter, the first step in epidemiology is "identifying" the disease or a health event or state, which is of interest to us. Hence at the very outset, the epidemiologist must clearly give a "case definition" of the disease or health related phenomena that she is going to study. It may appear too simple but is not so in reality. If our interest is to study "tobacco use", how do we define a tobacco user? - Anybody who has even once put tobacco inside the mouth in the lifetime? Or those who smoke at least one cigarette a week? Or who smokes at least one cigarette a day for at least three days in a week? Or moving towards an infectious disease, how do we say that a given child is a case of Dengue fever or not?

Apparently, one has to give some definition. This, in epidemiology, is known as "case definition". Naturally, we should have a case definition which identifies each and every person who has the disease (sensitive) and at the same time, excludes every person who does not have the disease (specific). In practice, getting a definition which is 100% sensitive as well as 100% specific is never possible, for pragmatic reasons. Hence, we draw an optimum trade - off between sensitivity and specificity, and quite often, make case definitions according to two or three levels of certainty, as "suspected", "probable" and "confirmed" (37), e.g. we may define the three levels for dengue as shown in Box - 1.

#### Box - 1 : Case Definition - Dengue Fever

**Suspected** : Fever of at least two days duration with myalgia, arthralgia, retro - orbital pain and severe backache, occurring between July to October in an area where at least one confirmed case of dengue had occurred during past 3 years.

**Probable** : A clinically compatible case with a single convalescent phase serum IgG titre of 1280 or above or positive IgM.

**Confirmed** : 4 fold rise in dengue antibody titre in paired sera taken at least 10 days apart, or detection of dengue virus.

Now, having defined the various diseases or health related phenomena that we are interested in studying, we would decide

the various headings on which we will make measurements on our subjects. In fact, not only in epidemiology and medical research, but also in medical practice, the process of measurement according to some pre - decided headings is inevitable. Let us say we are dealing with a patient who has come to us with history of fever and joint pains. Mentally, during the entire course of history taking and physical examination, something like the following chart would be drawn, (subconsciously, though) (Table - 1) :

We are often unaware, but such a data - sheet does form in our mind for every patient we see. Finally, we diagnose the patient as "compensated, uncomplicated rheumatic mitral stenosis" and proceed to manage her. The only difference between medical practice and research is that in clinical practice we stop at every patient and treat her; thereafter, a new chart forms up in our mind for the next patient. On the other hand, in epidemiology and medical research, we continue recording, explicitly, on a chart or performa, as shown in Table - 2, the details for a large number of patients as required by the sample size. Thus, epidemiological and medical research methods are nothing but an extension of the principles of medical practice.

In epidemiology, the above chart, duly completed with all details for the required sample of patients / subjects is what is known as '*Data - Set*'. Data can thus be defined as "*an organised collection of information, containing the 'values' of the various variables, obtained from a sample of subjects, and which would be subsequently used to derive conclusions through the process of scientific analysis and reasoning*". In any epidemiological study, data would be obtained by the process of making measurements, on various "items" which are of interest to us. In epidemiology, these "items" on which we make measurements are called as "Variables". All data is recorded in respect of variables. The headings given in the Table - 2 (Sex, Fever, Dyspnoea etc.) are all variables. A variable is thus *any quality, characteristic or constituent of a subject which can be measured and which 'varies', i.e. likely to have a different value from one subject to another*. In fact, when reduced to the lowest terms, all medical research is simply the study of relationship between variables. Thus in the above example, when we would finally try to show that Rheumatic Heart Disease (RHD) is more common in females, we are actually studying the relationship between two variables - Sex and RHD.

The next step is to decide, from the statistical point of view as to which "scale" would we be recording each of these variables. Whenever measurements are made, there has to be a "scale" of measurement, for each of these variables (like we measure length and mass on "metric" scale). In epidemiology, depending on the way we record the measurements, the variables can be, broadly, either of the following two types -

(a) **Quantitative variables** : When information is recorded in terms of mathematical figures; e.g. Blood Pressure, Serum lipids, Body Weight, Number of Carious teeth etc. Since such

Table - 1

Sex	Age	H/o fever & joint pains	Palpitations	Dyspnoea	Precordial pain	Fever	Pulse	Enlarged Liver & Spleen	Mid - Diastolic murmur
F	11	Yes	Yes	Yes	Yes	Yes	Irregular	Yes	Present

data is recorded in form of numerals, one can also call it as 'Numerical data'.

**(b) Qualitative variables** : When information is not recorded in form of numbers but according to certain defined attributes; e.g. Sex - Male/Female; Outcome of treatment - Recovered/ Dead; Blood group - A, B, AB or O; Satisfied with treatment - Yes or No, etc. It is also known as "attributive" scale or a "nominal scale" since it records the attributes or the characteristics by classifying the characteristic (or attribute) into categories to which a given subject belongs or does not belong, or else the property or quality that a subject possesses or does not possess.

It is quite simple to find out whether the data being collected for a particular variable is of qualitative or quantitative variety. Just see the space opposite that particular heading in your data collection form. If you are going to record the answers in mathematical figures, i.e. some sort of "numbers" which may be whole numbers, decimal figures or fractions (e.g. BP, Serum Cholesterol, No of Children) then the data is of quantitative type. On the other hand, if you are going to record the answer in words (e.g. sex - Male/Female; Response to treatment : Recovered/Not recovered, Blood Group - 'A', etc.) then the data is of qualitative type. Each of these two types of data (qualitative and quantitative) have 3 distinct sub - scales of measurement:

### Quantitative Variables

These can be further of 3 types

**1. Discrete Scale** : This type of data has the following characteristics

- They correspond with a count of some sort
- They are recorded as integer numbers
- They cannot take any decimal value
- The numbers have a definite mathematical relationship.

A number of variables are measured on discrete scale; e.g. No. of DMF teeth; No. of abortions; No. of spells of a given disease for individual subjects; No. of doses of a vaccine taken; No. of visits to the hospital and so on.

Let us take an example. We did a study about the number of episodes of haemoptysis among patients attending a chest hospital OPD. A sample of 1000 patients was studied. The 'variables' of interest were 'Number of episodes of haemoptysis'

and "Type of Respiratory disease - Tuberculosis or otherwise". The other variables were fever score (0= no fever, 1 = mild and so on), and Blood group. The "data - set" would look like as shown in Table - 3. In this data set, the variable 'Number of episodes of haemoptysis' is measured on a discrete scale because the measurements are made in the form of meaningful numbers which can take only integer values and never any decimal value (you can not have a patient saying that she had "2.31" episodes of haemoptysis!) and there is a definite mathematical relationship between these numbers, in that 4 episodes of haemoptysis are actually equal to two times of 2 episodes, or equal to 3 episodes plus 1 episode and so on.

**2. Numerical, Continuous Scale** : Like the numerical 'discrete' scale, in a numerical continuous scale, the observations are recorded as quantities which have mathematical relationship; however the major difference from discrete variable is that the observations can take any value (theoretically at least) along a 'continuum' between 2 integers (and not compulsorily restricted to integers, as in a discrete scale). Take, for example, a variable like systolic BP. While we would generally measure systolic BP as 118, 120, 122 etc., this is only because we have calibrated the instruments accordingly. Theoretically at least, SBP can be recorded as 199, 121 etc.; and can also be measured as 119.5 or 121.7, or even, for that matter, as 119.5397501 or 121.7039267 (provided we had a sphygmo - manometer so precise and the desire to do such a precise recording). Not only BP, but a large number of measurements in health practice are made on this scale - e.g. age, blood sugar, various other biochemical parameters, body weight, height, BMI, stroke volume, CSF pressure and so on.

Often, the continuous and the discrete scales are together referred to as "ratio" scale also.

**3. Numerical Ordinal Scale** : The ordinal scale is a very interesting one. It uses numerical symbols for recording the data, but these numbers do not have any meaningful mathematical relationship. Let us take the example of the hypothetical example of our data set that we have presented earlier. For recording the variable 'H/o fever', we can record it in terms of categories like No fever, Mild, Moderate and High fever. We can go further and give numerical values to these categories as No fever =0, Mild fever =1, Moderate = 2, High

Table - 2

S. No.	Sex	Age	H/o Fever & joint pains	Palpitation	Dyspnoea	Precordial pain	Fever	Pulse	Enlarged Liver, Spleen
1	STOP AFTER 1st PATIENT IN CLINICAL PRACTICE BUT CONTINUE TILL THE REQUIRED SAMPLE OF PATIENTS IS COMPLETED, IN EPIDEMIOLOGY AND MEDICAL RESEARCH								
2									
.									
.									
51									
.									
.									
100									

= 3. In fact epidemiology and medical research is full of such examples (grades of dyspnoea 0 to 5; grades of murmur 1 to 6; levels of satisfaction; grades of cancer 1 to 4; degree of relief from pain; APGAR Scores, and so on). However, it is here that the catch point lies. The numbers 0, 1, 2 and 3 are not real mathematical numbers - high grade fever is not really equal to 3 times mild grade nor do a patient each of nil, mild and moderate fever added together will give a clinical state equal to high fever! The catch point is important to understand because the statistical tests to be used in such situations (non - parametrics) are very different from the usual parametric tests used for discrete or continuous scales. For the present, it may be noted that it is advisable to work out the median and not the mean when confronted with ordinal numerical data. The non - parametric tests, in fact, compare the medians and not the means.

### Qualitative Data

The peculiarity of qualitative data is that the recording of observations is not made in form of numbers as in quantitative data, but in form of words. The major 'scale' for recording the qualitative data is "categorical", also called a "nominal scale" in which two or more categories are made; and depending on whether there are only 2 categories or else more than 2 categories, the scales are called as "nominal, dichotomous" and "nominal, polychotomous" respectively. In addition there is a third category of "polychotomous, ordinal" scale.

(i) **Nominal Dichotomous** : In nominal dichotomous there are only 2 possible alternative answers to the information being recorded; e.g. Hypertensive - Yes / No; Status - Dead / Alive; Response - Recovered/ Not recovered; Tobacco user - Yes / No; and so on. In other words, the response will be recorded as "either - or" of the 2 alternatives, in words, not numbers. (At this point it should be noted that the response may sometimes be recorded as '0' for No and '1' for Yes especially when a logistic regression analysis is being planned; however, even if the response is recorded as 0 (for No) and 1 (for Yes) (or 0 for male and 1 for female etc.), the scale remains a dichotomous one only. For example, in our hypothetical data set above, "Type of respiratory disease" is recorded as a dichotomous variable, being recorded as either 'TB' or 'non TB'. The presentation of the variable finally will be in the following form, by listing the various possible categories and calculating the percentages

(Table - 4)

Table - 4	
Type of respiratory disease	Numbers & percentage
TB	800 (80%)
Non TB	200 (20%)
Total	1000 (100%)

(ii) **Nominal Polychotomous** : In a nominal polychotomous scale, there are more than 2 alternative answers or possibilities for the information being recorded; and the information is recorded in words, not in numbers. In addition, the categories in a nominal polychotomous scale do not have any "natural" ordered relationship, in contrast to the ordinal scale where there is a definite ordered relationship. A number of variables in medical research are recorded on nominal polychotomous scale; e.g. Blood groups (A,B, O, AB), race, religion, geographic area of residence, hospital where being treated and so on. In our hypothetical data set, blood group is recorded on a nominal polychotomous scale.

(iii) **Ordinal Polychotomous** : Sometimes the investigator may not give numerical scores to his ordinal variables but treat them on a polychotomous (ordinal) scale. While doing so, he may not record the fever grade in numbers (0, 1, 2, 3) but in words (nil, mild, moderate, severe). This is also acceptable but the statistical analysis will be slightly different from the usual tests used for nominal polychotomous data. For example, in our hypothetical data set, we may decide not to give scores to fever grade but rather record and present it as shown in Table - 5 :

Table - 5		
Fever grade	Patients	
	Tubercular	Non TB
Nil	200 (25%)	50 (25%)
Mild	100 (12.5%)	75 (37.5%)
Moderate	200 (25%)	50 (25%)
High	300 (37.5%)	25 (12.5%)
Total	800	200

Table - 3					
S. No.	Particulars of patient	Fever Score	Type of Respiratory Disease (TB / non TB)	Number of episodes of haemoptysis	Blood group
1.	XYX	2	non TB	2	A
2.	XXY	3	TB	4	AB
3.	YYY	0	non TB	3	B
.	.	.	.	.	.
.	.	.	.	.	.
1000	XYXY	1	TB	1	O
Total : 1000			TB = 800 non TB=200	2850	



The relevant test in such a situation would be 'Chi square test for linear trends in proportions' rather than a 'non parametric' test, which would have been done if we were recording grades of fever in terms of numbers (0, 1, 2 etc.) as explained earlier under the "numerical ordinal" scale.

The difference between a "nominal polychotomous" and an "ordinal polychotomous" scale must be appreciated. In both of these scales, there are more than two possible categories (if there are only two possible categories then it would become a nominal dichotomous scale). However, the essential difference is that in "nominal polychotomous" scale, the various possible categories do not have any natural sense of ordering (e.g. Blood groups A, AB, O, B can be written in any order or Race - Caucasian / Mongoloid / Negroid can be written in any order). On the other hand, in an "ordinal polychotomous" scale, there is a definite natural ordering which stands to common sense reasoning; e.g. Grades of pain will be naturally appreciated in the order of no pain, mild pain, moderate pain and severe pain and no disturbance of such order (as moderate pain/no pain/marked pain/mild pain) would be appreciated. As far as dichotomous scale is concerned, there need not be any distinction between anything like "nominal dichotomous" and "ordinal dichotomous" for the apparent reason that there are only two possible categories.

It becomes very important for the investigator to specify, soon after he / she has formulated the epidemiological question, as to what 'variables' will be studied and what would be the 'scale for recording' each of them. The decision is important because the subsequent analysis of data will depend upon the type of recording scale for different variables. However, whenever in doubt it is wise to remember that a continuous (or discrete) scale contains the maximum amount of information followed by a ordinal scale while the dichotomous scale records the least information (DBP of 96 or 130 will both be recorded as 'hypertensive'). If the data has been recorded on a continuous or discrete scale (of course, if at all it is possible to do so), it can be later collapsed into polychotomous or dichotomous categories but if it has been recorded on a dichotomous scale it can not be expanded subsequently, because the detailed information was never collected.

## Summary

At each and every step of epidemiology & medical research, or even clinical practice, we are making measurements. We select certain headings (e.g. age, sex, BP, mid - diastolic murmur, history of joint pains etc.) and record the value of each and every such heading; these are called as "variables", since they are likely to have different values for every next subject. The organised collection of the values of various variables in respect of all the subjects is called "data - set". For recording the 'values' of the different variables, there are definite laid down scales of measurement. The final statistical analytic procedure will depend on the "scale" on which measurements were recorded for various variables. These scales of measurement are :

(a) Quantitative variables : When the various values of the variable are recorded as "quantities", i.e. mathematical numbers. These can be of further 3 subtypes

- (i) Discrete Scale : The values are recorded in real mathematical numbers which can take only integer (but no decimal or fraction) values.
  - (ii) Continuous Scale : The values are recorded in real mathematical numbers which can take any decimal or fraction value.
  - (iii) Ordinal Numerical Scale : The values are recorded in un - real numbers (i.e. these numbers are not meaningful from mathematical aspect).
- (b) Qualitative (categorical) variables : When the various values of the variable are recorded as "qualities" or characters, i.e. in words. These can also be of further 3 subtypes :
- (i) Dichotomous (Binary) Scale : When there are only two possible categories which are recorded in "either this or that" manner.
  - (ii) Polychotomous Nominal Scale : When there are three or more possible categories and there is no natural or common - sense ordering among these categories.
  - (iii) Polychotomous Ordinal Scale : When there are three or more possible categories and there is a definite natural or common - sense ordering among these categories.

## Study Exercises

### MCQs & Exercises

1. The association between exposure to television viewing and mental acuity in children was studied and the following information was recorded for each child in the study; Religion (Hindu or any other religion), age (in years), and amount of exposure to TV viewing (rated from 0 for no exposure to 3 for more than three years exposure to TV viewing). Which of the following choices lists these variables in the order of : dichotomous nominal, ordinal, and continuous? (a) Amount of exposure, religion, age (b) Age, religion, amount of exposure (c) Religion, age, amount of exposure (d) Religion, amount of exposure, age (e) None of the above
2. What are the alternative scales of measurement in which the variable "serum cholesterol" can be recorded in an epidemiological research work? Tick the correct combination : (a) Continuous, discrete, dichotomous, polychotomous - nominal; (b) Discrete, polychotomous - ordinal, polychotomous - nominal, dichotomous; (c) Continuous, numerical - ordinal, dichotomous, polychotomous - ordinal ; (d) All of the above
3. Data regarding a qualitative variable can be summarised by the following method : (a) By calculating the arithmetic mean (b) By making categories and calculating percentages in each category (c) Both the above methods (d) None of the above methods
4. APGAR scores of newborns were recorded in an epidemiological study and results were presented to state that the mean APGAR score of newborn was 6.43. Was this correct ?
5. Match the manner in which data was recorded for various variables as shown in column 'A' with the appropriate scale of measurement shown in column 'B'.

'A'		'B'	
S. No.	Method of recording the data	S. No.	Scale of measurement
a	Satisfaction with services provided by health worker. Responses recorded as - 2 (highly dissatisfied), - 1 (somewhat dissatisfied), 0 (neutral), +1 (reasonably satisfied) and +2 (Highly satisfied)	(i)	Dichotomous - Nominal
b	Obstetric history recording the gravida status	(ii)	Numerical - Continuous
c	Clinical efficacy of an anti - cancer drug recorded as either survived or died at end of five years	(iii)	Polychotomous - Ordinal
d	Coronary angiograms recorded as no blockage, mild, moderate and sever blockage of coronaries	(iv)	Numerical - ordinal
e	Coronary angiograms recorded as actual diameter of coronaries	(v)	Discrete - numerical
f	Indoor admission data from a chest diseases centre wherein diagnoses were recorded as lung disease, heart disease, diseases other than those of heart and lungs.	(vi)	Nominal - Polychotomous

Answers : (1) d; (2) c; (3) b; (4) Incorrect (5) a-iv; b-v; c-i; d-iii; e-ii; f-vi.

## 15 Populations and Samples

*RajVir Bhalwar*

A major reason for having an insight into the science of epidemiology and research methodology is that we always study a 'sample' and, based on the results obtained from the sample so studied, we draw conclusions about the whole lot of subjects having that particular disease or health related condition, from which the sample was drawn. In fact, the concept of studying 'samples' is not unique to the field of medical research alone - Let us take the examples of a housewife examining a fistful of rice from a sack to get an idea of the quality, or else a mother preparing feed for her baby. After she cooks the feed, she 'tastes' a tablespoonful after stirring the entire mixture well, and one can see the 'nod' of satisfaction on her face, approving the various characteristics of the feed, like adequacy of cooking, taste, salt and sugar content, warmth etc. Now, ideally, for drawing conclusions about these various characteristics of the entire feed, she should have eaten the entire feed, but she does not do that (and should not - she would be a fool if she does that). Rather she draws conclusions only from a tablespoonful (i.e. the sample). The analogous situation in epidemiology is that with the ultimate objective of finding the real state of affairs that exist in large collection of humanity or patients, we draw a 'sample' and depending on the results of the sample, we

draw conclusions about the 'reality' that would be existing in the entire population.

At this point, let us distract slightly and briefly discuss another common activity - the tossing of a coin. This is an experiment in which the 'reality' is already known to us - i.e. half of the coin is 'heads' and half of it is 'tails'. In other words if we toss the coin 10 times, we should get heads and tails on 5 occasions each. More generally, if we toss a coin 'n' number of times, we should get heads as well as tails on "n/2" occasions each. However, if we actually undertake this "tossing game" (you can do it yourself just for the sake of fun, as long as it remains fun) the results we would get would be something like shown in Table - 1.

Table - 1		
No. of times coin tossed	Results	
	Heads	Tails
1	1 (100%)	0 (0%)
10	8 (80%)	2 (20%)
100	72 (72%)	28 (28%)
1000	647 (64.7%)	353 (35.3%)
1,00,000	52825 (52.8%)	47175 (47.2%)
Infinite number of times	50%	50%

We can describe the above experiment as follows : “we were trying to estimate a truth that exists in the universe, i.e. how much of the coin is heads and how much is tails, on tossing. Unlike the usual situations wherein the ‘truth’ is not known to us and we try to estimate it with our sample, in this particular situation, luckily, the truth is already known to us - it is 50 % each. However, when we tossed the coin only once, we had widely missed the truth, concluding that the coin would exhibit 100 % heads and 0 % tails. On tossing the coin 10 times, we moved nearer to the truth, the results being 80% heads and 20% tails, but were still quite far away from the reality of 50% each. We kept getting closer and closer to the reality as we increased the number of tosses to 100, 1000 and so on; however, even after tossing it one lakh times, we were still not exactly at the reality of 50% each, though we did get quite close to it (52.8% and 47.2%). For exactly getting on to the reality, i.e. 50% each, we will have to toss the coin infinite number of times, and if ever we could do that, we would be right on the ‘truth’.

Let us see one more situation. Let us say we decided to estimate the truth about the coin with the sample of one lakh tosses and we decided to do five such experiments. The results are as shown in the Table - 2.

Table - 2		
Experiment No.	No. of Heads	Truth
1.	47800 (47.8%)	50%
2.	55301 (55.3%)	50%
3.	51980 (51.9%)	50%
4.	48002 (48.0%)	50%
5.	53067 (53.9%)	50%

The next take home message from the above study is - even if we study repeated samples of the same size, drawn in the most representative manner, no two samples are likely to give us the same result, nor the result for any sample likely to be the same as the truth which exists in the large population from which the samples were drawn. Why does this occur ? This occurs because of a very interesting natural phenomenon called “Random Error” or “Sample to Sample error” or more simply “chance”. As long as we are studying a sample, which we would be doing any way, some error should always be accepted.

Let us transpose this simple concept to epidemiology. Let us say, we have developed an important research question, viz, “What is the seropositivity for HIV infection among apparently healthy, young males in our country? This is a real epidemiological research situation, in which we are trying to estimate some “truth” (seropositivity for HIV) that exists in a “large population” (the entire healthy, young males in our country). Unlike the previous example of the tossing game in which the “truth” (50% each of heads and tails) was known to us ‘a priori’, in the present situation, the ‘truth’ is not known to us. Just for the sake of discussion, let us assume that the truth is, say, 1% (seropositivity for HIV infection among healthy young males in the country as decided by a confirmatory test like Western Blot).

Proceeding on the lines of the tossing experiment, if we do our

study on a sample of just 10 men, we may not get any positive, thus our conclusion about seropositivity would be 0%. If we do the study on 100 subjects, we may get 3 positives, thus concluding that seropositivity rate is 3% (again widely away from the reality or truth of 1%). If we increase the sample to 1000 or 10,000 respectively, we may get 15 and 80 positives, thus giving seropositivity rates of 1.5% and 0.8% respectively. Now, what is happening is, that, as we are increasing the sample size, we are definitely getting nearer and nearer to the truth; however, if we want to get a result which is exactly the truth (1%), we will have to study the “whole population” of all the healthy young males in the country.

The conclusion that can be therefore drawn is that as our sample size increases, we are more and more likely to get nearer to the truth or reality that exists in the “total population”, and which we are trying to estimate from our sample; however, we will never be able to confidently say that we have exactly estimated the truth, unless we study the whole population.

The take - home message for the medical researcher is that there is nothing like a “completely adequate” or “foolproof” sample size. We have to accept some “deviation” or “error” from the reality that exists in the “total population” (and which we are trying to estimate from our sample being studied). The only solace is that as we keep increasing the size of the sample, this error or deviation from reality will be lesser and lesser, but this error or deviation will certainly be there, more or less, unless we decide to study the complete “reference population”. We should be ready to accept some deviation that is likely to occur from the truth; even more than that, we should be able to specify the amount of deviation that is acceptable to us. Once this “acceptable deviation” has been specified, we can calculate the “optimum sample size”. For example, in our above mentioned study on seropositivity for HIV infection we may specify that “reality in the reference population is likely to be about 1%, and we are ready to accept a “deviation” of 0.2% on each side of this expected truth of 1% i.e. we accept that our sample is likely to give us a result that may vary from 0.8% to 1.2% (1% + 0.2%) and not exactly at 1%”. Once this has been specified the sample size for such a situation will work out to 9500 subjects. The details of statistical methods for calculating the sample size in different situation are dealt in detail in a subsequent chapter. What is more important at the present stage is that the epidemiologists and medical researchers should understand this concept and should be ready to specify these “parameters” (i.e. the expected truth that is likely to exist in the reference population, and the acceptable deviation from this likely level of truth) to our statistician colleagues if we approach him for calculating the sample size.

The Second Requirement of a ‘sample’ : By now, the foregoing deliberations would have amply clarified the fact that the first requirement of a sample is that it should be of “adequate size”. At this point, if we get back to the opening paragraphs of this chapter, we would notice a peculiar statement - the mother, before taking a ‘sample’ tablespoonful of the feed, stirs the entire feed well, before drawing the tablespoonful. This is because, had she not stirred it well and taken a spoonful from, say, the surface itself, she would not have got the correct estimate of taste, warmth, adequacy of cooking, etc. This idea

is central to another very important aspect while drawing a sample - that the sample should be “representative” of the reference population from which it has been drawn, otherwise the results obtained would be very different from the reality that we are trying to estimate.

Let us get back to the above mentioned research example on seropositivity for HIV infection. Suppose we have worked out the “optimum sample size” of 9500 and are prepared to collect it. Now, if we take these 9500 subjects from either a private blood bank patronised by professional blood donors or from subjects attending a STD treatment clinic, we may get a result which may be as high as 5% seropositivity, thereby grossly over - estimating the “reality” (which is likely to be around 1%, as assumed). In other words, if the subjects in a sample are “non - representative” (i.e. systematically different from the total or reference population), the result that we get will not be representative of the total population. Thus, we will not be able to “generalise” these results by saying that the seropositivity for HIV infection among healthy young males in our country is 5%. This is what we call as the “lack of external validity” which leads to loss of generalizability of results. The methods and techniques of drawing a representative sample are discussed in detail in a subsequent chapter.

However, there is a little piece of consolation. If the study itself has been conducted properly (i.e. proper procedures for drawing and testing blood samples by ELISA / Western Blot have been ensured, and so on) we may still be able to “generalise” our results to another “population” of professional blood donors or patients attending STD Treatment Clinics. Thus, from such a study, while we cannot conclude that the seropositivity among healthy young males in our country is 5%, we can, nevertheless, conclude that the same among professional blood donors or STD patients, is about 5%.

External validity, if lost, leads to loss of generalizability of results to the total population which the investigator has in mind. However, the results can still be generalised to another “population” of which the sample, so drawn, is representative. On the other hand, if the study itself has been undertaken using wrong methods (untrained laboratory workers, haemolysed blood samples, outdated kits, etc.), then it leads to loss of internal validity. If, in a study, internal validity has been compromised or lost (i.e. ‘bias’ has come in) , the study becomes fit for rejection only. Out of the two components of validity, internal and external, while both are important, it is the “internal validity” which has to be maintained at all costs.

Now that we have gone through the two important requirements of a sample, let us discuss some terms which are often used in epidemiological and medical research :

**1. Total Population (Syn - “Universe”; “Reference population”; “Source population”)** : This is the total collection of all subjects or units of study that the investigator keeps in mind while drawing her sample and on which she proposes to generalise her results. Quite often, the “total population” is very large, difficult to define precisely and more of “conceptual” in nature; e.g. “all healthy young males in the country”; or “all patients with acute Myocardial Infarction”, and so on. In a nut shell, it is the investigator’s study question / objectives and the

clinical and demographic characteristics that define the Total Population.

**2. Actual Population (Accessible population or Study population)** : Since the total population is usually difficult to precisely define, for actually drawing the study sample, the researcher often specifies a “subset” of the total population from which he proceeds to take the study sample. For example, in the HIV seropositivity study mentioned above, since the total population (i.e. all healthy young males in the country) is difficult to define precisely, the investigator may specify that he will select the sample from 5 Districts located at different places in the country. Similarly, in a study on the association of “Transverse Ear Lobe Crease” with IHD, while the “total population” is “all patients with IHD in the world”, the investigator will define his actual (study) population as “all IHD patients admitted to a particular teaching hospital”, and draw the sample from this actual (study) population. The assumption is that such “study population” is a “representative subset” of the “total population”. If, for some reason or the other, this assumption is not tenable, then the external validity and generalizability would become restricted. For example, if the 5 Districts selected for drawing the sample in HIV seropositivity study are those which have a high occurrence of intravenous drug abuse, we may not be able to generalise the findings to the entire country (though we could still generalise our results on to all districts having a high occurrence of intravenous drug abuse). Deciding whether the Actual (study) population is a representative subset of the total population depends on the experience of the investigator. One should not hesitate in seeking the advice of one’s peer groups and experts if ever in doubt. It is the similarity to the Total Population and the geographic and temporal (time related) characteristics that define the actual or accessible population.

**3. Sample (Syn - Study Subjects)** : From the actual (study) population, the investigator chooses a “sample” of the required optimum size, using methods which ensure that the sample so selected will be representative of the study population. In case the sample, for some reason, does not remain representative of the study population, the external validity, and hence generalizability, will be once again comprised, as explained above. The procedures for calculating the “optimum sample size” and methods of drawing a “representative sample” are elaborated in subsequent chapters.

**4. “External Population”** : For understanding the concept of “external population” and how it is different from “target population”, have a look at the following example : Suppose our results from our sample indicate that HIV seropositivity among our country is 1%. After some deliberations regarding whether our sample was representative of the actual (study) population and whether the actual (study) population was in turn, a reasonably representative subset of the target population, we could reasonably assume that the overall seropositivity in the entire country would also be about 1%. Can we, based on these results, derive some conclusion about our neighbouring countries also? Deriving such conclusions actually would go beyond simple methodological issues and would involve judgements about other findings, conceptualisation of the disease process, related biological processes and comparative



features of the “Target Population” (in this example, “the Indian people”) in relation to such “External Populations” (in this case the “Pakistani or Sri Lankan people”). However, this exercise (of applying the results from one Target population of a given research to another “External Population”) is very common in clinical research. Why go far - almost all the clinical research pertaining to preventives, diagnostics and treatment modalities, undertaken on USA population is also applied for practice in our Indian population, without any further research. External validity, thus, has to be assessed at three different levels.

The first external validity consideration (depicted by “1” in Fig. - 1) is the generalisation from the sample intended to be studied, to the actual (study or accessible) population. The issues of selecting a probability sample come into play at this level. The second consideration (denoted by “2”) comes when we are generalising from the accessible population to the target (syn : universe; reference) population. This goes beyond the issues of sampling methods and involves the understanding of the socio - demographic and temporal characteristics and similarities / dissimilarities between the accessible and the target population. Finally, the third consideration in external validity (denoted by “3”) comes when we further try to generalise our study results from the sample to some “external population”. As said earlier, deriving such conclusions actually would go beyond simple methodological issues and would involve judgements about other findings, conceptualisation of the disease process, related biological processes and comparative features of the “Target Population” in relation to such “External Populations”.

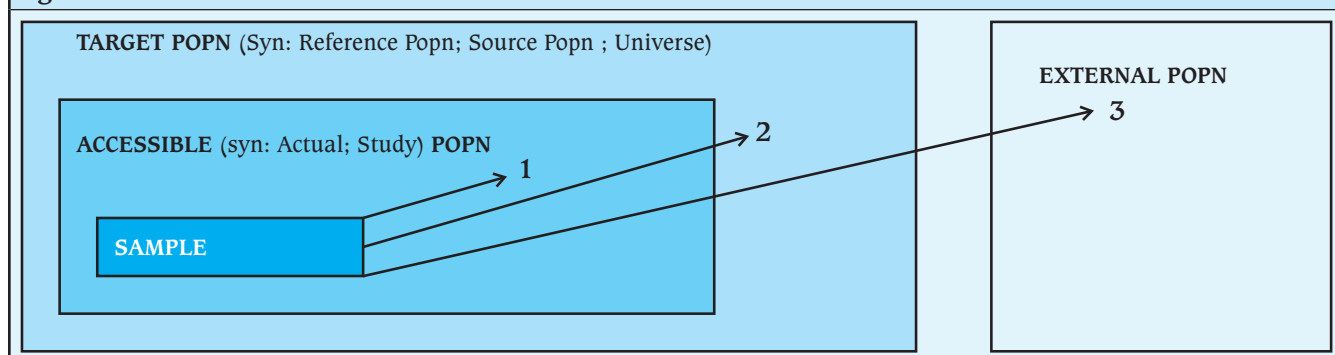
It is very important to think and decide on the issues related to the definitions of “populations” in one’s epidemiological study, right from the planning stage, and write them explicitly in the protocol. The following is the suggested sequence :

- (a) First of all, specify (preferably, write down) the target population (universe) on the basis of your research question and taking into consideration the various clinical and demographic characteristics that are relevant to your research issue. The basic guiding criteria at this stage is that the target population so specified by you should be well suited to your research question. For instance, let us say your overall research issue is to study the prevalence and risk factors for “Hepatitis - B” carrier state in middle aged male paramedical persons in our state. So, we can

define our target population as “all male personnel who are working as paramedical persons in our state and who are aged >35 years”.

- (b) As the next step, one should then specify the accessible population on the basis of temporal and geographical characteristics. The overall guiding criteria, now at this stage, is the overall representativeness of this accessible population, vis - à - vis the target population and the ease of study. Thus, in our above example, we may define our “accessible or actual or study population as all male paramedical persons aged above 35 years working in government and private hospitals in our city, during the period of July 2005 to July 2008”.
- (c) Next, one should design an approach to select a sample that will be representative of the accessible population. This is done by selecting an appropriate method of “sampling” as discussed in one of the later chapters. In our example, we may specify, at this stage, that we will select the sample from a list of all paramedical persons who are registered for work or on active payroll of government and private hospitals in our city, using the method of “Multistage sampling”.
- (d) Now, specify the “inclusion criteria”, looking at the target population. The guiding principle at this stage is to clearly think and specify as to what all characteristics of the target population need to be specifically included, to answer the issue adequately. For example, we may specify the inclusion criteria as all male paramedical persons, serving in either government or private hospitals in our city, who are aged above 35 years, and are apparently asymptomatic.
- (e) Now, apply the “exclusion criteria”. Be very sparing while formulating the exclusion criteria. Apply them for excluding those subjects who may be having a very high probability of being lost to follow up, or the particular treatment being tried may be contraindicated in these subjects, or some of their characteristics may directly interfere with the study results. In our continuing example, we may say that subjects who are already under treatment with interferon or are having any STD, will be excluded.
- (f) Finally, think of some possible “External Populations” to which you may contemplate generalising your results. In our continuing example, can these results about hepatitis - B among middle aged male paramedical persons of our state be also applied to the female paramedical persons? Or to paramedical workers of another state or country?

Fig. - 1



Clearly, this issue would need a lot of considered discussion with the experts.

## Summary

An extremely important consideration in epidemiology and medical research is that we nearly always keep a large population in mind, in our research question, but we actually undertake the study only on a “sample” and not on the total population. The total population (also known as the target population or universe) is that large collection of humanity which the investigator has in mind in the research question and on whom the results of the study are intended to be applied. Since this large total population is often very large and difficult to delineate, the epidemiologist specifies a subset of this total population, which is easily accessible and from which the sample is actually drawn. This is known as the “actual” (also called as accessible or study) population.

When we study a sample, two issues which come up are firstly, if the sample is not representative of the large population, we may not be able to apply the results from our study on to the total population; this situation is known as lack of generalizability or loss of external validity. For overcoming this problem, we should ensure that we draw a representative sample for our study, using one of the “probability sampling techniques”.

The second issue which comes up is that the results obtained from a sample are always likely to be different from the reality which exists in the large population, from which we have drawn the sample. This would happen no matter how accurate we have been in actually undertaking the various measurements and despite our having drawn the most representative sample. Similarly, the results from consecutive samples, drawn from the large population, in the most representative manner, are likely to be different from each other as well as likely to be different from the reality that actually exists in the large total population. This is a natural phenomena which is known as “chance” or sampling error or random error. Smaller the sample size that we have studied, more will be the likelihood of this error; conversely, as we increase the sample size, the probability of random error decreases to the point that if we study the entire population, there will be no random error. There are two steps that need to be taken for this error. Firstly, we should study a sample, which besides being representative, should also be of “adequately large” size, as determined by various methods as sample size calculations. Secondly, we should, at the end of our research work, estimate the probability of random error having produced results which could be different from the reality that is present in the total population. This is done by using various statistical procedures and calculating the “p” value.

## Study Exercises

**Short Notes :** (1) External validity (2) Random Error (3) Reference population versus external population.

### MCQs and Exercises

1. An epidemiological study was undertaken to find out use of condoms among truck drivers, by carrying out a personal, confidential interview of all truck drivers who ate at a road - side restaurant just outside Mumbai on the Mumbai - Pune Highway. Which of the following best

describes the reference population in this study : (a) All people who drive on highways (b) All Truck Drivers in India who use condoms (c) All truck drivers who eat on road - side restaurants (d) all of the above (e) none of the above.

2. In the above study, the workers found that condom usage among truck drivers who visited CSWs was 25%. They concluded that the condom usage among visitors of CSWs is likely to be 25%. Which population were the workers applying their results on.
3. If we study the entire source (reference) population, which of the following errors will not occur : (a) Random error (b) Measurement error (c) Error of External validity (d) none of the errors will occur.
4. After we have completed an epidemiological study and are calculating the p - value based on statistical tests, we are : (a) trying to minimize the random error (b) trying to see whether our study population was representative of reference population (c) trying to estimate the probability by which our results are likely to be different from the truth, because of random error (d) Trying to find out the extent of measurement error in our study.
5. Which of the following set correctly names all the synonyms of “chance” : (a) Sampling error, Sample to sample error, sampling variations, sample to sample variations, Random Error. (b) Sampling error, Measurement error, sampling variations, sample to sample variations, Random Error (c) Sampling error, Error of external validity, sampling variations, sample to sample variations, Random Error. (d) Sampling error, Measurement error, sampling variations, sample to sample variations, Error of external validity.
6. Which of the following set correctly lists out all the synonyms of “Reference Population” (a) Target population, Source population, Universe. (b) Target population, Study population, Universe. (c) Target population, Source population, External population. (d) All the above (e) None of the above
7. An epidemiological study was carried out in Delhi City (DC) to see whether obesity is associated with hypertension in young adults. The investigators decided that it was not feasible to take a sample from all the young adults in DC. It was felt by the investigators that commercial fitness centres may provide a good source of young adults in DC. A random sample of young adults was studied from several fitness centres, randomly selected from a detailed list of fitness centres in DC and the body weight and blood pressure of the selected subjects was measured. Answer the following questions : (a) What is the target (source) population for this study ? (b) What is the actual (study) population in this study ? (c) Does the sample represent the study population ? (d) Does the study population represent the source population ?
8. In the above example in Q. No. 7, suppose the researchers thought that it was important to obtain a sample from all young adults in DC and not simply from those who attend fitness centres. They used the census figures available with corporation office in DC to get a list of all young adults. A random sample was then taken from several randomly selected wards in the city and their body weight and

blood pressure levels are measured. Answer the following questions : (a) What is the target (source) population for this study ? (b) What is the actual (study) population in this study ? (c) Does the sample represent the study population ? (d) Does the study population represent the source population ? (e) can you visualize one situation in which the sample may not remain representative?

9. After the above study was completed, the investigators found an association between obesity and hypertension. They recommended obesity control measures for the entire country. Explain as to what type of population was being considered in this instance.

**Answers :** (1) e; (2) The workers were trying to generalize their results to an “external population”, which most probably can be defined as “visitors of CSWs”. This is quite different from the reference population defined above; (3) a; (4) c; (5) a;

(6) a; (7) (a) All young adults in DC. (b) All young adults who attend fitness centres in DC (c) Yes, since the sample studied was randomly selected from the study population at two stages - at the first stage some of the fitness centres were randomly selected from all the centres in DC and at second stage, young adults were randomly selected from all those who actually attended these selected centres. (d) No, since young adults who attend fitness centres are not representative of all adults in DC, being very different as regards their health related attitudes and obesity levels. (8) (a) All young adults in DC. (b) All young adults in DC (c) Yes (d) Yes (e) If all those selected for the study do not participate in the study, the sample may not remain representative. (9) External population, because the study was actually restricted to young adults of DC. Extrapolating the results to the entire India goes beyond the considerations pertaining to the methodological aspects of the study.

## 16

### Measures of Disease Frequency / Health Outcomes

*RajVir Bhalwar*

In one of the earlier chapters, we had discussed the fundamental principles of data management. To revise it quickly, with an example, a data - set of a hypothetical research work on the research question whether “Waist : Hip Ratio is related with IHD” is presented in Table - 1

This data - set has a lot of scientific information but does not convey much to the reader (or for that matter even to the

investigator who has undertaken this research). The investigator should therefore, reduce these ‘values’ to certain ‘summary’ figures. Depending on the type of ‘scale’, the summary figures can be of the following types :

- (a) For numerical continuous or discrete variables, the investigator would calculate the arithmetic ‘mean’; e.g. for waist - hip ratio, we may calculate the overall mean as 0.90.  
(b) For variables, measured on ordinal scale, work out the ‘median’, e.g. we may calculate the ‘median’ value of dyspnoea grade as ‘2’ among IHD cases and ‘1’ among healthy people.

Some variables are measured on “categorical” (dichotomous or

**Table - 1**

Sr. No.	Subject's Name	Dyspnoea grade	Waist (cms)	Hip (cms)	Body Mass Index	Tobacco Smoking	SBP	DBP	Physical Exercise	IHD
1.	XXXY	3	90	100	27.5	Yes	146	92	None	Yes
2.	ACDB	1	84	96	23.2	No	132	78	Regular	No
3.	XBTC	0	76	84	21.2	Yes	128	82	Irregular	Yes
i										
i										
i										
51	XXYX	0	88	97	25.1	Yes	138	86	Irregular	No
i										
i										
i										
400	AXBY	2	92	96	26.7	No	148	94	Regular	Yes

polychotomous) scale. These tell us if a health related outcome of interest has occurred or not.

While “outcome” forms the ultimate end point of research, the starting point is what we call as “exposure” or “cause”, the desire being to see whether a particular “exposure” leads to a certain “outcome”. Thus, smoking, ACE - inhibitor drug, and meningococcal vaccine are the “exposures” for the respective “outcomes”, viz., Lung cancer, control of hypertensive state and prevention of meningococcal disease, respectively.

It would also be appreciated that like the outcome, in most of the usual research situations, the exposure is also generally measured on a dichotomous scale (e.g. smoker / non smoker ; ACE - inhibitor drug given / not given ; Vaccine given / not given). Such dichotomous data is conveniently represented through a “2 x 2 table” (discussed in detail in another chapter) (Table - 2)

Table - 2			
		Outcome (O)	
		Present (O +)	Absent (O -)
Exposure (E)	Present (E +)	a	b
	Absent (E -)	c	d

### Can't we Compare Numbers ?

The first trap which we should always be aware of is that, comparing numbers is unscientific. One may “count” the patients of leprosy (all forms) in District “A” as 1000 and in District “B” as 100, thereby inferring that Leprosy is 10 times more common in District “A”. This difference, in reality, may be simply because the population of District “A” is 10 million while that of “B” is only 1 million. In fact, there are 1000/10,00,000 = 0.01% Leprosy patients in District A, and the same percentage, i.e. (100) / 10,00,000 = 0.01% in District B.

As another example, let us examine the following hypothetical study : A study collected the total number of cases of oral cancer which occurred in a defined district, in one year. All the cases were asked about the history of tobacco chewing. A total of 300 cases were thus studied, and the replies were as given in Table - 3.

Table - 3			
	Tobacco - Users	Non - Users	Total
Cases of Oral CA	100	200	300

The comparison based solely on numbers would give a fallacious impression that oral cancer is 2 times more common among those who do not use tobacco (200 cases) as compared to those who do so (100 cases). However, when we relate the above numbers to a “denominator” i.e. the total population in the same province which were tobacco users or non - users, we got the correct picture as in Table - 4.

The correct picture which emerges is that Oral CA is 10 times more common among tobacco users (rate : 1000 per million), as compared to the non - users (rate : 100 per million).

Thus, whenever we are measuring variables on a categorical scale (i.e. qualitative data), like dichotomous or polychotomous scales, we must convert the numbers, counted in each category, into some form of “frequency” by putting the numbers so counted into a “numerator” and relating this numerator to a denominator (e.g. total population in the example).

Table - 4			
	Tobacco Users	Non Users	Total
Cases of Oral CA	100	200	300
Total Population	1,00,000	20,00,000	21,00,000
Rate of Oral CA per million Population	1000	100	142.9

### The Choice of Denominator

Let us do a simple study on primary hypothyroidism in our teaching hospital. Out of the 100 patients of primary hypothyroidism, 10 were males and 90 were females. The various types of “frequency” measures which we can use can be explained as follows :

(a) **Ratio** : In the above example, for relating the females to males, we will use the following equation :

$$\text{Ratio of females to males} = \frac{\text{No. of females}}{\text{No. of males}} = 90/10 = 9 : 1$$

Thus, “ratio” is a measure of frequency in which the numerator is not included in the denominator. In the above example, the numerator (no. of females) is not included in the denominator (no. of males). The ratio also gives us the idea of another very important measure - the “odds”. Here, given that primary hypothyroidism has occurred, the “odds” of being a female in such a disease are 9 times as compared to being a male.

(b) **Proportion** : A proportion also has a numerator and a denominator; however, in contrast to ratio, the numerator is included in the denominator in a proportion. For example, in the above study,

$$\text{Proportion of females} = \frac{\text{No. of females patients}}{\text{Total No. of patients}} = 90 / 100 = 0.9$$

Here, the numerator (no. of female patients) is included in the denominator (total no. of patients).

The “proportion” gives the idea of a important measure in research methodology - the “probability”. In the above example we would draw a conclusion that the probability (or “chance”) that a patient of primary hypothyroidism would be female, is 0.9 (or 90%). (Multiplying a proportion by 100 would give us the percentage).

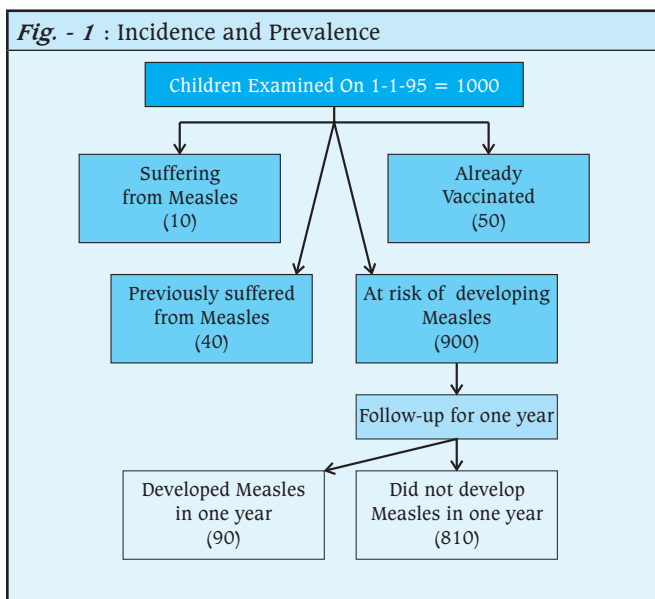
(c) **Rate** : The “rate” is basically a proportion, but with an added relationship with time. Let us say, we assembled 100 healthy ladies in their thirties, without any evidence of hypothyroidism. We now followed them for 10 years and found that over the 10 years period, 10 out of these 100 ladies developed primary hypothyroidism. Thus, the “proportion” of ladies who developed hypothyroidism is 10/100 = 0.1 (or 10%). However by relating



it to the time factor we would say that the “rate of development” (or occurrence) of primary hypothyroidism among ladies, is 10% over 10 years or 1% per year.

## The Two Basic Measures of Frequency in Epidemiology

Following an elaboration on the types of “frequency” measures, we are now in a position to discuss the two most basic (but, at the same time, the most important) measures of disease frequency used in epidemiology and medical research. Let us start with another hypothetical example. We took a sample of 1000 children aged 1 to 2 years from a rural community. We found that 10 of them were already suffering from measles. In addition to these, another 40 had already suffered from measles earlier, while yet another 50 had received measles vaccine. Thus, these  $(10+40+50) = 100$  children, were no longer “at risk” of getting measles; the remaining 900 were “at risk” of the same. We now followed up these 900 children for a period of 1 year and found that over this one year period, 90 developed measles (see Fig. - 1 below).



The ‘frequency’ of children who were having measles at the time of the first medical examination (on 1.1.95), was 10/100 or 0.01, or 1%. This is what we call “prevalence”, a very common measure.

**Prevalence** : Thus, prevalence is the proportion of persons “having” (i.e. found to be present with) the disease (or any other health related condition of interest), out of the total subjects who were examined. Thus,

$$\text{Prevalence} = \frac{\text{No of Subjects who are having (present with) the disease at that point of time}}{\text{Total no of subjects studied}}$$

**Incidence** : On the other hand, out of the 900 children who were initially at risk of developing measles, 90 developed the same over a period of 1 year. Thus, the “rate” at which susceptible children would develop measles is 90/900, i.e. 0.1 or 10% over a one year period. This is the second important

measure of disease frequency - the “incidence”.

Incidence is thus defined as the rate at which new cases of the disease of interest will occur out of those who were initially “at risk” of developing it, over a given period of time.

The specification of time is very important for incidence - an incidence of 10% over a 3 year period will have very different implication compared to an incidence of 10% over a 1 year period. For example, suppose you come across a journal article which says “Men aged 50 years have a 2% risk of dying from IHD”. This statement actually leads us nowhere. Is this 2% risk of dying due to IHD over the next one day or one month? Even 1 year may be an overestimate unless these men have some other major risk factor for IHD, as a previous attack of Myocardial Infarction. On the other hand this would be considered as too small a risk if it is over next 40 years. Therefore specification of time is extremely important in incidence. Thus,

$$\text{Incidence} = \frac{\text{No of new cases of the disease occurring during a period of time.}}{\text{No of people who were "at risk" of developing the disease, at the start of follow up}}$$

An epidemiologist must clearly appreciate the difference between incidence and prevalence. The differences are clarified in Table - 5.

**The Relationship between incidence and Prevalence** : If the disease takes a prolonged duration in its natural course (e.g. leprosy), the prevalence will be high despite a low incidence because more and more of the cases will keep on getting added on to the “pool” of disease. On the other hand, if the disease has a short duration (e.g. common cold, most of the acute infectious diseases, etc.), the prevalence will be low despite a high incidence. In fact, the relationship between prevalence, incidence and duration of a disease is so characteristic, that if the conditions are stable, i.e. there has been no change in the natural history of disease due to, say better treatment or better diagnostic facilities and there was no change in the population “at risk” (unlike migration during natural disasters) and the prevalence has been low (i.e. <5%), then,

$$\text{Prevalence} = \text{Incidence} \times \text{Duration} (P = I \times D).$$

**Incidence actually measures the “RISK” of developing a disease** : For example, if we examine 100 patients of viral hepatitis in our medical wards and find that one of them is having clinical evidence of hepatic failure, the prevalence of hepatic failure out of all cases of viral hepatitis is 1/100 or 1%. It is the probability of any patient of viral hepatitis having hepatic failure at any given point of time is one in a hundred (1%). However, it does not mean that only 1% of all patients with viral hepatitis will develop hepatic failure, since some of them might have already died before we did our prevalence study. On the other hand, let us say, we followed up 100 cases admitted, with viral hepatitis, from the day of their admission for a period of one month, and 5 of these 100 patients developed hepatic failure over the observation period of one month. The incidence of hepatic failure among cases of viral hepatitis is therefore  $5/100 = 5\%$  over a 1 month period. We would thus conclude that a patient who is admitted to our medical wards with a diagnosis of viral hepatitis has an overall 5% risk of

<b>Table - 5 : Difference between Incidence and Prevalence</b>		
<b>Point of Difference</b>	<b>Incidence</b>	<b>Prevalence</b>
Numerator	New case of the disease of interest occurring over the defined time	Cases found to be present at the time of study
Denominator	All persons who were “at risk” of developing the disease at the start of follow up	All persons who were examined at the time of study
Relation to time	There is always a specified time period of follow up	No relation to time period of follow up; Cases detected with disease are taken to be at that point of time.
Rate or proportion	It is truly a rate since it relates to a time period of follow up	Is not truly a rate but only a proportion since there is no relation to time
Number of times a subject is examined	Each subject is examined at least twice - once initially to exclude the presence of the disease, so that only those who are “at risk” of developing the disease are followed up and later, at least one more examination of all these subjects being followed up, to see whether they have developed the disease or not. In our above example on measles, each of the 1000 subjects in our study were examined on two occasions - initially, to exclude the 100 subjects who were not at risk of developing measles and, subsequently, at least one more examination of the 900 children being followed up, to find out whether measles occurred during this period or not.	Subjects are examined only once. For instance, in the above example on measles, when we worked out the prevalence as on 1 - 1 - 95, we examined all the 1000 children once, and during this single examination, all those who were found to be having measles (i.e. 10) were included in prevalence (while the process of examining 1000 children would have certainly taken a few weeks or even months, the fact remains that each child was examined only once while we were working out “prevalence”).
Evidence of temporal relationship	Incidence gives a proof of temporal relationship since we start observations at a point of time when the disease had not occurred (only the exposure to suspected risk factor had occurred), and follow up till a later point of time when the disease occurs; thus we are sure that the suspected risk factor actually preceded the disease	Prevalence does not give a proof of temporal relation since both the disease and the suspected risk factor are found to be present at the same point of time. It thus gives an indication of association between the two but we are not sure that the risk factor actually preceded the disease
“Occurrence” (how things came to be) versus “State”(how things are).	By following up the persons from the point of exposure to final occurrence of the disease, incidence tells us as to how the disease occurred, like a video recording. It is therefore very valuable when studying the natural history of a disease, its causes, risk factors, prognostic factors, and therapeutic / preventive modalities.	Prevalence, like a “snap shot photo” shows only the “state”, i.e. how things are? For this reason, it is not very scientific when drawing conclusions regarding natural history of a disease, its causes, risk factors, prognostic factors, and therapeutic / preventive modalities.
Time, money and logistic efforts	Involves high cost and efforts since a large number of subjects have to be examined, assessed on at least two occasions and followed up for a period of time, which, in many diseases could be long.	Results are obtained quickly since only one assessment is done in prevalence study and no follow up is done. For this reason prevalence studies are cheaper, less difficult and quicker.

developing acute hepatic failure over a period of 1 month. Thus it is the incidence (and not prevalence) which gives us the idea of the “risk” of developing a disease (see Box - 1)

### The Two Types of Incidence Measures

Having made a detailed discussion on incidence and prevalence, let us now deliberate upon the two types of measures of incidence used in epidemiology and medical research. These are Cumulative Incidence and Incidence Density.

**Cumulative Incidence (CI)** : Let us take a situation in which the disease is such that the period of follow up required is

short, say, 3 to 5 years (e.g. risk factors / natural history / prognostic factors / therapeutic and preventive trials in case of most of the infectious diseases, obstetric outcomes, pediatric settings, etc.). Secondly, we should be having reasons to believe that the subjects in the sample being studied are fairly ‘stable’. i.e. in general, they will not be leaving the study group during the follow up period and new subjects from outside will not keep on entering the study sample. If these two assumptions can be made then the incidence rate can be measured as “Cumulative Incidence” (CI). The definition of CI is exactly the same as we had used to define “incidence” earlier in this

chapter. i.e.

$$CI = \frac{\text{No. of people who develop the outcome of interest over the specified time period of follow up}}{\text{Total no of people who were "at risk" of developing the outcome at the start of follow up}}$$

The CI gives the “risk” of developing the disease over the specified period of time. In our example on the study of measles, the CI was  $90/900 = 0.1$ , or 10%. This means that a child aged 1 to 2 years, (who is at risk of developing measles) has 10% “risk” or “chance” of developing measles over the next 1 year. Since CI measures the risk, it is also often called as “Risk Rate” or simply as “risk” or “Incidence” in epidemiologic and research terminology.

**Incidence Density (ID)** : Recent advances, following increasing interest in chronic diseases, have been responsible for forwarding the concept of ID. Let us take a disease which takes long time to develop (as CHD, effects of drugs in therapy of cancers etc.) and secondly it is not possible to follow up each and every person till the end point of the predicted period of follow up. Thus a number of subjects will go out of the study group (due to migration, development of the outcome of interest, death, etc.) before the specified period of follow up is completed. Similarly, new subjects will keep on entering the study group as the study progresses. A hypothetical situation that will result is presented in Fig. - 2.

We started the above study to find out the incidence of cervical cancer. Naturally, we started with ladies who were “at risk” of developing the disease. We planned to have a 10 years follow up, from 1.1.80 till 1.1.90. When we started our study we had 5 subjects (subject nos. 1 to 5). In addition, 5 more subjects (subject nos. 6 to 10) entered our study at different points of time.

Subject no. 1 and 2 were followed up till the end (i.e. till 1.1.90), for 10 years each and none of them developed cervical

cancer. Subject no. 3 was followed up for 5 years, when finally on 1.1.85 she was found to have developed cervical cancer. The fourth subject was followed up for 7 years, till 1.1.87, after which she migrated to some other country (i.e. lost to follow up). The fifth subject could be followed up for only one year since on 1.1.81 she died of some other disease (say, vehicle accident). Subjects no. 6 and 7 were enrolled in our study on 1.1.81. The former was followed up for 7 years till 1.1.88; thereafter she emigrated to some other place. The latter was followed up till 1.1.90, i.e. for 9 years and did not develop cervical cancer. The eighth subject entered the study on 1.1.83 and did not develop cervical CA till 1.1.90, i.e. after 7 years of follow up. The ninth and tenth subjects were enrolled in our study on 1.1.84; the former was followed up for 4 years, when on 1.1.88 she was detected to be having cervical cancer, while the latter completed 6 years of follow up till 1.1.90 without developing cervical cancer.

Now, the total time of follow up given by our subjects was  $(10+10+5+ \dots +4+6) = 66$  years (or better called as 66 person years). Out of these 66 “person - years” of follow up, 2 new cases of cervical cancer occurred among our subjects, who were initially “at risk” of developing cervical cancer. The Incidence Density of Cervical Cancer from our study is thus,

$ID = 2/66 \text{ Person years} = 0.03 \text{ per person year}$  (or multiplying by 100, it becomes 3 per 100 PY). (The figure is also written as  $0.03 \text{ per PY}^{-1}$  or as  $3 \text{ PY}^{-100}$ ).

This means that in that particular age group of ladies, there will be 3 cases of cervical cancer if 100 person - years of follow up is done.

ID thus gives the idea of an “instantaneous change” in the rate of a disease at a given point of time, corresponding to the statement “the speed of my car is 60 kilometers per hour” gives an idea of the instantaneous change at which our vehicle is moving. Thus, if we find that the ID of cervical cancer in another country is 6 per 100 person years, it indicates that at any given point of time, cervical cancer is occurring at a much

**Fig. - 2**

Subject No	Follow up details for CA Cervix											Total time of Observation
1	>-----O											10 Years
2	>-----O											10 Years
3	>-----X											5 Years
4	>-----?											7 Years
5	>-----A											1 Year
6	>-----?											7 Years
7	>-----O											9 Years
8	>-----O											7 Years
9	>-----X											4 Years
10	>-----O											6 Years
Year	1980	81	82	83	84	85	86	87	88	89	1990	66 Years
Legend : > = Follow up starts; O = Follow up ends, subject remains without cervical CA; A = Subject died due to some other disease; ? = Subject was lost to follow up; X = Subject developed CA cervix												

faster speed (i.e. twice the speed or rate) as compared to our study population. Thus ID gives the “forces of morbidity” (or mortality) due to a disease at given point of time. ID is also often called as “person - time in epidemiologic practice”. Very frequently, ID is referred to as “Incidence Rate” and sometimes as “Hazard”, since it also gives an idea of the hazard that a subject has of developing an outcome at a given point of time, which we found the ID to be 3 per 100 person years.

Of course, a problem with ID is that the same person - time may be obtained differently. In our above example of cervical dysplasia, such 100 person years could be achieved if 10 ladies are followed up for 10 years each or if 4 ladies are followed up for 25 years each or even if 100 subjects are followed for 1 year only. If a disease has long latent period, as IHD or cancers, the last situation (i.e. following 100 persons for 1 year) may reveal a very low incidence rate because hardly any case would occur in 1 year follow up. The researcher should therefore be careful in deciding what would be the optimum time of follow up required for the particular disease / outcome being studied.

The following example will further help clarifying the difference between CI and ID. Suppose we follow up 2 groups of asymptomatic HIV positive subjects, each group having 50 subjects. All subjects were having CD4 cell count of between 300 and 400 when follow up started. The follow up continued for 3 years. One group was given ART while the other group was given placebo. Different subjects gave us different time periods of observation in both the groups. The hypothetical results are shown in Table - 6.

<b>Table - 6</b>		
<b>Characteristic</b>	<b>ART group</b>	<b>Placebo group</b>
Total subjects	50	50
Total person years of observation	113	61
Total who died of AIDS in 3 years	50	50
CI (Risk of death)	100%	100%
ID (Hazard of death)	44.25 per 100 person years	81.97 per 100 person years

The above hypothetical results indicate the difference between CI and ID. The CI, which is 100% in both the groups indicates that the “risk” that a patient of either of the two groups will die in next 3 years is 100%, whether given ART or not. However the ID is much higher in the untreated group (81.97 per 100 PY), compared to the ART treated group (44.25 per 100 PY). This indicates that patients of such type who are not given ART will die at a much “faster speed or rate” compared to those who are given ART, though at the end of 3 years all would be dead, anyway. The medical researcher should therefore be clear in her mind as to what the objective of her research is? If the overall interest is the overall risk or probability of developing a disease, death or outcome of interest at the end of the follow up period, then CI is the correct measure. On the other hand if the interest is to know as to how quickly the outcome is going to occur, then ID would be the appropriate measure.

**Which incidence measure to use - CI or ID :** In most of the “usual” settings of epidemiology and clinical research, we can reasonably assume that our study subjects form a “fixed, stable population”, i.e. there will be only minimal movements in the form of new entries and exits during the intervening period of follow up. Secondly, in most of the usual medical and health settings, (risk factors for infectious diseases / non communicable diseases which do not take more than 3 to 5 years to develop / pediatric and obstetric studies / drug trials / trials of operative procedures etc.), the period of follow up is not very long, rarely beyond 3 to 5 years. In all such settings, CI is the preferred measure of incidence.

On the other hand, if our epidemiological research work is going to have a prolonged period of follow up because the outcome of interest has a long “latent” or “induction” period, (e.g. IHD, Neoplasms, Stroke, Emphysema etc.) and there is likelihood, as given in the above example, that subjects will keep leaving the study group or keep entering during the intervening period of follow up, then ID is definitely the better measure of incidence.

### **The Two Types of Prevalence Measures**

Like the incidence measures, prevalence measures are also of two types - point prevalence and period prevalence.

**Point Prevalence :** The word ‘prevalence’, as we described earlier, when used in an unqualified manner, refers to “point prevalence”. Thus, the number of cases of the disease refer to a single point of time, though, of course, the actual study on such prevalence may take a long time, may be months or even years. The essential feature is that while the actual process of assessment for presence or absence of the disease in the sample may take many months, the study subjects are examined only once, and the study is deemed to have taken place at a particular point of time. Most of the comparisons in medical research are made using “point prevalence”.

**Period Prevalence :** Period prevalence is actually more of academic importance. It essentially involves calculation of both, the point prevalence at the time of starting the study, as well as the incidence over the subsequent period of follow up. A combination of the initial point prevalence and the subsequent incidence gives us the period prevalence. Since period prevalence is a mixture of two entirely different frequency measures, viz., incidence and prevalence, it is not recommended for scientific research work.

Let us illustrate this with an example. With an interest in Leprosy, we did a point prevalence study on 1.1.94 on a sample of 100 subjects and found that there were 10 patients of leprosy present at that point of time (though the actual conduct of this survey may have taken 1 month, say, from 1 - 1 - 94 to 31 - 1 - 94, but this would be basically taken as a point prevalence as on 1 - 1 - 94). Now, having identified the 10 prevalent cases on 1 - 1 - 94, we followed up the remaining 90 cases (who were at risk of developing leprosy) for a 1 year period, till 31 - 12 - 94. During this 1 year period, 9 new cases of leprosy occurred out of the 90 at risk, while 3 cases out of the 10 cases found on 1 - 1 - 94 died during this period. The findings are summarized below :



(a) Total Sample = 100; (b) Cases found present on 1.1.94 = 10; (c) Persons "at risk" on 1 - 1 - 94 = (a - b) = 90; (d) New cases of leprosy developing between 1.1.94 and 31.12.94, out of (c) above = 9; (e) Old cases of leprosy, out of (b) above who died during the period = 3; (f) Cases of leprosy present on 31 - 12 - 94 = (10 - 3 + 9) = 16.

Thus,

- (a) Point prevalence as on 1 - 1 - 94 =  $10/100 = 10\%$
- (b) Cumulative Incidence for 1 year period of 1 - 12 - 94 to 31 - 12 - 94 =  $9/90 = 10\%$  per year
- (c) Period prevalence = (Initial Point prevalence + Incidence)

$$= \frac{(\text{Cases existing at start} + \text{new Cases occurring during follow up})}{\text{Total population at start of study}} = \frac{(10+9)}{100} = 19\%$$

- (d) Point prevalence as on 31 - 12 - 94

$$= \frac{\text{No. of patients present on 31-12-94}}{\text{Total population present on 31-12-94}} = \frac{(10+9-3)}{(100-3)} = 16/97 = 15.9\%$$

(e) In this example, 3 cases died of leprosy. However, if we could assume that the disease is 'stable' i.e. there are no deaths occurring due to the disease and there is no likelihood of a change in the natural history of the disease in future (e.g. due to possible introduction of an effective therapy), then the prevalence after 5 years, i.e. on 31 - 12 - 1999 can be calculated as follows :

Prevalence = (Incidence X Duration) + Initial Prevalence

Now, Point prevalence as on 31 - 12 - 94 = 15.9% (say, 16%)

Incidence = 10% per year

Duration = 5 years

Thus, prevalence on 31 - 12 - 99 = (Initial Point Prevalence) + (Incidence x Duration) = 16 + (10 x 5) = 66%

(Readers may note that incidence and duration should be measured in the same units of time, e.g. in this case, both are measured in years).

### Comparative Uses of Incidence and Prevalence

Both incidence and prevalence measures have their own utilities, as follows :

**Prevalence** : It is desirable to work out prevalence measures under the following situations :

1. When assessing the "load" of a disease or risk factor in a community or in a health care facility.
2. For planning the health and hospital services.
3. Prevalence helps us in deciding the correct clinical approach, based on the "commonness" as shown by prevalence. For instance, while dealing with a case of "lymphadenopathy", the clinical approach would be towards "tuberculosis" in a developing country, but "lymphoma" in a developed country.
4. Prevalence of a disease helps us in correct application of a diagnostic test. As we shall see later, in the chapter on diagnostic test evaluation studies, the yield of cases in screening of disease is much better when applied in a population which has higher prevalence of the target disease.

5. Prevalence measures help the clinician become aware of new diseases in a population, and the particular age / sex / occupational groups that are involved by those diseases, as HIV, SARS, Legionellosis, Avian Influenza, etc.
6. Prevalence does give an initial idea of some association between an exposure (cause) and an effect (outcome), though incidence is the ideal measures for studying such associations. This is especially useful since prevalence measures, as compared to incidence measures, can be worked out quickly and at little cost. Hence, prevalence measures are good for development of hypothesis regarding a possible exposure - outcome relationship and also for initial exploration of a hypothesis through cross - sectional analytic studies.
7. Prevalence measures are not very useful for final testing of hypothesis regarding a risk factor or the effectiveness of a treatment or preventive modality. They are also not very suitable for evaluation of the natural history of a disease or evaluation of a prognostic factor.

**Incidence** : As compared to a prevalence measure, the epidemiologist should use incidence measure in the following situations :

1. When studying the natural history of a disease (e.g. natural history of the course of HIV infection) or the course of a natural phenomena (e.g. growth and development of children).
2. When evaluating a prognostic factor.
3. When assessing the role of a risk factor in a disease, especially after initial prevalence studies have given an indication of an association.
4. When evaluating the effectiveness of a treatment modality.
5. When evaluating the effectiveness of a preventive modality.
6. When evaluating the effectiveness of a screening programme.

### Summary

In epidemiology and medical research, a large amount of data is collected, in respect of the various variables for a large number of subjects who have been studied in the epidemiologic or research work. This large collection of information, known as the "data set" has a lot of information in it but conveys no meaning to the medical fraternity, unless the information is reduced to certain "summary figures" for drawing conclusions from the data.

When talking of the summary figures, the first pitfall which every epidemiologist and researcher should guard against is that comparisons or conclusions should never be made based solely on numbers, since this may be quite fallacious. Scientifically speaking, the numbers counted in epidemiology should be reduced to some frequency measure, by putting these numbers so counted as the numerator and relating this numerator to a denominator. The final summary figure would firstly depend on the scale on which the outcome variable has been measured. If the outcome was measured on a discrete or continuous variable, the summary figure would be a "Mean"; it would be a "Median" if the outcome variable of interest was

measured on a numerical - ordinal scale, while it would be a “frequency” measure (like a percentage or a fraction) if the outcome was measured on a qualitative scale.

Now, depending on the choice of the denominator the frequency measures could be of 3 types, viz., “ratio”, in which the numerator is not included in the denominator; “Proportion” in which the numerator is included in the denominator; and, “rate” in which besides the numerator being a part of denominator there is also a specification of time over which the numerator (i.e. the disease or the outcome of interest) has occurred.

The two major types of frequency measures used in epidemiology and medical research are “Incidence” and “Prevalence”. Incidence is defined as the new cases of a disease (or any other specified outcome of interest) which occur over the specified period of follow - up, out of those who were initially at risk of developing the outcome. On the other hand, prevalence is defined as the total number of subjects who are found to be present with (i.e. having) the disease, out of the total examined at that point of time. Incidence gives us the “risk” that a person has of developing the disease over the defined period of follow - up; prevalence tells us the probability that a person would be found to be having the disease at that point of time. Incidence is truly a rate while prevalence is not a rate but rather a proportion.

Incidence has the advantage that it gives us an estimate of the ‘risk’, is ideal for evaluation of natural history of a disease, its risk factors, prognostic factors, preventive modalities and therapeutic regimens, and tells us as to “how” the disease develops over time. However, it takes long time to measure, is costly and logistically difficult. On the other hand prevalence gives us quick and cheap results and is quite good for obtaining data for planning the health and hospital services and for generation of hypothesis as well as “quick - initial testing” of hypothesis regarding risk factors, prognostic factors, treatment and preventive modalities. However, prevalence data is quite often biased due to the type of people who survive with the disease, whether they are in the remission stage and does not prove that the cause actually preceded the effect; hence prevalence is not the ideal measure for inferences regarding the role of a risk factor, prognostic factor, treatment modality or a preventive regimen, for which only incidence can give the final and accurate answer.

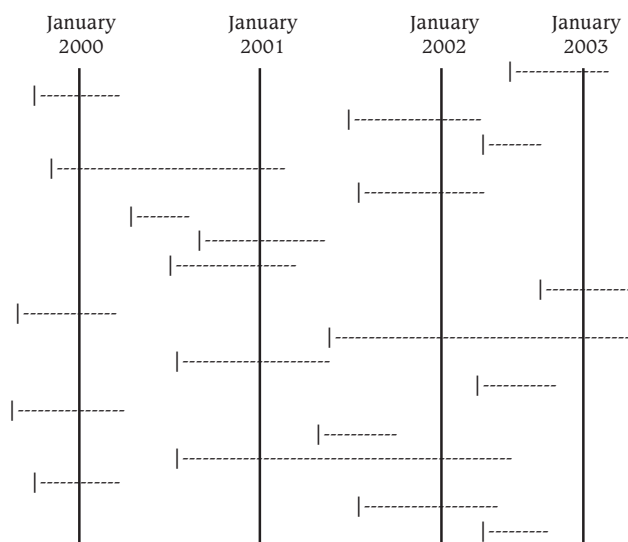
Incidence measures can be further of two types, viz., the Cumulative Incidence (CI), also known as “risk”, or “risk rate” and is measured as has been described for incidence above. The other incidence measure is the “Incidence Density” (also called as hazards or incidence rate or force of mortality or morbidity) in which the denominator is the “person - time” instead of “number of persons at risk” which is the denominator in CI. Similarly, prevalence measures can also be of two types, viz., point prevalence, which is same as we have defined prevalence as above and secondly, period prevalence (which is not much used), which is the initial point prevalence plus the incidence over a defined period of time.

## Study Exercises

### MCQs and Exercises

**Problem-1** : A researcher followed up a group of pregnant ladies from the date of registration in the ante - natal clinic, till delivery. She measured the haemoglobin level as well as also the height. Ladies were divided into low maternal height (145 cms or less) and normal height (> 145 cms). The birth weight of the new born was also measured and divided as normal weight (2500 gms and above) or low birth weight (< 2500 gms). In addition, the APGAR score of the newborn and the fact whether the mother had Antepartum haemorrhage (APH) or not was also recorded. Which summary measures should she use to finally describe her findings as regards the undermentioned variables (you can select your answer out of the following options - Mean, Median, Prevalence, Cumulative Incidence). (a) Maternal Haemoglobin (b) Mothers with low maternal height (c) APGAR Score (d) Whether APH occurred (e) Children delivered with low birth weight.

**Problems - 2 to 5** : The figure below depicts the occurrence of Tuberculosis (TB) (Pulmonary and Extra - pulmonary) in a population of 100 subjects with HIV infection treated at a research hospital over a four - year period. During the observation period, the population remains stable (i.e. no members die, move away, or refuse to be examined at the beginning of every year).



- What is the prevalence of TB in January 2000? : (a) 5 / 100 (b) 8 / 100 (c) 5 / 95 (d) 8 / 95 (e) 5 / 92
- What is the prevalence of TB in January 2002? : (a) 5 / 100 (b) 9 / 100 (c) 5 / 95 (d) 5 / 80 (e) 9 / 80
- What is the three - year CI of TB for the period January 2000 to January 2003? : (a) 20 / 100 (b) 15 / 100 (c) 20 / 95 (d) 15 / 95 (e) None of the above
- What is the CI of TB for the year 2002? : (a) 5 / 100 (b) 5 / 85 (c) 5 / 95 (d) 10 / 85 (e) None of the above

(Incidentally, if you are asked “what was the period prevalence for the period January 2000 to January 2002?” Now period

prevalence = (prevalence at start + new (incident) cases during the period) divided by total population at start. The prevalent cases at start (Jan 2000) were 5. 5 new cases each occurred in period Jan 2000 to Jan 2001 and in period Jan 2001 to Jan 2002. thus, period prevalence =  $15 / 100 = 15\%$  .

**Problem - 6 :** Calculate the incidence (specifically as Cumulative Incidence or else Incidence Density) in following situations :

- (a) In a study of IHD, 100 subjects not having any evidence of IHD at the start of follow up, were followed up. The study started on 01 January 1997. The subjects entered the study at different points of time and were followed up till they developed IHD, or died of some other cause, or were lost to follow up or the date of 01 January 2007 was reached, on which day the study ended. Out of these 100 subjects, a total of 10 cases of IHD occurred from 500 person - years of follow up.
- (b) In an outbreak of measles in a primary school, 50 of the children developed measles over the next 20 days. It was also found out that out of these 200 children, 60 had already suffered from measles earlier while another 65 had already been immunised against measles much earlier.

**Problems 7 - 10 :** Trishul estate is a tea plantation community with a population of 99,000. Its residents can be divided into three age ranges : 25 - 44, 45 - 64, and 65 and older - each comprising one third of the population. In 2007, 100 cases of hepatitis E occurred in Trishul Estate and were traced to the consumption of water contaminated with sewage due to cross - connections between water pipe lines and sewer trunks. Of these 100 cases, 20 between the ages of 25 and 44, 10 between the ages of 45 and 64, and five over the age of 64 ultimately proved fatal. Prior to 2007, Trishul had never reported a case of hepatitis E.

7. What is the year 2000 disease specific mortality rate for hepatitis E in Trishul? : (a) 350 per 10000 residents (b) 1.01 per 10000 (c) 3.54 per 10000 (d) 1.06 per 10000 (e) Cannot be determined from the data
8. What was the incidence of hepatitis E in 2007 (assuming that no cases of the disease occurred in Trishul prior to 2007)? : (a) 0.00101 (b) 0.00035 (c) 0.35 (d) 0.04 (e) Cannot be determined from the data
9. What is the age - specific mortality rate for residents (per 10,000) over 64 years of age? : (a) 3.03 (b) 4.55 (c) 6.06 (d) 3.54 (e) 1.52
10. What is the case - fatality rate (per 10,000 residents) for hepatitis E? : (a) 3.03 (b) 3.54 (c) 350 (d) 1.01 (e) Cannot be determined from the data

**Problem - 11 :** If 20 guests arrive every day in a hotel and each guest stays for 5 days, how many guests will be there on the tenth day.

**Problem - 12 :** A prevalence survey conducted from 1st January to 31st December 2007 in a large metropolis of 2 million population, identified 1000 cases of schizophrenia. Earlier data

shows that the incidence rate of schizophrenia in this city is 5 per lac per year. You can assume that cases of schizophrenia have a fairly long life and the population of the city is fairly fixed with little inward or outward migration.

(a) what percentage of the 1000 cases detected in 2007 would have been newly diagnosed in 2007? (b) what would be the possible duration of schizophrenia?

**Answers :** (1) (a) Mean Hb% (b) Prevalence of mothers with low maternal height (c) Median APGAR score (d) Cumulative Incidence of APH during pregnancy (e) Prevalence of low birth weight at delivery (2) a; (3) a; (4) d; (5) b; (6) (a) Incidence Density = 10 per 500 PY or 20 per 1000 PY or 0.02 per PY or 0.02 PY - 1 (b) Cumulative Incidence = No. developed the disease over the period of follow up / No. at risk at start of follow up =  $(50) / \{ 200 - (60+65) \} = 50 / 75 = 66.7\%$ ; (7) c; (8) a; (9) e; (10) c;

**The clarifications for solution 7 to 10 :** Because Trishul estate did not report a case of hepatitis E prior to 2007, all 99,000 residents were at risk for dying from the disorder at the beginning of the follow - up period. During 2007, 35 deaths from hepatitis E occurred. The 2007 hepatitis - E specific mortality rate is therefore  $35 / 99,000 = 0.000354$ , or 3.54 deaths per 10,000 residents. The population at risk for contracting hepatitis E at the beginning of 2007 (assuming no prior cases) was 99,000. During the one year observation period, 100 individuals contracted hepatitis E. The cumulative incidence (CI) of hepatitis A in 1990 was therefore  $100 / 99,000 = 0.00101$  (i.e. 10.1 cases per 10,000 residents). An age specific mortality rate refers to the death rate within a specified age group. Five deaths from hepatitis E occurred in 2007 among the 33,000 residents over the age of 64. The age specific mortality rate for this group is therefore  $5 / 33,000 = 0.000152$ , or 1.52 per 10,000 residents. The case fatality rate is the proportion of cases that ultimately result in death. Thirty - five deaths occurred among the 100 cases of hepatitis E in 2007. Thus, the case fatality rate is  $35 / 100 = 0.35$  or 35% or 350 deaths for every 1000 cases of hepatitis A.

(11) The problem pertains to the relationship between incidence and prevalence in a stable state, which is given by the term  $P = I \times D$ . In this problem, the incidence is 20 per day and the duration is 5 days. We need to work out the prevalence. This would be  $20 \times 5 = 100$ . Note that on days 1, 2, 3, and 4, this equation will not hold since the number of guests on these days will be 20, 40, 60 and 80 respectively. (12) (a) Since the incidence is 5 per lac, therefore, out of the population of 2 million in the city, 100 new cases would have been newly occurred in one year (2007), which is 10% of the 100 cases detected by the prevalence survey. (b) Duration = Prevalence / Incidence. The prevalence was 1000 per 2 million or 50 per lac. Incidence was 5 per lac per year. Hence average duration of schizophrenia is 10 years.



As said earlier, “data” means an organised collection of individual measurements for each subject, in respect of every variable of interest. Once this data has been collected, collated and “summarised” it is called “Information”. Thus, information is a “factual presentation” i.e. a “Summary of facts” from the data and as they exist without any added element of interpretation of facts. Once this information is viewed and evaluated against the backdrop of a given “socio - demographic” setting by experts in their respective fields, it becomes transformed into what is called as “Intelligence”. Finally, intelligence is viewed against various socio - economic and political considerations and depending upon the priorities allocated by the society and government, a “policy” is finally developed. Obtaining data, in epidemiologic practice, may take either of the two modalities. Firstly, the investigator may decide on the epidemiologic or research question, select an adequately large and representative sample, and collect the data by making measurements on each subject, herself. This situation, when the data is collected by the investigator primarily for the purpose of the epidemiologic study is called “primary data”. In most of the medical research work, primary data is generally collected, specifically suited for the research question. Sometimes, in public health work, the epidemiologist resorts to collection of primary data, by means of surveys, to make a community diagnosis and for planning the health care services, especially if no data is available from any other source.

However, often the epidemiologist, especially in public health care, cannot be so idealistic but rather has to be more realistic. She may have to depend on various “other” sources of information as information on a wide variety of subjects is needed (Box - 1).

Getting information on all these aspects, by resorting to primary data collection, may be an impossible task. Moreover, it would be a tremendous waste of money and resources. In such situation, the epidemiologist utilizes the data which has been collected for some other purpose, and is already available at other places. Such method is called “secondary data” analysis. In the present chapter, we would have an overview of the various common sources of obtaining such secondary data for community health care. Such sources of information can be those as shown in Fig. - 1 (39).

The “individual data” and “aggregate data” are two different entities. Let us say, we collected information from hospital records (case sheets and autopsy reports) from patients of oral cancer, regarding their tobacco chewing habits and show that 80% of the oral cancer cases gave history of oral tobacco use. This data, though secondary data, is apparently coming from individual persons and is an example of individual data. On the other hand we may collect information about oral cancer cases from cancer registry in a state and tobacco sale from the excise department and show that districts which have high sale of tobacco also have higher incidence of oral cancer.

This data is not from individuals but is rather an aggregate of data, and is referred to as aggregate data. Aggregate data is frequently used while undertaking ecological (correlational) type of epidemiological studies which is discussed in detail in another chapter.

#### Box - 1

Minimum Information required by a Public Health Specialist in most Settings

**General Information** : Location, Governmental and Societal patterns, geographical and topographical features, roads & other communications, languages, physical and climatic characteristics of the block / district.

**Socio - demographic profile** : Population size, age & sex constitution, distribution of population in different areas of the district, fertility indicators, growth rate, education, occupations and economic strata.

**Morbidity and Mortality** : Incidence or prevalence of mortality, morbidity and diseases with epidemic potential; demographic indices as infant mortality and maternal mortality rates.

**Health Related indicators** : water supply, disposal of excreta, housing patterns, food availability.

**Health Services** : Strength and location / distribution of various categories of health care personnel, governmental and non - governmental; availability, location and adequacy of health care supplies, equipment and other logistics.

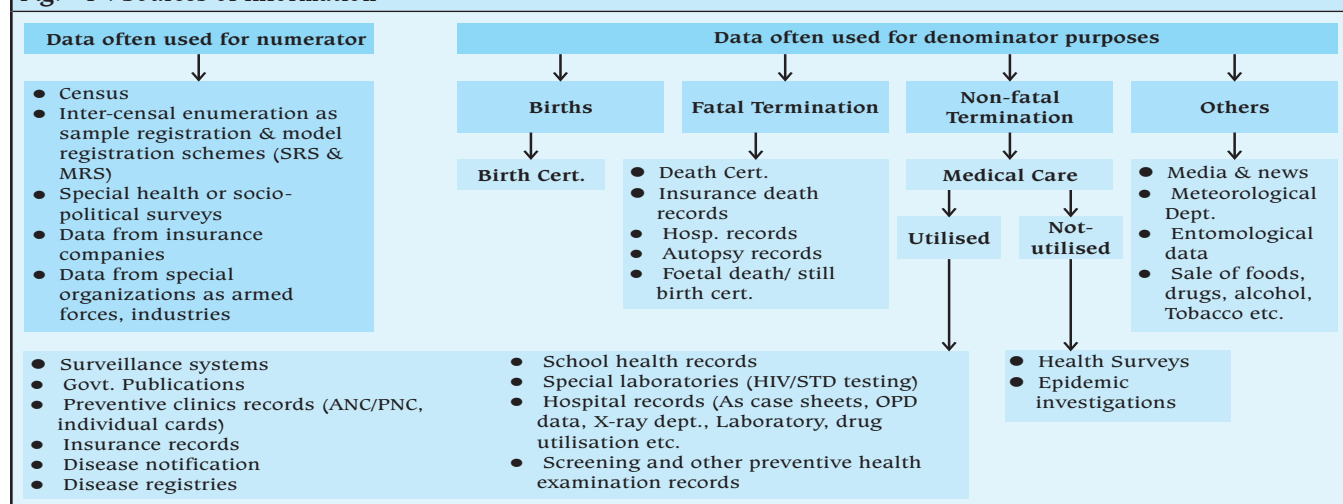
**Preventive / Promotive Health programmes** : Availability, locations and adequacy of major programmes as immunization, HIV - AIDS / TB / ARI / Diarrhoeal diseases / malaria control programmes.

#### Census

Census means “to enumerate”. It consists of a sequence of activities concerned with collection, collation and factual presentation of data pertaining to social, demographic and health related factors, in respect of a nation (or large population group), undertaken periodically, and having some sort of statutory back - up for it to be undertaken. A census, in essence, gives the information, regarding the size and composition of a population, the forces that determine such size and composition, and the trends anticipated in future. The periodicity of census is generally kept as once in ten years, and it is generally undertaken during the first quarter of the first year of the decade. The amount of data collected may vary, from as little as population size and age / sex structure on one end to a large number of social, economic, demographic and health related variables on the other end; however, a fairly developed census mechanism would usually provide information regarding total population, density according to per square kilometers of land area, decadal growth rate, literacy rate, economic conditions, occupational characteristics, and selected indicators of mortality like overall death rate and infant mortality rate. A legal authority constituted by the government is generally made responsible for the collection, collation and publication of census data. There are two general



**Fig. - 1 : Sources of information**



methods of collection of data in a census :

**(a) de - facto method** : Persons are enumerated according to their location at the time of enumeration. This method is used in developing countries like India.

**(b) de - jure method** : This method is used in developed countries like U.S.A. The persons are assigned according to their “usual” place of residence and not according to their location at the time of census, as practiced in de - facto method. This method provides a better indication of permanent population and related socio - demographic factors of an area, though it is more expensive and needs much better level of training of census - data collectors.

### Indian Census

In India, the activity of census started in 1881 and is carried out once in ten years, during the first quarter of the first year of the decade (i.e. 1981, 1991, 2001, and so on). The census is an official task under the authority of the Census Commissioner of Govt of India, with adequate legal backing provided by the census Act - 1948. Census 2001 was carried out in two phases - the house numbering and the house listing operations followed by population enumeration. If we talk of the last census, the house listing operation was conducted in during April to September 2000. In addition to collecting data on characteristics of the house, information on availability on certain amenities and assets were also collected during this phase. The population enumeration was undertaken between 9th and 28th Feb 2001 with a revisional round from 1st to 5th March. The “census moment”, i.e. the referral time at which the snapshot of the population is taken was 00.00 hours of 1st Mar. 01. For the first time during census 2001, permanent location code numbers were assigned to ensure comparability of the data at the village & other administrative levels. Special features of Census 2001 included additional collection of data on drinking water (within premises/outside premises), source of lighting, availability of toilet facility within the house and type, number of married couples living in the household having independent room for sleeping, disposal of waste water, availability of separate bathroom and kitchen etc. For the first

time during this census, the signature/thumb impression of the respondent was taken. The salient findings are shown in Box - 2.

<b>Box - 2</b>	
<b>Population</b>	
Total population	1,027 million
Total increase in population since last census	180.6 million
Annual growth rate	2.1% (it was 2.5% for last 30 - 40 yrs)
Children in the age group 0 - 6	15.42 % (17.94 % in 1991)
<b>Population Density</b>	
	324 persons per sq km (267 in 1991)
	Highest density : 9,294 persons per sq km (Delhi)
<b>Sex ratio</b>	
	933 females per 1000 males (927 in 1991)
<b>Overall Literacy</b>	
Male literacy rate	65.4 % (52.2 %in 1991)
Female literacy rate	75.8 % (64.1 %in 1991)
	54.2 % (39.3 %in 1991)

### Sample Surveys

In sample surveys, instead of covering the whole population as is done in census, only a sample, which is representative of the population, is studied and inferences about the population strength and composition are made. Sample surveys are quite relevant in underdeveloped countries where full fledged census is not possible; they are also useful in countries where census mechanism is present because they give interim information without waiting for the census which is generally done after 10 years. Sample surveys are retrospective in nature, in which the trained data collectors ask the selected households about events (usually births and deaths and other selected events) for a defined period of recall, usually kept as 1 year form the date of interview. The important forms of sample surveys in India

are the Sample Registration System (SRS) and the National Sample Survey (NSS).

**SRS** : The SRS is undertaken under the authority of the Registrar General of India. At present there are more than 3,700 sample units, each consisting of a set of villages and urban blocks. Each rural sampling unit has a complete village (subject to maximum population of 1500) while each urban sampling unit is equivalent to an urban census enumeration block with population of 750 to 1,000. As of now, the SRS has more than 6670 sampling units, including 4435 in rural and 2235 in urban areas, covering a sample population of almost 6 million population.

SRS is based on a system of double recording method. The first part of record collection is done by a part time enumerator (usually the local school teachers) in his or her area. In the second part, once in six months, an official from the SRS department, who is a full time enumerator independently collects data on these aspects from all the households in the sample villages and urban blocks. Each independent full time enumerator is in charge of about 6 sample units. The two sources of information are cross checked and the data which does not match or only partially matches is then actually verified in the field. Before the entire process of survey is launched, an initial baseline collection of data is undertaken which includes listing and numbering of houses and basic socio - demographic information as name, age, sex and marital status.

The reports of findings are published as annual report and half - yearly bulletins, which provides the age and sex structure of the population, fertility indicators and age and sex specific death rates.

**NSS** : The NSS functions under the National Sample Survey Organisation (NSSO), Govt of India. The NSSO undertakes surveys, usually on an annual basis, and provides useful information on one particular aspect of social, demographic or health issue in a particular survey; for example, the survey during 1995 - 96 provided information on medical care and ageing, and during 1998 on hygiene and sanitation, besides other useful information.

**The Rapid Household Survey (RHS) and the Facilities Survey (FS), under the Reproductive & Child Health (RCH) Programme** : These two surveys are being conducted as an ongoing component of the RCH program. The RHS is undertaken in all districts of our country, from women in the age group 15 to 44 years, from about 1000 selected households in both urban and rural areas of each district, with a view to obtain information on the coverage of ante - natal and immunization services, method of deliveries, contraceptive use and intentions to use contraceptives, utilization and satisfaction from health services and knowledge about RTIs and HIV / AIDS. The sample households and eligible couples for the survey are selected as a multistage random sample, selecting districts in the first stage, villages / urban blocks in the second and the households in the third stage. The FS is carried out to assess the availability of trained personnel and manpower, and the utilization of these facilities at PHC, CHC, First Referral Unit (FRU) and District Hospital level. In states with population more than 20 million, the FS in one district every month, while for states with population between 5 and 20 million it is carried out in one

subdivision of a district every month. For UTs it is carried out in one block of a district every month.

## Vital Statistics

Vital statistics means the ongoing recording of all vital events' such as births, deaths, marriages etc. Registration of Births and Deaths is a legal requirement in our country.

**(a) Death Certificate** : It is one of the most important source of information about the distribution of a number of diseases. The death certificate as recommended by the WHO is depicted in the example in Box - 3. The standard death certificate has two parts. Part - I requires the cause of death to be filled up. Cause of death is defined as "morbid condition or disease process leading directly or indirectly to death". It does not mean the mode of dying as "heart failure" "asphyxia" "Hepato - renal failure" "circulatory collapse" etc. In part - I, there are usually three lines. Here, the particular cause which started the final chain of events should be entered in the bottom most line, and this is taken to be the cause of death; on the other hand, the condition in the chain of events which finally directly led to death is shown in the top most line.

<b>Box - 3 : Death Certificate</b>
<b>PART I</b>
<b>Disease Or Condition Leading To Death</b>
(a) Pulmonary Embolism
<b>Due to or as consequence of</b>
(b) Pelvic Vein Thrombosis
<b>Due to or as consequences of</b>
(c) Septic Abortion
<b>PART II</b>
<b>Other significant conditions contributing to death but not related to the disease causing it.</b>
Non Insulin Dependent Diabetes Mellitus

In the example given above, the patient had septic abortion which is entered in the bottom line of part - I and will be taken as the cause of death during compilations. This led to pelvic vein thrombosis which finally led to pulmonary embolism directly leading to death (note that cardio - respiratory failure is not entered as the final cause since it is the "mode of dying"). In this part II, NIDDM is entered as a significant condition contributing to death but not related to the disease causing it (i.e. septic abortion). In addition to entering the cause of death correctly, the international classification of Diseases (ICD) number of the particular cause should be entered. The problem with death certificates, regarding cause of death, is the inaccurate/incomplete filling of certificates as also inadequate reporting to the relevant statistical authority. This aspect must be especially considered if comparisons regarding cause of death are being made between two countries or areas.

While utilizing death certificates as a source of data, the epidemiologist should keep a guard against certain biases that may occur, as follows

- Diseases that are rapidly fatal, or have high "Case fatality ratio", or the ones which can be diagnosed with relative

ease (as oral cancer, pulmonary tuberculosis, etc.) are most likely to be accurately recorded in the death certificate, while diseases like chronic bronchitis may not be so well recorded.

- Diseases which have a long time between onset and death (as chronic leukaemia) may not be entered and another more acute cause as pneumonia may be entered instead.
- Diseases that are apparent (as melanoma skin) are more likely to be entered as compared to carcinoma of pancreas.
- Diseases which carry stigma (as AIDS, suicide) are less likely to be entered as a cause of death.
- Very often, the physician who has actually been caring for the patient and knows the totality of her medical background, may be different from the one who actually prepares or signs the death certificate (often, in a hospital, the death certificate is prepared by the duty nurse and signed by the casualty medical officer).
- Diagnostic fads may occur in a state or a country, e.g. chronic bronchitis could be more popular in one country and emphysema in the other.
- Availability of diagnostic procedures or introduction of a new diagnostic procedure may make a difference all of a sudden, as regards the causes of death.
- The elderly often die of multiple pathologies but generally only one cause of death is entered.

**(b) Birth Certificates** : These are useful for epidemiologic research as well as health services management; they provide a denominator data for calculating various important rates IMR, MMR, etc. Ideally, a birth certificate should contain information about date, place of birth, details of parents, domiciliary/institutional birth, sex of newborn birth attendant's details, type of delivery and complications if any, age of mother and birth order of the child.

**(c) Other vital events** : These include registration of marriages and divorces; reporting of still births; and reporting of foetal deaths.

### Health Surveys

Health surveys are an important source of reliable health information. Such surveys may be directed towards a particular disease (e.g. sample survey for TB); or general health surveys directed towards specific population groups like a cluster of villages/ a tribal area/school children; or surveys concerned with planning and evaluation of health services in the form of survey committees appointed by the Government or private agencies to evaluate health programmes or assess general health situations and needs; or surveys directed towards determinants of health, like dietary surveys or air/water pollution surveys. Surveys provide valuable information for planning/evaluation of health services/programmes; for identifying community needs; for providing information about available health manpower and other resources; for suggesting "hypothesis" regarding individual or community risk factors; and for providing statistics for public health/educational programmes. A paradigm situation can be quoted regarding the "National Health Survey" of USA.

In India, the National Family Health Survey (NFHS) is an important step for generating epidemiologic information. The

NFHS - 3 has provided information on population, health & nutrition in India as a whole and each of its 29 states. The main objectives of NFHS are

- to collect data at the national and state level on demographic rates pertaining to fertility, IMR, PMR, and reproductive health patterns
- to measure prevalence of contraceptive practices
- to collect and analyze data on HIV/ AIDS related behaviour
- to collect and analyze data on health of slum populations.

The survey is based on a sample of households which is representative at the national and state levels. Total of 10.9 million households including 19.8 million men and women were interviewed using the method of multistage sampling, the sample being selected in two stages. Three types of questionnaire were administered in NFHS : The village questionnaire to collect information about basic health care and education facility; the household questionnaire to collect general data about household and women's questionnaire for eligible women from household sample. The findings of NFHS - 3 revealed that knowledge of HIV/ AIDS among men and women was found to be 80% and 57% respectively. In general, knowledge found to be much better in urban setup rather than rural areas. Some findings regarding key indicators are shown in Table-1.

Table - 1 : Important findings of NFHS - 3		
S. No.	Indicators	Fig-ures
1.	Total Fertility Rate	2.7
2.	Institutional Deliveries (%) last 3 yrs	41
3.	Contraceptive Use (%) (Currently married woman (15 - 49 yrs)	56
4.	Childhood Immunization & Vitamin A supplementation (12 - 23 months fully immunized children)	43.5
5.	Children under 3 yrs who are underweight (%)	45.9

### Disease Notification and Registration

At the international level, cholera, plague and yellow fever are notifiable to the WHO under International Health Regulations. In addition, Malaria, Rabies, Salmonellosis, Influenza, Polio, Epidemic (louse borne) Typhus and Relapsing Fever are subject to international surveillance. Similarly, under the National Integrated Disease Surveillance Programme (NIDSP), a number of diseases have been made notifiable in our country. The general problems with notifications and registrations of diseases is the inadequacy in respect of complete coverage and the delay in initiating the notification report. However, it may be mentioned that even though under-reporting is common, still one can always monitor the trends and take action to prevent/control impending epidemics, using such information.

### Disease Registries

A disease registry keeps a record of salient features of the cases suffering from a particular disease in a defined population or geographical area. It also helps in monitoring trends of a disease. Population based as well as hospital based cancer



registries have been established quite methodically in many countries over the world, including India (40). In India, registration of cancers is being undertaken under the overall auspices of the ICMR, as a part of the national Cancer Control programme and publishes valuable data on the occurrence of cancers in our country.

### Information from Special Populations

Some groups have well maintained and extensive health data (e.g. uniformed services, factories, mines, occupational groups, Insurance policy holders, persons covered by various health insurance programmes etc.). However, one must remember that these groups have special characteristics and it may be difficult to apply the findings regarding health status and its determinants on the general population.

### Records of Hospitals and Health Services

In developing countries with inadequate notifications of morbidity and mortality, hospital records are important tool for the epidemiologist as well as the health administrator. Even in countries with a well developed system of notification, hospital records are often used for epidemiological assessments and clinical research. In addition to hospitals, records from other health services (national health programme offices, Community/Primary Health centers) also provide valuable data. There may be a large number of sources of epidemiological data within the hospital/health centres and the investigator would need to decide the relevant sources depending on the objectives. However, the important inpatient sources are : Hospital admissions and discharges book and discharge slips, case sheets for indoor patients, Reports and returns raised by the hospital as an administrative requirement, Laboratory investigation registers, especially microbiology department, Registers and log books of radiology department, "Health cards" issued by hospitals/health centres to patients, as Ante Natal / Post Natal cards, under fives card and so on, OPD records and emergency department records, Records of specialized clinics as diabetes clinic, Birth and death certificates, Immunization and other preventive health care activities records, Data on drug inventory, and, Autopsy reports.

**Advantages and Disadvantages** : Data from hospitals / health centers has its own advantages as well as disadvantages which have been reviewed in detail by Masi (41). The advantages are that hospital data can be utilized very appropriately (in fact, it may be the only available data at times) in the following epidemiological situations

- For establishing "sentinel surveillance". The classical example is sentinel surveillance of Acute Flaccid Paralysis (AFP) and other vaccine preventable diseases
- To study the risk factors/etiology/treatment of rare diseases, since these are very likely to be admitted to the hospital, but very difficult to search in the community.
- To establish "Registries". The classical example is Cancer Registries, registration of Stroke, IHD, Congenital malformations, and so on.
- During the initial stages of establishing a "surveillance" system to monitor the "trend" of a disease and to give early warning of an epidemic
- For studies into the epidemiology of hospital acquired

infections.

- For studies into the planning and evaluation of hospital/ health centers services as well as for planning of "satellite" hospitals and outreach centers/ super specialty centers.
- For studies on "adverse drug reactions" and "drug resistance patterns".
- For epidemiological studies of "delayed effects of medical treatment".
- For epidemiological studies on Diagnosis, Prognosis and Therapy
  - Performance of diagnostic tests
  - Trial of new drugs/treatment modalities
  - Studies on prognosis of a disease
- For studies of natural history of a disease since patients admitted to the hospital generally represent the serious form of the spectrum and thus help in completing the entire picture of natural history of disease
- When a case control study is being planned, especially if the disease is rare or effects of multiple exposures are being studied.
- For undertaking "Retrospective Prospective Studies" starting from hospital records. (See chapter on cohort studies for further details).

There are, of course a number of disadvantages in hospital/ health centers data and the epidemiologists should be careful about these. The major disadvantages are :

- The patients in a hospital are generally not completely representative of the general population for several reasons like
  - a. Accessibility - The hosp may not be accessible to all because of distance, communication problems or ability to meet the hospital cost.
  - b. Utilisation - The catchment area population may not be equally utilizing the health services of hospital because of attitude towards health services or behaviour of hospital staff.
- Hospital patients represent the survivors and not those who have died due to the disease, and those who died may be systematically different from those who have survived.
- The patients admitted to hospital represent only 'severe' part of the spectrum. If a disease has a wide spectrum (as low backache) then the mild and asymptomatic cases may not be found in the hospital.
- Data which is recorded in forms and case sheets may not contain the information which is actually required by the epidemiologist.
- In case sheets there is hardly any 'structuring' of format of recording the details. Thus, the epidemiologist may have to sift through large volumes of information to get the few pieces of information actually required by her.
- Problems of disclosure of identity of the patients may come up. Moreover, the hospitals generally give permission to utilize/scrutinize their record only after great difficulty.
- Going through the records, particularly hand written case sheets, may be a very tedious job. However, if the hospital records are automated, it may be helpful.
- The diagnostic capabilities of different physicians within the hospital may be different and hence biases due to over/



under - diagnosis.

**How best can we utilise hospital/ health centre data for epidemiological purpose :** As we have seen, hospital/health centre data plays an important role in epidemiological practice; however it has its own advantages and disadvantages. Hence, whenever we wish to utilize hosp/health center data for epidemiological purposes, we must work out as to how best we can utilize this so that it remains 'adequate' and 'accurate' (i.e. has internal validity) as well as 'generalisable' (has external validity). At the outset, we should analyze for 'appropriateness'. Such appropriateness may be

- **Appropriateness in the hospital**
  - (a) Within the hospital, use multiple sources of information, as, besides, case sheets also see records of x - rays and laboratory reports.
  - (b) Try to get an approximate idea about the population base that hospital is serving so that the disease frequency can be calculated. Try to relate this with local census data.
  - (c) Take a group of hospitals at different levels (primary/secondary/tertiary) in an area rather than only one hospital.
- **Appropriateness of the disease**
  - (a) Prefer data for diseases which are commonly treated in hospital (e.g. cancers, acute MI, etc.)
  - (b) Prefer data on diseases which are clearly defined diagnostically (e.g. fracture of tibia on x - ray) rather than vague ones (e.g. chronic fatigue syndrome)
  - (c) Prefer data which has been obtained in the hospital as a part of sentinel surveillance of diseases, for disease registry, for hospital acquired infections and drug reaction.

### Epidemiological Surveillance Data

Ongoing surveillance systems are generally built up in the various national health programmes. Such data can be used for calculating the incidence of the particular disease by relating it to population size being served by the surveillance system. Similarly, 'sentinel surveillance' data from selected hospitals can be utilised for various epidemiological purposes. Detailed discussion on epidemiological surveillance has been made in another chapter in this section. In India, vast amount of information is available from Integrated Disease Surveillance Programme (IDSP) from NICD, Delhi and the State / district headquarters.

### Health Related Publications

A number of publications are available which are rich sources of health related information at all levels : state, national and international levels. The Ministry of health & Family Welfare, publishes an annual report "health information - India" which gives details of various causes of morbidity, mortality and health services in the country. Similarly, the ICMR, the Director General of Armed Forces Medical Services, DGHS Govt. of India, and the State Health Directorates publish their respective annual reports. On the International level, The WHO, the UNICEF and the CDC Atlanta bring out various publications as MMWR, Weekly Epidemiological Reports, Report on the state of health of world's children, and so on which can be gainfully utilized.

### Other Sources of Information

Depending on the information needs, the epidemiologist may need data from the meteorological / environmental departments; from governmental offices regarding availability of medical/paramedical manpower and available training facilities; or data of controlled drugs and their utilization may have to be obtained from the relevant Drug Controller's office.

### Summary

In most of the real life situations of epidemiology as applied to public health, the epidemiologist may not be able to collect the data for the purpose of his epidemiological requirements, as is often done in most of the clinical research settings. Rather, the epidemiologist has to obtain information from sources which have already collected the data, albeit with some other objective. Such data, which has not been collected for the purpose of one's epidemiological study, but has rather been collected with some other purpose, is called "Secondary Data". The advantage of such secondary data is that since it is already available, it minimizes the cost and also ensures quick decision. However, the disadvantage is that since the data has not been collected for the purpose of present epidemiological study, it may not have information on many aspects, may be incomplete and may lack adequate coverage. The common sources of secondary data in our country are :

Census, Sample Registration Scheme, Model Registration Scheme, Death Certificates, Registration of Marriages, Records available from various Govt hospitals and Primary / Community Health centres, School Health Records, Industrial Health Records, Records of Armed forces Medical Services, Data from various National Health Programmes, Cancer Registry Programme, Reports of Notifiable diseases, Integrated disease Surveillance Programme - from NICD and state / district headquarters, Reports from Public Health laboratories of States, Reports from Laboratories of special institutions as NICD, NIV, NIN, etc., National Sample Survey Reports, National Family Health Survey Reports (NFHS), Records of special clinics and surveillance centres as STD clinics, VCTC / ICTC, Ante - natal clinics, etc., Special survey reports as National Tuberculosis Survey, etc., Health Information - India and other Publications by various Governmental and Private offices, Reports of Epidemic Investigations, News broadcasts, news magazines and newspapers.

### Study Exercises

#### MCQs & Exercises

1. Miss 'ABCD', a 15 years old girl child, daughter of Mr. 'XYZ' resident of 24 - B Indra Colony, Pune was a case of rheumatic mitral stenosis with mitral regurgitation. The child developed fever and was admitted to the district hospital. On examination, she was found to have fever, irregular pulse, tender splenomegaly, BMI of 16.5 and splinter hemorrhage in the nails. After 3 days she developed edema feet, engorged neck veins and ascitis. The child died on 13 Aug 05. The attending physician filled up the cause of death as 'cardio respiratory failure'. Comment on the cause of death and fill up a draft death certificate.
2. The national tuberculosis survey was undertaken with the objectives of finding out the magnitude of problem

of tuberculosis in the country and the high risk groups. Trained investigators collected data from randomly selected households. This was an example of : (a) primary data collection (b) secondary data analysis (c) aggregate data analysis (none of the above)

3. What is the best routinely available source of data for the following : (a) Cancer morbidity in India (b) Accidents in Dhanbad coal mines (c) Incidents of malaria in a district in a year (d) Possible impending out break of meningococcal meningitis (e) 5 leading causes of death in a state (f) Decline in female : male ratio
4. Encircle all the possible advantages that death certificates have, in our country, as a source of epidemiological information : (a) There is a uniform national law for enforcing filling of death certificates (b) The cause of death is usually confirmed by autopsy (c) The ICD system of cause of death has remained constant over last 50 years (d) Nearly all deaths are recorded (e) The personal physician of the deceased has to complete the death certificates based on his own knowledge of past illnesses of the deceased.
5. How will you go about organizing the following information: (a) Incidence rates of breast cancers in Mumbai (b) Incidence rate of acute appendicitis among residents of Pune during 2007 (c) The prevalence rate of osteoarthritis among women in Delhi (d) Changes in blood pressure level as age advances, among army officers (e) Deaths due to Road Traffic Accidents in Lucknow during 2004
6. Which of the following statements are true for YPLL (more than one statement can be true) : (a) It is a probability statement (b) It is a measure of premature mortality (c) It is used to determine the major causes of death in a population (d) It can be used to compare premature

mortality in different segments of the population.

7. Which of the following statements are true for certificate of registration of death (more than one statement can be true): (a) It is the basis for making policy decisions regarding allocation of finances to various health programmes (b) It is issued by the treating physician (c) It is legal requirement in our country (d) It is a basis of important vital statistics.
8. The referral date for Indian census 2001 was (a) 1st April 2001 (b) 1st Feb 2001 (c) 1st March 2001 (d) 1st Apr 2000.
9. The sex ratio is described as (a) Females for every 1000 males (b) males for 1000 females (c) fraction of females divided by males (d) fraction of males divided by females
10. The greatest advantage of hospital data is : (a) Incidence rates can be calculated (b) Diagnosis recorded is quite accurate (c) Clinical research can be undertaken (d) all patients of fatal diseases will definitely be admitted.

**Answers :** (1) The entry was wrong since cardio - respiratory failure indicates a mode of dying and not a cause of death. The death certificate should have been filled as : Congestive Heart failure, due to or as a consequence of Sub Acute bacterial Endocarditis, due to or as a consequence of Rheumatic Mitral valve Disease; (2) a; (3) (a) Annual report of National Cancer Registry Program (ICMR) (b) details of Claims submitted under Workmen's compensation Act (c) records of District malaria Officer (d) Annual Health Report issued by the State health directorate (e) Census. (4) a, d; (5) (a) Numerator data from cancer registry program office at Mumbai and denominator data from census bureau (b) numerator data from all government and private hospitals in Pune and denominator data from local census office (c) sample survey of middle aged / elderly women in Delhi (d) Individual Health record cards of the Army Officers (e) From the office of Police Chief of Lucknow district. (6) b and d are correct. (7) c and d are correct. (8) c; (9) a; (10) b.

## 18 Measures of Association & Effect

*RajVir Bhalwar*

In the previous few chapters we have seen that the epidemiologist or researcher specifies the "variables" which are of interest to her in the research question, specifies the "scales of measurement" of these variables, collects the "data" on the variables as per the scale of measurements and finally, the data is reduced to summary figures as mean, proportions or rates (incidence, prevalence). The conclusions which the researcher would derive would be in the form of the following statements, shown as hypothetical example :

- The average serum homocysteine among patients of IHD

was found to be 14 mcg/dl. Thus, patients with IHD have a high serum homocysteine; hyperhomocysteinaemia, therefore, MAY be important in the etiology of IHD.

Our results, in the form of summary statements, given above, thereby "describe" the phenomena of interest (raised homocysteine in IHD, etc.). In addition, they help us to develop certain guesses or hypothesis about "cause and effect" relationship, e.g. "serum homocysteine, if raised MAY have a role in the etiology of IHD".

However, mark the word "MAY". While we do get an indication that possibly a cause and effect relationship may be existing, i.e. we are able to develop a hypothesis, however, it is no proof of the cause and effect relationship. So what if the mean serum homocysteine in IHD patients is 14 mcg / dl ? For all you know, it may be 15 mcg / dl among healthy people of the same age

group! In that case, nobody would agree to an etiologic role of serum homocysteine in IHD.

Thus, it is logical that once we have summarized our data in the form of summary expressions like “mean”, “prevalence” or “incidence”, we are able to “describe” the phenomena of interest and also develop certain “hypothesis” regarding possible “cause and effect” relationship. However, the final proof of such hypothesis will involve a “COMPARISON”, wherein we would have to prove that the phenomena observed (e.g. homocysteine among IHD patients be 14 mcg/dl) is really “outstanding”. In that while the levels are high in IHD cases, it is low in normal population. In other words, our summary measures of disease frequency (incidence or prevalence) help us develop a hypothesis; to finally accept or reject such hypothesis, we have to proceed with “comparative measurements”. Once we compare the disease frequency (incidence or prevalence) among two such groups, we get another “summary expression” which tells us the extent of “association” or “effect” or “risk”; this is the topic of deliberations in the present chapter.

### **The Preliminary Method of Making “Comparisons” : Looking for Significant Difference**

The measurements in respect of various variables can be made, in general, on either of Numerical - Continuous, Numerical - Discrete, Numerical - Ordinal, or else on Categorical scales (Qualitative) (of which the Dichotomous scale is the most common). Depending on the type of scale that has been used, the comparisons between two groups can be made as follows :

**(a) When the variables have been measured on a numerical continuous or numerical discrete scale** : Take an example of an epidemiological question for studying whether breast CA is related to the number of living children (a numerical discrete variable) born to the lady. In such a study, we could take two groups of ladies, one having breast CA and the second group not having the same (to serve as “comparison” group). We would then take the history of number of live births from all the subjects and work out the average number of children in both groups. Using the procedure explained later in the chapter on testing the difference between means, in the section on statistics, we would compare the two groups by a ‘t’ test to see whether the average number of children in breast CA group is “significantly different” from the healthy group.

To answer the research question regarding role of serum homocysteine (a numerical - continuous variable) in the etiology of IHD, we would take a group of IHD patients, measure their serum homocysteine. Similarly measure serum homocysteine of a group of well matched healthy subjects (who do not have IHD). Carry out a ‘t’ test to see whether the average serum homocysteine level in IHD patients is “significantly different” from that of healthy subjects.

**(b) When the variables have been measured on a Categorical (Qualitative), i.e. Dichotomous or Polychotomous scale** : Let us take up an example of whether Streptococcal sore Throat (SRT) is a precursor of Acute Rheumatic Fever (ARF). We would pick up, say 100 children who have suffered from SRT and another 100 who have not; we would then follow up the 2 groups for a reasonable period to see how many in each group develop ARF. Let us say 20 children in the sore throat group

and 10 in the other develop ARF. We would now convert these numbers into a measure of disease frequency (i.e. 20% and 10% respectively) and compare the two groups to see whether this difference in the two proportions is “significant” or not, using a Chi - square test or a test for the difference between proportions, as explained in the chapter for testing the difference between proportions.

### **Limitations of Tests for Difference between Means, Medians or Proportions**

The problem with the ‘t’ test, Mann Whitney U test or Chi - square test for seeing the difference between means, medians and proportions is that they only test a hypothesis (i.e. the research hypothesis which says that there is a difference versus the null hypothesis which says that there is no difference). This is explained in detail in the section on statistics. However, such hypothesis testing procedures based on critical level of p - value (usually 0.05) do not tell us anything, about the “magnitude of association or effect”. We will clarify this with an example. Let us say, in the sore throat - ARF study quoted above, we found 20% of the children with sore throat and 10% of the children in the other group developed ARF. Apparently, the incidence of ARF was two times higher among children who had suffered from sore throat (20% compared to 10%). A Chi - square test would tell us that the incidence of ARF is “significantly” more among sore throat group as compared to the other group

Assume the incidence to be 40% and 10%, and not 20% and 10% as mentioned earlier. In this situation the incidence of ARF is “4 times more” among the sore throat group (instead of only 2 times more which was found earlier). However, a Chi - square test would even now only tell us that the incidence of ARF is significantly higher in sore throat group, a result which it (Chi - square test) had given us in the earlier situation also. Thus, significance testing for difference between means, medians or proportions using ‘t’, non - parametric or Chi - square tests, only test a hypothesis which says that one of the two means / medians / proportions is significantly higher (or lower) than the other. However, these tests do not tell us the “magnitude”. For answering these two extremely important questions, we have the measures of “Effect”.

### **Measures of Effect**

The 2x2 table is formed when the “exposure” (i.e. cause) variable and “outcome” (effect) variable take a dichotomy of either absent or present. On the axis of exposure, we have two categories : exposure present (E +) and exposure absent (E -). On axis of outcome, we have, outcome present (O +) and outcome absent (O -). The typical 2 x 2 table is shown in Table - 1 :

To answer whether smoking is a risk factor for IHD, assume that a study was started with 5000 healthy adults and IHD was excluded at the start by means of relevant diagnostic work - up. These 5000 subjects were interrogated about smoking habits (exposure); it was found that there were 1500 smokers (E +) and 3500 non smokers (E -). These two groups (E+ and E -) were then followed up for 10 years to see whether IHD (the outcome) developed (O +) or not (O -). It was found that out of 1500 smokers (E +), 150 developed IHD (E + O +) while 1350 did not (E + O -). On the other hand, out of the 3500 non



smokers (E - ), 175 developed IHD (E - O +) while 3325 did not (E - O - ). The typical 2 x 2 table can be constructed as shown in Table - 2 :

Table - 1			
Exposure (or cause)	Outcome (or Effect)		Total
	Present (O +)	Absent (O -)	
Present (E +)	a	b	a + b
	(E + O +)	(E + O -)	(all E +)
Absent (E -)	c	d	c + d
	(E - O +)	(E - O -)	(all E -)
Total	a + c	b + d	a + b + c + d
	(all O +)	(all O -)	(grand total = n)

Table - 2			
Smoking (Exposure)	IHD (Outcome)		Total
	Developed (O +)	Did not Develop (O -)	
Present (E +)	150 (10%)	1350 (90%)	1500 (100%)
	a	b	a + b
Absent (E -)	175 (5%)	3325 (95%)	3500 (100%)
	c	d	c + d
Total	325	4675	5000
	a + c	b + d	a + b + c + d

The heart of the 2 x 2 table has 4 “cells”, represented by ‘a’, ‘b’, ‘c’ and ‘d’ as follows :

a = Subjects who have both the exposure as well as the outcome, i.e. E + O + (e.g. all those smokers who develop IHD, i.e. 150 in above example).

b = Subjects who have only the exposure but not the outcome, i.e. E + O - (e.g. all those smokers who do not develop IHD, i.e. 1350 in above example).

c = Subjects who do not have the exposure but develop the outcome, i.e. E - O + (e.g. all those non smokers who developed IHD, i.e. 175 in the above example).

d = Subjects who do not have the exposure and also do not develop the outcome, i.e. E - O - (e.g. all those non smokers who develop the outcome. i.e. 3325 in the above example).

a+b = Total number of subjects who have the exposure, irrespective of whether they develop the outcome or not, i.e. E+ (e.g. all smokers, whether they developed IHD or not, i.e., 1500).

c+d = Total number of subjects who do not have the exposure, irrespective of whether they develop the outcome or not, i.e. E - (e.g. all non smokers, whether they developed IHD or not, i.e. 3500).

a+c = Total number of subjects who developed the outcome, irrespective of whether they had the exposure or not, i.e. O+

(e.g. all those who did develop IHD, whether they used to smoke or not, i.e. 325).

b+d = Total number of subjects who did not develop the outcome, irrespective of whether they had the exposure or not, i.e. O - (e.g. all those who did not develop IHD, whether they used to smoke or not, i.e. 4675).

a+b+c+d = The grand total of all subjects studied (or simply “n”) (e.g. 5000 in the present example).

**Note :** Often in epidemiological and research parlance, the terms “exposure”, “predictor”, “independent” and “cause” variable are used interchangeably; similarly, the terms “outcome”, “effect” and “dependent” variable stand for the same meaning.

## Relative Risk

The above 2 x 2 table tells us that the incidence of IHD (over a 10 year period) was 10% among smokers (150 out of 1500) while it was 5% among non smokers (175 out of 3500). This can also be taken as the risk of developing IHD.

When asked if smoking is a risk factor for IHD, your answer, almost instantly, would be “yes, it is two times more among smokers”. You are correct. This conclusion of “two times” more is arrived at by simply dividing 10% by 5%. “Incidence of the outcome (IHD) among those with the exposure (smokers)”, (i.e. 10%) is divided by the “incidence of the outcome (IHD) among those without the exposure (non - smokers) (i.e. 5%). This equation is the Relative Risk (RR) or the “Risk Ratio”. Thus,

$$RR = \frac{\text{Incidence of outcome among those having the Exposure (I}_E\text{)}}{\text{Incidence of outcome among those not having the Exposure (I}_O\text{ or I}_{NE}\text{)}}$$

More precisely, if we are measuring Cumulative Incidence (CI), then we would write  $CI_E$  and  $CI_O$ ; while if we are measuring Incidence Density (ID), then we would write  $ID_E$  and  $ID_O$ . In certain texts on Epidemiology, “Risk Ratio” is taken to indicate the ratio of  $CI_E$  and  $CI_O$  while “Incidence Rate Ratio” or “Hazards Ratio” is taken to mean the ratio of  $ID_E$  and  $ID_O$ .

The Relative Risk (RR) gives an idea of the number of times that the Incidence is likely to be more among those who have the exposure compared to those who do not have the exposure. An increasing value of RR indicates increasing quantum of risk. If the RR is very high (say, 5 or more), we are convinced that, particular exposure carries a very high risk of the outcome to develop. In other words, higher the RR, there is a higher likelihood of an association between the exposure and the outcome. The RR indicates, in addition to the magnitude, the “strength of association” between an exposure and the outcome variable.

**What happens if the RR is equal to one or less than one ?** : Let us change the findings of our study on smoking - IHD association a little, and assume that the findings were as per Table - 3.

**Here the incidence of IHD among smokers as well as non smokers is 10% each (RR = 10% / 10% = 1). Thus the incidence (i.e. Risk) of developing IHD among both, smokers and the non smokers is the same.**



<b>Table - 3</b>			
Smoking	IHD		Total
	Developed	Did not Develop	
Present (100%)	150 (10%)	1350 (90%)	1500 (100%)
	a	b	a + b
Absent (100%)	350 (10%)	3150 (90%)	3500 (100%)
	c	d	c + d
Total	a + c	b + d	a + b + c + d
	500	4500	5000

Consider yet another situation that could occur (Table - 4)

<b>Table - 4</b>			
Smoking	IHD		Total
	Developed	Did not Develop	
Present (100%)	150 (10%)	1350 (90%)	1500 (100%)
Absent (100%)	700 (20%)	2800 (80%)	3500 (100%)
Total	850	4150	5000

Here the RR would be  $10\% / 20\% = 0.5$ . The data would indicate that if one smokes, the risk of getting IHD is 10%; on the other hand if one does not smoke, the risk is 20%. Smoking thus reduces the risk of getting IHD by half. If RR is less than 1, it indicates declining risk, i.e. a protective effect. With the above finding of RR as 0.5, we would say that smoking protects against IHD by 50%. (i.e. reduces the risk of IHD by half). Moreover, farther the RR is from one (towards zero), more is the strength of this protective association.

The interesting part of this scale of RR is that with a null value of 1, while the increased risk ranges on a very wide gradient of more than one to infinity (if incidence in exposed group is 100% and in unexposed it is 0%, the RR will be  $100\% / 0\% = \text{infinite}$ ); however, on the protective side it can range only in a narrow range from zero to one (in the most protective situation, the incidence among exposed group can be 0% while in the non - exposed group may be 100%; thus, RR in this extreme situation would be  $0\% / 100\% = 0$ ).

### How to Estimate the “Risk” When We are Doing Our Research “The Other Way Round” : The Odds Ratio

The examples we just discussed were the ideal settings of research in which we start from a point when the outcome (e.g. IHD) has not occurred and we follow up the subjects forward (a group with the exposure and not having the outcome when we start, i.e. at risk of developing the outcome and another group not having the exposure and also not having the outcome).

Scientifically ideal though it may be, such “forward proceeding” research has its own drawbacks too, as we shall discuss in detail in a later chapter on architecture of epidemiological

designs. In short, it needs a very long time of follow up (may be 10 years or even more) which may be logistically difficult. Such research also needs a large number of subjects to be followed (usually in thousands) for that long a time, thus making such research very costly and tedious.

For these reasons, a good alternative is to do this research the “other way round”, i.e. instead of starting from a point when the outcome has not occurred and then proceeding into the future, we could pick up some subjects in whom the outcome has already occurred and a comparison group in which the outcome has not occurred, and compare these two groups regarding the history of exposure. For example, we can take 50 persons diagnosed with IHD and 50 without IHD, obtain the history of smoking during past 10 years from them and set the data into the following 2x2 table (Table - 5).

<b>Table - 5</b>			
History of Smoking (Exposure)	IHD (Outcome)		Total
	Present	Absent	
Present	25 (50%)	17 (34%)	42
	a	b	a + b
Absent	25 (50%)	33 (66%)	58
	c	d	c + d
Total	50 (100%)	50 (100%)	100
	a + c	b + d	a + b + c + d

The above setting is the classical “case control study” which, we shall discuss in another chapter. Apparently, this 2 x 2 table may appear to be similar to those presented earlier. However, there are many fundamental differences. The most important difference is that in the present setting we are not following up, in a FORWARD manner, the 2 groups of subjects (smokers and non - smokers developing or not developing IHD); but since the outcome (IHD) had already occurred, we are picking up “samples” of cases and healthy persons (50 each) and going BACKWARD from outcome to exposure. Thus we cannot calculate the “incidence” of IHD in smokers and non - smokers as  $a/(a+b)$  and  $c/(c+d)$  respectively. Since incidence cannot be calculated, the RR too cannot be calculated.

Another parameter, the Odds Ratio (OR) can be calculated from a case control study. The OR is a valid estimator of the RR as it gives as a reasonably accurate idea of the RR. However, for the “valid estimator” concept to hold good, there are two assumptions which should be met with :

- The outcome, i.e. the disease of interest (e.g. IHD in this case) should be a ‘rare disease’, i.e. the incidence of the outcome should be  $<5\%$  in the total population. Luckily, most of the human diseases are uncommon ones, with this parameter of  $<5\%$ .
- The “controls” i.e. the comparison group (the 50 healthy persons) should be “representative” of the same total population that gave rise to the “cases”.

The odds ratio in a case control study is calculated by the

equation :

$$OR = \frac{(E+O+) \times (E-O-)}{(E+O-) \times (E-O+)} = \frac{(a \times d)}{(b \times c)} \quad (\text{also called "cross product ratio"})$$

(where a, b, c and d are the 4 cells described earlier in this chapter, in the form of E+O+, etc.). In our present example, the odds ratio

$$= \frac{(25 \times 33)}{(17 \times 25)} = 1.94$$

And since the OR is a valid estimator of RR, we would conclude that the risk of IHD due to smoking is 1.94 times as compared to non - smoking.

The odds ratio in a case control study basically measures the "exposure odds ratio". To clarify the aspect, let us once again draw the 2 x 2 table (Table - 6).

Table - 6			
Total Exposure	Outcome (Diseases)		Total
	Present	Absent	
Present	a	b	a + b
Absent	c	d	c + d
Total	a + c	b + d	a+b + c+d

The "odds" of a case being "exposed" = Ratio of "exposed" cases to "non - exposed" cases = a/c and similarly, the odds of a control being exposed = b/d. Thus, the "Ratio" of the "odds of exposure among cases" to "odds of exposure among controls"

$$= \frac{a / c}{b / d} = \frac{(a \times d)}{(b \times c)} = OR$$

Technically speaking therefore, the odds ratio from a case control study means that the "odds" of cases being exposed are "so many times higher" compared to the "odds of controls being exposed". In our above example, the correct interpretation of OR = 1.94 is that a case of IHD is 1.94 times more likely to be having the exposure (i.e. history of smoking) as compared to a person not having IHD. However, if the 2 assumptions, enumerated above are met, the OR approximates the RR and so we conclude that the risk of IHD is 1.94 times more if one smokes.

### Interpreting Increase or Decrease in RR or OR in Terms of Multiples or Percentage Change

There are various ways, in which the RR or OR may be interpreted. An RR or OR of 1.5 means "one and a half times increase in risk" (of getting the outcome when exposure is present as compared to when exposure is not present). It also means the risk is increased by 50% among those with the exposure as compared to those without the exposure. An RR or OR of 0.33 means that the risk is only one - third among those who have the exposure as compared to those who do not have the exposure; it also means that the risk among the exposed is only 33% as compared to those not having the exposure; it also means that there is a 66% decline in risk when exposure is

present; it can also be interpreted as that there is a two - third reduction in the risk, if exposure is present. In general, if we have to calculate the percent increase (or decrease) in risk for a given value of RR (or OR), the general equation is :

**"Percentage increase or decrease in risk among the exposed group = {(RR or OR) - 1} X 100"** (where the symbol ≈ means "difference, ignoring the minus or plus sign"). Thus if OR is 1.85, the percentage increase in risk will be (1.85 - 1) X 100 = 85%; if RR is 0.4 the % decrease in risk will be (1 - 0.40) X 100 = 60%. Similarly if RR is 8, it would also be stated as an increase in risk by 700%.

## The Measures of Differences in Risk

The measures of "effect", i.e. "risk ratios" that we have discussed till now were RR and OR in a case control study. They are extremely important measures of the "strength of association" between an exposure and its suspected outcome. The further the RR (or OR) is from the value of one, the more confident we become about a "cause and effect" relationship, be it regarding risk factors for a disease, or prognostic makers, or evaluation of efficacy of drugs, vaccine or any other therapeutic/ preventive procedure. For example, if the RR (or OR) of lung cancer due to smoking (as compared to non - smokers) is 5, we are quite confident of the role of smoking as an important risk factor in lung cancer.

But the measures of "risk ratio" (RR or OR) do not tell us anything about one aspect - "how much more" (though they answer the issue "how many times"). If the cost of a brand new music system is five times more than a second hand one, you may start considering buying a second hand one only; however, if we tell you that the cost of the brand new system is Rs. 2500 and that of second hand one is Rs. 500, you may rethink in terms of buying the brand new one itself because while the cost of buying the brand new system is five times more but the absolute difference is Rs. 2000 only. On the other hand, if a brand new car costs Rs. 5 lakhs, while a second hand model costs Rs. 2.5 lakh, the cost of a brand new model is only 2 times of the second hand one, but one may still think of buying the second hand model, because the absolute difference is, in this situation, Rs. 2.5 lakh. Let us look at this situation from a clinical point of view, by browsing at the hypothetical data shown in Table - 7 :

Table - 7			
		Incidence per lakh population per year	
		Lung CA	IHD
a)	Among Smokers	10	250
b)	Among Non - Smokers	1	125
	RR for smokers (a / b)	10	2
	Absolute difference (a - b)	9 per lakh	125 per lakh

Apparently, with a relative risk of 10, there is little doubt that smoking is a very important "cause" of Lung CA. However, if we examine the above data from a slightly different perspective, we will find that if smokers were to stop smoking, it will result

in a decrease of 9 cases of Lung CA per lakh population, but the same action will result in a decrease of as much as 125 cases of IHD per lakh population. Thus, while smoking may not be a very strong causal factor for IHD (as much as it is for lung CA), the amount of difference that it is going to make on public health will be tremendous for IHD but meager for Lung cancer.

### Measures of Risk difference (impact) in a forward study

In a hypothetical data set of typical “forward - moving” study, we studied a sample of 60,000 male subjects, aged 40 - 49 years, who were initially free of IHD. Further, out of these 60,000 subjects, 20,000 were smokers and 40,000 were non - smokers. We followed up all these subjects for a period of 10 years, looking for the development of IHD. The results are presented in Table - 8.

Table - 8			
	Developed IHD	Did not develop IHD	Total
Smokers	400	19600	20,000
Non Smokers	400	39600	40,000
Total	800	59200	60,000

From Table - 8, Incidence of IHD among those “exposed” to smoking and “not exposed” can be calculated as :

$$I_e = 400 / 20,000 = 0.02 \text{ (or 2\%)}$$

$$I_o = 400 / 40,000 = 0.01 \text{ (or 1\%)}$$

$$RR = I_e / I_o = 2\% / 1\% = 2$$

**(a) Measure of Absolute Effect** : The difference in two incidence rates therefore gives us the “absolute effect” and is measured in terms of “Attributable Risk” (AR). Truly and very technically speaking, the absolute effect should be more appropriately called as Absolute Risk Difference (ARD) or simply as Risk Difference (RD); this RD can be either “Absolute Risk Reduction” (ARR) or else an “Absolute Risk Increase” (ARI), depending upon whether the risk (incidence) is increasing or decreasing in one group, as compared to the other. The AR or RD is defined as the difference between the incidence among exposed group ( $I_e$ ) and the incidence among unexposed group ( $I_o$ ). Thus,  $AR = I_e - I_o$ . In our example,  $AR = 0.02 - 0.01$  (or 1%). We would describe this finding as “there is likely to be one ‘additional’ case of IHD among every 100 smokers as compared to 100 non smokers”.

**(b) Measures of Attributable Fractions (Impact)** : These are of the following categories : Attributable fraction for exposed; and, population attributable risk. We deliberate on these in the succeeding paragraphs.

**i) Attributable Fraction for Exposed (AF<sub>e</sub>) (Syn, Etiologic Fraction (EF), Etiologic Fraction for Exposed (EFE), Attributable Risk Percent (AR%))** : This is calculated as :

$$AF_e = \frac{(I_e - I_o)}{I_e} \times 100$$

Now, dividing both the numerator as well as the denominator by  $I_o$ , we get

$$AF_e = \left[ \frac{\frac{I_e}{I_o} - \frac{I_o}{I_o}}{\frac{I_e}{I_o}} \right] \times 100$$

Now, since  $(I_e/I_o) = RR$

$$AF_e = \frac{(RR - 1)}{RR} \times 100$$

In our example above, RR was 2, thus,

$$AF_e = \frac{(2 - 1)}{2} \times 100 = 50\%$$

The  $AF_e$  tells us as to what percentage of the load of outcome among the exposed is because of the exposure; in other words, it tells us that if all the exposed people were to give up their exposure, then it would result in so much percentage reduction in the outcome among the exposed group. To simplify this statement, in our example, this means that 50% of the IHD load AMONG SMOKERS is due to smoking. If smoking is given up by SMOKERS, a 50% reduction in IHD AMONG SMOKERS will be obtained.

The limitation of AR% is that it tells us the quantum of reduction in the disease that would be achieved in the “exposed” group if “exposure” was given up by them. However, it does not tell us about the reduction that will occur in the “total population”. It would be noted that, as health administrators, we would be also interested in the possible reduction in IHD that would occur in the total population (consisting of a mixture of smokers and non - smokers) if this total population stops smoking, and not only in the reduction in IHD that would occur among smokers if they stop smoking (which is the AR%). This difficulty is overcome by calculating the PAF or else PAR%, which we shall now discuss.

**ii) Population Attributable Risk Percentage (PAR %) (Syn. Etiologic Fraction in Total Population (EFTP))**

The PAR % is given by the equation

$$PAR \% = \frac{P_e \times (RR - 1)}{1 + [P_e \times (RR - 1)]} \times 100$$

In our example on smoking - IHD association;  $P_e = 0.33$  as calculated above;  $RR = 2$

$$PAR \% = \frac{0.33 \times (2 - 1)}{1 + [0.33 \times (2 - 1)]} \times 100 = 24.8\% \text{ (25\% approx.)}$$

The PAR % can also be worked out using another equation, namely,

$$PAR \% = \frac{PAF}{I_t} \times 100$$

Where, PAF = Population Attributable Fraction as described above, and  $I_t$  = Incidence of the disease in the total reference population. In our example, the representative sample of 60,000 subjects showed that 800 cases of IHD developed over a 10 year period. Thus,  $I_t = 800 / 60,000 = 0.0133$  over a 10

year period.

$$\text{Thus, PAR \%} = \frac{0.0033}{0.0133} \times 100 = 24.8\% \text{ (25\% approx.)}$$

Another equation for calculating PAR% is  $\text{PAR\%} = \{(I_t - I_o) / (I_t)\} \times 100$ , where,  $I_t$  = incidence in the total population and  $I_o$  is the incidence in the non - exposed group. In our example,  $I_t = 800 / 60,000 = 0.0133$  (or 1.33%) and  $I_o$  was  $400 / 40000$ , i.e. 0.01. Thus,  $\text{PAR\%} = \{(0.0133 - 0.01) / (0.0133)\} \times 100 = 24.8\%$  (25% approx.). This means that if cigarette smoking is one of the causes of IHD, then about 25% of all IHD in the total reference population can be prevented if smoking is completely stopped by the entire reference population.

**iii) Population Attributable Fraction (PAF) :** For details of this particular measure of risk difference and its calculations, readers are suggested to consult one of the books quoted in further suggested readings, at the end of this chapter.

**(c) Preventive Fractions :** The term Preventive Fraction (PF) is used as a replacement of Attributable Fraction for exposed (AR %), when the exposure is protective, i.e. reduces the risk of outcome. For example, if “physical exercise is the “exposure” and IHD is the “outcome”, then the incidence of outcome (IHD) in the exposed group (doing physical exercise) will be lesser than the incidence in non - exposed group (not doing physical exercise). In such a case, the RR will be less than one (protective RR). Now if we calculate the AR % in this case using the equation

$$\text{AR\%} = \frac{I_e - I_o}{I_e} \times 100$$

Then the AR % will come out in negative sign (since  $I_e$  will be lesser than  $I_o$ ) and will cause difficulty in interpretation. One way of sorting out this problem is to put the “risk increasing” factor as the “exposure”, e.g. in this case we can take “Lack of Physical exercise” as the exposure, in which case the RR will be more than one and this difficulty will be sorted out. However, often for reasons of clinical interpretation we may feel that this may not explain our findings well. For example, we may feel that it is better to put the things as “If physical activity is promoted, it will lead to a decrease in IHD by 50%” rather than putting it like “If *lack of physical activity* is removed, it will lead to a reduction in IHD by 50%”. In such cases, Preventive Fraction (PF) is calculated as

$$\text{PF} = \frac{I_o - I_e}{I_o} \times 100$$

The use of PF becomes most apparent in trials of vaccines where it is also called as “Efficacy of Vaccine” (EV) and is measured as :

$$\text{PF(EV)} = \frac{\left[ \begin{array}{l} \text{Incidence in Unvaccinated (I}_o\text{)} \\ - \text{Incidence in Vaccinated (I}_e\text{)} \end{array} \right]}{\text{Incidence in Unvaccinated (I}_o\text{)}} \times 100$$

As a hypothetical example, in a study on the association between physical activity and IHD, presence of regular physical exercise was defined as the exposure variable (E+), while those not undertaking regular exercise were taken as (E-) . It

was found that the incidence of IHD among those who were physically active (E+) was 4% (0.04 as a fraction out of one), over 10 years of follow up, while the incidence among inactive (E - ) was 10% (i.e. 0.1). The PF in this example is  $\{(0.1 - 0.04) / (0.1)\} \times 100$ , i.e. 60%. The interpretation is that there will be a reduction of IHD by 60% among those who are physically inactive if they become physically active.

### Calculation of Measures of Differences from a “Case Control” Study

As we would recall that in a case control study, we cannot calculate the incidence and hence we cannot calculate the RR. What we can do is that we can calculate the Odds Ratio (OR) which is a valid approximation of (i.e. almost as good as) the RR, and thus, it gives us an approximate idea of the “risk” due to the exposure of interest. Since the measures of “risk difference” that we have discussed above involve calculation of RR, a direct calculation of these measures of difference in a case control study is difficult. However, certain methods have been devised by which we can calculate the measures of difference from a case control study also, basically by using the concept that OR from a case control study is approximately equal to the RR.

Let us consider another hypothetical example of a case control study which was undertaken to study the risk of Thrombo - Embolism (TE) due to Oral Contraceptive (OC) use. 100 ladies suffering from TE were taken from a hospital (cases) and another 200 healthy ladies of same age who had not suffered from TE were also taken up for comparison (controls). History of intake of OC was obtained from all the 300 subjects. The hypothetical data is as per Table - 9 :

Table - 9			
History of OC Intake	TE Cases	Controls	Total
Present	42	38	80
Absent	58	162	220
Total	100	200	300

Now, in the above data set,

$$\text{OR} = \frac{(a \times d)}{(b \times c)} = \frac{(42 \times 162)}{(38 \times 58)} = 3.09$$

Since OR is approximately equal to RR, we can conclude that the risk of getting TE is more than 3 times higher among OC users as compared to non - users. Now, the measures of difference can be calculated as follows :

**(a) Attributable Fraction for Exposed (AF<sub>e</sub>) (Syn - EF; EFe; AR %) :** We would remember that earlier we had calculated the AR% as :

$$\text{AR\%} = \frac{(RR - 1)}{RR} \times 100$$

and since OR is approximately = RR, therefore,

$$\text{AR\%} = \frac{(OR - 1)}{OR} \times 100 = \frac{(3.09 - 1)}{3.09} \times 100 = 67.64\%$$

This means that 67.6% (i.e. more than two thirds) of



Thromboembolism among OC users is because of OC use; if OC users give up its use, then there will be a 67.6% reduction in TE among them (of course, the remaining 32.4% TE will still remain because of causative factors other than OC use).

**(b) PAR % from a case control study :** In a forward type of research, calculation of PAR % involves two parameters - the 'RR' and 'Pe'. Since OR is approximately equal to RR, we can do this substitution. As far as 'Pe' (i.e. proportion of total population likely to have the exposure) is concerned, we would fall back on our assumption that in a case control study, for OR to be a valid estimator of RR, the controls should be representative of the total population. Thus, the "proportion of controls having the exposure" can be used as a good approximation to the proportion of total population having the exposure; thus,

$$Pe = \frac{\text{Number of Controls having the exposure}}{\text{Total number of controls}} = \frac{b}{(b + d)}$$

It may be contested at this point that the total population will have both cases and controls. Apparently, the level of exposure among the cases will be likely to be much higher than the exposure among controls. Therefore, in the total population (having a mixture of both cases and controls), the proportion of exposure is likely to be higher than the proportion among controls alone, and if this be true, then we cannot estimate "Pe" as " $b / (b + d)$ ".

To counter this argument, we will use the first assumption that we have made in a case control study - that the disease being studied should be rare. Hence, the total number of cases in the total population will form a very small fraction of the total population, the large majority of the total population will be made of the controls. Thus the higher rate of exposure among cases will not make any practical difference and therefore the proportion of controls having exposure can be used as a valid approximation to the proportion of total population having exposure. Now, since,

$$PAR \% = \frac{Pe \times (RR - 1)}{1 + [Pe \times (RR - 1)]} \times 100$$

now, substituting RR by OR

$$PAR \% = \frac{Pe \times (OR - 1)}{1 + [Pe \times (OR - 1)]} \times 100$$

Where  $Pe = b / (b + d)$  of the 2 x 2 table of the case control study.

In our example,  $b = 38$ ,  $d = 162$ ,  $b + d = 200$

Therefore,  $Pe = 38 / 200 = 0.19$  and  $OR = 3.09$ , and hence

$$PAR \% = \frac{0.19 \times (3.09 - 1)}{1 + [0.19 \times (3.09 - 1)]} \times 100 = 28\%$$

This means that 28% of all TE in the total (reference) population can be prevented if OC use is stopped by the reference population.

**Can we work out the AR and PAF from a case control study?:**

Based on the data of case control study alone, we cannot work out the AR. We can only work out the AR% and PAR%, as described earlier. However, if we have an idea regarding

incidence of the disease, from some other source (or else, if the case - control study is a nested case control design), then we can work out the AR. Readers are suggested to consult one of the advanced textbooks cited in the list of further suggested readings, for details of calculations.

**The interesting and paradoxical feature of attributable risk in public health policy - "Preventive Paradox" :** A peculiar situation while studying and formulating the public health policy may come up in situations in which the RR for a given disease or a particular level of a given disease process may be much lower but the Attributable Risk or AR% may be much larger. Take for example the fact that increasing levels of diastolic BP (90 to 104 mm Hg, 105 to 114 mm Hg and 115 mm Hg or above may carry consistently and markedly larger RRs for increasing the risk of mortality due to stroke, CHD and heart failure. However, what also is a fact is that a substantially large proportion of hypertensives is actually in the 90 to 104 mm Hg category, lesser in 105 - 114 mm Hg and very few in  $\geq 115$  mm Hg category. Thus the greatest % of excess deaths in the population due to hypertension (in fact, almost 60%) is attributed to mild levels of hypertension of diastolic 90 to 104 mm Hg category. Paradoxically, then, physicians could save more number of lives with effective treatment of lower rather than higher levels of hypertension. This fact, so counter - intuitive to clinical thinking, has been termed as the *preventive paradox*. The explanation of the above phenomenon is that even with a large relative risk, the AR or AR% may be small if the disease is rare or else the risk factor is uncommon, and vice versa.

### Measures of Benefit - Numbers Needed to Treat (NNT)

This measure is being increasingly used to describe the practical utility of a treatment. It indicates the number of patients who will need to be treated with the treatment modality under study, to get one additional case of cure, as compared to the standard modality of treatment which was used as a control procedure. It is calculated as the inverse of AR.

$$NNT = \frac{1}{AR} = \frac{1}{I_e - I_o}$$

For example, in a trial of a new oral antidiabetic, 60 of the 75 patients were rendered normoglycaemic while 50 of the 75 in the control group getting standard oral hypoglycaemics could be controlled. Thus,  $I_e = 60 / 75 = 0.80$  and  $I_o = 50 / 75 = 0.67$ . Thus  $NNT = 1 / 0.13 =$  approximately 8. Thus, we will need to treat 8 cases with the new drug to get one additional case of cure, as compared to the existing oral hypoglycaemics.

### Summary

Once data has been collected in an epidemiological study, the same has to be reduced into summary figures, usually incidence or prevalence, which give us an idea of the entire data in one look. These summary figures help us in developing certain hypotheses regarding the possible role of a variable as a treatment / preventive modality or regarding its possible role as a risk factor. However, while we can develop hypotheses on the basis of such summary figures, it is no final proof; for finally accepting these hypotheses, one needs to make comparisons.

This is done by comparing the summary figures (incidences or prevalences) in two groups, one group having the factor and the other not having the same. Thus, we get another summary figure, which gives us the magnitude of the effect. The larger this magnitude, the more we are convinced about the role of that factor as a therapeutic, preventive, prognostic or risk factor. Such summary figures which compare two frequency measures are called as measures of effect or impact.

Measures of effect can be broadly of two types - Ratio measures and Difference measures. Ratio measures answer the question "How many times is the difference?" On the other hand, difference measures answer the question "How much is the absolute difference?". In a classical "forward-looking" study, we calculate the incidence of the "outcome" in the two groups the exposed and the non - exposed group. The ratio between the incidence in the exposed (Ie) and the non - exposed (Io) is called as the relative risk (RR). Since incidence also gives us an idea of "Risk", RR is also called as Risk Ratio. RR gives us an idea of the strength of association. Farther the value of RR from "one", stronger is the relationship between exposure and outcome likely to be. Values of RR higher than one indicate increasing risk of outcome due to the exposure; values lower than one indicate decreasing risk (protective effect). Value of exact one indicates no effect, this way or that way, and hence the value of one is called as "null" value of RR.

In a case control study, we cannot calculate the incidence and hence we cannot calculate the RR. However, given the assumption that the outcome being studied is "rare" and the controls have been derived from the same source population which gave rise to cases, we can calculate the Odds Ratio (OR) as the cross - product ratio  $(a \times d) / (b \times c)$  and this OR is a valid estimator of RR. While measures of risk ratio (RR or OR) are important for assessing the association between two variables, the overall clinical or public health impact of an exposure is measured by measures of Risk Difference (RD); The commonest and the simplest of these is "Attributable Risk" (AR). It is calculated as the absolute difference between Ie and Io and tells us the number of additional cases with the outcome among those having the exposure as compared to those not having the exposure. Another common measure of RD is the AR%, also called as etiological fraction in the exposed; it tells us as to what percentage of the load of outcome among the exposed is because of the exposure; in other words, it tells us that if all the exposed people were to give up their exposure, then it would result in so much percentage reduction in the outcome among the exposed group. In addition, there is a measure which tells us the total contribution which the exposure variable makes for the outcome in the total population - this is called population attributable risk or etiologic fraction in total population. In a case control study, there are different methods of calculating the measures of impact, as have been described in the text.

## Study Exercises

### MCQs & Exercises

1. The following table shows the annual incidence of Thrombo-Embolism (TE) for every lakh women using and not using Oral Contraceptives (OCs) according to age groups 30 to 39 years and 40 to 49 years. Calculate the RR and AR in each

age group.

History of OC use	Incidence of Thromboembolism (TE) per lakh	
	Age Group (Years)	
	30 to 39	40 to 49
Users	5.3 per lakh	29.15 per lakh
Non - Users	1.8 per lakh	9.9 per lakh

2. In one of the studies, smokers and non - smokers, not having lung cancer, were followed up for 15 years and observed for the development of lung cancer. The data is set out in the following table. Calculate the various measure of risk ratio and risk difference.

Cigarette Smoking	Developed Lung CA	Did Not Develop Lung CA	Total
Smokers	70	6930	7000
Non Smokers	3	2997	3000
Total	73	9927	10000

3. From the health department of the country, the following data is available for the incidence of Lung cancer and IHD among smokers and non - smokers. Calculate various measures of effect and make your clinico - epidemiological interpretations

Smoking habit	Incidence per lakh population	
	Lung cancer	IHD
Smokers	10.1	242
Non Smokers	1.48	119
Total Population	2.13	207

4. The overall incidence of IHD in a state is 191 per lakh population. Among smokers and non smokers, the incidence is 242 and 119 per lakh respectively, while among obese and non - obese people it is 172 and 113 per lakh respectively. In the state, 20% of the people are smokers and 54% are obese. Calculate the various measures of effect and give your main interpretations.
5. In what all different ways would you interpret (a) RR of 3.25 (b) OR of 0.11.
6. Say true of false : RR or 4.0 indicates 3 times more risk as compared to an RR of 2.0.
7. A journal review article regarding air pollution - related lung disease says that the disease has increased by 900% in the last half century. What level of RR does it correspond to?
8. A disease has been consistently increasing in a country. What will be the level of RR that will correspond to (a) 20% increase in risk (b) 900% increase in risk ?
9. Which of the following procedure will give us an idea about the strength of association between an exposure and an outcome variable : (a) 't' test (b) chi - square test (c) both

the above (d) none of them

**Answers :** (1) RR of TE due to OC use in age group 30 to 39 years is  $5.3 / 1.8 = 2.9$ ; in age gp 40 to 49, the RR is the same  $(29.15 / 9.9) = 2.9$ . The AR for these two groups is  $5.3 - 1.8 = 3.5$  per lakh while for the higher age group it is  $29.15 - 9.9 =$  approximately 20 per lakh. (2)  $I_e = 70 / 7000 = 0.01$  or 10 per 1000;  $I_o = 3 / 3000 = 0.001$  or 1 per 1000;  $I_t = 73 / 10,000 = 0.0073$  or 7.3 per 1000;  $P_e = 7,000 / 10,000 = 0.70$  or 70%;  $RR = 0.01 / 0.001 = 10$ ;  $AR = 0.01 - 0.001 = 0.009$  or 9 per 1000;  $AR\% = \{(0.01 - 0.001) / (0.01)\} \times 100 = 90\%$ ;  $PAR\% = \{(0.0073 - 0.001) / (0.0073)\} \times 100 = 86\%$ ;  $PAF = 0.09 \times 0.7 = 0.063$  or 63 additional cases per 1000 ; (3) RR (due to smoking) = 6.8 for Lung CA and 2.03 for IHD;  $AR = 8.62$  per lakh and 123 per lakh respectively for Lung CA and IHD;  $AR\% = 85.3\%$  and  $50.7\%$  respectively;  $PAR\% = 30.5\%$  and  $42.5\%$  respectively;

For PAF (use the equation "PAF (as fraction) =  $\{I_t \times PAR \text{ (as \%)}\} / 100$ , in this case, since  $P_e$  is not known from the data); thus  $PAF \text{ for Lung CA} = (0.0000213 \times 30.5) / 100 = 0.000065$  or 6.5 cases of lung cancer per million population; for IHD the  $PAF = (0.00207 \times 42.5) / 100 = 0.00088$ , or 880 cases of IHD per million population.

The interpretation from clinical and epidemiological point of view is that while smoking is a very strong risk factor for Lung Ca (there remains little doubt as the association seems to be very strong with a RR of almost 7), it is a moderately strong risk factor for IHD. However, on the large population basis in the country, the good effects of giving up smoking will be mainly seen in reduction of IHD rather than Lung Ca; if smoking was stopped in the country, there would be, for every million population in the country, 880 lesser cases of IHD and 6 to 7 lesser cases of Lung cancer. Thus, the incidence of the disease in the total population greatly determines the load of

disease that will be prevented due to removal of a risk factor.

(4) For IHD :  $RR = 2.03$ ;  $AR = 0.00123$  (123 per lakh);  $AR\% = 51\%$  approx;  $PAR\% = 17\%$  approx;  $PAF = 0.00035$  (35 per lakh). For Obesity,  $RR = 1.5$  approx;  $AR = 0.00059$  (59 per lakh);  $AR\% = 33\%$  approx;  $PAR\% = 22\%$  approx;  $PAF = 0.00042$  (42 per lakh).

The interpretation is that while smoking has higher RR as well as higher AR and AR% for IHD, when it comes to PAR% and PAF, it is higher for obesity. Thus, on a population basis, control of obesity in the total population may bring about more reduction in IHD than smoking control. This paradoxical situation has occurred because the  $P_e$  for obesity is much higher than  $P_e$  of smoking. Thus, if a risk factor is more commonly distributed in the population, the overall reduction in the disease caused by it will be much more than a risk factor which is less commonly distributed in the population, even though the risk that this factor carries for causing the disease may not be so high.

(5) (a) 3.25 times increase in risk, or risk is increased by three and a quarter times, or 187% increase in risk (b) risk is only one - ninth in the exposed group; or risk decreases by 89% in exposed group; or risk decreases by eight - ninth in exposed group.

(6) It is True. RR of 4 indicates 300% increased risk while RR of 2 indicates 100% increased risk. Thus the increased risk is  $300\% / 100\%$  i.e. 3 times.

(7) RR of 8.0. Since % increase in risk =  $(RR \approx 1) \times 100$ , and since % increase in risk = 900%, thus,  $900 = (RR \approx 1) \times 100$ ; or  $RR - 1 = 9$ ; thus  $RR = 8$  times.

(8) (a)  $RR = 1.2$  (b)  $RR = 10.0$ ; (9) d.

## 19

### Errors of Measurement, Confounding and Bias

*RajVir Bhalwar*

The very basis of any scientific activity, be it medical research, clinical practice or any other discipline is to make measurements. At every step in our medical practice - whether asking the history of a symptom, looking for a sign or reviewing the investigations, we are in fact making 'measurements'. When we ask our patient regarding history of smoking, we have made a 'measurement', treating the variable 'smoking' on a dichotomous scale of measurement (smoker / non - smoker). Of course, most of the times we are not conscious of the fact that we are making 'measurements'. We usually tend to refer to the process of making measurement when the

process is explicit, e.g. measuring the enlargement of liver in mid - clavicular line, in centimeters. Moreover, we tend to refer to instruments as only the 'physical instruments' (as sphygmo - manometer, ECG machine, reagents and so on). However, in the process of medical research any implement we use to make a 'measurement' is referred to as an instrument. Thus, the questionnaire used to record the history of certain exposures like tobacco use and knowledge regarding a disease, is also an 'instrument'.

#### What all Variables should be Measured

Before proceeding to make any measurements, we must decide as to what all variables we would be measuring, and the 'scales' on which we would measure them (continuous, ordinal, dichotomous etc.). This will, in turn, depend on our research question. In general we should list out the following categories of variables related to our research objectives :

(a) The exposure variable (s)



- (b) The outcome variable (s)
- (c) The potential confounding variables and probable effect modifiers.

For example, in a study proceeding with the research objective of studying the association between alcohol use and oral cancer, the variables of study would be :

Exposure variable : Alcohol use

Outcome variable : Oral cancer

Potential Confounding variables and possible effect modifying variables : Age, Sex, tobacco use, oral hygiene, dental malformations and genetic background. (A detailed discussion on confounding variables is being made in this chapter).

### Where all can a Measurement Process go Wrong

Measurements of the variables listed in the above 3 categories (exposure, outcome and confounders) should ensure “correctness” of measures. Broadly, there are three reasons due to which our measurement process may become incorrect, as follows :

- The basic technique of measurement may be incorrect, due to defective instruments, wrong techniques, inadequately trained data collectors, etc. This is the situation of “measurement error”.
- While selecting the two groups or else while making measurements on the two groups of subjects, which are to be compared, we start treating the two groups in a differential manner. This is known as systematic error or Bias.
- The observed association which we have shown between the exposure and the outcome variables, is actually due to a third, indirectly acting variable and not really due to an association between the exposure and outcome variables. This is the situation of confounding error.

Any one or more of the above erroneous situations, if present, will lead to “lack of internal validity” of the epidemiological or research work.

### Basic Measurement Technique

The basic measurement process should have two essential requirements. i.e. it should be “valid” and “reliable”, as follows:

(a) **The measurement process should be valid**, i.e. the measurements which we are making and recording should correctly measure what we really intend to measure. For example, if we desire to measure ‘anaemia’, then visual examination of nails and palpebral conjunctiva may not be very ‘valid’ process, while measurement of Hb% would definitely be. This aspect is called as ‘validity’; any systematic departure, in the process of making measurements, wherein we start measuring something different from what we actually intend to measure, leads to a loss of validity, i.e. measurement error. Validity (syn : accuracy) of a measurement has two major components, viz.

**Sensitivity** : That is, any person who has the disease being looked for should be identified as positive by our measurement process.

**Specificity** : This means that all those who are not having that disease should be called as “negative” by the measurement process.

(b) **Secondly, the measurement process should have “Reliability”** (Syn : Precision, consistency, replicability, repeatability) : This is the ability of a measurement process to give consistent results when repeated applications are made. Reliability would be compromised in the following situations :

**Due to observer** : This can occur due to “between observer variations” (2 different data collectors can produce different results from a medical interview or even BP measurement) or may be due to “within observer variations” (same interviewer can get different values of BP on 2 different occasions using the same sphygmomanometer and patient).

**Due to subjects** : Again this may be to “within the subject variations” (circadian - rhythm, mood fluctuations) or “between the subjects variations” (biological variations - no two human beings are alike).

**Due to instruments and techniques** : Different BP instruments or different techniques (recumbent or sitting position) will produce different BP values.

The degree of reliability is judged using statistical procedures of correlation coefficient for continuous variables (e.g. 2 BP readings); or Kappa coefficient for categorical variables. Details of calculation of kappa coefficient are given in the chapter on “studies on diagnostic test evaluation and screening for disease”.

### How to Ensure Correctness of Basic Measurement

A checklist of major steps which will greatly help in reducing measurement errors is as follows :

- Clearly write down the research question in adequate detail. Identify the “variables” in the study, in respect of which the measurements are going to be made. This should be written down as “Exposure”, “Outcome” and “Confounding” variables.
- Now, write down clear details of what measurements should ideally be made for each of these variables. This is done by going through the published evidence and consultation with experts. For example, if one of the outcome variables is IHD, the ideal (gold standard) measurement would be either coronary angiography, or a combination of echocardiography and exercise ECG.
- Now, write down how you are actually proposing to measure this variable in your study and whether it is scientifically acceptable. How near does it come to the gold standard? Most of the times the measurement process actually being used may not be (rather cannot be) the gold standard itself. For instance, in a field / community based research on IHD, it may not be at all possible to do coronary angiography on such healthy, free living subjects. In such case, one may decide to use a combination of symptoms with resting ECG as evidence of coronary insufficiency.
- Next, discuss with the experts whether the methods of measurements you are planning for each of the variables is scientifically sound / accepted by eminent organisations/ has already been used by some eminent workers earlier ? For example, a combination of symptoms and resting ECG, using the laid down Minnesota code criteria, is often used for healthy, population - based subjects for evidence of IHD in epidemiological research work which is accepted



by WHO and used in earlier large scale community - based epidemiological studies.

- Now, write down a detailed “protocol” on how exactly the measurement is going to be made, e.g. how the ECG will be recorded, who will record it, and how it will be read.
- Next, write down how “quality control” will be ensured. For example, one may specify that a random sample of the positively and negatively read ECGs will be reviewed by a cardiologist for independent evaluation and quality control.
- Now, see the equipment, reagents etc., which will be used for measuring this variable. Are they accurate? Standardise them, initially and periodically in between the study, against some standard machine. Remember that questionnaires are also instruments. Develop them properly. As far as possible, use the questionnaires and other scales which have already been used and standardised (e.g. Jones criteria; quality of life questionnaire; MPQ etc.).
- Standardise the method (technique) of making any measurement. Preferably use a standardised technique as recommended by a standard professional body (e.g. WHO, American Heart Assn etc.) or a standard text book. Write down the detailed technique in an “operations manual”.
- Train all the interviewers/ data collectors centrally, test them and certify them. If you are yourself the sole data collector get trained and certified by an expert.
- If possible, take repeated measures (e.g. 3 readings of BP).
- Try to make “unobtrusive” measures so that subjects are unaware; e.g. alcohol consumption may be recorded by going through wine bills rather than only asking the subjects.

## Confounding

Let us take a hypothetical study which was done to see whether consumption of alcohol is a risk factor for oral CA. 100 cases of oral CA and 100 healthy subjects were asked regarding the history of alcohol consumption during past 15 years. The results are presented in the 2 X 2 table below (Table - 1) :

Table - 1			
History of Alcohol	Oral Cancer		
	Present	Absent	
Present	80	20	100
Absent	20	80	100
Total	100	100	200

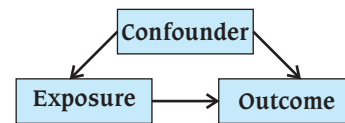
Since the above is a case - control type of study, we can calculate the odds ratio as  $(a \times d / b \times c)$  i.e.  $(80 \times 80) / (20 \times 20) = 16$

Thus we would conclude that the risk of getting oral cancer is 16 times higher if a person drinks alcohol. Someone would object to our findings, saying that this observed association is false, due to the “hidden” effect of tobacco use. This is because people who drink alcohol are also often the ones who also use tobacco; and tobacco use is itself a direct cause of oral cancer, whether one drinks or not.

It would also be evident that this occurred because the variable

“tobacco use” was directly related to both, the exposure variable (people who drink alcohol are also usually the ones who use tobacco) and was also directly related to the outcome variable (people who use tobacco are at higher risk of getting oral cancer, irrespective of whether they drink or not). Thus, a confounding variable is defined as one which explains away the observed association between an exposure and an outcome variable. A confounder variable should have the following properties :

- Be associated with the exposure of interest.
- Be (independent of the exposure), related to the outcome of the interest.
- It should not be in the direct chain or link between the exposure and outcome; its associations with exposure and outcome are indirect and independent.
- It exerts its effect because it is differentially distributed in the two groups (see later).



Medical literature is replete with examples when a particular factor has been proved to be a risk factor for a disease simply because the effect of third variable (the confounder) was not thought of, thereby making the entire research work invalid.

**So, what do we do now?** Apparently with the above observation, the only way left for us is to make two “strata” or groups - the group which uses tobacco and another which doesn’t use tobacco. Now, by simple reasoning, if the risk of cancer due to alcohol remains high in both the strata, i.e. the risk of cancer due to alcohol is high whether a person uses tobacco or not, we would conclude that the risk is not due to tobacco but due to alcohol itself. On the other hand, if the risk is not evident in the 2nd stratum, then we would conclude that there was a “confounding” due to tobacco; alcohol, by itself does not carry any risk. Let us see what happens when we dissect our hypothetical data into two strata (Tables - 2 and 3) :

Table - 2 : Stratum - I : Tobacco users			
History of Alcohol	Oral Cancer		
	Present	Absent	
Present	60	15	75
Absent	20	5	25
Total	80	20	100
Stratum OR = $(60 \times 5 / 15 \times 20) = 1$			

Table - 3 : Stratum - II : Non - users of tobacco			
History of Alcohol	Oral Cancer		
	Present	Absent	
Present	5	20	25
Absent	15	60	75
Total	20	80	100
Stratum OR = $(5 \times 60 / 20 \times 15) = 1$			

Surprisingly, we notice that after making adjustment for the use of tobacco as above, the odds ratios in both the strata fall down to 1 each, i.e. there is no risk of cancer due to alcohol, after adjusting for the effect of tobacco. The earlier observed association between alcohol and oral cancer (OR=16) was only because of a confounding effect of tobacco. When we made adjustment for this confounding effect of tobacco, we found that alcohol, by itself, has no risk. Had we not done this adjustment for confounding, we would have drawn a wrong conclusion that alcohol causes oral cancer. The phenomenon of “differential distribution” also becomes more apparent from the above 2 strata tables. We would appreciate that a very large number of cancer patients who consume alcohol are tobacco users (60 out of 80 i.e. 75%) while very few patients who consume alcohol are non - users of tobacco (5 out of 20, i.e. 25%).

**How do we overcome the problem of Confounding :** There are various methods by which we can overcome this issue, either while we are planning our research or else during the stage of analysis. However, what remains extremely important is that all the PCFs must be identified and, if the adjustments are going to be in the stage of analysis, the data on them must be recorded. Now, since all the PCF must be identified before the actual study, one must work meticulously on this issue from the very time he / she is working on the issue of developing the research question itself. In fact, while reading and discussing as regards the research question, one must very specifically start identifying what are the exposure and outcome variables of interest and what all PCF can confound this relationship between exposure and outcome because of their independent and indirect relationship with both the exposure as well as the outcome variable.

## Methods for Controlling for Confounding

Once the confounding variable(s) have been identified, action must be taken to prevent or adjust for them. Such actions can be taken either during the conduct of a study - at the stage of planning and, secondly, during the stage of analysis.

### Control during Planning (Designing) Stage

This can be achieved by any one or more of the following methods :

**(a) Randomisation :** If a group of subjects is divided into two, using “random allocation” (syn. Randomization) (described in the section on Biostatistics and in the chapter on experimental designs), the 2 groups will be similar to each other in all respects. The beauty, therefore, is that the 2 groups will be “similar” to each other not only in respect of all “known PCF” (age, sex, blood groups and so on) but also in respect of those factors which may be “confounders” but we are not aware of them (e.g. HLA type and, may be, the average number of hair on the head!). Thus the 2 groups will be absolutely similar to each other with the only difference being that one group gets the trial modality while the other will get the control modality. Any difference in the outcome between the two groups can be safely assumed to be due to the intervention being studied. The singular drawback of randomisation is that it can be done only in an experimental design (e.g. drug trial, vaccine trial etc.); however, it is not applicable to most of the “cause

- effect” research that we do in clinical practice (you can not “randomise” people into 2 groups, telling one group to “smoke” and the other “not to smoke”).

**(b) Restriction :** We can so plan our study that the subjects having the particular confounding variable(s) are not taken up at all; e.g. in a study of the possible association between physical inactivity and IHD, young age (< 35 years) and female sex may be the PCF. In this case, we may restrict our study to “only males more than 35 years of age”. The difficulty with restriction is that one tends to exclude out a lot of potential subjects, thus increasing the cost and effort of study; Secondly, the effect of the variables on which restriction has been done can not be studied - e.g. in this example, the role of female sex and younger age can not be studied.

**(c) Matching :** We said earlier, that a confounding variable exerts its nuisance effect due to “unequal distribution” in the two groups. It stands to simple reasoning, therefore, that if the groups could be made “equal” in respect of the confounder, the nuisance effect can be nullified. This is the basic principle behind the very commonly used procedure in epidemiological research - “Matching”. Let us say we are doing the above - mentioned study on alcohol and oral CA. Once we identify tobacco use as a confounder, what we can do is that for every case of oral CA, we would take a healthy person as control who has the same tobacco use as that of the case, i.e. if the case is a tobacco user, we take the control who is also a tobacco user and vice versa. The final result will be that we will have equal number of tobacco user cases and controls as well as equal number of non - user cases and controls in our study and any relation between alcohol and oral CA will now be due to alcohol, without any confounding due to tobacco.

This method in which we match “one for one” (i.e. for every subject or case, we take a control who is similar to that case in respect of the confounding variable), is called as “Pair Matching”. The second method of matching is to do a “group matching” or “frequency matching”. Suppose we want to match on 3 variables (tobacco use, age and sex) . Let us say, out of 100 cases we have 25 of them as “40 - 50 years old female tobacco users”. We will then select out an equal number of controls who fit into this criteria, i.e. 25 healthy females who are 40 - 50 years old and tobacco users as controls.

In general, it is advisable for the researcher engaged in usual clinical/health research not to lay too much stress on matching. “Frequency matching” can be done for the ‘universal confounders’, i.e. age and sex and additionally for any particular confounder which can be easily matched. As regards other PCF, which have not been matched, data regarding them must be collected and later adjustment for their confounding effect should be made during analysis (45 - 47).

### Adjustment During Analysis

If matching has not been done for a PCF (but the data has been collected), adjustment for its confounding effect can be done during analysis by following methods :

**Stratified analysis :** The logic of stratified analysis has been presented earlier when we described that we would make 2 strata, one with the confounder (tobacco users) and one without the confounder (non - users). If the risk in individual stratum is

the same as overall risk, then there is no confounding. On the other hand, if the odds ratios in the strata are very different from the overall OR (e.g. in our very first example of alcohol - oral CA study where the overall OR was 16 but the stratum OR after adjusting for tobacco was 1 each), we would conclude that there is confounding. In stratified analysis, we use certain specialized statistical procedures (Mantel - Haenszel adjustment technique) and calculate the adjusted estimates, which give us the estimate of risk due to the exposure variable, after adjusting for the effect of the confounding variable.

### Confounding

**Definition :** A confounding variable is one which throws into confusion, an observed association between an exposure and an outcome variable, since :

- It is related with the exposure variable.
- Independent of it's association with the exposure variable, is also associated with the outcome variable.
- It does not lie in the chain of sequence between the exposure and outcome variable.
- It is "differentially" distributed in the two groups.

**How do we control for confounding :** The most important step is to be aware of the phenomena of confounding and to identify all Potential Confounding Variables (PCV) right at the time when the research question is being developed. Once all PCV have been identified, action may be taken to control them either in planning stage or during analysis, by following methods :

- During planning : By
  - Randomization (random allocation)
  - Restriction
  - Matching
- During analysis : by either "Stratified Analysis" or by "Regression Analysis".

### Multiple regression analysis in the control of confounding:

While stratified analysis is very effective in control of confounding during analysis, however, if there are a large number of confounding factors, then a large number of strata will have to be made and the individual figures in the individual strata will become very small, often zero. This is the limitation of stratified analysis. In such cases one has to resort to regression analysis (48). Further explanation about the 3 common types of regression analysis is presented in the section on Biostatistics.

### Bias (Syn : Systematic Error Measurement Error Misclassification, Lack of Internal Validity)

Let us take an example of a simple clinical trial in which we gave a new drug, 'A' to a group of patients with headache while the standard existing drug 'B' was given to another group. After analysing the data we finally concluded that drug 'A' was better in relieving headache than drug 'B'.

Such conclusion might have been correct, but may also have occurred because we might have selected subjects who were

mentally robust in gp 'A', or weaklings in gp 'B'; or else, the severity of headache in gp 'A' as such was lesser than gp 'B'; or perhaps the subjects, knowing that we (their treating physicians) were studying the good effects of drug 'A' were too willing to please us, without our knowledge; or maybe, the nursing officer, knowing our hypothesis, ensured a high level of drug intake (compliance) in gp 'A'; it may also be possible that gp 'A' was assessed in detail by a highly experienced professor while the task of assessing gp 'B' was left to inexperienced interns; or perhaps our questions regarding relief from headache were ambiguous - we were actually asking them "how are you feeling?" Finally, it may have occurred that a much larger number of subjects in gp 'B' who actually finally got relief, also got them discharged before our assessment and so were not available for the final evaluation (selective loss to follow up). Thus, at a number of points, we systematically departed from the correct state, making measures which were different than what we really intended to.

Loss of validity (accuracy) will occur if there is any process, which while making the measurements, will tend to produce results that depart systematically from the true value. This state is also called 'measurement error'. The first place this can occur is when the basic process of measurement is wrong, as discussed in detail in the earlier part of this chapter.

Secondly, whenever we are testing hypothesis regarding associations or differences, we would apparently be comparing two "groups". Remember that validity will be compromised and bias (systematic error) will occur if at any point, while either selecting the subjects or else while making measurements on them, we tend to systematically depart (consciously or as happens most of the times, unconsciously), thereby treating the two groups being compared in a different manner (49). Thus, bias can occur at two points. Firstly, it may occur if the two (or more) groups of patients or subjects that we intend to compare, are selected in a differential manner. This is called "Sampling" or "Selection" bias. Secondly, it can occur if while recording the information (i.e. making measurements), we tend to treat these two groups differentially. This is known as the "Information" or "Measurement" bias.

"Systematic error" or "Bias" leads to Loss of Internal Validity. This will occur when we are actually measuring something other than what we actually wanted to measure, as follows:

- Basic measurement technique is wrong
- Variations between observers or subjects
- Systematically differentiating between the two groups being compared at the point of
  - Selection (Selection Bias)
  - Making measurements (Measurement or Information Bias)

### Selection Bias

Selection bias is a systematic error resulting from the way the subjects are either selected in a study or else are selectively lost to follow up. In a case control study, the major source of selection bias is the manner cases or controls or both are selected and the extent to which the presence (or absence) of



exposure may influence such selection. On the other hand, in cohort and experimental studies, the major source of selection bias is non - response / withdrawal from the study / losses to follow - up. In a cross - sectional study (as also in a case control study), the primary source of selection bias is “selective survival”, because only those who are alive can be included in such studies. The following are the ways in which selection bias can occur :

**(a) Self selection bias / Volunteers induced bias :** In general, as far as possible, avoid volunteers in any research study since they may be systematically very different from the usual population (50, 51).

**(b) Berksons' bias (hospital selective admission) (52 - 54) :** This can be a problem in case - control studies. It occurs because patients with two concurrent diseases or health problems are more likely to be admitted to a hospital than those with a single condition. For example, people who have both peptic ulcers and also smoke are more likely to be admitted to the hospital than people who have either of them. A case control study trying to evaluate the relationship between smoking and peptic ulcers may therefore find a much stronger association between the two than would really exist in the general community.

**(c) Incidence - prevalence bias (Syn - Survivorship bias, Neyman's bias) :** This is a major issue in case - control and cross - sectional studies (55, 56). For example, a case control study to evaluate the protective effect of physical exercise on MI was undertaken by taking cases of MI and healthy controls and asking them about the history of regular physical exercise. Surprisingly, a large no. of both the cases and controls give a history of regular physical exercise; the study concluded that regular physical exercise does not protect against MI. The conclusion was, in reality, a biased one. We know that 25% to 33% of the cases of acute MI die within the first 3 hours. Only those who live get admitted to the hospital and are available as cases. Now, regular physical exercise may be an important factor in helping the person to overcome the acute myocardial episode. Thus, out of the cases of MI, those who did not undertake regular exercise died, while the ones who did exercise were the ones who lived to give such a history.

**(d) Healthy worker effect :** A comparison between health status of military and civilian population may show a better health status of the soldiers; one of the important reasons may be because of the initial medical examination during which the ‘unfit’ persons are excluded and only ‘healthy workers’ are included in the army. The basic dictum of selection and comparisons in research should be to “compare likes with likes” (57).

**(e) Exposure related bias :** This is a special type of Berkson's bias. If the hospital admission probability is different among those who have and those who do not have the suspected cause, such a selection bias can occur. This is specially liable to occur in case control studies. As an example, such an exposure related selection bias was viewed with concern in a case - control study that found an association between use of dietary supplementation with L - tryptophan and “Eosinophilia - Myalgia Syndrome” (EMS). The main criticism was that the initial press publicity about a suspected association may have

resulted in a preferential diagnosis among known users of L - tryptophan as compared to non - users. Thus the estimate of risk (OR) obtained from such studies may have overestimated the true effect of risk.

**(f) Bias due to loss to follow - up :** This is a special problem in cohort and experimental studies. If subjects drop out / are withdrawn / die before assessment of outcome / Do not respond later on / cross over to the other treatment modality in between the follow up phase, then it is also possible that those who were lost to follow up could have been systematically different from those who continued.

**(g) Bias due to selection of inappropriate control group :** This is another major issue in case control studies. The basic dictum that should be followed in a case - control study is that the controls should be derived from the same source population from which cases have come and that the controls should also be equally at risk (i.e. have equal opportunity of being “exposed” to the suspected risk factor) as the cases. Take the example of a case - control study which desired to assess the risk associated with non - use of condoms (exposure) with the development of STD (outcome). In a hurry, the investigator selected cases from a STD clinic and also controls from the same STD clinic who were found to be free of STD after evaluation, at this clinic. However, many of these controls may not have developed STD probably because they had sex partner who did not himself / herself had STD, and hence these subjects had no chance of exposure (to STD) whether they used condom or not. Hence the right choice of control group in this research would have been to take people who were known sex partners of persons known to be having STD but were themselves found clear of STD, while cases should have been those who had known STD persons as sex partners and were detected to be having STD.

### Information (Measurement) Bias

Information bias is a systematic error that arises because of incorrect information while making measurements on one or more variables in the study. As said earlier, it may occur, firstly, when the basic measurement process is incorrect (Wrong instrument, wrong technique, wrong definitions, and so on). Secondly, it would occur even when the basic process of making the measurement is correct but the measurements are made in a systematically “differential fashion” between the two (or more) groups being compared. This will result in “misclassification” of either the disease (outcome) or “exposure” status, or even both of them. Information bias is likely to occur in the following ways :

**(a) Recall bias :** This is a major problem in case - control as also in cross - sectional studies. The fact that a person has become diseased, he or she is more likely to recall the possible exposure; e.g. in a study of X - ray exposure during pregnancy and subsequent leukaemia in children, mothers of leukaemic children are likely to recall more and thus give more history of X - ray exposures (58).

**(b) Detection bias :** This is more of a problem in prospective studies. Those who are exposed to the factor of interest may also be more liable to be subjected to diagnosis and hence detection of the disease of interest; e.g. in a follow up study on the question whether smoking is the cause of emphysema,



we would take a group of smokers and another group of non-smokers (both groups free of emphysema at the start of follow-up) and would follow them for a defined period of time to see for development of emphysema. Now, smokers are more likely to report sick because of various other problems (cough, IHD, dyspnoea etc.), and hence more likely to be diagnosed as emphysema, once they report to a medical facility.

**(c) Observer's (Interviewer's) bias** : If the interviewer is aware as to which group is having the particular exposure (in a follow up study) or the disease (in a case control study) then he/she would be more inclined (subconsciously) to interrogate/examine that particular group more exhaustively, to prove the research question.

Types of Bias	
Selection Bias	Measurement Bias
Self selection (volunteers) Bias	Recall Bias
Berksons' Bias	Detection Bias
Survivorship (Neyman's) Bias	Observer's Bias
Healthy worker effect	
Exposure - related Bias	
Loss to follow - up Bias	
Inappropriate control gp.	

### Prevention of Bias : Checklist

The following check list will help in preventing bias in most of the "usual" settings of epidemiology and clinical research.

- As far as possible, ensure blinding - definitely in an experimental design; even in a case control study or cohort study, the observer can be "blinded".
- If possible, do not tell your research hypothesis to the subjects (helps preventing recall bias). In addition, if possible, try and take information about exposure from other sources, in addition to the subjects.
- In a follow-up study (cohort study or clinical trial), take a well defined population to avoid loss to follow up; develop methods to retrieve those subjects who are getting lost to follow up.
- Select two or more than 2 "groups" of controls in a case control study (e.g. one from hospital and another healthy group); try and take different categories of diagnoses if selecting hospital controls.
- In cohort or experimental studies (follow-up studies) specify clearly the future dates of examination and examine all subjects of both groups at the pre-decided dates using "similar" methods of history taking, physical examination and investigations, and make arrangements that losses to follow up are minimized.
- In a case control study, use the correct time frame for recording exposure (e.g. for a study between pneumonia and cold exposure, the time frame should be 6 days and not 6 months).
- See, in a case control study, specifically for
  - That the controls come from the same "source" population from where cases have come; and that cases

and controls have the same "selection factors" for getting admitted to that particular hospital.

- Is there any possibility of "survivorship" bias ?
- Is the disease such that the initial symptoms may have led to a change in exposure? (e.g. initial dyspeptic symptoms of gastric CA may cause the patient to give up tobacco).
- Did the controls have a reasonable chance of being exposed to the factor of interest? (hysterectomised women in any case do not have a 'chance' of exposure to OC, so do not keep them in controls in an Oral Contraceptives - Thromboembolism study).
- In any type of study, see the "entire spectrum" of the outcome or disease - e.g. in IHD, also see in addition to MI, angina, sudden death and asymptomatic ECG changes.
- In an experimental design (clinical trial), ensure Random allocation, Blinding and Placebo control.

### Summary

The indispensable issue in any epidemiological or medical research study is that we should measure what we really intend to measure; in other words, any error of measurement has to be avoided.

Broadly, errors of measurement can occur at one or more of three situations - the basic measurement process is wrong (error or basic measurement); or else, systematic error or bias in which we have systematically differentiated between the two groups being compared, either while selecting them (selection bias) or else while making measurements on them (measurement bias); and, thirdly, the observed association between the exposure and the outcome variable is explained away by a third, indirectly related variable (confounding error).

Any measurement process that we select should have validity (should measure what we actually intend to measure) and reliability (repeated applications of the measurement process should give consistent results). The key to preventing basic error of measurement is to ensure "standardization" by selecting the correct instruments and techniques, having proper pilot testing, frequent quality control procedures and adequately training all data collectors in the measurement process.

The second type or error occurs due to confounding. This happens when the observed association between an exposure and an outcome variable is explained away by a third variable, called as the confounder variable. A confounder variable is one which is related to the exposure variable, is also related to the outcome variable (independent of its relation with the exposure variable), does not lie in the direct link of chain between the exposure and the outcome variable, and is "differentially" distributed in the two groups. What is extremely important is that all the potential confounder variables should be identified by thorough academic reading and discussion with experts. Once identified, confounder variables can be controlled during planning stage of a study (by either of restriction, randomization or matching, which could be individualized pair matching or group / frequency matching). Confounders can also be controlled during analysis of data by either stratified analysis using Mantel - Haenszel technique or by linear regression analysis.

The third type of error is systematic error or Bias. In most of the situations in epidemiology and medical research, we would be comparing two or more groups. This could be comparisons between a group having the exposure and the other not having the exposure, as regards the frequency of out come in the two groups; or else, it could be comparison of a group of subjects having the outcome with another group not having the outcome, as regards the frequency of exposure in these two groups of subjects. Whenever we tend to systematically differentiate between these two groups, while selecting the subjects in these two groups or else while making measurements in these two groups, bias will occur, which will be either selection (or sampling bias) or else measurement (or information) bias respectively. The various types of selection biases are : Self selection bias, Berkson's bias, Incidence - prevalence bias (Syn: Survivorship bias, Neyman's bias) , Healthy worker effect Bias, Exposure - related bias, Bias due to loss to follow - up and Bias due to selection of inappropriate control group. The various types of information bias are : Recall bias, Detection bias and Observer's (Interviewer's) bias. The important aspect of bias is that all possible sources of bias should be visualized during the planning stage of the epidemiological study and steps taken to prevent them, since unlike confounding, it is very difficult to control or adjust for it during analysis stage, once the study has been completed.

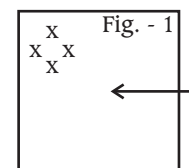
## Study Exercises

### MCQs & Exercises

1. An investigator developed the research question as to what percentage of IHD patients take aspirin prophylaxis. She defined her reference (target) population as "all patients in the country having IHD", and the phenomena of interest to be studied was the percentage of IHD patients taking aspirin for prophylaxis. She defined the actual study population as all patients of IHD seen at her clinic during last calendar year and obtained the information about aspirin use by mailed questionnaire. Out of the 287 patients of IHD seen at her clinic last year, 270 were sent the questionnaire (addresses of remaining 17 were not recorded in her clinic records, being emergency cases which were referred to ICU after first aid). After repeated requests, 118 questionnaires were received back. Out of these 118, total of 19 (16.1%) reported use of aspirin. Examine, where all errors can occur in this study.
2. Kappa coefficient is a procedure which can be used to (a) assess the validity of answers given by a group of patients (b) assess the agreement, beyond chance, as regards responses to two different sources (c) assess the correlation between blood pressure readings taken on the same patient by two different nurses (d) all of the above.
3. The ability of a measurement process to diagnose correctly as positive those who really have the disease is called as (a) sensitivity (b) specificity (c) precision (d) reliability.
4. Which of the following is not an essential characteristic of a confounding variable : (a) It should lie in the direct chain of causation between exposure and the outcome variable (b) It should be related to the exposure variable (c) It should be related to the outcome variable, independent of it's relationship with the exposure variable (d) it should

be differentially distributed.

5. Which of the following is not a method of control of confounding : (a) Restriction (b) Matching (c) Stratified analysis (d) Ensuring use of accurate instruments.
6. Another name for randomization is : (a) random sampling (b) random allocation (c) random error (d) random variable.
7. During a rifle firing practice, a soldier fired the shots Which are depicted in Fig. - 1. The point of the Arrow indicates the centre of target on which the soldier was actually aiming, while the four crosses "x" indicate the points on the target that he actually fired. In this example, there was (a) neither accuracy nor precision (b) both accuracy and precision (c) precision but poor accuracy (d) accuracy but poor precision.
8. To identify patients having jaundice, a medical officer examines the bulbar conjunctiva for yellowness, a procedure for which she has been well trained during graduation. This method of detecting jaundice : (a) lacks validity (b) lacks reliability (c) lacks both validity as well as reliability (d) has both, adequate validity as well as reliability.
9. In the above example given in Q.8, the method of assessing jaundice will be (a) Quite sensitive (b) quite specific (c) neither sensitive nor specific (d) both sensitive as well as specific.
10. Which of the following is not a method of control of confounding during planning stage : (a) stratified analysis (b) restriction (c) pair matching (d) frequency matching.
11. An epidemiologist wanted to study whether blood group 'O' is protective against peptic ulcer disease as compared to the other three blood group types. Here, the outcome variable is : (a) blood groups (b) peptic ulcer disease (c) both the above (d) none of them.



**Answers :** (1) (a) The patients at her clinic may not be a representative subset of all patients of IHD in the country (which was the defined reference population). This is problem of external validity (generalisability). (b) The 270 patients who were sent the mailed questionnaires and finally out of them the 118 who actually returned the questionnaire may be systematically very different from those who received the questionnaire, as regards their aspirin use - this is a problem of internal validity of the type of selection bias. (c) Responses on mailed questionnaire by the 118 subjects who returned the questionnaire may have been inaccurate, depending on how well the questionnaire was designed and how well the subjects understood the questions - this is again the problem of internal validity, of the type of information (measurement) bias. (d) The estimate of 16.1% is subject to random error or chance - the reality in the real population may be different and also repeated samples from the same clinic's patients may show different estimates. This needs to be minimized by studying an adequately large sample size and calculating the 95% Confidence Interval around the estimated percentage, by statistical procedures. (2) b; (3) a; (4) a; (5) d; (6) b; (7) c (8) a; (9) b (10) a; (11) b.

RajVir Bhalwar

## Developing Questionnaires

In a large number of health - related measurements (pain, fear, satisfaction, attitudes, practices, beliefs, etc.), there is no clear cut physical standard. The usual approach in such settings is to construct a questionnaire, consisting of a group of questions designed to measure these specific phenomena.

### Selecting the Items to be Included in Questionnaire

The first thing to do is to undertake an extensive reading in the subject to find out whether any questionnaire is already existing which can cater to one's requirement in "toto", or after slight modifications. If so, it is advisable to use such an existing questionnaire since it has already been validated by the earlier workers. However, one must remember that if the general nature of population of the earlier work was different from one's own study, or else if major changes have to be made in the existing questionnaire, then the same must be pre - tested and validated on the population in which the study would be conducted. If no questionnaire is already existing then one would need to develop a questionnaire of his own. In such cases, the following steps should be undertaken.

### General Steps in Developing a Questionnaire

- i) Make a detailed list of the following variables of your study, based on your extensive reading undertaken while developing the research question :
  - Exposure variable (s).
  - Outcome variable (s).
  - Potentially Confounding Factors (PCFs).
- ii) Recapitulate your own theoretical and practical knowledge, thinking extensively on what all can be included.
- iii) Consult at least 3 different experts in the field of proposed research for their opinion regarding various items to be included.
- iv) To start with, collect as many items / questions as possible (though many may appear instantly irrelevant). Subsequently, keep "pruning" away the irrelevant items so that the final questionnaire, after pre - testing would have only a few, relevant items.
- v) For each of the exposure, outcome and confounding variables, make out questions which must cover the following 5 aspects :
  - When did that particular variable start.
  - When did it end (if applicable).
  - The dose during each episode of exposure.
  - The frequency of exposure.
  - The duration during each period of exposure.

(For example, if asking about the details of tobacco smoking, draft out questions which refer to the exact age when the person first took on to smoking, when did he stop, when did he again start, what is the present status, how many cigarettes or other forms as pipe / beedis on an average in a day are / were

consumed during each spell of smoking, how frequently, i.e. whether daily, alternate day and so on).

- vi) Now write a draft questionnaire, which apparently will be quite long. Revise it yourself and show it to 3 different experts to remove a large number of items which are not relevant for your research; thus, a more consolidated questionnaire will be available.
- vii) Pre-test this consolidated questionnaire on your population of interest using a small "convenience" sample (friends, colleagues, etc.). Further revision would now occur. Now pretest this further revised version on a random sample of 25 - 50 subjects from the study population and make the final revision.
- viii) Do the pre - coding of the final revised version. Get it printed in a neat, legible and presentable format.

### "Structured" or an "Unstructured" Questionnaire

In the former, the interviewer asks the same questions in the same way and in the same order from all subjects; in other words there is a pre - designed schedule on which questions are already written down in sequence. On the other hand, in "unstructured" questionnaire, there is lot of flexibility and the questions asked from the study subjects may vary at the discretion of the interviewer (e.g. interviews taken by a journalist; psychiatric history taking). By and large, it is always desirable to have a structured questionnaire since it ensures standardisation and reduces variations.

### "Closed Ended" or "Open Ended" Questions

**(a) Closed ended questions :** All the possible answers are listed in front of the question and the respondent has to simply indicate the answer he feels correct, by a tick or encircling the number besides that answer, e.g.

"AIDS" is caused by :

1. A small germ. 2. Chemical pollution of water. 3. Bad air.
4. Dirty under - garments.

Closed ended questions are always desirable, since they have the obvious advantage of standardized answers. While constructing closed ended questions, the investigator should mention all possible answers - this will be possible by extensive reading of the subject and a proper pre-testing of the questionnaire. It will also be advisable to have a final category of answer as "any other? (specify) \_\_\_\_\_" for few of those respondents, who do not find a suitable answer from the list provided. The answers should be simple so that the respondents understand them. In fact, a good method of making closed ended questions is to start with open ended questions, do a pre-testing, and based on the various answers obtained on pre-testing, finally convert them into closed ended questions.

Two more aspects which should be kept in mind while developing closed ended questions are :

- If there are more than one possible correct answers, indicate the same in the question, by asking the subject to tick more than one answer if he/she feels so.
- If there is a possibility that some subjects may not be sure of any alternative answer, put, in addition to "any other (specify)", another category as "Don't know / Not sure".

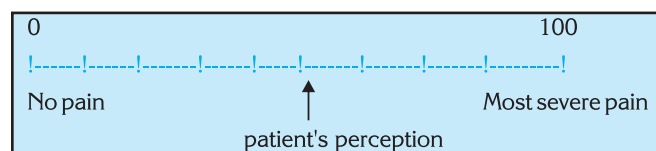


**(b) Open ended questions** : In open ended questions, a blank space is provided after the question and the respondent's reply is recorded verbatim, without any structured choices as happens in closed ended questions, e.g. "What is the cause of AIDS?" \_\_\_\_\_.

The problems with open ended questions are that they lack standardization, the responses would be very variable and thus the subsequent analysis of data and interpretation of results would be very difficult. As a general recommendation, in a usual medical research work, one should keep closed ended questions (with a last open ended category of "any other (specify)", if required). However, open ended questions may be preferable in some of those settings in which simple facts are being elicited and in which there would be a large number of different responses; e.g. "which Textbook of Medicine do you follow?" Even in such situations, one can intelligently, after a proper forethought and pre-testing, convert it to a closed ended question as : "Which Textbook of Medicine do you "usually" follow : Harrison / Davidson / Oxford / API / Any Other (specify) \_\_\_\_\_".

### Recording the Responses

If the outcome is to be recorded on a "continuous" scale, try to record the answer on a Visual Analog Scale (VAS), to get the maximum possible information. E.g. for a question on pain, we can draw a line of 100 mm, with '0' indicating 'no pain' and 100 indicating 'pain of the most extreme type' and ask the patient to put his finger at the point he feels optimally describes his severity of pain.



If the response is to be recorded on a "nominal" scale (i.e. as "categories"), the optimum is to keep 5 to 6 categories. Also try and change the order of response in successive questions; e.g. if Q.1 is recording the response from "high" to "low" try to record the response on Q.2 as "low" to "high". "Likert's" type of scales, in which the responses are framed on an "Agree - Disagree" continuum can often be used in such situations. E.g. for a question "Is the OPD giving satisfactory service?", the responses could be

Strongly agree	Agree	No opinion	Disagree	Strongly disagree
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### Precautions to be Observed while Making the Questions

**Avoid ambiguity** : Avoid statements or questions which are likely to be interpreted differently. E.g. instead of the question "Have you been recently away from home?", it will be more apt to ask "Have you been away from home since 01.01.2007?".

**Avoid "double - barrelled" questions** : e.g. "Do you have precordial pain and dyspnoea while walking?". Now, what if the subject has any one of them? In such cases make two

different questions.

**Avoid technical jargon** : The question "Are you hypertensive" may be interpreted by a layman as "too much mentally tense".

**Avoid "value - laden" words or hypothetical questions** : e.g. In the question "Would you like to move to a better hospital?" would evoke various judgement responses because of words "like" and "better" which are hypothetical. In such cases, increase the number of questions and be more specific, e.g. :

- Do you want to move out from this hospital? Yes/No.
- If Yes, to which hospital? \_\_\_\_\_
- Why do you want to move to that hospital? Better administration/ better doctors/ better investigations / less expensive/ any other (specify)

**Avoid questions that are not self explanatory** : e.g. the answers to question "What type of home do you have?" may bring out different answers like "happy", "concrete", "well ventilated", "small" and so on. In such cases, specify the question in details or give closed / semi closed answers in front of the question.

**Do not ask about events which most people will not remember** : e.g. "How many times per week did you drink milk when you were between 6 and 10 years old?" may be quite difficult to answer. In such cases, if you must ask about such a long past, try to verify/ supplement this information from other sources (records, parents, friends, siblings, spouse etc.).

**Alternate questions** : Alternate questions which are likely to bring out 'yes' answers with those likely to bring out 'no' answers.

**Dummy, Check questions** : Keep some "Dummy, check questions" in the questionnaire. These questions may not be related to the study but may enable us to cross check the validity of information. E.g. in a study on sexual practices, details of alcohol and tobacco use may not be directly relevant to study objectives; however, answers to such questions may be cross checked with records, friends, family members, etc. and would give an overall idea of the validity of information being provided by the subject.

## Interviews in Epidemiological Research

### Types of Interview

There are three types of interviewing formats :

**(a) Structured interview** : Where everything is set out in advance. In addition to a closed - ended questionnaire, even the places where probing is to be done, the words in which the probing is to be done, the introductory statements - everything is written down and followed in "letter and spirit" by the interviewer, without any deviation.

**(b) Semi-structured** : This interview is done using a closed - ended questionnaire with general, broad directives written down; however at certain, unforeseen situations, the interviewer is allowed to make use of his experience and tact in, say, making probes, giving introduction or providing explanations. Semi structured interview is the most commonly used. It has the advantage of structured interview in reducing errors, and at the same time, it carries the advantage of unstructured interview in establishing rapport between subjects and interviewers which



is also quite important for ensuring accuracy.

**(c) Unstructured** : This consists of only an open ended questionnaire with everything else left to the discretion of the interviewer, e.g. a journalist's interview.

### **Actions before Starting an Interview**

There are certain steps which should be taken before an interview, as they go a long way in ensuring the success of the interview :

- (a) As an interviewer, develop a personality which shows that you have a sincerity of purpose, straight - forwardness, politeness, proper attire and a clear, non - shaky voice.
- (b) Practice the confidence to deal with awkward replies like "what is the catch in this question", "why don't you take somebody else for your research", etc.
- (c) Take necessary administrative sanctions for conducting interviews from relevant authorities like Principal of School, Government Officers, Superintendent of the hospital etc.
- (d) Secure a proper appointment from the subject. Try and take a time when the respondent is likely to have the least commitments; e.g. school games time for children, weekend holidays for office going personnel, midday for house wives etc.
- (e) Try and find a place for the interview that is comfortable, has optimum privacy and there are no barriers to communication.
- (f) Do not forget to carry your identity card / introductory letter issued to you from your department.

### **Starting the Interview**

Once the interviewer and interviewee have moved to the selected site of the interview, a few minutes must be spent in developing rapport. Introduce yourself briefly and thank the subject for accepting to be interviewed. This should be followed by a brief and general description of the purpose of the research, and an assurance that the identity of the subject will be kept confidential. It is worthwhile telling the subject that the interest of research is not at all in the personal identity of the subject but rather in collecting some information which would be analysed 'in toto' and not according to "individuals". In fact, if possible, the interviewer can go one step forward by specifically saying that we do not want to note the name (or any other personal identifier, as official "number" of industrial workers); this would further enhance the faith of the subject in "assured confidentiality" and he/she would give more accurate replies, especially for sensitive issues. A few minutes spent on these various aspects before actually starting the interview would go a long way in ensuring its success.

### **Asking Questions**

When asking the questions, give consideration to the following points :

- (a) Read the questions exactly as they are worded in the questionnaire.
- (b) Read each question aloud and at a slow speed; in fact, slower than we normally read.
- (c) If a question is not been understood by the subject, read entire question again (and not a part thereof)
- (d) Read the questions with correct intonation and emphasis.

(e) If the subject needs to be 'probed', use the following methods of probing :

- i) Repeat the question after an appropriate introduction like "I am not sure that I got your answer right. So, let me repeat the question - - - - -" .
- ii) Give an 'expectant pause' to indicate to the subject that you are waiting for more information.
- iii) Put some 'neutral' questions in the following ways;
  - What do you mean by - - - - - ?
  - In what way?
  - Could you explain that a little?
  - Can you tell me what you have in mind?
  - Anything else?
- iv) Try and give assurance, e.g. by saying, to a subject who seems to be stuck up, "there are no right or wrong answers in these questions. Just give whatever answer you think is the right one".
- v) Give feedbacks like "Yes, yes"; "that's exactly how we wanted the information". Also, if needed, give negative feedbacks as "I think you have answered that a bit too quickly", to an incomplete answer.

### **Recording the Responses**

Take care to follow the under mentioned guidelines while recording the answers given by the respondents :

- (a) Do not "infer" a response from an incomplete reply. Probe on to get a complete response.
- (b) Let the respondent answer; you do not answer for the respondent.
- (c) Record all the responses during the interview itself; do not leave things to memory.
- (d) Preferably, repeat aloud the subject's response as you are writing - this may prompt him to give more information.
- (e) Record the answers verbatim as said by the respondents (and not what the interviewer has apparently "inferred").
- (f) Write clearly "refused to answer", besides any question that the respondent refuses to answer.
- (g) Immediately after the interview is over, but before leaving the place, check the questionnaire for the following :
  - All questions have been answered.
  - If missing data is discovered, the question should be immediately asked from the respondent.
  - Important 'probes' (if used) are noted in a pencil, below the questions.
  - All unclear responses are clarified by a parenthetic note.
  - Abbreviations have been explained.

### **Supervision of Interviewers**

During the first 2 days, the interviewer should be accompanied by the principal worker(s) who act as observer only, without interfering in the process of interview. In addition, during the first month of the study, all filled up questionnaires should be personally 'edited' by the principal worker(s). Subsequently, throughout the study period, the main worker should :

- Re - interview about 10% of the subjects independently, as

a quality control procedure.

- Constantly analyse data in respect of few selected variables for seeing variations between interviewers; e.g. one interviewer may be reporting too many subjects as undertaking physical exercise, compared to others.
- Provide immediate feedback and corrective advice.

### Training of Interviewers

The principal worker should undertake the responsibility of training, pre - testing and supervision of interviewers. The training should be done centrally. The following topics should be covered.

- (a) General introduction to surveys and sampling methods.
- (b) Questionnaires and their types; details of questionnaire being used in the "present study".
- (c) Operating procedures manual of the present study.
- (d) The role of interviewer, seeking the interview, initial contact, rapport building, confidentiality, ethical issues, dealing with difficult respondents.
- (e) Asking individual questions and recording replies in the present questionnaire; how to deal with complex questions; how to 'probe'.
- (f) Transferring information from questionnaires to manual or computer "data sheets".

The methods for training should consist of permutation and combination of Lectures, Discussions, reading the operations manual, "query solving" sessions, Demonstration of interviews in progress, Mock interview exercises, Real interview exercises, and Final assessment and certification.

### Summary

Most studies depend on questionnaires for data collection. Questionnaires may be structured or unstructured, closed - ended or open - ended. Structured questionnaires are designed in such a way that the identical questions in fixed sequence are put to each study subject. Unstructured questionnaires do not follow any fixed sequence of questions, allowing for flexibility according to the discretion of the interviewer. In closed - ended questionnaires, the respondents have to choose from fixed options whereas in open - ended questionnaire, the participant can answer in his own words. Unstructured and open - ended questionnaires are difficult to standardize and analyze. Structured and closed - ended questionnaires are preferred in quantitative research. Questionnaires should be developed after thorough academic reading into the subject and discussions with the experts in that field. If any questionnaire which has been used for the particular type of study is already

available, the same should be used, as far as possible. If a new questionnaire is being developed, it should be developed scientifically, as per guidelines given in detail in this chapter. All questionnaires need to be pre - tested and validated in a pilot study and suitably modified if indicated.

Interviews may be structured, semi - structured or unstructured depending on the type of questionnaires used in the study. The investigator should ensure that prior permission and consent are obtained from all concerned before starting the interview. The interview should be carried out in quiet surroundings allowing for privacy and in an atmosphere of confidentiality. Training and supervision of interviewers are an important activity during the conduct of the study.

### Study Exercises

(Study Exercises and chapter Summary contributed by A Banerjee)

**Long Question :** Discuss the process of development of a questionnaire in epidemiological research.

**Short Notes :** (1) Visual analogue scale (2) Actions to be taken when starting an interview (3) pretesting a questionnaire

#### MCQs & Exercises

1. How much visible saturated fat such as ghee and butter do you consume daily? : " \_\_\_\_\_ ". Discuss the inadequacies in the above question. How will you elicit the desired information?
2. Which of the following is NOT a feature of structured questionnaires? (a) Fixed sequence of questions (b) Less flexibility in conduct of the interview (c) Easily standardized (d) Lead to wide inter - observer variation of the information elicited.
3. Pre - testing and validation of the questionnaire is done : (a) During the pilot study (b) Can be done concurrently as the main study is in progress (c) Is done midway during the study (d) Can be done during the analysis stage.
4. Likert Scale is a type of : (a) Categorical scale (b) Ordinal scale (c) Dichotomous scale (d) None of the above
5. Visual Analog Scale is used for : (a) Testing of visual acuity (b) Measurement of abstract variables such as pain (c) Computer recognition of data (d) None of the above.

**Answers :** (1) The major flaws in the question are that it is double barreled, open ended, and uses technical jargon like, 'saturated fat.' To elicit the information on consumption of visible saturated fat, the investigator should first list all the common sources, and design closed-ended question for each source. (2) d; (3) a; (4) b; (5) b.

The various aspects covered till now deal with the basic, fundamental principles, a knowledge of which is essential for any type of epidemiologic and medical research. However, once the correct epidemiological question has been asked and due consideration has been given to the various basic principles dealt with earlier, the worker has to select out the particular type of epidemiological "design", most suitable for the question (59). As described earlier, any epidemiologist would be, very broadly, undertaking one of the following 2 types of exercises:

- (a) He/She may be simply 'describing' a phenomena of interest, expressing it in terms of a measure of health or disease (as mean, median or incidence or prevalence). In such instances, we do not have a 'preformed hypothesis' regarding cause and effect relationship (i.e. this particular 'exposure' leads to that possible 'outcome'). It is only after a 'descriptive study' has been completed that the researcher, based on the results of the study, develops one or more hypothesis regarding causal association. Such studies are called "Descriptive Studies".
- (b) The second general situation is that the investigator may be proceeding with a "preformed hypothesis" regarding a cause - effect relationship (i.e. this 'particular exposure' leads to that particular 'outcome'). In other words, the investigator proceeds to investigate his hypothesis of cause - effect relationship between a possible exposure and postulated outcome. These studies are called 'Analytical Studies'.

### Descriptive Studies

As stated earlier, on a number of occasions the epidemiologist does not have any preformed hypothesis regarding a cause - effect relationship. His object is, rather, to describe certain clinical or health related phenomena and, at the end of study, to develop some sort of hypothesis regarding a possible cause - effect relationship, which can be further subjected to evaluation by analytical studies. A descriptive study gives a strong suggestion that a causal association may be present but doesn't prove it. For example, the incidence of acute glomerulonephritis among children developing sore throat may be found as 10%. This gives a strong indication that sore throat may be causally related to glomerulonephritis; however for proving such an association, one has to do an analytic study by comparing the incidence of acute glomerulonephritis in two groups - a group which had suffered from sore throat and another that did not. Thus, a descriptive study does generate hypotheses; however to prove them, analytical studies are required.

As is evident from the nomenclature, a descriptive study "describes" our findings of the epidemiologic study. Such descriptions are given according to three types of epidemiological variables, namely, distribution of the disease according to time (when does the disease occur), place (where all) and persons (who all are affected).

In contrast to descriptive studies, in analytical studies, the investigator proceeds with a 'preformed hypothesis' regarding a "causal exposure". A large number of epidemiological and health research questions are answered by undertaking analytical studies. The various settings in which the epidemiologist proceeds to establish a relationship between exposure and an outcome may address issues related to treatment, preventive or diagnostic modalities, or regarding the role of a risk factor or prognostic marker (Box - 1).

#### Box - 1

##### Issues in which "Comparative" (Analytical) studies are required

**Risk factor** : e.g. "Is tobacco smoking a risk factor for IHD (as compared to when people do not smoke)?"

**Prognostic marker** : e.g. Is appearance of melena in viral hepatitis associated with increased mortality"? (as compared to when melena doesn't appear).

**Treatment modality** : e.g. can "Dopexitine be effective in treating premature ejaculation" (as compared to when only placebo is given) ?

**Preventive modality** : e.g. "Can use of condom be effective in preventing STDs among promiscuous persons" (as compared to when condom is not used) ?

**Diagnostic modality** : "Can a combination of cold intolerance and unexplained weight gain diagnose hypothyroidism" (compared to the gold standard of T3, T4 and TSH) ?

The key word in analytical studies is "COMPARISON". The basic prototype of such comparative research is the 2 X 2 table which we have already explained at length, earlier in the chapter on measures of effect and which gives us the notations E+, E-, O+ and O- (see Table - 1).

Table - 1

Exposure (E)	Outcome (O)		Total
	Present (O+)	Absent (O-)	
Present (E+)	E+O+ (a)	E+O- (b)	All E+ (a+b)
Absent (E-)	E-O+ (c)	E-O- (d)	All E- (c+d)
Total	All O+ (a+c)	All O- (b+d)	a+b+c+d

Now, "Comparison" of the two groups in any analytical study can be made by either of the two methods :

- (a) Either we take a group with the exposure (E+) and another without it (E-); follow them up for a reasonable period of time and observe how many in each group have developed the outcome (O+); e.g. we can collect two groups of subjects, all free of colonic CA, one group eating low fibre diet (E+) and another eating high fibre diet (E-); follow up both these groups for 15 - 20 years and see how many in each group develop colonic CA.

The comparison would then be made between "those who develop the outcome out of total exposed" (i.e.  $a / (a+b)$ ) and "those who develop the outcome out of the total not exposed", (i.e.  $c / (c+d)$ ). This can be demonstrated as

$$\text{Criteria for comparison} = \frac{a/(a+b)}{c/(c+d)} = I_e / I_o = RR$$

In case this resulting figure from this comparison is “much more than normally expected” (the “normally expected” being defined by statistical tests) we would conclude that the exposure is definitely associated with (or carries a high risk of) the outcome.

(b) The second way of doing the comparative analysis could be to collect a group of subjects who have already developed the outcome (O+) and another group of subjects who do not have the outcome, and then interrogate all the subjects regarding history of exposure (E+ or E - ) e.g. we may take a group of patients already suffering from colonic CA (O+) and another not suffering (O - ) and take the history of low dietary fibre intake during last 15 - 20 years from all of them. In this contingency, the comparison would be made between “those with the outcome having the exposure” (i.e. a / (a+c)) and those without the outcome but having the exposure (i.e. b / (b+d)). The comparison thus would be :

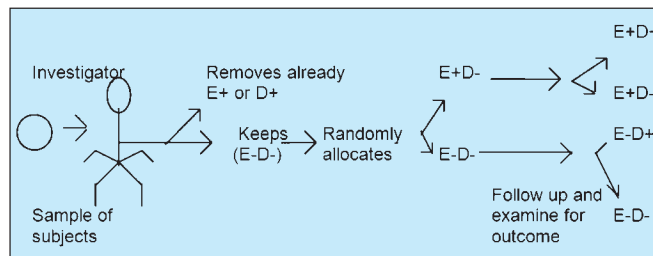
$$\{a / (a+c)\} / \{b / (b+d)\}$$

If the result is much more than ‘normally expected’, we would conclude that the association exists; i.e. the exposure carries a risk of the outcome.

### The Individual Types of Analytical Designs

**(I) The ideal setting - Experimental Design :** The most scientifically reasonable setting would be, apparently, when the researcher collects a group of subjects in whom neither the exposure nor the outcome has occurred; i.e. all subjects are initially “E - O - ”. Now the researcher “randomly allocates” these subjects into two groups, so that both these groups are exactly similar to each other in all respects. Now, one of the groups is deliberately given the exposure (i.e. made to become E+O - from E - O - ) and the other group is not given the exposure (i.e. continues to be E - O - ). The investigator now follows up both these groups over a reasonable period of time to see how many in each group become O+ and makes the comparison as

$$\frac{(E+O+) / (a+b)}{(E-O+) / (c+d)}$$



This type of research design is called the ‘Experimental’ or “Intervention” design. This is scientifically the strongest design, because :

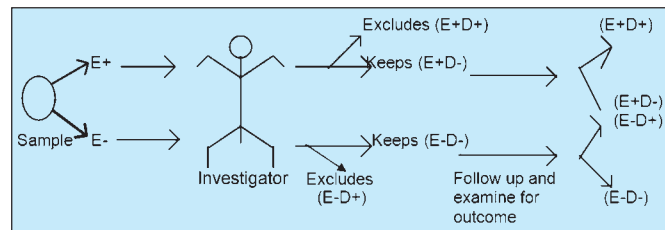
- Since it is the investigator who decides (on a random basis) and allocates the exposure, the possibility that “subjects might have taken up the exposure due to natural selection factors which may also be related to the outcome”, is ruled out.
- Since the outcome has been excluded from both the groups to start with, (the investigator takes only E - O - to start

the study) and then both the groups are followed up over a period of time for the development of outcome (O+ or O - ), one is definite that exposure preceded the outcome; i.e. the absolute requirement of “temporality” for a “cause - effect” relationship is fulfilled.

- Since the exposure status (E+ or E - ) has been recorded by the investigator himself at the start of the study, there is no possibility of recall ‘bias’ which could happen if the investigator was asking the history of “exposure” from the subjects who have already developed the outcome (O+ or O - ).

This type of research, while scientifically the most sound, suffers from the problem that while studying “risk factors”, “markers” and “prognostic factors” it is impossible for the investigator to randomise the subjects into two groups - one getting the exposure and the other not. E.g. in a study of the association between cigarette smoking (exposure) and Lung CA (outcome), it is impossible for the investigator to “randomly allocate” the subjects into 2 groups, one group being told to smoke and other being told not to do so”. However, for any study directed to answer the questions about “treatment (therapy)” or “preventive procedure”, the experimental design must be used since the subjects can be randomised into 2 groups, provided it is ethically correct do so.

**(II) The next situation - “Cohort Study” :** In case it is not possible to “randomly allocate” the subjects into two groups, what we can do is that we can select out two groups at the start of the study, one having the exposure (E+) and other not having the exposure (E - ). Now, those subjects, in both the groups, who already have the outcome (O+) at this point of starting the study are excluded, so that we have two groups, one having the exposure but no disease (E+O - ) and the other neither having the exposure nor the disease (E - O - ). The groups are followed up for the required period of time and comparisons made between (E+O+) / (a+b) and (E - O+) / (c+d) as for an experimental study.



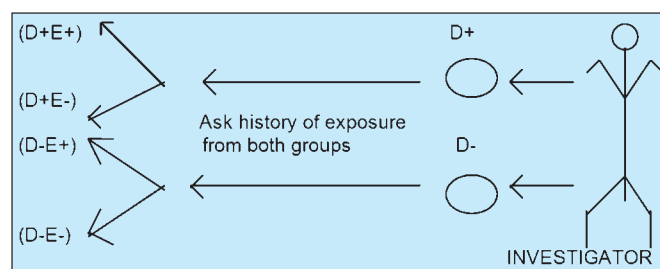
The advantages of this design, called ‘Cohort Design’ are the last two mentioned for experimental design, i.e. temporal association is ensured and recall bias is minimised. The main scientific drawback of this study is that it lacks the effect of “equal distribution due to random allocation” and hence the problem of “natural selection factors” related to both exposure and outcome may be forwarded. Hence, as far as effects of therapeutic regimes or preventive measures are to be seen, the experimental design is to be taken up, since random allocation can be undertaken. However, for study of “risk factors”, “markers” and “prognostic factors”, the cohort study remains the choice.



This design has disadvantages too. Firstly, if the period of follow up is very long, the medical fraternity has to wait for many years before the final conclusions can be drawn. Secondly, if the outcome is rare, the investigator needs to follow up a very large number of subjects to get a reasonably adequate number of subjects who develop the outcome. Thirdly, a large number of subjects may be lost to follow up/die/ drop out during the period of follow up leading to “loss to follow up bias”. Fourthly, such study needs quite a bit of logistical effort in terms of men, material and money.

**(III) The third situation - Case control study :** The problem of “cohort study” can be sorted out by using the method we mentioned in making the second type of comparison between the two groups. What we can do is that we can start by selecting a group of subjects who have already developed the outcome (O+) and another who have not developed the outcome (O-) and ask the history of exposure (E+ or E-) from all the subjects. The comparison is then made as :

$$\frac{(O+E+) / (O+)}{(O+E-) / (O-)}$$



The above situation is a very special type of study, the “case - control” design. Intuitively, this study design appears very appealing. However, it suffers from a large number of problems:

- The fact that the investigator has not recorded the exposure (E+ or E-) himself but is dependent on the history given by the subjects leads to possibility of “recall bias”.
- Since the investigator has not started from the exposure and followed up subjects till the outcome (as happens in an experimental or cohort study), one is not sure whether exposure really preceded the outcome i.e. “temporality” is not guaranteed.
- What the investigator starts with in such a design are the subjects who are present with a given outcome, i.e. living with the outcome of interest but not those who have already died of, or have been cured of, the outcome. The possibility of “survivorship bias” is, therefore, high.
- The problem of confounding also remains high as in cohort study.
- As explained in detail in the chapter on Measures of Association and Effect, we cannot calculate the incidence of the disease either in the exposed or else in the non - exposed groups and hence we cannot calculate the RR. What we can calculate is the Odds Ratio (OR), which is a reasonable estimator of RR.

The case control design has its own advantages, however. It is very good for a rare disease (in contrast to a cohort design)

because a large number of cases of a rare disease can be picked up from a hospital. It does not need any (prolonged) follow up effort. It is cheap and logistically simple. It becomes the method of choice when we are doing an initial evaluation of a hypothesis (fishing expedition) for “risk factors” and “markers”. It becomes particularly good method if the exposure is not likely to change over time and can be objectively ascertained (e.g. blood group, race, religion, sex, seropositivity for certain infections etc.).

#### **(IV) The fourth setting - Cross - sectional analytic design:**

In a case control design, the researcher starts by collecting a group of subjects who have the outcome (O+). This he does in a hospital. But if a disease is mild, or has a marked ‘gradient’ of mild, moderate and severe cases, a large number of cases will not be admitted in the hospital and hence will not appear in the case control study. In fact the mild (not admitted) cases may be systematically different from the serious hospitalised cases as regards the exposure itself.

In such settings, therefore, instead of doing a case control design, the researcher takes a “sample” of subjects from the ‘total population’. At this point he is not aware whether the subjects are having the disease or not. Now, the investigator examines each and every subject for the presence / absence of outcome (O+ or O-) and exposure (E+ or E-) at the same point of time and hence gets the four groups, E+O+, E+O-, E- O+ and E- O- at a given point of time. This is what we call the “Cross - Sectional Analytic Design”. In addition to those diseases that have a wide spectrum of symptoms, the design is also quite useful when the investigator wants to see for correlations between variables which need to be studied among healthy people and not necessarily hospitalized patients; e.g. if we want to see whether waist circumference correlates well with blood pressure, we will have to do such a study and not a case control one. The problems of proving temporal relationship, survivorship and recall bias are major drawbacks of cross sectional analytical studies as they are for a case - control study.

The essential difference between a case control study and cross-sectional study is the point of start - it is a known “case” in a case control study while it is a “subject” (who may be a case or control) in a cross - sectional study. Thus, in a case control study, the investigator starts by picking up people who have the disease (cases) and those who do not have the disease (controls) and thereafter makes an assessment of the presence or absence of the exposure, usually by taking the history or on the basis of some type of records. On the other hand in a cross - sectional study, the investigator starts with a subject (not knowing whether this subject is a case or a control) and assesses the presence of both exposure as well as the outcome in the subject at the same point of time.

The essential difference between the four types of analytical studies (experimental, cohort, case control and cross - sectional) is explained in the following paragraphs, using an example. Let us say, we are interested to determine whether physical activity is protective against IHD (or conversely, is lack of physical exercise a risk factor for IHD). We can take the following 4 approaches depending on how we wish to approach the issue; in any of these approaches we would be completing

the four cells of 'a', 'b', 'c', and 'd' (E+O+, E+O-, E-O+, E-O-), as follows :

**Experimental Design** : We may take a group of healthy persons who are free of IHD at present. We would randomly allocate these persons into two groups and tell one group to start exercising while the other group is told not to exercise. We now follow up these two groups for the next about ten years and see as to how many subjects develop IHD in each group, calculate the incidence of IHD in the two groups and make comparisons of the two incidences to get the RR.

**Cohort design** : We take a group of subjects, do an initial assessment and exclude all those who already have IHD. Now we find out from each subject as regards the physical activity details and thus get two groups - a group who are exercising and another who are not. We now follow up both the groups for another about 10 years and compare the incidence of IHD in the two groups, as above.

**Case - Control Design** : We take a group of patients who have already got IHD and another group of similar persons who do not have IHD. We now take the history of physical exercise carried out by both these groups during the past 10 years and calculate the Odds Ratio (OR).

**Cross - Sectional Analytic Study** : We take a sample of subjects from the general population. Put each subject to the diagnostic tests and find whether he / she has IHD and, at the same time, we ask for the details of physical exercise undertaken during past 10 years. We would get 4 groups of the 2X2 table (subjects not undertaking exercise and having IHD (E+O+), not undertaking exercise and not having IHD (E+O-), undertaking exercise and having IHD (E-O+), and undertaking exercise and not having IHD (E-O-). With these 4 groups we will calculate the OR.

**(V) The last setting - The Diagnostic test study** : The analytical approach for the evaluation of a diagnostic test (which may be a Pathological / Radiological/ Microbiological procedure or even a "set of signs / symptoms") in diagnosing a given outcome (or disease) is slightly different. Firstly, in such a study the investigator must enunciate a "gold standard", against which his diagnostic tool which is to be evaluated, will be validated. Secondly, each and every subject must be subjected to both the procedures (the gold standard as well as the test under study), thereby getting 4 category of subjects. Let us say, we are evaluating the efficacy of pap smear in diagnosing CA Cx, the gold standard being biopsy. We will then have the following setting, as shown in Table - 2 and Box - 2.

**Table - 2**

Result of Pap Smear	Biopsy (Gold standard) results		Total
	CA Cx present	CA Cx absent	
Positive	a	b	a + b
Negative	c	d	c + d
Total	a+c	b+d	a+b+c+d

The investigator now does not work out the statistical tests

for associations (as Chi - square) and risk (as RR or OR), but something different - he works out the validity (or accuracy) of the test under consideration by calculating the sensitivity, specificity, positive and negative predictive values and likelihood ratios, the details of which we shall discuss in the chapter on screening for disease and chapter on diagnostic test evaluation studies.

#### Box - 2

a = Subjects who are having the disease (+ve by gold standard) and also identified +ve by the test under consideration (True Positive or TP); b = do not have the disease but called +ve by the test (False Positive or FP); c = have the disease but called -ve by the test (False Negative or FN); d = do not have the disease and -ve by the test (True Negative or TN) ; (a + b) =Total number found +ve by test (i.e. TP + FP); (c + d) =Total number found -ve by test (i.e. FN + TN); (a + c) =Total number actually having the disease, by gold standard (i.e. TP + FN); (b + d) =Total number not having the disease by gold standard (i.e. FP + TN)

#### How do we Decide as to which Epidemiological Design we should use?

It is of importance that the correct "Research Design" be selected by the researcher. The following guidelines, are shown in a flow chart in Fig. - 1, to assist you in selecting the design most appropriate to your epidemiological research question.

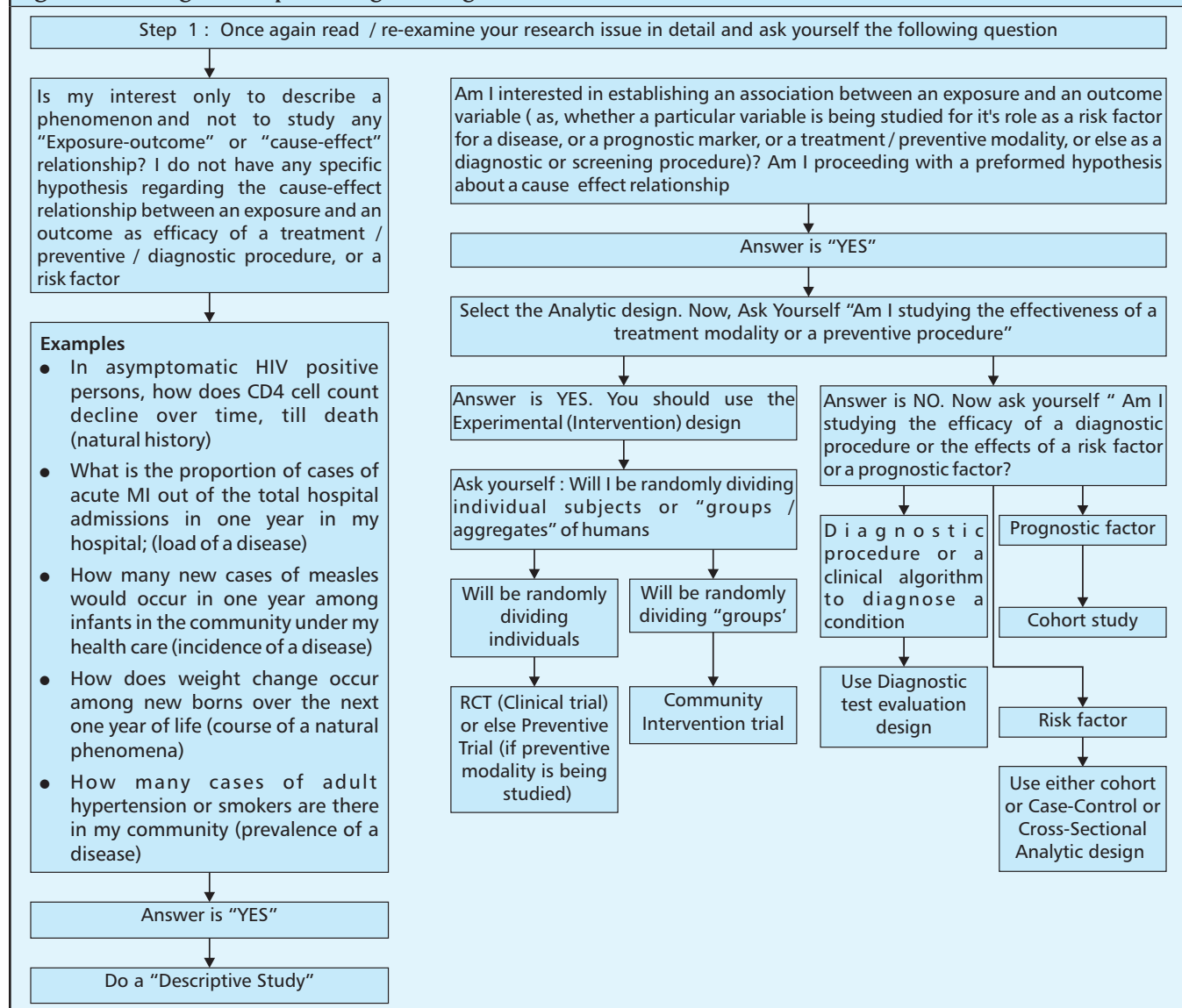
#### Deciding how Strong is the Evidence ?

Very often, in public health and epidemiologic / research situations, a decision has to be taken whether the evidence which has been put forward by a particular epidemiologic research is compelling or not, and whether it needs to be considered for developing the public health policy? In such situations, there are three aspects which need to be considered for assisting in taking a decision :

- What is the magnitude of association as indicated by relative risk? An RR of 1.01 till 1.50 (or 0.99 till 0.90) indicates a mild strength of association; between 1.51 till 3.0 (or 0.89 till 0.75) indicates a moderate strength; 3.01 till 4.99 (or 0.75 till 0.50) indicates a strong association, while an RR of > 5.0 (or < 0.5) indicates a very strong association.
- What is the strength of the study design used? As per the hierarchy of the strength of epidemiological designs, as shown in Box - 3, evidence coming from a Randomized Controlled Trial (RCT) is the strongest, while that coming from an ecological study or descriptive study is the weakest.

Based on the above evaluation, the evidence may be classified as "definite" (RR or OR is > 3 or < 0.5, evidence has come from a experimental design or meta - analysis and similar results shown by most of the studies in different settings); probable (RR or OR 2.0 to 2.99 or 0.5 to 0.75, evidence from cohort or many cross - sectional studies, more than half of the studies show such results); possible (evidence from case - control studies, RR 1.2 to 2.0 or 0.76 to 0.90, few studies show such results); or suspect (evidence from correlational or descriptive

**Fig. - 1 : Deciding which Epidemiological design to use**



studies, RR or OR between 1.0 to 1.2 or 0.91 to 0.99, only few studies show similar results).

**Box - 3 : Strength of Evidence Based on Type of Epidemiological Designs**

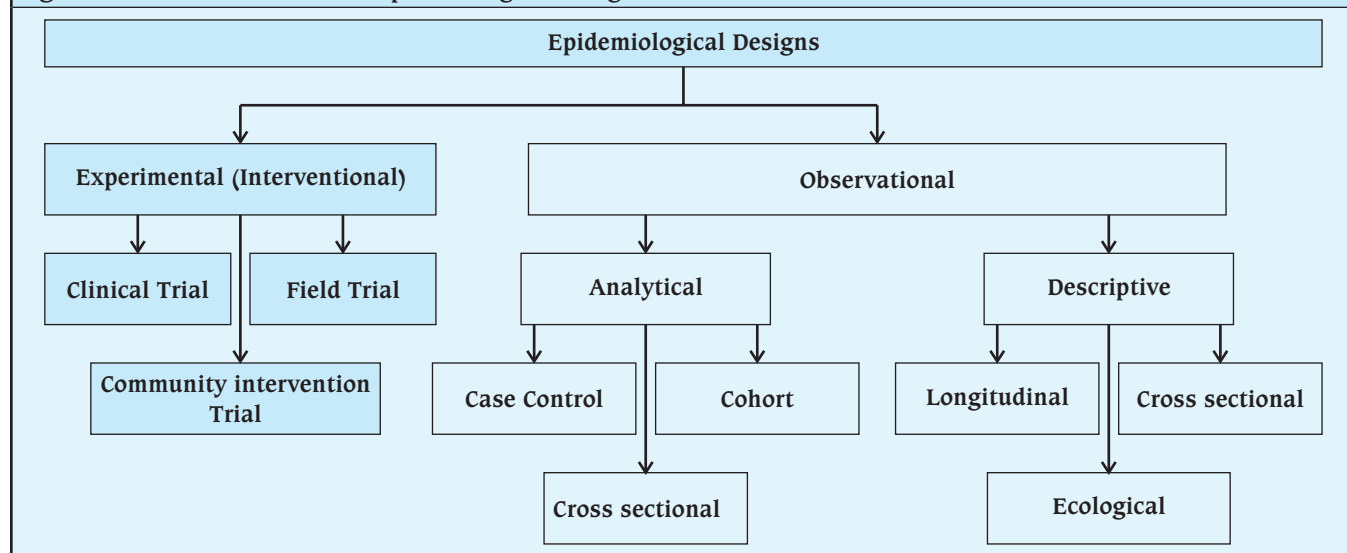
Strongest	- Randomized Controlled Trials
	- Community Intervention Design
	- Quasi Experimental design
	- Meta-analysis
	- Cohort Design
	- Cross-sectional design
	- Case-Control design
Weakest	- Ecological & other descriptive designs

Classification chart of Epidemiological designs is shown in Fig. - 2.

**Summary**

Epidemiological studies are broadly of two types, Observational and Experimental (Interventional). Observational studies are of further two broad categories, viz., descriptive and analytical. Experimental studies, in which the subjects are randomly assigned to exposed and unexposed groups, provide the best evidence of causal association, as they control for both known and unknown confounders. Ethical considerations, however, restrict the conduct of experimental studies in many situations. Experimental studies are therefore utilized when studying the efficacy of a treatment or a preventive modality, in which situations, they become an essential scientific requirement. Of the observational studies, Descriptive studies describe the occurrence of a disease or a health related event in terms of time,

**Fig. - 2 : Classification Chart of Epidemiological Designs**



place and person. However, they can only generate hypotheses; not test them. For testing hypotheses, analytical studies are undertaken. Among analytical studies, Cohort studies are forward - looking studies in which two groups of subjects, one with the exposure and one without the exposure are followed over a period of time, after which the outcome in the two groups are compared. The strength of association is calculated by the RR. Advantage of cohort studies are : no ambiguity about temporal relation, absence of recall and survivorship bias. They are also suitable for rare exposures. Major disadvantages are the high cost, resources needed and loss to follow up. They are also not suitable for rare outcomes. Case control studies are backward looking studies which assemble a group of cases (persons with the disease) and controls (persons without the disease) and presence or absence of exposure (which has occurred in the past) is ascertained from history given by the respondents. The advantage of case control study is the low cost and availability of study results in quick time. The disadvantages are recall bias, and survivorship bias. Moreover, the incidence of disease and exposure cannot be calculated directly and instead of RR, an estimate of RR is calculated, i.e. the OR. In cross sectional studies, a cross - section (sample) from the target population is studied. Measurement on exposure and outcome are carried out at the same point of time. Drawbacks are the inability to ascertain temporal relationship and survivorship bias. In studies of diagnostic tests, the performance of a diagnostic test is compared with a 'gold standard' or confirmatory test. The quality of the new test is evaluated by measures of validity (accuracy). These are : Sensitivity, Specificity, Positive and Negative Predictive Values (PPV and NPV).

## Study Exercises

### MCQs and Exercises

Study Exercises & summary contributed by Amitava Banerjee

- (1) Identify the study designs from each of the following narratives :
  - (a) Cases of viral hepatitis are monitored by the District

Health Officer in his district. Each case of viral hepatitis is indicated by a dot on the map of the district. He also records the seasonal variations annually by monitoring the number of cases each month. He classifies the cases according to age, gender, occupation, source of water supply and other personal attributes.

- (b) Two groups of teenagers were identified, one who were given education on safe driving by their parents or school teachers and the second who did not receive such education. The outcome measure which was compared was the rate of involvement in both fatal and non - fatal traffic accidents in the two groups over the next 10 years.
  - (c) To test the hypotheses that children of separated parents are more likely to become drug addicts, cases of drug addiction were identified from a de - addiction centre. They were compared with people without drug addiction, who were matched for age, sex, literacy and socioeconomic status with cases of drug addiction. The history of separation of parents was obtained from both cases and controls and cross checked from records.
  - (d) Using two masked pieces of paper, one labelled study group and the other control group, each participant in a study is offered to pick up one chit and replace it after he is allotted the group according to the chit he picked up. After this method of going either into study and control group, the participants in the study group are given Deltamethrin (an insecticide) impregnated mosquito nets, to use during night time, while the control group is given ordinary mosquito nets. The outcome measured is incidence of malaria in the two groups.
  - (e) A survey among under - five children is carried out in five selected villages to find out malnutrition among them and the factors associated with various grades of malnutrition.
2. Descriptive studies perform all the following functions Except : (a) Test hypothesis (b) Describe disease occurrence by time (c) Describe the place distribution of health related



- event (d) Generate hypothesis.
- Which of the following is not a unique feature of experimental study : (a) The study is prospective (b) The study can be both prospective and retrospective (c) There is random allocation of subjects to the study and control groups (d) The investigator introduces an intervention.
  - It is sometimes difficult to establish temporal association in the following study design : (a) Experimental study

(b) Cohort study (c) Cross - sectional study (d) All of the above.

- Loss to follow up or attrition is a problem with : (a) Case control study (b) Cross - sectional study (c) Cohort study (d) All of above.

**Answers :** (1) (a) Descriptive, (b) Cohort, (c) Case control (d) Experimental (e) Cross sectional; (2) a; (3) b; (4) c; (5) c

## 22

## Cause and Effect Relationship

*RajVir Bhalwar*

Except in the limited situations of describing a phenomena of interest, most of the times the epidemiological and clinical research is directed towards finding out the “causal” association; e.g. “Is smoking a cause of IHD ?” or “is giving vaccine or a drug a cause of reduced sickness?” In epidemiologic research this is called as study of “cause - effect” relationship; it is also equivalently called as “exposure - outcome” relationship. E.g. “not giving the vaccine” is the exposure (or cause) “and getting the disease” is the outcome (or effect). These aspects have been discussed in detail, in an earlier chapter.

At the outset let us clarify that modern medicine takes into consideration the multi factorial causation of disease. Thus, while M tuberculosis is necessary for the causation of TB, TB may not necessarily occur even in the presence of M tuberculosis; various other factors like race, genetic factors, immunity, etc. may also have a role. Similarly, smoking may be an important cause of IHD; however various other factors like obesity, physical inactivity, dietary patterns, hypertension, genetic background, age, sex may also have a role. In other words epidemiological and medical research today is interested in finding out “a cause of a disease” rather than “the cause of a disease”, giving due consideration to the fact that there may be various other factors also which may act independently, or cause ‘confounding’ or lead to an effect modification, as described in the last chapter.

A “cause and effect” (or exposure and outcome) relationship can be defined as one in which a change in the frequency or quality of one leads to a detectable change in the other; e.g. if smoking is a cause of Buerger's disease, increase or decrease in smoking should lead to a corresponding change in the disease occurrence.

### The Process of Establishing a “Cause and Effect” (or “Exposure and Outcome” Relationship)

Establishing a cause and effect relationship, i.e. this particular ‘exposure’ is the cause of that particular ‘outcome’, needs a research on the lines of ‘hypothesis testing’, i.e. it is not simply

a descriptive study but rather an analytical study. Once the investigator proceeds with a “cause and effect” hypothesis and conducts a study, the final establishment of an “exposure - outcome” relationship consists of a sequence of steps as follows :

**Step 1 :** Has the study been done using correct methods ? Has the investigator ‘measured’ what he or she really wanted to ‘measure’ ? Has the validity and reliability been preserved in the study and there is no bias ? In other words, we ensure that the results of the study are accurate and not “spurious”.

**Step 2(a) :** Do the statistical results indicate that the ‘exposure’ and ‘outcome’ are “associated”? In this step, the investigator ensures, through statistical tests of significance and 95% Confidence Interval, that the differences / associations observed in his sample are not simply due to matter of “chance” or in other words, variations that could occur when different samples from the same whole population are drawn (chance; random variations; sampling variations). For usual settings of clinical research, if the ‘p’ value after the test of significance is less than 5% (0.05) or the 95% CI of the difference between means / proportions does not include zero, we conclude that the exposure and outcome are statistically related. The details of these calculations have been elaborated in relevant chapters in the section on biostatistics.

**Step 2(b) :** If the statistical results show that the statistical relationship is not significant, we must still give consideration to the possibility that a real association might have been missed out due to low power of the study, i.e. a high Beta (type II) error consequent to a small sample size. Hence, before finally denouncing the association as “not statistically related”, the investigator must back - calculate the “power” of the study (of having detected a difference or association if it really existed); in case it is found that the power was inadequate (say less than 80% for the usual research settings), the investigator should suggest additional studies using large sample (or else, a ‘meta - analysis’ type of study), rather than straightaway dismissing the ‘exposure - outcome’ association as non - causal. Details of power calculation are discussed in an exclusive chapter, later on.

**Step 3 :** If the tests of step 2 show that the relationship is “statistically significant” the investigator should now evaluate as to whether this relationship is due to ‘indirect relationship’

with a third variable; in other words, the investigator should undertake analytic procedures for control of confounding (stratified analysis or regression analysis) and work out the “adjusted estimates” i.e. the independent relationship that is still present between exposure and outcome variables after making “adjustments” for the various PCF, as described in the last chapter.

**Step 4 :** Once it has been demonstrated in step 3 that the exposure - outcome relationship is not due to confounding (i.e. holds good even after adjusting for confounding variables), the investigator should now test this postulated “causal” relationship on the following criteria of “causal association” :

**(a) Temporality :** The absolute requirement for any postulated cause and effect relationship to hold good is to demonstrate that the suspected cause (exposure) preceded the effect (outcome). E.g. for smoking to be a cause of IHD, smoking should start before the occurrence of IHD.

**(b) Strength of Association :** The “strength of causal association” is shown by Relative Risk (RR) or Odds Ratio (OR); farther the RR or OR is from the value of “1”, more is our confidence regarding the causal association. In general, if (after ensuring validity, controlling for confounding and ensuring statistical association) the RR or OR is 3 or above or 0.8 and lesser, our belief in cause - effect relationship becomes strong; if it is 5 or more (or 0.5 and lesser), little doubt then remains regarding such an association. However, one must remember that a low RR or OR (say 1 to 3 or else between 0.99 to 0.8) does not exclude a causal relationship. The only thing is that in such cases it becomes difficult to exclude alternative explanations.

**(c) Consistency :** Whether a number of different studies conducted by different investigators at various times in different geographical areas on different populations have indicated similar “cause and effect” association as regards our exposure and outcome variables. E.g. smoking - lung CA association has been consistently demonstrated in various countries, religions and sex, etc.

**(d) Biological gradient :** Usually, increasing dose of exposure should be associated with increasing occurrence of outcome; e.g. with increasing consumption of tobacco, the occurrence of IHD rises. This is also called “dose - response relationship”. However, the investigator should remember that not all causal associations would demonstrate this phenomenon; e.g. the association between DES consumption by mothers and vaginal CA in daughters many years later does not exhibit this ‘gradient’ phenomenon, possibly due to a phenomenon called “sufficient dose for maximum effect”.

**(e) Biological plausibility :** Does the cause - effect association forwarded by us “stand to reasoning” i.e. commensurate with the already known and accepted facts. However, here too the researcher must note that biological plausibility is a relative phenomena based on present day knowledge of the state of affairs; what we think nonsensical today may be accepted as correct tomorrow, e.g. in the mid 19th century when a clinician recommended hand washing by medical students and teachers before attending obstetric units, his recommendations were dismissed by medical fraternity as “doesn’t stand to reasoning”! The rest is history.

**(f) Experimental evidence :** An evidence, in the laboratory or in human subjects, based on deliberate introduction of the cause (exposure), thereby demonstrating that the outcome (effect) occurs in the group which has been subjected to the exposure and not in the other group, further strengthens our faith in the cause and effect relationship. Here again it should be noted that such experimentation on human subjects may be often impossible; (e.g. we cannot deliberately tell a group of human beings to smoke and the other group not to smoke and watch them for the development of lung CA). However, even in such cases, basic laboratory proof (e.g. microscopic demonstration of histological changes in the respiratory tract of animals subjected to tobacco smoke or in tobacco using humans) may further strengthen our belief in a “causal” association.

**(g) Other criteria :** Like ‘analogy’ (e.g. if one drug can cause congenital malformations, others can also do so); ‘Specificity’ (i.e. one cause, one effect) and ‘coherence’ (findings should not conflict with the known natural history of the disease) have also been forwarded to finally test a causal association. However, in general, criteria mentioned in step 4(a) to (c) are most important; (d) to (f) may lend additional support to the causal reasoning while those mentioned in (g) may also be considered.

## Summary

Most research aims at studying aetiological or cause - effect relationships in which change in the cause produces change in the effect. Diseases may have a single cause or (more commonly), have many causes (multifactorial). To establish cause - effect relationship one should choose the appropriate study design. During conduct of the study, measurement errors and bias should be eliminated or minimized. The role of chance should be ascertained by appropriate statistical tests. Control or adjustment for confounders should be done during planning or analysis stage. In the next step one needs to ascertain whether the association observed is statistically significant or not. Finally, once it has been ascertained that the study has been undertaken using the correct epidemiological design and using the correct, valid method of measurements, the associations observed are statistically significant and are not due to indirect relationships (confounding), then additional criteria for causation (as enunciated by Sir A B Hill) should be applied. These are : temporality, strength of association, consistency, dose - response relationship, biological plausibility, analogy, and experimental evidence.

## Study Exercises

(Study questions and chapter summary contributed by Amitav Banerjee)

**Long Question :** Define “causal association”. Describe the sequence of steps while establishing a cause and effect relationship.

**Short Notes :** (1) Hill’s criteria for causal association (2) Indirect association (3) Insignificant association

### MCQs

1. Cause effect relationship can be tested by the following study designs *Except* : (a) Ecological study (b) Case - control study (c) Cohort study (d) Randomized Controlled

- Trial.
- Most likely reason for failure to establish a cause effect relationship with small sample sizes is : (a) Alpha error or Type I error (b) Beta error or Type II error (c) Measurement errors (d) Observer errors.
  - The strength of association in a cause effect relationship is indicated by : (a) 'p' value (b) The magnitude of the RR or OR (c) Consistency of association (d) All of the above
  - If RR or OR is 1, it indicates that : (a) There is no cause effect relationship (b) There is Alpha Error (c) There is type 1 error (d) None of the above.

- The fact that most people infected with *Mycobacterium tuberculosis* do not suffer from Tuberculosis indicate that : (a) *Mycobacterium tuberculosis* is not a necessary cause for tuberculosis (b) *Mycobacterium tuberculosis* is a necessary but not sufficient cause for Tuberculosis (c) *Mycobacterium tuberculosis* may be of atypical form (d) None of above.

**Answers :** (1) a; (2) b; (3) b; (4) a; (5) b.

23

## Descriptive Studies (Including Ecological Studies) & Epidemiological Distribution According to Person, Place & Time

RajVir Bhalwar

### Definition

A descriptive study can be defined as one in which only one group, i.e. subjects having the outcome (disease or any other health related phenomena of interest) are studied, without any comparison group, for describing the outcome or health - related phenomena according to its frequency or such other summary figures (as mean), and its distribution according to selected variables related to person, place and time. Finally, it forwards tentative guesses (hypothesis) about the possible causal role of certain factors in the outcome of the interest, but does not confirm such causal role because of the absence of a comparison group.

### Characteristics of a Descriptive Study

The characteristics of a descriptive study can be described as follows :

- They do not proceed to test a "pre - formed hypothesis" regarding an association between a particular exposure and an outcome.
- The study is done only on one group of subjects; there is no comparison group.
- The main objective of a descriptive study is to "describe" the "mean value" of a health related condition, or a "proportion" (i.e. incidence or prevalence of a disease or health - related condition) or the natural history of disease or a health - related phenomena; and, in addition, the study also intends to describe the "distribution" of such means, proportions or natural progress of health - related phenomena, according to variables related to "person" (e.g. age, sex, blood groups etc.), "Place" (e.g. residential area)

and "time" (e.g. seasons).

- Having described the means / proportions / progression of health related phenomena and the "distribution" of these health problems according to various characteristics of person, place and time, a descriptive study culminates by making suggestions / hypotheses about certain "cause and effect" relationships which can be further tested by analytical studies.

### Essential Differences between a Descriptive and an Analytical Study

It is important, at this juncture, to understand the difference between a descriptive and an analytical study. The difference is, at times, so fine that it leads to confusion. The essential differences are given in Table - 1.

Table - 1 : Difference between Descriptive and Analytical Study	
Descriptive	Analytical
Only one group is studied	At least 2 groups are studied for making comparisons.
At the start of the study, there is no explicit hypothesis regarding cause - effect relationship	At the start of the study there is a definite hypothesis regarding an exposure possibly causing an outcome
The study ends with development of possible hypotheses regarding cause and effect relationship but does not confirm or reject such hypothesis.	At the end of the study, it confirms or rejects the hypothesis with which it started.

### Types of Descriptive Studies

#### (a) Case Reports and Case Series

This type of study is based on reports of a single, or else a series of cases of specific treated or untreated condition without any specific comparison (control) group. In addition to describing

the signs, symptoms or patho - physiological parameters in the series of patients, we may also work out “proportions” (e.g. percentage of cases that belong to a particular age group, sex, ethnic group etc.). However, we must remember that these proportions do not indicate risk since the denominator is still the number of cases and not the population at risk, e.g. in a case series of STD, we may find that 80 out of 100 cases (80 %) belong to a particular community. This should not be interpreted as that the risk for that particular community of getting STD is very high, since this may have happened because the particular community may as such be forming 80 % of the total population. This aspect must be kept in mind since it has been a common source of confusion and misinterpretation in medical literature.

### (b) Cross Sectional Descriptive Studies

Such descriptive studies are done on a sample of the total population and may be community based or hospital based. They are mainly directed to work out the :

- i) “*Prevalence*” of a factor of interest, e.g. prevalence of leprosy among general population, i.e. community based, or prevalence of nosocomial *Pseudomonas* infection in renal units, i.e. hospital based.
- ii) “*Mean*” of a factor of interest (e.g. Hb% level in ladies in the community; or serum protein levels among patients admitted with open pulmonary TB).
- iii) *Description of a “Pattern”* (e.g. pattern of antibiotic prescription in an Acute Medical Ward; or knowledge, attitudes and practices regarding contraceptives in a community).
- iv) *As a surrogate for longitudinal descriptive studies* : say, for weight charting of children from birth till 5 years age, on a monthly basis, ideally, we should collect a group of (say 1000) children born recently, and follow them up for next 5 years, recording their weight every month. This is the ideal, but often a difficult way (longitudinal descriptive study). To overcome the problems of follow up, what we can do is that we can take a “cross sectional” sample of say, 100 children each of ages 1, 2, 3 and so on, till 60 months and weigh them; the average weights could be used for making a growth chart as would have been done by a longitudinal study. Excellent and easy though it may look, the method has a flaw. The children whom we take up in such a study at different age groups are the ones who have survived to this age. It is quite possible that malnourished (under weight) children might have been dying progressively more, and not reaching the next month of age. If this were true, a chart based on cross sectional study would show higher mean values as compared to a (more correct) chart based on longitudinal descriptive study.

### (c) Longitudinal Descriptive Studies

In contrast to a cross sectional descriptive study, a longitudinal descriptive study follows up a single group of subjects over a defined period of time. These studies are more scientific than cross sectional ones but at the same time more costly and time consuming. These studies are undertaken with the following general objectives :

- i) To see the *incidence* of a disease (e.g. the incidence of poliomyelitis among children in the community or the

incidence of acute glomerulonephritis among children admitted in hospital, with acute sore throat).

- ii) To describe the ‘*natural history of a disease*’ (e.g. the clinical progression of cases of AIDS in hospital; or the clinical progression of cases of viral hepatitis in a community).
- iii) To describe a health related *natural phenomena* (e.g. the examples of weight charting of children given earlier).
- iv) To study the ‘*trend of a disease*’ (e.g. to see whether the incidence of TB is rising or falling in a community).
- v) To study the ‘*trend of a health - related phenomena*’ (e.g. to see whether the blood pressure of children from well - to - do families rises progressively; or whether the level of knowledge regarding prevention of AIDS is rising, falling or remaining stationary).

The basic difference between a cross sectional and a longitudinal descriptive study can be appreciated by the essential difference that in a cross sectional study the researcher examines every subject only once; while in a longitudinal study each subject is examined *at least* twice. For this reason, a cross - sectional study gives us the “prevalence” while a longitudinal study gives us the “incidence”.

## Epidemiological Descriptions according to Person, Place and Time

Having identified the disease, or the health related outcome that is of interest to the epidemiologist, and having collected data using valid and reliable methods, the epidemiologist takes the next step, i.e. of “describing” his findings about the disease, in terms of its “distribution” according to relevant variables of person, place and time, and the relevant combinations of person, place and time related variables. Such detailed description regarding distribution of the disease helps the epidemiologist in developing “hypothesis”, i.e. tentative guess - works regarding the various possible causes of the disease or its prevention / mitigation (i.e. why does the disease occur and what can be done for it). The important variables related to person, place and time, which the epidemiologist commonly studies, are described in succeeding paragraphs.

### Person Related Variables

People may be characterized according to an infinite number of variables. However, in practice, the number must be limited according to specific purposes of the study and resources available. The more commonly studied person related variables are :

1. **Age** : Age is a person related variable that is almost universally studied. One should always see the distribution of the disease that one has studied, according to “age - specific” rates, both for morbidity and mortality. In general, death rates tend to be highest during the infant & preschool age and extreme old age, while they tend to be lowest during 5 - 24 years group. Diseases like Road accidents and AIDS have a mortality peak in young / early middle age, while non - communicable (chronic) diseases show a rising trend during middle age. “Bimodality”, i.e. two peaks in the age distribution of morbidity or death due to a particular disease (as occurs in Hodgkin's disease) must always arouse interest - it indicates that the total subjects in the study do not form a homogenous material and the entity under examination needs to be divided into at least two distinct



subgroups with different experiences.

**2. Sex** : In general, while death rates are higher for males, the morbidity rates are higher for females. This differential is present irrespective of age, occupation, rural - urban differences, etc. Also, some diseases as those of gall bladder and thyroid are more common in females while CHD and lung cancer is less common. The sex related differences may be due to hormonal or other biological differences or due to differences in attitude towards life.

**3. Ethnic Group** : Ethnic group is defined as a group of persons who have a greater degree of homogeneity than the population at large in respect of biologic inheritance and present day customs. Various categories of variables, that are studied under the broad heading of 'ethnic group' are :

- Race - e.g. Mongoloid, Caucasian & Negroid.
- Nativity - e.g. European, Indian, Chinese etc.
- Religion
- Local reproductive and social units - These are groups which have maintained strictness regarding marriage within the group, e.g. certain religious communities. As an example, Jews have higher prevalence of the gene for Tay - Sachs disease as compared to non - Jews.

In addition to genetic differences between ethnic groups that may account for the disease differences, such differences may also be due to differences between these groups and the population at large as regards customs, diet, life style, socio economic factors etc.

**4. Social Class** : Social status or socio economic status is one of the most commonly studied person - related variable. Social status may be an independent risk factor for the disease or it may be indirectly associated with the disease in question, e.g. due to association with the type of housing. In India, two commonly used scales are the Prasad's scale based on per capita per month income and Kuppaswamy scale which takes an ordinal combination of education, occupation and income. The details are given in the section on Social & Behavioural Sciences.

**5. Occupation** : Association of disease with occupation is often studied, particularly in context of diseases that are likely to be related to occupation. The stress of occupation and exposure to various physical, chemical and biological disease agents therein, may be associated with high occurrence of such diseases. On the other hand, entry into occupation is itself likely to be related to particular physical (e.g. soldiers) and mental (e.g. Doctors) capabilities and this aspect must be considered since it can be an important source of selection bias in epidemiologic studies. In case of studies on children, it is also usual to study the occupation, education and income of the father and mother.

**6. Education** : Education leads to an improved level of knowledge and hence is likely to be associated with reduced risk of disease. This is the traditional "Knowledge Attitudes and Practices" (KAP) model, though it may not hold true in all conditions. In epidemiologic studies it is usual to study the distribution of disease according to level of formal education as illiterate, just literate (upto 5th standard), upto matriculation,

upto college, graduate, and post - graduate or Doctoral level.

**7. Marital Status** : In general, mortality rates are lowest among married, followed by single, widowed, and divorced, in that order, irrespective of sex. In addition, concordance of disease among spouses points towards strong environmental influences as infections, diet, customs and reduces the chances of genetic or immunological mechanisms in being operative in such diseases.

**8. Family Variables** : Depending on the scope of the epidemiological investigations at hand, various family variables as family size, birth order, maternal age, parental deprivation during childhood, familial aggregation of disease, and so on, are studied.

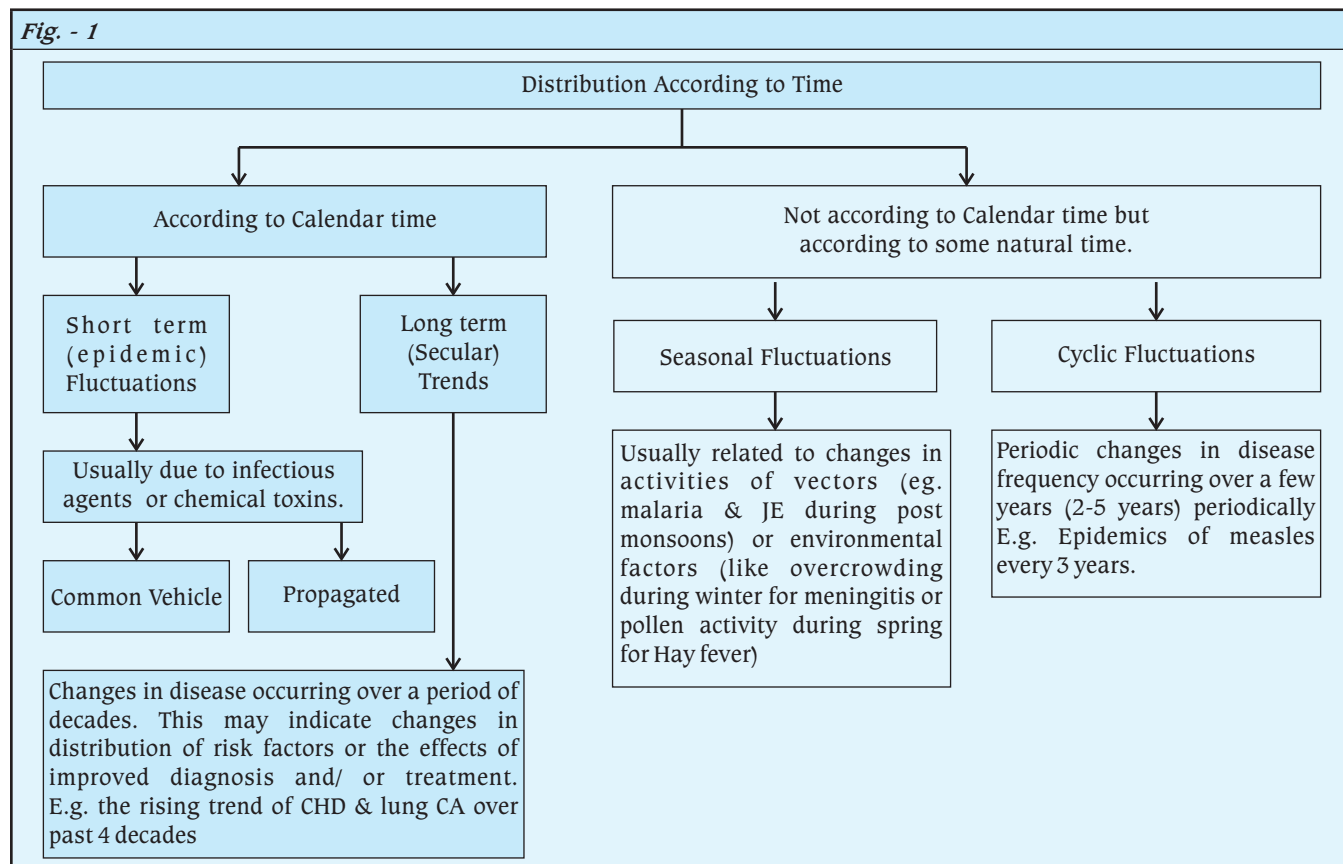
**9. Twin Studies** : These are very powerful methods for evaluating the genetic background of a disease. They work on the premise that monozygotic twins (being formed from the division of a single fertilized ovum) carry identical genes, while dizygotic twins are simply like two different siblings from genetic point of view. Thus, concordance of a disease in monozygotic twins as compared to dizygotic, is a strong indication of genetic background. On the other hand, discordance as regards a disease among monozygotic twins points towards environmental etiology. Developed countries have established "twin registries" for large scale epidemiological studies in this field.

**10. Other Variables** : The variables described above are the ones which are quite commonly used in epidemiological studies. However, as said earlier, there can be thousands of possible "person - related" variables in the form of various Socio - Demographic, Physiological, Biochemical, Immunological characteristics. An epidemiologist will have to choose the relevant ones, depending on her epidemiological question.

**Interpretation of Person - Related Descriptive Epidemiology:** While assessing the results from person related variables and forming hypothesis based on these descriptions of a disease, one must consider whether any of the following points could give an alternative explanation :

- (a) Differences in availability of health services (the rich may go to private doctors for treatment of STDs so that their disease is not reported and hence it may seem that STD is lesser among the rich); differences in utilization of health services (girl child may not be taken to the health care facility and hence a disease may appear to be lesser among girls); differences in precision of diagnosis (STDs are more difficult to diagnose among women than men); or differences in reporting the disease (Females may report STDs less often than males).
- (b) Differences which may be due to indirectly associated variables, i.e. confounders; e.g. difference in CHD between whites and blacks may not be because of racial factors but rather because of differences in socioeconomic status of the 2 racial groups.
- (c) Once the above 2 possible causes of apparent differences have been excluded, one should explore the possible environmental, biological and genetic factors as an explanation for the observed person - related distribution.

Fig. - 1



### Distribution According to Time

Descriptions of changes in disease pattern occurring over time are important in developing hypotheses regarding its etiology and prevention. Distribution in time may be of the following types, as shown in Fig. - 1.

**1. Common Vehicle Epidemics** : A common vehicle epidemic occurs due to presence of infectious or a chemical noxious agent in a common vehicle which serves as the channel of transmission, e.g. food, drink, air, pooled blood etc. Depending on the duration of persistence of the agent in the vehicle and the frequency of contact of the vehicle with the susceptible population, these may be of 3 types (refer to Fig. - 2 for graphical presentations) :

**(A) Common Source (Vehicle), Single (Point) Exposure:** The infective material remains present in the vehicle for a brief period of time; during this period all those who come in contact with the vehicle become exposed to the infection. This is classically seen in outbreaks of food poisoning and such outbreaks of cholera that are due to brief contact of an incubatory carrier with food or water. An epidemic curve, plotted with the frequency of the disease along the vertical (Y) axis and measure of time (dates, hours, weeks etc.) along the horizontal (X) axis shows certain characteristic features :

- (i) All cases occur within one known incubation period of the disease.
- (ii) The epidemic curve has a sharp onset and an equally abrupt decline.

- (iii) The peak of the epidemic is sharp and coincides with the median incubation period of the disease.

**(B) Common Source, Continued exposure** : Such an epidemic would occur when an infectious agent persists in the common vehicle for some amount of time. The final decline of the epidemic occurs either because the cause of contamination is removed or else because of the fact that all possible "susceptibles" have become infected. Such curves are seen in contamination of surface / ground or piped water supplies with human excreta, as in infectious hepatitis or cholera, or food borne typhoid fever outbreaks due to carriers or contaminated tinned foods. The epidemic curve rises slowly, and also falls gradually; the peak is not sharp but rather plateau - like and the duration of epidemic is stretched out, depending on the duration that contamination had persisted in the vehicle.

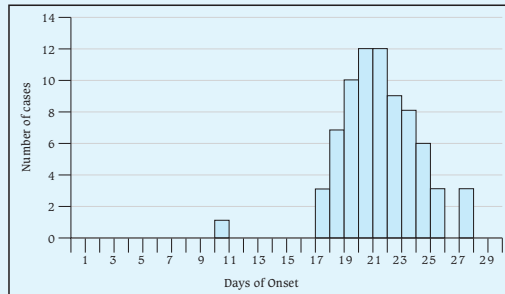
**(C) Common Source, interrupted exposure** : In such epidemic, there is a common source, but the source introduces the infection into the vehicle only interruptedly. For example, out of the 4 nurses looking after a urological ward, 1 maybe carrier of *Pseudomonas aeruginosa*. Now, as and when this particular sister is on duty, she would introduce the infection through the catheters that she may be passing into the patients. Such a curve will show an increase in frequency but the curve will be almost flat with occasional irregular waves coinciding with the periodic introductions of infection.

**2. Propagated Source** : In such an epidemic, the source itself propagates, i.e. multiplies. For example, in a group of school

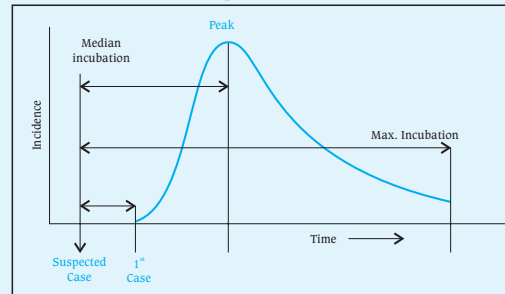
**Fig. : 2 : Graphical Representation of Epidemic Curves**

**Common Vehicle, Point Source Epidemic Curve**

**As Histogram**

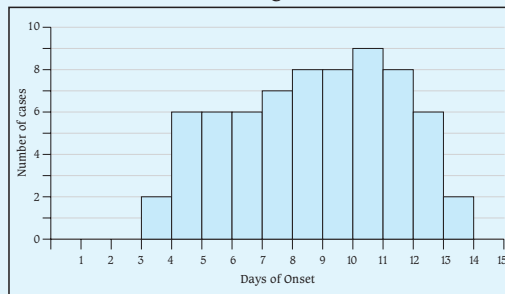


**As Epidemic Curve**

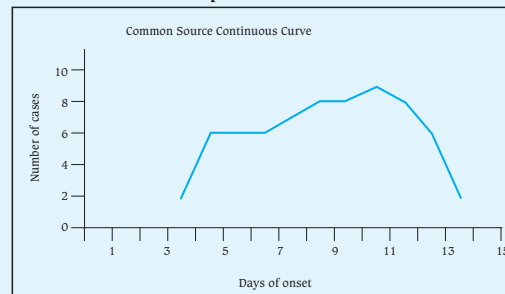


**Common Source Continuous Curve**

**As Histogram**

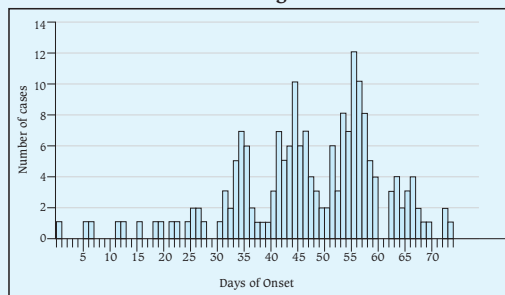


**As Epidemic Curve**

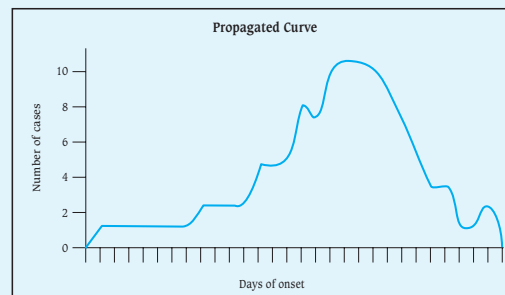


**Propagated Epidemic Curve**

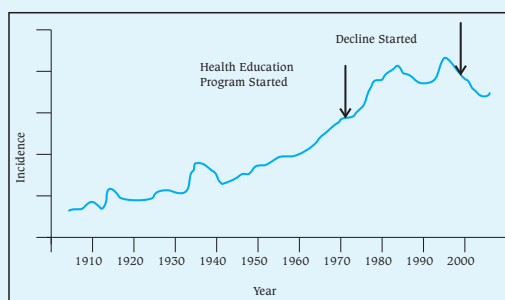
**As Histogram**



**As Epidemic Curve**



**Secular Trends of Incidence of Lung Cancer in a developed country**



children, the first (index) case of diphtheria may pass on droplet infection to 3 others; these 3 may then pass on to 9 others and thus the source multiplies. The fall of the epidemic occurs due to development of enough herd immunity so that no more susceptibles can be effectively infected. The epidemic curve rises slowly, in waves, reaches a flat plateau and then declines slowly. Such curves are seen in droplet infections like Diphtheria, Mumps, Measles; in vector borne diseases like Malaria, JE and Dengue epidemics, Influenza and in STD and HIV epidemics.

**Seasonal fluctuations** : Diseases like Malaria and JE are commoner during immediate post monsoon season due to increased breeding of vectors; airborne / droplet infections are commoner in winters when people tend to congregate and overcrowd. Similarly, asthma shows highest incidence during spring and autumn suggesting specific environmental factors in its causation. In fact, till the early years of 20th century, European as well as American typhus were both believed to be epidemic, due to lice transmission; however, Maxcy, while studying the seasonal pattern of these two groups of typhus fever demonstrated that while the European (louse borne, epidemic) typhus was higher in the first half of the year, the American form was higher during the second half of the year. This difference in seasonal pattern, coupled with the subsequent person and place related factors finally pointed out the fact that American typhus was clearly distinct from the European form and was possibly associated with rodents; today we know it as Rat flea borne (murine, endemic) typhus.

Seasonal fluctuations are usually demonstrated by line diagrams. They may help differentiating two similar - appearing illnesses like JE and meningococcal meningitis - the former having a peak during post monsoon and the latter manifesting a peak during peak winters.

**Cyclical Changes** : These are periodic peaks in disease frequencies occurring every 3 - 5 years. The common example is of measles in which epidemics tend to occur in cycles of 2 - 3 years, possibly due to accumulation of enough susceptibles.

**Secular trends** : These are time trends occurring over a period of decades. Secular trends during this century have been noticed for cancers of various sites - a declining trend in death rate due to cancers of stomach and uterus and a rising trend for cancers of lung and pancreas, while there is no change in breast cancer mortality rate.

**Interpreting the distribution according to time** : Changes in trends of morbidity or mortality of a disease may be real or artifactual and hence, while evaluating secular trends, one must consider whether such an observed trend could be artifactual due to any one of the following reasons :

**(a) Errors in numerator :**

- (i) Change in recognition of a disease, e.g. better diagnostic facilities.
- (ii) Change in rules for classification of cancers or death or procedures in ICD which is brought out decadal by WHO.
- (iii) Changes in accuracy of reporting the age at death.

**(b) Errors in denominator due to errors in enumeration of population**

Once the above alternative explanations have been considered, the epidemiologist should consider the following possibilities for a real change in time trends :

- (i) Changes in age distribution of a population.
- (ii) Changes in survivorship (e.g. better treatment available).
- (iii) Changes in actual incidence of disease resulting from changes in environmental or genetic factors. This final evaluation may bring out very important epidemiologic findings; e.g. an increasing trend during 1959 - 67 in asthma mortality, after excluding all the other possibilities, pointed towards some environmental factors. Further investigations showed that this had occurred due to increased availability (due to over - the - counter sale) of pressurized aerosol bronchodilators, especially which contained isoprenaline, which had led to a large number of sudden deaths.

**Distribution According to Place**

Place is the third determinant of the distribution of disease. Many diseases have typical spatial relationships; goiter is common in foothill regions, Anthrax and brucellosis in rural areas and CHD is commoner in affluent countries. Thus, differences in the distribution of a disease according to place may be made according to political boundaries (e.g. international comparison, regional comparison within countries) or according to natural boundaries (e.g. rural - urban differences, altitude, or local distribution of disease) as follows :

**1. International Comparisons** : Japan has very low CHD mortality rates but high rates for cerebro - vascular accidents, Hypertension and gastric CA; UK has high lung CA rates while USA has high CHD rates. When making such international comparisons in respect of a disease, one must initially assess whether these observed differences are artifactual due to errors in numerator or errors in denominator (as already explained under "TIME"). Thus, National, Regional or International differences in the availability of medical services, diagnostic practices of physicians, quality of available diagnostics, differences in disease classification procedures, completeness of reporting of death & disease and completeness of census may all introduce artifactual differences.

Once these considerations indicate that the differences are not artifactual, but real, i.e. either due to the play of environmental factors or else genetic factors, a good method of dissecting this out are "*Migrant Studies*". Let us say a group of people 'M', have immigrated from the original country 'X' to a new country 'Y'; Now, these immigrants will carry with them their genetic background of the original country to the new country; however they would be exposed to a set of environmental conditions (lifestyle, housing, water supply, nutrients) which would be different in the new country as compared to the original country. Let us say, the mortality (or morbidity) rates due to a given disease of interest 'A' are as follows :

Rates in original country = 'X'; Rates in new country = 'Y'; Rates among the migrants = 'M'.

Now, if the international differences in a disease are due to environmental factors, then 'M' would approximate 'Y' but 'M'



would tend to be different than 'X'. On the other hand, if the disease is determined by genetic factors, 'X' and 'M' will be equal, and 'X' and 'M' will be different from 'Y'.

International immigrant studies have been done in respect of CHD, CVD and CA esophagus, while within the country immigrant studies have been done in USA on multiple sclerosis.

**2. Regional Variations within countries** : e.g. goiter is a place related disease in India with high frequencies in the foot hill areas. Such regional differences help in developing hypothesis about role of possible environmental agents (as Iodine content of water and soil), in the etiology of the disease.

**3. Rural - Urban differences** : Rural - Urban differences again would point out towards possible environmental factors; e.g. IHD, STDs, Hypertension etc. are more common in the urban areas while oro - faecal infections are more common in rural areas. While making interpretations, one must evaluate the role of possible confounders like housing, education, economic status etc., in causing such differences.

**4. Local distributions** : Most often, the epidemiologists have to study local distributions, i.e. the differences in disease occurrence according to place within small, defined localities. For examining such differences, the epidemiologist makes a "spot map" which is a detailed layout map of that area or locality, showing the accommodation, water sources and supply lines, nightsoil disposal systems, vector breeding areas, eating establishments and various other environmental factors of relevance. On the same map, the epidemiologist plots the cases of the disease according to their frequency, looking for the places where there is a high frequency of cases and then trying to relate them with the possible environmental factors. Proper use of 'spot map' is almost mandatory while investigating most of the epidemic outbreaks; in fact, spot maps have provided important clues in finding out disease etiology, e.g. John Snow's investigation on cholera in London and Maxcy's investigation on Typhus (endemic) in USA.

The finding that a disease is related to a given place may finally be due to one of the two reasons :

1. The inhabitants of that place, by virtue of their genetic factors (e.g. sickle cell trait prevalence in African regions leading to differences in malarial prevalence) or because of their socio-environmental factors (e.g. Kuru due to cannibalistic ritual feeding in new guinea), are different from those at other places.

OR

2. Some etiologic factors, characteristic in the place are present. If this is the reason, then :
  - (i) High rates of disease will be observed in all ethnic groups in that area.
  - (ii) High rates are not observed in persons of similar ethnic groups living in other areas.
  - (iii) Healthy persons entering that area become ill with a frequency similar to the indigenous inhabitants.
  - (iv) Inhabitants who have left that area do not show high rates.
  - (v) Some evidence of the disease may also be found in animals in the same area.

**Methods of Displaying and Analysing Place Related Disease:** the common methods used in epidemiology are :

**1. Spot Mapping** : The details of making a spot map have already been explained above. It is the simplest, yet a very productive method of displaying the place - related distribution of a disease and must be practiced well by all persons proceeding to study public health and epidemiology.

**2. Map - on - map** : In this technique we combine two maps to bring disease frequencies, plotted as coloured dots, into visual approximation with other variables like roads, rivers, indices of poverty etc. This technique may also be used for studying "movement" of a disease in both time and place.

## Steps in Designing a Descriptive Study

The following is a sequential plan of steps for undertaking a descriptive study :

1. Write down your research question and its background significance (e.g. "to study prevalence of seropositivity of HIV among voluntary blood donors at a blood bank") and the design to be used (e.g. cross - sectional or longitudinal descriptive study or case - series).
2. What are the variables you want to study?
  - (a) Main variables : Name one or two variables which are of most interest to you, e.g. HIV seropositivity; any other STD.
  - (b) Other variables of secondary interest : These are the variables which you would like to study in addition to the main interest variables. Try to limit these to not more than 3 to 5 (e.g. other chronic diseases).
  - (c) What are the variables related to person, place and time according to which you will describe the "distribution" of the "main" and "secondary interest" variables, e.g. :
    - i) Person related : as age groups (less than 20, 20 - 30, 30 - 40, more than 40); sex; socio - economic status; history of needle sharing; marital status; frequency of visits to CSWs; use of condoms; knowledge about HIV and STD etc.
    - ii) Time related : as month - wise detection of cases out of total tested.
    - iii) Place related : as rural - urban differences of cases.
3. Specify the 'scales' of measurements in respect of the each of the main variables & secondary variables and those person / place / time variables on which "distribution" is to be described; i.e. whether on continuous / discrete / ordinal / dichotomous / polychotomous scales.
4. Define the 'total' and 'actual' (study) population, as per detailed discussion undertaken in the chapter on population and samples (e.g. in our above example, total population can be defined as voluntary blood donors in the country while actual (study) population may be voluntary blood donors in large hospitals in a particular district).
5. Calculate the sample size and specify the sampling procedure : Sample size is calculated by specifying the 'p', (or mean and SD), in respect of the main study variables and the acceptable deviation (d). (Refer to chapters on sample size and sampling methods). If there are more than 1 main study variable, calculate the sample size in respect

of all the main variables and study the largest calculated sample size.

6. Explicitly state any specific 'inclusion' or exclusion criteria: for example, you may make an exclusion criteria that "female blood donors will be excluded".
7. Give a detailed thought to your methods of 'measurement' and how you will obviate bias/ensure validity and reliability : Refer to chapter on measurements and validity for details. Preferably, write down entire methodology in a small "operations manual".
8. Pilot study : Do a pilot study on about 10% of the total sample size for pretesting your instruments, questionnaire and techniques (including interview methodology) and refine your methodology. Meet the relevant administrative authorities and seek their permission / clearance to do the study.
9. Conduct the data collection : Explain your study to the subjects; assure confidentiality; take informed consent. Keep supervising your data collectors and undertake various quality control steps.
10. Organize data management : Transfer the data recorded on the individual performae to master charts and if computer is available, from master chart to a standard computer package. Do not wait for the study to be completed before transferring the data to master chart and computer. Do this as a continuing process, say once a week. Meticulously check the performae / master charts for any missing data and get back to the subjects to get the information that is missing.
11. Analyse the data : Analysis of data in a descriptive study should be very clear, simple and appropriate. The following steps are generally undertaken :
  - (a) Calculate the "summary statistic" to describe the condition" - Depending on the scale on which the "target condition" is being measured, the "summary statistic" would be :
    - i) If the target condition is measured on categorical scale : The summary statistic would be a proportion, (percentage, if multiplied by 100). This proportion would be "prevalence" in case of a cross sectional descriptive study and "incidence" in case of longitudinal descriptive study.
    - ii) If target condition is being measured on numerical - continuous or numerical - discrete scale : For example, we may be trying to describe the serum LDL among patients of IHD (continuous variable) or number of children among households (discrete). In such exigencies, we will calculate the "mean" and Standard Deviation (SD). In addition, data on continuous and discrete variables can also be "categorized" into groups, by making frequency distribution tables.
    - iii) If target condition is measured on numerical - ordinal scale : E.g. we may be describing the APGAR score of children born in our hospital. The summary statistic in such cases will be the Median and Range.
  - (b) Calculate the 95% confidence intervals : The details of calculation of 95% CI have been explained in the section on biostatistics and this should be calculated to give an

estimate of the range in which the "reality" in the total, reference population is likely to lie.

(c) Describe the data according to the selected variables related to person, place and time : This is a very important step as it is crucial for drawing conclusions and developing hypotheses. The key word is to make sensible "subgroups" of selected person, place and time related variables and calculate "subgroup specific summary statistic" for these selected variables.

(d) Describe the data according to graphical methods like Bar diagram, histogram, time - curve, spot map etc. Intelligent use of the various methods, as described in the section on biostatistics, must be made to describe the distribution of the target condition, according to selected variables related to person, place and time.

12. Draw conclusion : See the statistical findings against the light of your clinical/health experience and draw conclusion and recommendations. Write down only the conclusions and recommendations that you have actually studied and not the ones that are simply based on your imaginations / assumptions. Finally, suggest one or more hypotheses that emerge out of your findings of the descriptive study.

## Ecological Studies (Syn. Correlational Studies)

One of the very well quoted studies on women's health (60) obtained data from 20 developed countries from western Europe, USA, Australia, New Zealand and Eastern Asian regions. National data was obtained on per capita consumption of fats in diet as well as incidence of female breast cancer in these countries. The results very clearly showed that as the per capita consumption of fat in a country increased, the incidence of breast cancer also increased. This finding could compel us to finally agree that dietary fat is a risk factor for breast cancer. Should we finally accept this result and start making a policy on lowering the fat consumption to prevent breast cancer? Or is there some lacuna?

There is a lacuna - with this data, we do not know whether the individual subjects who developed breast cancer in these countries actually had high fat intake or not, because the data is an aggregate (group) data for the entire country. Thus, while the country as a whole may be having high incidence of breast cancer as well as high per capita consumption of dietary fats, it is also quite possible that those who actually develop breast cancer may be eating less amount of fat, while those who did not develop breast cancer were the ones who were eating more fats. All that we know is the mean value of fat consumption for each country as well as the incidence of breast cancer for each country; no consideration is given, as would have been expected in an ideal epidemiologic design, to obtain the presence or absence of breast cancer and the level of fat consumption of each individual. This fallacy, that we may be ascribing, to members of a group, a risk factor that they do not actually possess as an individual, is called "*ecological fallacy*" or "*ecological bias*", which is quite common in these studies. Ecological fallacy can be defined as the state when an association which has been seen among variables, on an aggregate level may not necessarily represent an association at

the individual level.

This problem actually occurs in an ecological study because we only have data for groups but we do not have exposure and outcome data for each individual in that group. This issue would become clearer with the following example : Let's say we wanted to undertake the fat consumption - breast cancer study as a typical epidemiological study, which could be either case - control, cohort or cross - sectional type. Let's choose cross - sectional type. We would have taken a sample of say, 10 lakh women, asked each and every woman about her dietary fat consumption history and also examined her to ascertain whether she has breast cancer or not. Thus, we would have got data on each and every cell (recapitulate the cells a, b, c, and d of the 2 X 2 table in chapter - 9), as per Table - 2. However, in an ecological study as presented above, we only have data on the total having exposure (i.e. a + b) and the total diseased (i.e. a + c) (Table - 3).

Table - 2 : Cross - sectional study			
Exposure (Fat in diet)	Outcome (Breast cancer)		Total
	Present	Absent	
Present	(a) Y	(b) Y	a + b Y
Absent	(c) Y	(d) Y	c + d Y
Total	a + c Y	b + d Y	a + b + c + d Y

Table - 3 : Ecological study			
Exposure (Fat in diet)	Outcome (Breast cancer)		Total
	Present	Absent	
Present	(a) N	(b) N	a + b Y
Absent	(c) N	(d) N	c + d N
Total	a + c Y	b + d N	a + b + c + d N

*Index : Y = Data will be available in the study; N = Data will not be available*

For the reason that the data is not complete, as explained above, ecological studies are also known as "incomplete designs". At this juncture, one may ask as to why don't the investigators obtain data from individual subjects as regards the individual level of fat consumption as well as ascertain from each of them whether they have breast cancer or not. The reason is simple - the investigators obtained data from the cancer registries of these countries as regards breast cancer incidence, and from the central marketing organizations of these countries as regards sale of edible fats. Both these type of data are easy to obtain and takes little logistic effort, especially when data has to be obtained over 20 different countries. Obtaining data from individuals for these two variables would have been an almost impossible task.

The question which arises, then, is whether ecological studies are of value, given the problem of "ecological fallacy"? The answer is, Yes, they are valuable. If there are suggestions from ecological studies about a cause - effect relationship, our hypothesis becomes more strong and we could then further

explore this issue by specifically designed studies, either case - control type or of the cohort type. Ecological studies are therefore valuable for opening up avenues of research and for further strengthening a possible cause - effect relationship which has been earlier developed by other descriptive studies, so that these hypothesis can be further explored by specific hypothesis testing studies. However, alone and by themselves, ecological studies do not give final proof of cause - effect relationship. In fact, some epidemiologists do not consider ecological studies as a part of the basic epidemiological designs but place them in a separate category of "incomplete designs", for reason enumerated above.

Ecological studies can be of two types, viz., cross - sectional and longitudinal. In a cross sectional ecological study, the association between variables is seen at a given point of time, as the example of breast cancer - dietary fat study given above. Longitudinal ecological studies, on the other hand, are usually a part of ongoing surveillance systems. For example, in USA, ongoing surveillance data on the incidence of malaria has been correlated with the return of large numbers of soldiers from abroad and it was shown that the upsurges in incidence during 1950s, 1960s and 1980s coincided with return of soldiers from Korea, Vietnam and increased immigration into USA, respectively.

## Summary

Descriptive studies address only one group of subjects having the outcome of interest. There is no comparison group. Such studies do not have any pre - formed hypothesis. They may, however, generate a hypothesis at the end of the study, after studying the person, place and time distribution of the outcome of interest.

Different types of descriptive studies in increasing order of complexity are : case reports, case series, cross - sectional and longitudinal studies. Case reports and case series describe the signs and symptoms or other unique features such as a lab investigation, X - ray features, etc. in a single or a group of patients, treated or untreated. Since there is no information of the population at risk (denominator), nor a comparison group, neither can risk be calculated nor can a hypothesis be tested. Cross - sectional descriptive studies estimate prevalence only, as measurements are made only at one point in time, whereas longitudinal studies can record incidence, as well as study the natural history of disease or trends in health related phenomenon over time.

Person related factors are age, sex, ethnicity, socioeconomic status, marital status, family history, lifestyles, etc. Time distribution may show short term changes as in acute communicable diseases or long term changes (secular trends) as observed in most non communicable diseases. Time trends may be also seasonal (as observed in most vector borne diseases), or cyclical (e.g. measles outbreaks every 2 - 5 years before the era of vaccination). Place distribution may be international comparisons which may offer clue to etiology, or regional variations within countries. Diseases may also show rural - urban difference. Spot map can depict the place distribution of disease occurrence in defined localities.

In ecological studies the unit of measurement is undertaken

at the population level rather than at the individual level. This can lead to ecological fallacy or bias since the association seen at the aggregate level may not necessarily represent an association at the individual level.

## Study Exercises

Study questions and chapter summary contributed by Amitav Banerjee

**Long Questions :** What are the merits and demerits of descriptive studies as compared to analytical studies. Enumerate the major person, place and time related variables which are usually presented in a descriptive study.

**Short Notes :** (1) Ecological fallacy (2) Epidemic curves (3) Secular trends (4) Twin studies (5) Migrant studies

### MCQs & Exercises

- The following is the hypothetical data obtained year-wise, as regards the seroprevalence of HIV (per 1000) among truck drivers, obtained from the national serosurveillance system and also the number of states that had launched a condom promotion program for truck drivers

Year	Seropositivity	Number of States
1997	1.93	5
1998	1.87	7
1999	1.81	8
2000	1.82	8
2001	1.50	10
2002	1.47	12
2003	1.29	15
2004	1.10	18
2005	1.01	22

- What conclusions can you draw from the above data?
  - What can be the fallacy in the above conclusion?
  - What type of study design is the above study?
  - Is the above design a descriptive or an analytical design?
  - Besides the fallacy you have named in (b) above, what other bias could have happened?
- During a year, all consecutive full time normal births were studied in a teaching medical college hospital. Each infant's birth weight was measured, and at the same time, the mother's attendance at antenatal visits was ascertained from the records. The antenatal visits was classified into more frequent (i.e. > 3) and less frequent (3 or < 3). Analysis of data showed that

the mean birth weight of infants born to mothers who attended > 3 antenatal clinics was more than the mean birth weight of infants born to mothers who attended 3 or < 3 antenatal clinics. This difference was statistically significant.

- What type of study is this and why?
  - What 'person - related' variables which are potential confounders should be adjusted for before we put forward the hypothesis that number of antenatal visits is related to birth weight?
  - What other factors may affect birth weight?
- The following is age distribution of cases during an outbreak of viral hepatitis E in a hostel

Age group (Years)	Number of cases (%)
17 - 20	195 (73.58)
21 - 25	40 (15.09)
26 - 30	11 (4.15)
Above 30	19 (7.16)
Total	265 (100)

The above table shows that 195 or 73.58% of the cases were in the age group 17 - 20 years. Do we conclude from this data that Viral Hepatitis E is more common in this age group? Explain your answer with reasons.

**Answers :** (1) (a) A hypothesis can be considered that implementation of condom promotion program for truck drivers may be effective in reducing the HIV infection among them. (b) Ecological fallacy, since the data is reflective of "groups" or aggregates and not from individual truck drivers. (c) Ecological (Correlational) study design. (d) Neither descriptive nor analytic; it is classified as a separate category as "Incomplete Designs". (e) Effect of other factors cannot be studied; for example the reduction in seropositivity among truck drivers could have been due to an intensive health education programme so that the visits to CSWs came down rather than due to increasing use of condoms.

- (a) The study is cross - sectional because the cause i.e. number of antenatal visits and the outcome i.e. birth weight are measured at the same time. (b) Potential confounders such as socioeconomic status should be adjusted for since mothers with better socioeconomic status are more likely to have more number of antenatal visits as well as higher birth weight of their infants because of associated factors such as better nutrition during pregnancy. (c) Other variables such as tobacco use, maternal disease, etc. may also affect birth weight.
- No we cannot conclude that the disease is more common in this age group as we do not have the denominators or population at risk in each age group.



RajVir Bhalwar

We have already deliberated on the situations in which a medical researcher should select the case control design to answer her research question. The case control design is one of the finest and easiest methods of analytical research available to the doctor who has an easy access to patients of a particular disease admitted to the hospitals. At the same time, case control studies may be considered as the “Acid Test” for the capabilities of an epidemiologist and seasoned researcher because of the high potential for ‘bias’ that they have.

**Definition :** A case control study is defined as an epidemiological approach in which the researcher starts by picking up ‘cases’ who have already developed a particular disease or ‘outcome’ of interest, and a comparison group (controls) of subjects who, except for the fact that they have not developed the particular disease, are otherwise similar to the cases. Having assembled the two groups, the investigator finds out the presence (or the history) of the particular ‘exposure’ which she thinks is a risk factor and compares the two groups (cases and controls) as regards the presence (or history) of exposure.

The case control study has a special value in epidemiology and medical research because of the special advantages that it offers. However, the method carries certain distinct disadvantages and the researcher choosing this design must remain careful to take preventive action against them (see Box - 1).

#### Box - 1 : Case - Control Studies

##### Advantages

- Inexpensive, requires only a few subjects gives quick results
- Well suited for diseases which have a long latent period (e.g. cancers, AIDS, MI, CVA etc.)
- Well suited for an outcome which is ‘rare’
- Well suited for conditions in which medical care is usually sought
- Helps in examining multiple etiologic factors - once we have the cases of the disease, we can take history of all the factors that we feel may be risk factors
- Reasonably good for diseases that have a “relatively rapid onset” and are usually hospitalised (e.g. most of the acute infections; injuries etc.)

##### Disadvantages

- Not a good method for studying rare ‘exposures’
- Does not give any idea of ‘incidence’ or ‘prevalence’; it only gives us a measure of Odds Ratio (OR)
- Particularly prone to various forms of selection and information biases, particularly survivorship Bias, Recall Bias and observer’s bias.
- ‘Temporal Relationship’ is usually only a matter of conjecture but not a proof

## Designing and Conducting a Case Control Study

**Step 1 - Specify the total population and actual (study) population :** Specification of actual (study) population at this stage becomes especially important as it will give us an idea of the “population” from which cases have come and thus we would be able to ensure that our controls should also represent the same population, (an essential requirement of a case control study).

**Step 2 - Specify the major study variables and their ‘scales’ of measurement:**

- **Outcome variable :** In case control study this will be the particular disease or outcome of interest. Most of the times this will be measured on a ‘dichotomous’ scale (i.e. disease present = cases, and disease absent = controls).
- **Exposure variable(s) :** This is the suspected ‘cause’ that the investigator is studying for the association with the disease under study.
- **Specify the scales of measurement of the exposure variable -** usually it is dichotomous (exposure present or absent).
- **Potential Confounding Factors (PCF) :** List out all the PCF by thorough reading of the literature and discussion with experts. Specify the ‘scales’ of measurement.

**Step 3 - Calculate the sample size :** The details have been discussed in the section on Biostatistics.

**Step 4 - Specify the selection criteria of cases as per following headings :**

- **Diagnostic criteria :** Enunciate clear cut diagnostic criteria for the disease of interest. As far as possible use criteria given by expert bodies. If there is doubt, make categories like “definite”, “probable” and “possible” and analyse them separately.
- **State the inclusion or exclusion criteria :** One of the central issues in a case control study is that cases should have had a reasonable possibility of the disease being induced by the suspected exposure; and that the controls should have had a “reasonable chance” of being exposed to the exposure. This leads to the fact that any case or control who does not meet these criteria should be excluded from the study. E.g. in a study of recent OC use (exposure) and TE (outcome) we would like to exclude “TE cases occurring postpartum/ during pregnancy / post operatively/ post menopausal ladies / ladies on other contraceptives / hysterectomised ladies”. One thing the worker must ensure is that the exclusion / inclusion criteria should be clearly defined and must equally apply to cases as well as controls.
- **Source of cases :** The usual source of the cases is “hospital”. However, for diseases for which a large number of subjects may not be admitted (low backache; anal fissure etc.), the researcher must tap the OPDs, General practitioners or even think of population based cases by searching them in the population.
- **Incident or prevalent cases :** Specify whether you would like to consider only the newly occurring (incident) cases or all those who are already present including the old cases (prevalent). It is always advisable to take the incident cases since the prevalent cases might have changed their exposure status due to medical advice etc.

- *Method of sampling* : The most common method of sampling is either to take a systematic random sample of cases as they keep reporting; alternatively, if all the cases have already collected and a detailed list is available, a simple random sample may be drawn.

**Step 5 - Specify the selection procedure of controls** : One of the most important issues in a case control study is the selection of controls. The following specifications are to be made :

- *Source of Controls* : Whether Hospital based or else Population based controls : Patients admitted to the same hospital for diseases other than the one under study can be used as controls. They are easy to obtain, cooperative, and more likely to remember the exposure. The disadvantage is that they do not represent the healthy population and being ill, may be different from the healthy persons in number of ways. While selecting hospital controls, the best is to take a diagnostic assortment, i.e. patients from various diagnostic categories. On the other hand, healthy controls from the population would give a very good comparison provided it is logistically possible to study them and provided that they represent the same source population that gave rise to cases. The difficulties are that they are expensive and may refuse to participate.
- *Exclusion / Inclusion criteria* : The same criteria as for cases should equally apply.
- *Number of controls per case* : In general, 1 control per case is studied. The number of controls per case may be increased to upto 4 or 5 per case with slight increase in statistical precision but the cost of the study will increase tremendously. In any case the number of controls should never be less than the cases.
- *Number of control groups* : Usually, one "control group" is studied. However, if feasible, the worker may study 2 different control groups (e.g. one from population and another group from hospital); the procedure will improve the validity of the results.
- *Matching* : The details of 'matching' have already been explained in the chapter on control of confounding. In general, in a case control study it is recommended that one must carefully list out all the PCF; match for the universal confounders, i.e. age (in broad categories of 5 or 10 years of age groups) and sex, using frequency (group) matching. Record the data on all other PCF and adjust for confounding during analysis.

**Step 6 - Specify the procedures of measurement and specially take care to ensure validity and reliability** : The biggest disadvantage of a case control study is its particular susceptibility to various forms of selection and information biases. The detailed methods of prevention of bias and ensuring validity and reliability have been presented in chapter on confounding and bias. A summary is given in box - 2. In addition, quite often the investigator would be using a questionnaire in a case control study. The guidelines for preparation of questionnaires have been given in an earlier chapter.

**Step 7 - Do a pilot study** : Pre-testing on 5 - 10 cases and controls would be adequate in most situations to refine the methodology. If major changes are made following the results

of pilot study, then do not include the pilot study cases and controls in the analysis.

**Step 8 - Conduct the study** : Ensure valid collection of data, as described under the details of making measurements.

**Step 9 - Analysis of data** : Calculate the Odds Ratio (OR) and its 95% Confidence Interval (95% CI). Undertake hypothesis testing as described in the chapter on Biostatistics. Usually it will be a chi - square for 2X2 table or at times, a chi - square for linear trends in proportions. At times there may be requirement of a 't' test instead of chi - square test, depending on the way the variables have been measured. Control of confounding will require stratified analysis using Mantel - Haenszel technique or a multiple logistic regression. The details are described in the section on Biostatistics. If the data is from a "Pair matched" study, use McNemar's procedure for calculating chi square and odds ratio (OR) and 95% CI of OR. Consult a research methodologist for assistance.

## Summary

### Planning, Design, Conduct & Analysis of a Case - Control Study

- Review your research question and confirm that case - control study is the right design (you should be studying a risk factor and not any prevention / treatment / diagnostic/ prognostic factor).
- Specify the outcome, exposure and confounding variables.
- Specify the "reference" and "actual" populations.
- Specify the inclusion and exclusion criteria; apply them equally to cases and controls.
- Specify the selection modality for cases :
  - Diagnostic criteria for cases / case - definitions.
  - Source (hospital, OPD, or population based).
  - Sample size for cases
  - Procedure for sampling the cases
  - Incident (new) or prevalent (old & new) cases.
- Specify the selection procedure for controls :
  - Source of controls (healthy population based or hospital based)
  - No. of controls
  - No. of control groups
  - Method of sampling the controls
  - Matching, if considered.
- Specify the methods of measurement of various variables.
- Set up checks for obviating "biases" :
  - Ensure that controls are derived from same source population from which cases have come.
  - Ensure that controls have same chances of getting the exposure as cases had.
  - See if there is any problem of survivorship.
  - Avoid recall bias
  - If possible, blind the observers to case / control status.
  - If possible, use multiple sources of information and make "unobtrusive" measurements
- Do a pilot study on 5 to 10 cases and controls.

<b>Box - 2 : Biases in a case - control study (See chapter on Bias for details of examples quoted herewith)</b>
<b>Selection Biases</b>
<b>Berksonian Bias</b> : The probability of admission to hospital or detection of the outcome (disease) may be more among the cases simply because of the exposure. See example on unduly high chances of detection of cervical cancer (outcome) among OC users (exposure).
<b>Selection of inappropriate Cases or Controls</b> : Cases or controls who do not have adequate chance of exposure. For example, in a study of OC use (exposure) and thrombophlebitis (outcome), cases or controls who have undergone hysterectomy or using some other contraceptive, will not have adequate chances of exposure.
<b>Self selection Bias</b> : Patients who are admitted to a particular hospital and hence taken as cases may be systematically very different from most of the patients with the disease but who are not admitted to that hospital, as regards the exposure status.
<b>Survivorship Bias</b> : Case control study generally takes the patients who are living. Cases who have died are generally not taken and these may be systematically very different from living case as regards the exposure status (see example on Physical exercise and Acute MI).
<b>Incidence Prevalence Bias</b> : Cases who have been prevalent for long may have changed their exposure status due to medical advice or symptoms of disease (see examples on IBD and dietary fibre and hypertension and physical exercise).
<b>Selection of wrong control group</b> : Controls who are not from the same source population from where the cases have come; selection of close friends of cases - since they would in general have the same behavioural factors as cases (birds of a feather flock together !); or example of condom use and STDs given in the chapter on validity.
<b>Information (measurement) Biases</b>
<b>Recall bias</b> : Cases who are suffering from a disease are likely to recall much more as regards their exposure (example on congenital malformation and exposure to X - rays).
<b>Observer bias</b> : If observer is aware of the case - control status, she may subconsciously tend to ask much more from cases.
<b>Confounding Bias</b>
This is an important issue in case - control study (see chapter on confounding).
<b>Bias due to lack of evidence on temporality</b>

- Conduct the study.
- Statistical analysis
- Calculate Odds Ratio (OR) as  $(a \times d) / (b \times c)$  and not the Relative Risk (RR)
- Calculate 95% CI of OR
- Do a Chi - square test for hypothesis testing, or a 't' test, depending on scale of measurement.
- For control of confounding, undertake stratified analysis using "Mantel - Haenszel" method.
- For many confounders, undertake multiple logistic regression analysis.
- Make interpretations : specifically see if "temporal relation" can be shown; is there any possibility of bias remaining; have all potential confounders been identified and controlled.

## Study Exercises

Study questions contributed by Amitav Banerjee

**Long Question** : Enumerate the advantages and disadvantages of case control studies. Discuss, in detail, the various biases that can occur in a case control study and the methods of preventing them.

**Short Notes** : (1) Measurement of outcome in a case control study (2) Compare and contrast Case control study with Cohort study.

## MCQs & Exercises

- Case control studies are : (a) Forward looking studies (b) Backward looking (c) Can be both backward looking and forward looking (d) Same as cross - sectional studies
- All of the following are true about case - control studies Except : (a) Both exposure and outcome has occurred before start of the study (b) Study progresses backwards from outcome to exposure (c) Uses control group for testing hypotheses (d) Loss to follow up (attrition) is the main disadvantage.
- Berkson's bias refers to : (a) Interviewer's bias (b) Recall bias (c) Bias due to different rates of admission to hospitals for those who have more than one disease (d) None of the above.
- Odds ratio is a measure of : (a) Confounding (b) Strength of association (c) Attributable risk (d) Burden of disease
- Which of the following is the most problematic in conduct of case control studies : (a) Time (b) Cost (c) Attrition (d) Selection of appropriate controls
- All are true about case - control studies Except : (a) Risk factors can be identified (b) It measures incidence (c) Used for rare diseases (d) Takes less time
- In planning a case control study to test the hypothesis whether a person with a family history of breast cancer has higher risk of developing breast cancer : (a) How will you select the cases? (b) How will you select the controls? Can

you take controls from the same family? (c) How will you measure family history of breast cancer? What can be the bias in this method? (d) How will you measure the strength of association and what statistical test of significance can you apply? (e) How will you deal with confounders?

**Answers :** (1) b; (2) d; (3) c; (4) b; (5) d; (6) b; (7) (a) Cases can be selected from malignant disease hospital or a cancer registry. (b) Controls should be selected from the general population in the catchment area of that hospital or cancer registry. They should be matched for potential confounders such as age, age at first pregnancy, lactation, etc. Family control could not be selected in this case at this will lead to 'overmatching' i.e. predictor variable of interest (family history) will also be matched masking the association, if any. (c) Family history of breast cancer can be elicited from interview of cases and

controls. There may be information bias in form of "recall bias" if cases recollect positive history more vividly than the controls. Another form of information bias can be observer bias, in case the observer elicits the history more persuasively from the cases than from the controls. To some extent, these biases can be minimized by masking the status of cases and controls from the observer and the study question from the respondents. (d) Strength of association should be measured by odds ratio with 95% confidence intervals after tabulation of the data in the 2x2 table. Chi square test can also be performed. (e) Confounders can be dealt with by matching during the planning stage. During analysis, they can be adjusted for by stratified analysis (Mantel - Haenszel) or by multiple logistic regression.

## 25 Cross - Sectional Analytic Studies

*RajVir Bhalwar*

The case control study is a very practical and quick method of ascertaining the association between (and indirectly estimating the risk due to) a suspected exposure (cause) and an outcome (effect), when both the cause and effect have already occurred and one has to go back retrospectively, tracing the history of exposure among the cases and controls. However, under the following situations, the case control design may not suit the needs of the investigator :

- If cases of the disease are not likely to be admitted, since the disease is perceived to be a "routine" illness; e.g. influenza, sore throat, scabies, dental caries, pediculosis, pyoderma and so on.
- If the disease has a "wide clinical spectrum" so that a large number of cases who are from the milder part of the spectrum may not come to the hospital, e.g. low backache, anal fissure etc.
- When the objective is not to study the cause of a disease but rather the cause of a health related phenomena and hence the subjects have to be obtained from the general population and not from the admitted patients from a hospital; e.g. Is the "health awareness regarding use of contraceptives" (exposure) more among the users of contraceptive (cases) as compared to non users (controls); or "Is tobacco smoking by adult males (cases) related to the history of their father being smoking (exposure)".
- When the objective is to see the "correlation" between two continuously distributed variables either in the hospital settings (e.g. In a group of diabetics, is serum cholesterol related to blood sugar?) or in the settings of healthy

community subjects (e.g. in the general population of adult males, is waist : hip ratio correlated with HDL : LDL ratio).

In all the above settings, the investigator cannot proceed starting with cases and controls. Instead, he has to take a 'sample' of subjects from the study population and then search for the presence or absence of the disease (e.g. anal fissure, sore throat etc.) or the attribute (presence or absence of adequate knowledge regarding contraceptives) or make readings about the two continuously distributed phenomena (e.g. collect data on serum cholesterol & blood sugar, or waist : hip and LDL : HDL) from each and every subject.

The above instances, when the investigator draws a 'sample' out of the study population of interest, and examines all the subjects to detect those having the disease / outcome and those not having this outcome of interest; and also, at the same time finds out whether or not they have the presence of the suspected cause (exposure) (or give a History of such an exposure in the past), is called the "Cross sectional analytic study". It is so named since it is like cutting a "cross section" of a sample of the study population and ascertaining the presence/ absence of both the exposure and the outcome at a single, given point of time.

This form of study differs from the case control study in that in a case control study the investigator starts with a group of subjects already diagnosed to be having the disease (or health outcome) of interest and picks up a comparison group (of usually equal number) of controls (presumed to be coming from the "same source population that gave rise to cases") and compares the two groups regarding the presence (or history) of the suspected exposure. On the other hand in a cross sectional analytic study, the investigator starts with a "sample" of subjects and then finds out who in this sample have the disease (or the health related outcome) of interest and who do not have



it, as well as finds out, at the same time, whether or not they have the exposure (or give a history of exposure).

### **The Cross-Sectional Study Design has Certain Additional Distinct Advantages over a Case-Control Study :**

- (a) Since the subjects having the disease (or the health related outcome) of interest, i.e. the cases, as well as those not having it, i.e. the controls, are derived from the same 'sample', one is definite that the controls represent the same source population that gave rise to cases (a requirement which is mandatory for the validity of case - control studies but, however, many a times the investigator is never really sure that this assumption holds good or not).
- (b) While in a case control study one does not get any idea of either the incidence or the prevalence, in a cross - sectional analytic study, one straightaway gets the prevalence of the disease or outcome of interest, e.g. in the preceding example, the prevalence of scabies is  $100/1000 = 10\%$  in the population; one also gets an idea of the prevalence of the exposure of interest, e.g. the prevalence of "wrong apprehensions" about Tubectomy / vasectomy is  $770/1000 = 77\%$  in the population.
- (c) Having worked out the 'prevalence', one is really sure whether the disease or outcome of interest is really a 'rare' one or not (an assumption central to the validity of the odds ratio (OR) from a case control study being a valid estimator of risk; however once again the investigator is often not sure in a case control study whether this is really so or not).
- (d) The investigator can study "correlations" between two "continuously distributed phenomena" (e.g. Blood sugar and serum cholesterol; waist; Hip ratio and LDL : HDL ratio) - an objective which cannot be fulfilled in a case control study.
- (e) The cross - sectional analytic study at many times can be used as the starting point of a cohort study (which can not be achieved in a case control study). For example, having identified the 'acceptors' and 'non acceptors' of vasectomy/tubectomy, the investigator can now follow up these 2 groups (taking acceptors as 'exposed' and non acceptors as 'non exposed' groups from now), and compare the rate of certain given medical complications (e.g. low backache, neurosis etc.) in the 2 groups.

### **The Advantages of a Cross-Sectional Analytic Study over Case-Control Study come at the Cost of Certain Disadvantages :**

- (a) The investigator has to take a much larger sample; e.g. for studying the association between Lung CA and smoking, the investigator may need to examine about 1 million healthy subjects to get 100 cases; on the other hand for the same objective to be fulfilled by a case control study, the investigator needs to collect 100 cases from a cancer hospital and another 100 controls - just 200 subjects would suffice.
- (b) In addition to the large number of subjects, the logistic support needed for diagnostic work up would be tremendous - imagine a large number of specialist Doctors and their diagnostic back up equipment moving around in

the community, examining one million persons !

### **When to Use the Cross-Sectional Analytic Study ?**

Keeping in view the advantages and disadvantages of the cross sectional analytic design versus case control method, it is recommended that when the investigator is faced, as her research objective with any of the four situations (a) to (d) mentioned on the first page of this chapter, she should consider using the cross - sectional analytic approach.

### **If there is a 'Cross-Sectional Analytic', then there should be a 'Longitudinal Analytic' Design also !**

Yes, the 'Cohort study' and the 'experimental studies' are what we can call "longitudinal analytical studies", studying the exposure - outcome relationship by starting from the exposure (or cause), following up the subjects (i.e. moving longitudinally) and finally assessing the development of outcome of interest.

### **Steps in conducting a Cross-Sectional Analytical Study**

**Step 1 :** State your research question, research hypothesis, objectives, and background significance of the research question.

**Step 2 :** Define the "Total (whole, reference) population" on which the study results will be applicable; and the "actual (study) population from which the sample will be drawn. The "actual (study) population" may be hospitalized patients or general community. Ensure that the actual population is a "representative subset" of the total population.

### **Step 3 - Specify your study variables and the 'scales' of measurements :**

**(a) Outcome variable :** This may be dichotomous (e.g. low backache present or absent) or polychotomous ordinal (normal, mild backache, moderate, severe) or continuous (Blood pressure, Serum cholesterol etc.) or discrete (e.g. number of DMF teeth) or ordinal (satisfaction scores regarding health services, minus 2 as very dissatisfied, minus 1 as slightly dissatisfied, 0 as neutral, +1 as slightly satisfied, +2 as highly satisfied).

**(b) Exposure variable :** Once again, the exposure variable may be measured on any of the scales mentioned under outcome variable. One has to intelligently decide this, based on the research question and objectives, as to what she really wants to study.

**(c) PCF :** Make a detailed list of all the variables that can confound the exposure - outcome relationship and specify the scales of their measurement - usually the scale would be dichotomous (e.g. smoking present / absent) or polychotomous (cigarette smoking categories) : non smoker / mild smoker (0 - 10 per day) / moderate (10 - 20) / Heavy (>20). If the purpose of research is to see the correlation between two continuous variables (e.g. between waist : hip ratio and LDL : HDL ratio), one may decide to measure certain confounders either on a continuous scale (e.g. Body Mass Index, Alcohol intake etc.), or on a discrete scale (e.g. no. of days on which physical exercise is done in a week).

**Step 4 - Calculate the sample size :** For example, we may be doing a cross sectional research with the objective of seeing the association between veg or non veg diet (exposure) and presence

or absence of anal fissure (outcome), the outcome being measured on a dichotomous scale. The general equation for calculating the number of cases required to be studied will be (see chapter on sample size calculation and case control studies for use of this equation).

$$\frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \times 2 \times p \times q}{(P_1 - P_0)^2}$$

Now if the number of cases calculated by the above equation comes out to be 100; and say, the expected prevalence of the disease is 10%, i.e. 0.1, then the total sample size required for the cross sectional study

$$= \frac{\text{No. of cases required}}{\text{Prevalence}} = \frac{100}{0.1} = 1000$$

Thus, we will need a sample of 1000 subjects to do this study, in which we will get about 100 cases and 900 controls.

**Step 5 - Describe the sampling method :** Having determined the sample size, the investigator has to specify the method to choose a random, representative sample. In a hospital based cross - sectional analytic study the advisable method is to draw a systematic random sample or a consecutive sample. In a community based study with large population of subjects, it is usually advisable to go in for a multistage sampling, selecting randomly, administrative or geographical units in the first and second stages and finally drawing a systematic random sample of subjects from the selected units (See chapter on sampling methods).

**Step 6 - Ensure validity and reliability, prevent bias :** Thorough consideration must be given to these aspects before starting the data collection. In general, the checklist which has been given in the chapter on case - control studies for prevention of bias applies equally well for cross sectional studies and should be checked meticulously.

**Step 7 - Data Collection :** Collect the data on a predesigned form. Ensure that before you start the data collection, you have undertaken a pilot study on a sample of 10% of the total required sample (5% in case of large sample studies) for validating and standardizing all your instruments, questionnaire and techniques. During the data collection of the actual study, frequently examine your performae for any missing data and get back to the subjects if there is any missing data, at the earliest. If data collection is being done by different data collectors, cross check at least 20% of the filled performae independently for ensuring quality control of data and reducing observer variations. Enter data into Master chart or computer periodically and at an early date.

**Step 8 - Analysis of data :** The various procedures of analysis are the same as explained in the previous chapter on case - control studies, viz., calculation of OR and statistical hypothesis testing by chi - square test (or a 't' test if either the exposure or the outcome variable has been recorded on a numerical scale). In case both the exposure as well as the outcome variable have been recorded on numerical scale, then correlation coefficient is calculated. Control of confounding is undertaken by Mantel - Haenszel stratified analysis, or else by regression analysis if

there are a large number of confounding variables.

## Summary

The case control study is a practical and quick method of ascertaining the association between a suspected exposure (cause) and an outcome (effect), when both have already occurred. However, it may not suit the requirement of investigator under certain conditions like if cases of the disease are not likely to be admitted, if the disease has a "wide clinical spectrum", when the objective is not to study the cause of a disease but rather a health related phenomena and hence the subjects have to be obtained from the general population and not from the admitted patients from a hospital or if the objective is to see the "correlation" between two continuously distributed variables either in the hospital settings or in the settings of healthy community subjects. In such settings the investigator cannot proceed starting with cases and controls. Instead, he has to take a 'sample' of subjects from the study population. This kind of study is known as "cross sectional analytic study". It is so named since it is like cutting a "cross section" of a sample of the study population and ascertaining the presence or absence of both the exposure as well as the outcome at a single, given point of time.

The cross - sectional study has certain distinct advantages over a case - control study in that one is definite that the controls represent the same source population that gave rise to cases; also, it gives an idea about the prevalence of the disease of interest and hence we can find out whether the disease is rare or not, both of which are essential assumptions for the Odds Ratio. It can also be taken as the starting point of cohort study. Disadvantages are larger sample size and huge logistic support required.

In a cross sectional analytic study, each subject is examined only once and the assessment regarding the presence or absence of exposure as well as regards the disease in each subject is made at this single point of time. This design gives us the 'prevalence' and, as a measure of risk, the 'Prevalence Odds Ratio' (POR). It remains prone to the problem of recall bias, survivorship bias and the difficulty in proving temporal relationship.

For conducting cross sectional analytic study enlist outcome variable, exposure variable and potential confounding factor and their scale of measurement in actual study population. Sample taken should be of adequate size and representative of actual population. Data should be collected on above mentioned variable and analyzed by relevant statistical test. The measure of risk calculated from the cross sectional analytic study is the Odds ratio which is calculated as the cross - product ratio, as for a case control study.

## Study Exercises

**Long Question :** Describe the steps in planning, conduct and analysis of a cross - sectional analytic study to answer the question "Drinking hard water is likely to be protective against systemic hypertension".

**Short Notes :** (1) Biases in cross sectional analytic studies  
(2) Cross sectional versus longitudinal analytic studies  
(3) Sample size calculation in a cross sectional analytic study.

### MCQs & Exercises

1. What does cross sectional study give as a measure of risk?  
(a) Prevalence odds ratio, (b) Risk odds ratio (c) Exposure odds ratio (d) None of the above
2. When we want to study the “correlation” between two continuously distributed variables either in the hospital settings or in the settings of healthy community subjects, the design used is (a) Cohort study (b) Case control study (c) Cross sectional analytic study (d) None of the above
3. The disadvantages of cross sectional study vis a vis case control study are (a) Huge logistics (b) Large sample size (c) Both (d) None of the above
4. Cross sectional study gives (a) Incidence of the disease (b) Infectivity of the disease (c) Prevalence of the disease (d) None of the above
5. All these bias are present in cross sectional study except  
(a) Recall bias (b) Hospital related bias (c) Survivorship bias (d) Measurement bias

#### True or false

6. In longitudinal analytic study each subject is examined only once.
7. In Cross sectional analytic study each subject is examined more than once.
8. Cross sectional analytic study gives incidence of the disease.
9. In cross sectional analytic study exposure and outcome are measured in subjects simultaneously.

**Answers :** (1) a; (2) c; (3) c; (4) c; (5) b; (6) F; (7) F; (8) F; (9) T.

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### Cohort Studies

*RajVir Bhalwar*

As discussed earlier, a major disadvantage of case control study is that it is prone to various types of selection and information biases. Some of the major problems of case control study are overcome by cohort study, though by paying a higher cost and tremendous increase in logistic effort.

A ‘cohort’ means a group of people sharing a common exposure. In this study, the investigator starts by picking up two comparable groups, one having the exposure (e.g. tobacco users) and the other not having the exposure (e.g. non users of tobacco). She then excludes the presence of the outcome of interest (e.g. lung CA) in both the groups at the start of the study, and then follows up both the groups for a reasonable amount of time, observing for the outcome of interest in both the groups and finally makes comparison as regards incidence of the outcome in the two groups. The cohort study has certain major advantages in medical research.

#### When to Select a Cohort Design

The cohort design should therefore be undertaken if the answer to the following question is “Yes” :

- Is the disease a reasonably common one?
- Is the follow up period required “reasonably short”, so that you can conveniently complete the study within the time frame?
- Has some amount of evidence regarding the association between exposure and outcome been provided by case control studies?
- Are the subjects in your two groups (exposed and not exposed) reasonably likely to continue in the study?

- Are you sure you are studying risk factors / markers/ prognostic factors and not therapeutic/ preventive/ diagnostic procedures?

#### Steps in Designing, Conducting and Analysing a Cohort Design

**Step 1 :** Specify the research question, objectives and background significance.

**Step 2 :** Specify the variables of interest and their scales of measurement

- *Exposure variable* - Usually in a cohort study the exposure variable is measured on a ‘dichotomous scale’ (i.e. exposed or not exposed), or at times on a ‘polychotomous ordinal scale’ (not exposed, slightly exposed, moderately exposed, intensely exposed etc.).
- *Outcome variable* - The outcome variable would be the disease or other health related outcome which the investigator hypothesizes to occur as a result of the exposure. The outcome may be dichotomous (e.g. developed/did not develop lung CA) or polychotomous ordinal (remained normotensive/ developed mild hypertension / developed moderate hypertension / developed severe hypertension) or quantitative (e.g. serum cholesterol levels, no. of DMF teeth, score of respiratory disability 0,1,2,3 due to occupational exposure).
- *PCF* : Make an intensive search of the literature and contact the experts to find out all the variables that could be potential confounders of the exposure - outcome relationship. And record the data regarding confounders during the study.

**Step 3 - Specify the exclusion criteria** : e.g. we may like to restrict the study to males with a view to control confounding due to sex, or exclude such subjects who are likely to be lost to follow up or subjects with a disease which may interfere with



the occurrence of outcome of our interest.

**Step 4 - Calculate the sample size** : The details have been discussed in the section on Biostatistics and “use of Statistical software”. The researcher would need to specify the magnitude of acceptable type - 1 and 2 errors, the expected proportion of non - exposed cohort who are likely to develop the outcome (Po) and the magnitude of risk (RR) that the study desires to detect in a significant manner.

**Step 5 - Select the study cohort** : The study cohort is the one which has the ‘exposure’. This may be either *Special Exposure Groups* (e.g. radiologists for studies on effect of radiation; ANC cases having PIH for studying the outcome of pregnancy, etc.); or else it could be *Cohort defined on basis of geographical or administrative boundaries* (e.g. people living in a given state or district like Framingham heart study). The special advantage of such cohort is that the same group will give an exposed as well as unexposed (comparison) cohort; e.g. for the study on association of smoking during pregnancy (exposure) and low birth weight (outcome), all patients enrolled at an ANC may be followed up. This group will give, within itself, an exposed cohort (smokers) and an unexposed cohort (non - smokers). Thirdly, we may select a study cohort from *Groups offering special resources* (e.g. all registered doctors can be followed up for development of IHD after recording their physical activity levels. They will give special advantage of an accurate reporting as well as ease of follow up).

**Step 6 - Select the comparison cohort** : This is very important. It can be done by either selecting an “inbuilt comparison group” as in example given in step 5 above. This is, in fact, the best method of obtaining a comparison group in general, in the usual settings of clinical research. Secondly, we may make comparisons with general population rates, often done in study of diseases due to occupational exposures. Finally, if required, we may assemble a special comparison cohort - e.g. in a study of the association between exposure to petroleum fumes and subsequent bone marrow damage, workers handling the filling equipment at petrol pumps may be taken as exposed cohort while workers sitting in the offices or ancillary workers in the same petrol pumps may be taken as the specially assembled comparison cohort.

**Step 7 - Specify the sampling procedure** : The usual method of sampling in both the exposed and unexposed cohort groups is by simple random or by systematic random sampling method. Select about 20% extra subjects, because some will be removed on initial medical examination as already having the outcome and some will be lost to follow up.

**Step 8 - Exclude the disease or outcome of interest in both the exposed and unexposed cohort groups at the outset** : Do an initial medical examination to exclude out all those subjects, in both the cohort groups, who already have the disease (or outcome) of interest.

**Step 9 - Obtain data on exposure level** : This is an extremely important issue. We obtain this data by various methods, including *Direct interview of cohort members* (e.g. details of smoking, alcohol, sexual activities, personal habits, dietary information, physical exercise, personality type etc.); secondly, by *medical examinations or diagnostic procedures* by examining

both (exposed as well as non - exposed) groups similarly; thirdly, by measures of environment - (e.g. levels of pollutants in home environment, drinking water pollution levels etc.); and fourthly by going through existing “records” (e.g. for recording the levels of exposure to irradiation, use of drugs, etc. medical records can be used. Initial medical examination card at the time of entry to school or service can provide valuable details of an exposure).

**Step 10 - Obtain Data on all PCF** : Using methods as described in step 9 above, record detailed data on all the potential confounding factors.

**Step 11 - Consider matching** : Usually, in a cohort study, matching is not important; Data should be collected for all PCF and adjustment for confounding may be made during analysis. However, if considered feasible, the exposed and non exposed cohort groups may be “frequency matched” in respect of important confounders like - age, sex or other important PCF.

**Step 12 - Follow up and ascertainment of ‘outcome’ of interest** : Follow up should be meticulously undertaken for the period already decided. Due attention should be paid while making measurements for detecting the outcome of interest. The general measures for ensuring validity and reliability have already been detailed in chapter no. 1. In addition, special attention should be paid to the following types of measurement biases that can crop up in the cohort studies :

- **Measurement (Ascertainment) bias** : This would occur because of ‘differential ascertainment’ of the outcome between the two groups. For obviating this, inform all subjects of both groups well in advance of the dates and timings of medical examination and ensure that both the groups are examined by observers who have similar type of training and using similar type of instruments and techniques.
- **Observer bias** : This occurs because the investigator is aware about the fact as to which subject is ‘exposed’ and who is not exposed. For obviating this, if possible, ‘blind’ the observer to the exposure status, the details of exposure being known only to another co - worker who is, himself, not making any observation regarding ascertainment of outcome.
- **Cross over bias** : This may happen because those having the exposure (e.g. smokers) may cross over to the non exposed group (i.e. become non smokers) and vice versa. Periodic evaluation of both the groups as regards level of exposure, making record entries and subsequent adjustments in the data analysis can help overcoming this problem.
- **‘Loss to follow up’ bias** : Some subjects in any case are likely to be lost to follow up / drop out. However, at times it may become a substantial problem. It is generally accepted that if more than 30% of the study subjects are lost to follow up, then the results of the study are to be viewed skeptically. The following step help in overcoming this type of bias :
  - Take detailed addresses of the subjects as also of their friends and relatives; contact them and make best of efforts to trace those who have been lost to follow up.
  - If the subjects have migrated, try to get information about them through a mailed questionnaire. If they



have died, try and obtain information from medical records and death certificates.

- Do an analysis in respect of certain demographic variables (e.g. age, sex, education, general health status etc.) to see whether those who have been lost to follow up are similar or else quite different from those who have remained in the study.

**Step 13 - Analysis** : In a cohort study we would calculate the relative risk (RR) as (incidence among exposed divided by incidence among non - exposed), the 95% confidence interval of RR, and hypothesis testing, using a chi - square test or a 't' test or such other relevant procedure as described in the section on Biostatistics.

### Certain Special Types of Cohort Studies

**Retrospective cohort studies** : The investigator identifies a group of individuals based on their characteristics in the past and reconstructs their subsequent disease experiences upto some defined time in the more recent past; e.g. in a study, all military persons who were exposed to "agent orange" many years back during wartime were identified on the basis of records, along with another similar group of soldiers who were not exposed to this agent. Both these groups so identified on the basis of records were then traced forward till the more recent past for various organ / system diseases. This type of study thus differs from the usual prospective cohort study (as described above) in which the cohort is identified on the basis of current characteristics and then followed forward in time.

**Nested cohort (Syn - Nested case control) study** : Combines the advantages of a cohort and a case control study. The investigator identifies a cohort and follows it up for the required period of time, after recording details of exposure in the subjects. As the cases of disease keep occurring, the investigator keeps picking up these cases along with equal number of controls from the same cohort and compares them for the exposure history. As an example, we may be working on a hypothesis that high serum lithium levels are a cause of subsequent mental illness. The problem is that undertaking serum lithium analysis may be a very costly affair; however, blood samples can be preserved for 15 - 20 years. So, we can take a cohort of say 1000 persons who are free of mental disease, collect their blood sample, cold preserve them and watch for 15 - 20 years. Over this period if 20 cases of mental disease occur, we can take out their blood samples along with 20 randomly selected samples of those who have not developed mental illness (controls who are "nested" in the cohort), analyse these 40 samples for serum lithium and make comparisons between the two groups (who developed mental illness and did not develop it) as regards lithium levels. The tremendous advantages that have occurred are that firstly, instead of doing 1000 serum lithium tests (as we would have done in a normal cohort study) we have done only 40 samples. Secondly, we can calculate the incidence of the disease which would not have been possible in a usual case control study. Thirdly, the problem of recall bias and that the controls may be from a different source population than cases (which occur in a case control study) have been prevented.

Advantages & Disadvantages of Cohort Design are shown in Box - 1. Comparison of case control and Cohort Design is given in Box - 2 at the end of this chapter.

#### Box - 1 : Advantages & Disadvantages of Cohort Design

##### Advantages of a Cohort Study

- Scientifically a much "stronger" design as compared to case - control or cross - sectional study.
- Temporal association is more convincingly demonstrated since investigator actually starts from exposure, before outcome has occurred and follows up till outcome.
- No recall bias since exposure is objectively assessed by investigator at start of the study.
- Can study many outcomes of a given exposure of interest.
- Provides a direct estimate of "incidence" of outcome in exposed and non - exposed groups and hence the "RR".
- Results are not biased due to "survivorship".
- Good for studying 'rare' exposures.
- Any change in exposure status during the course of study can be recorded.

##### Disadvantages of Cohort Design

- Quite expensive; needs large number of subjects.
- Results may take very long time to be available.
- Ascertainment bias due to "differential" assessment of exposed and non - exposed groups can lead to bias.
- "Loss to follow up" is a major potential for bias.
- Some subjects may "cross - over" i.e. exposed may leave the exposure and vice versa, during the study.
- Inefficient for study of a rare outcome.

### Summary

A Cohort study is defined as an analytical, observational investigation in which the epidemiologist starts by identifying a group of subjects who have the exposure of interest but have still not developed the outcome (the exposed cohort) and a comparable group of similar subjects who also have not developed the outcome and do not have the exposure (the comparison cohort). Having identified these two groups, the investigator follows up these two groups forward in time, to observe the incidence of the outcome in the two groups and calculates the Risk ratio of developing the outcome due to the exposure.

A cohort study starts with clear statement of the research question and statement of the exposure, outcome and confounding variables. The exclusion criteria are enunciated and the total population and actual (study) populations are defined. Sample size is calculated by specifying the type - 1 and 2 errors, the expected proportion of the non - exposed cohort who are likely to develop the outcome and the magnitude of risk (RR) desired to be detected in a significant manner.

Next, the "exposed" cohort is assembled either by sampling the general population which contains both, the exposed as well as non - exposed cohorts. Alternatively, the exposed cohort can be identified on the basis of specially exposed groups or on basis of groups which offer special resources. The non - exposed cohort is selected usually as a part of inbuilt cohort when general population has been used to obtain the exposed cohort; alternatively, a special comparison cohort can be assimilated or else, comparison of incidence rates in exposed cohort can be made with incidence rates in general population.

Having assembled the two cohorts, data on baseline exposure level, as well as also data on all the potential confounders is recorded. Any subject who already has the outcome or else is not at risk of developing the outcome due to any other reason is excluded from the study at this point.

The two cohorts are now followed up for the defined period of time, examining both the groups using methods which are similar and valid. All efforts are made to prevent loss to follow up and any cross over. The occurrence of outcome in both the cohorts is recorded and data is analysed for calculation of Risk (Incidence) in the two cohorts, the RR and additionally, for control of confounding.

In addition to the above - mentioned classical 'prospective cohort study design', other special type of cohort designs include the "retrospective cohort study" in which the study is initiated after the outcome has most probably occurred but the researcher starts by identifying the exposed and non - exposed groups and then moves forward to find the incidence of outcome in the two groups. Another design is the nested case - control study in which the cases are nested in a cohort; as the study proceeds, the cases occurring in the cohort as also controls from the same cohort are picked up and compared.

## Study Exercises

**Long Question :** Give an outline of the steps you would undertake in planning, designing and analysis of a cohort study for answering the issue whether smoking by the mother

during pregnancy is associated with prematurity / low birth weight among newborns.

**Short Notes :** (1) Advantages and disadvantages of a cohort study (2) Biases in a cohort study (3) Compare and contrast case control study with cohort study.

## MCQs & Exercises

- Measure of risk in cohort study is : (a) Relative risk (b)Prevalence odds ratio (c) Exposure odd ratio (d) None of the above
- Cohort study can be used to study all of the following, except : (a) Risk markers (b) Risk factors (c) Prognostic factors (d) Preventive factors
- Direction of reasoning in cohort study is (a) Prospective (b) Retrospective (c) None (d) Ambidirectional
- Temporal association of disease is best established by : (a) Case control study (b) Cross sectional study (c) Cohort study (d)None of the above
- Which of the following is correct for a cohort study : (a) We take two groups which neither have exposure nor outcome and follow them for defined period of time (b) Take two groups in which one group have the exposure and other does not, and both groups do not have the outcome and follow both for defined period of time (c) Single group is studied for the presence of exposure and outcome at given point of time (d) Take a group which has exposure but not the disease and follow it for defined period of time.

**Answers :** (1) a; (2) d; (3) a; (4) c; (5) b.

**Box - 2 : Comparison of Case - Control and Cohort Designs**

	Heading	Case Control Study	Cohort Study
1.	Type of design	Observational, analytical	Observational, analytical
2.	Temporality	Retrospective (backward in time)	Prospective (Forward in time)
3.	Direction of reasoning	From outcome to exposure	From exposure to outcome
4.	Occurrence of outcome when study is started	Outcome must have already occurred	Outcome would have usually not occurred (however, in a retrospective cohort study, the outcome may have occurred when study is started)
5.	Calculation of risk estimates	Neither incidence nor prevalence can be calculated. Only the Odds Ratio (OR) can be calculated which under certain assumptions is a valid estimator of RR	Calculates the incidences (risk) in the exposed and non - exposed cohorts and the Risk Ratio (RR)
6.	Temporal association	Never proven; only a matter of conjecture	Proven
7.	Recall, Survivorship bias, incidence - prevalence, hospital related and Berksonian biases	Potential problem	Not an issue
8.	Loss to follow - up and cross - over Biases	Not an issue	Potential problem
9.	Ascertainment Bias	Potential problem	Potential problem
10.	Confounding Bias	Potential problem	Potential problem
11.	Time taken	Results available quickly	Takes longer time
12.	Number of subjects	Small sample size required	Requires large sample
13.	Logistic efforts	Cheap, requires little logistics	Expensive, requires lot of effort

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The ideal design to practice in medical research settings is the experimental design; in fact it is a model (paradigm) scenario in epidemiology. In this approach, the epidemiologist (investigator) draws a random, representative sample from the study population. He then excludes out, from this random sample, all those who already have the outcome of interest, thus retaining only those who do not have the outcome of interest at the time of starting the study. In addition, quite naturally, none of these selected persons would have the exposure of interest at this point of time. Now, having assembled such a group, the investigator "randomizes" (i.e. randomly allocates) this group into two, such that every subject has similar chance of coming in either of the two groups. He now gives the "exposure" of interest to one group (O - E+) and a 'placebo' only to the other group (O - E -) and follows them up for a relevant period of time, at the end of which he compares the two groups as regards the development of the outcome of interest.

The noteworthy aspect in the experimental design is, thus, that it is the investigator who intervenes actively, deciding (of course, in a random fashion) as to who will get the exposure and who will not. It is this aspect which differentiates the experimental design from the other type of prospective study (the cohort study) in which the subjects have themselves taken up the exposure by their own choice (e.g. smokers and non smokers), the exposure not being dictated by the investigator. This issue may sound trivial, but has far - reaching consequences in the validity of research - e.g. lung cancer may be higher among smokers as compared to non - smokers because persons may take on to smoking because of certain genetic factors, and by virtue of these genetic factors, they may be more prone to lung cancer; thus, the cause of lung cancer may not be smoking but those peculiar genetic factors. On the other hand, if the investigator would have "randomly" divided a group of human beings, (initially non smokers and not having lung cancer) into two groups and asked one group to smoke and the other not to, then these two groups would have been exactly similar to each other in all aspects, including genetic factors, being dissimilar to each other only in respect of the exposure so allocated (i.e. smoking), and any difference in the two groups as regards subsequent lung cancer occurrence would have been due to the exposure (smoking). Apparently, such a design using a harmful exposure like smoking is only a theoretical possibility but, nonetheless, explains the scientific importance of "intervention" in epidemiology and research methodology.

To further explain the conduct of an experimental (intervention) design, let us say, we want to study whether it is worthwhile to give Isoniazid chemoprophylaxis to children who are close contacts of open cases of pulmonary TB. For undertaking an experimental study, we would take a random sample of, say, 100 children, out of the study population of, say 1000 children who are close contacts of open cases of pulmonary TB. We would now examine all these 100 children and would exclude,

from our study, all those children who already have our "outcome" of interest, i.e. "Tuberculosis" at this point. Let us say we had to exclude 10 children out of these 100 since they already had TB, thus leaving 90 non tubercular children in our study. Now, we would 'randomly' divide these 90 children (say by drawing lottery chits or tossing a coin) into 2 groups and give the 'exposure' i.e. Isoniazid tablets to one group (say group 'A'), while the other group will only get a placebo (i.e. a tablet containing calcium, having shape, size, taste, colour and dosage exactly the same as for Isoniazid). The two groups A & B, of 45 children each, would then be 'followed' up for a "clinically meaningful" period of time, say 5 years, and we shall examine all the children (in both groups) periodically during these 5 years for the development of Tuberculosis. Let us say, 3 out of the 45 children in the Isoniazid group developed TB during the 5 years follow up period while 9 children of the 45 given placebo developed TB. Thus, the incidence of TB among 'exposed' group (i.e. getting Isoniazid) is  $3/45 = 6.67\%$  and among the non exposed (i.e. not getting Isoniazid) is  $9/45 = 20\%$ ; thus, the "relative risk" of developing TB when getting Isoniazid is

$$\frac{\text{Incidence in exposed}}{\text{Incidence in non exposed}} = \frac{6.67}{20} = \frac{1}{3}$$

Thus, we would conclude that the chances of developing TB if Isoniazid chemoprophylaxis is given (to children who are close contacts of open pulmonary TB cases) is only third as compared to when Isoniazid is not given; in other words, Isoniazid chemoprophylaxis reduces the chances of getting TB by two thirds or 66.7%.

The above example of a hypothetical experimental design would let us easily understand the advantages and disadvantages that are inherent in this design :

#### Advantages

- Scientifically ideal method.
- Removes a large number of biases related to selection and measurement.
- Controls for confounding through randomization; thus the two groups are exactly similar to each other excepting for the exposure of interest. Thereby, it fulfills the basic dictum of research, which says "all other things being equal, it is the exposure of interest that has made the difference in the "outcome".
- Ensures temporal relationship between exposure and outcome.
- Builds up "faith" in the findings of the study.

#### Disadvantages

- In many situations, especially those which concern study of "risk factors" or "prognostic factors", one can not "randomly" allocate human beings into two groups; e.g. in our earlier example on smoking and lung cancer, we can not randomly divide human beings into two groups and ensure that one group smokes while the other does not.
- The second major disadvantage, even when "random allocation" is possible, is the ethical issue; at times it may not be ethical to randomly divide, thus exposing the 'exposed' group to a potentially harmful treatment or procedure; or to deprive the 'non exposed' group of a



potentially useful measures.

### When to Use an Experimental Design

Apparently, one has to carefully examine the advantages and disadvantages that are inherent in an experimental design and decide whether it is correct to use an experimental design for answering his research question. In general, one should ask himself the following two questions; if the answer to both of them is 'Yes', one can go ahead with an experimental design :

#### Q. No. 1

- (a) Are you studying the efficacy of a therapeutic procedure (Drug, Surgical procedure etc.); OR
- (b) Are you studying the efficacy of a preventive procedure (Vaccine, Sera, Chemoprophylaxis, personal protective measure, exercise programme etc.); OR
- (c) Are you studying the efficacy of a health care system or procedure (e.g. domiciliary v/s. institutional care).

Now, if the answer to any one of the above questions Q. No 1 (a) to (c) is 'Yes', go to question no. 2. However, if the answer is 'No', explore the possibility of using an observational design (cohort; case control etc.).

#### Q. No. 2

Can you "randomly divide the subjects into two groups, one getting the intervention and other not to get it? : Is it "feasible"? Is it "ethical"?

If the answer to the above (2 (a) and (b)) is "Yes", go ahead with an experimental study. However, if the answer to any one or both of 2 (a) or (b) is "No", consider the possibility of a "quasi experimental" design. If quasi experimental design is also not possible, consider an observational study (case control or cohort) or still better, review and revise your research question - there may be some flaw in your research question.

### Types of Experimental Studies

The experimental typology may be adapted to different research settings :

**(a) Clinical (Therapeutic) Trial** : This is the classical setting of an intervention (experimental) design. Examples are drug trials, trials of surgical procedures or other medical therapeutic procedures concerned with individual patient care. The "unit of study" in a clinical trial are "patients" suffering with a given disease, the therapy of which is to be studied.

**(b) Field Trial** : As compared to the clinical trial, in a field trial, the unit of study are healthy individuals, usually in the community. The trial is usually undertaken in respect of a preventive procedure as a vaccine, sera, chemoprophylaxis, personal protective measures, etc. For example, the trial of injectable polio vaccine is possibly the largest human experiment ever conducted. Over a million children, apparently healthy, living in the community, were randomly divided and offered either the vaccine or the placebo; the trial finally provided strong evidence of the efficacy of injectable polio vaccine.

**(c) Risk Factor Trial** : Risk factor trial, is in ethos, same as preventive trial. However, the difference is that the intervention in a preventive trial is an actual medical procedure (as vaccine) which is given (or not given) to individual subjects. On the other hand, in risk factor trial, the intervention is not an actual physical administration but rather an abstract phenomena, e.g.

asking a group of subjects (randomly selected, of course) to start "regular physical exercise". Here, regular physical exercise is the "intervention" of interest which is not physically administrated (like a vaccine or drug) but is rather a "conceptual" procedure.

**(d) Community Intervention Trial** : In a field trial (e.g. trial with a vaccine) we would randomly allocate the subjects, e.g. we will allocate the individual children to the vaccine or the placebo group. However, in a trial which seeks to study whether providing fluoridated water supply is effective in reducing the occurrence of dental caries, it would be practically impossible to randomize individual children to receive or not to receive the intervention (fluoridated water supply). In such a setting, we would randomize at the level of "communities" or "clusters of humans", thus allocating, randomly, a few villages to get the fluoridated water supply and few others to get ordinary supply. However, the unit of assessment still remains the individual subject; e.g. in this example, we would examine each and every child of all the villages (being supplied or not being supplied with fluoridated water) for DMF teeth. This is an example of community intervention trial, where "random allocation" is done at the level of "communities" or "groups" of subjects, though the assessment of outcome is done at individual subject's level. Such trials are of special interest for public health administrators for evaluating the effectiveness of environmental procedures, health educational measures, etc. The understanding of this type of experimental study becomes important since the "unit of random allocation" (i.e. the communities) is different from the "unit of assessment of outcome" (i.e. individual subjects). It is quite possible that the two groups (of communities) formed after random allocation may be quite different from each other in as far as characteristics of subjects are concerned e.g. the children in the group of villages going to receive fluoridated water may be otherwise well nourished, or may be having better oral hygienic practices. A "baseline" comparison between the two communities as regards relevant characteristics of subjects should therefore be done in such studies to show that the two groups are similar to each other (e.g. in the above study, we would compare the children of the two "community groups" regarding their age and sex structure, oral hygienic practices, educational and economic status of parents and habits of eating starchy/sugary foods to show that there is no significant difference between the two communities as regards these characteristics of children; if there is, then data for all the relevant factors should be recorded and later adjusted in analysis (see chapter on confounding).

**(e) Health Services Evaluation Trial** : Community intervention trials may often be used to answer research questions pertaining to the efficacy or effectiveness of health services or health policies; e.g. "whether to provide 10 Doctors or 100 Multipurpose health workers within the same budget" or "whether to provide free oral rehydration salt packets or else to provide health education to mothers" etc. Basically, the architecture is the same as that of community intervention trials, with an added element of health economic analysis (see chapter on studies on health economic analysis).

**(f) Cessation Experiment** : A contemporary of "risk factor trial", the only difference being that while in a risk factor trial, a preventive 'concept' is introduced as an intervention



(e.g. physical exercise package), in a cessation experiment, a harmful factor is “removed” from the intervention group (e.g. a group of smokers, free of IHD, may be randomly divided into two groups, and one group may be asked to give up smoking, while the other group continues to smoke; the two groups are then followed up for development of IHD).

The difference between a clinical trial, field trial and community trial should be noted. In a clinical trial as well as in the field trial, the unit of randomization as well as the unit of study (persons on whom measurements are made) are individuals; however, in a clinical trial these individuals are patients suffering from the target disease and usually obtained from the indoor or outdoor of a health care setting, while in a field trial, these are apparently healthy individuals, selected from the community. In a community trial, the unit of study are healthy persons living in the community but the unit of randomization are “communities” or clusters of free living healthy human beings as villages.

## The Quasi - Experimental Designs

Ideally, an experimental design should have the three essential elements of “Randomization”; Controls (usually placebo - control); and Blinding. This is what is called the “Randomized, Controlled, and Blinded Trial” (RCT). This is the most scientific way of conducting an experimental study and which we shall discuss subsequently.

However, often such ideal conduct on the basis of RCT may not be possible; one has to be pragmatic and take a practical approach. Say, at times, one may not be able to “randomly” allocate subjects into two groups. At times the “placebo” part of control may be impossible (e.g. surgical v/s medical management of IHD). Such circumstances, when an “intervention” has been given to one group of subjects and not given to another group, but the procedure of “random allocation” or “placebo” control has not been enforced for various reasons of practicability or ethics, are called as “Quasi - experimental” studies. Quasi - experimental studies may be of following types :

**(1) Non randomized “concurrent” trial** : The subjects keep entering the study and are divided into the two groups, not by random allocation by the investigator but by various other circumstances, e.g. patients of IHD may automatically get divided (depending on their clinical condition, ability to pay etc.) into a group who would continue on medical management and another who would go up for surgical treatment. The two groups can then be compared for studying the efficacy of medical versus surgical treatment for IHD. Another setting could be to take patients of IHD from a cardiology clinic (medical treatment) and post - op cases of CABG attending a chest surgery unit (surgical treatment) and follow them up.

**(2) Before and after trial using “historical controls”** : The results of a new medical procedure can be compared with the results that used to come up before the procedure was available. e.g. the results of selective vagotomy may be compared with the earlier results when truncal (and not selective) vagotomy was used. Such studies are also quite common in public health administration, e.g. the death rate due to car accidents after introduction of compulsory seat belt legislation was compared, in Australia, with the death rates before such legislation.

## The Disadvantages of Quasi - Experimental Design

- High potential that the intervention and control group used for comparison are not similar to each other. One crude method to improve the faith in the findings of a quasi - experimental study is to make a “base line” comparison between the two groups as regards certain important variables like age, sex, education, income, clinical condition etc.; if the two groups are not equal at baseline, efforts to adjust for such confounding variables should be made during analysis.
- “Selection” factors may be operating; e.g. patients who are taken into surgical treatment group for IHD may be in a much better state of cardiovascular function as compared to medical treatment group.
- Improvement noticed in a ‘before and after trial’ may simply be because other patient management techniques may also have improved recently; or else because the data collected earlier was incomplete or erroneous.

It is therefore imperative that whenever a researcher proposes a “Quasi - experimental” study, she should carefully view the above facets to see whether any bias may come up in her study and take actions to obviate such bias; or at least collect the data on all factors so that adjustment during analysis can be done.

## Planning, Designing and Analysis of Randomized Controlled Trial (Clinical Trial)

In medical research practice, a clinical trial or RCT represents the strongest design, the ultimate in medical research. The history of clinical trials is not very old. In fact the first scientific clinical trial was done just 250 years ago under the name “Ceterius Paribus”, on board the British Naval Ship “Salisbury” when James Lind had tried out various treatment modalities and shown that a ration of fresh lime juice and oranges was curative for scurvy (61).

### Phases of a Clinical Trial

Actually, what we commonly refer to as clinical trial is just one phase of the entire gamut of clinical trials. In fact, clinical trials have four phases which are sequentially studied on human beings, viz. Phase I to IV (37 - 42). Before phase I is undertaken, the new drug or treatment modality should have passed through the animal and laboratory testings and should have shown to have pharmacological effect, safe and free of malignancies and teratogenic effects. Only thereafter can a drug enter the phase I of clinical trials.

- *Phase I* studies are basically “‘clinico - pharmacological studies” which are undertaken on a small number of patients (20 to 80) (sometimes on healthy volunteers) and refers to dose finding studies, to find out as to how large a dose can be given before an unacceptable toxicity is experienced by patients (Maximally Tolerated Dose or MTD) as well as looking for various toxic and pharmacological effects of the drug.
- *Phase - II* are clinical investigations of a larger number (100 to 200) of patients with the target disease, looking for pharmacokinetic and pharmacodynamic effects of the drug on these patients, looking for the efficacy, biological activity and relative safety of the drug in these patients

- and to estimate the rate of adverse events at that MTD.
- **Phase - III** is the actual, classical stage of clinical trial which is also known as the Randomised Controlled trial (RCT). Following phase III, the drug is marketed and simultaneously phase IV also starts.
- **Phase - IV** is also called as “Post Marketing Surveillance”. Data on the effect of the drug or procedure is collected from various agencies. Side effects which did not appear in phase - III, are detected in this phase and the drug may be withdrawn or its usage modified. Classical examples are Thalidomide, Isoprenaline containing bronchodilators, and DES.

### Steps in Planning, Designing and Conduct of a Clinical trial

The steps in conduct of an experimental study including clinical trials are outlined in the succeeding paragraphs. In addition, readers are advised to go through the published reports on some of the large scale clinical trials (77 - 86).

**Step 1 - Deciding - Is clinical trial really required? Should it be done? Can it be done?** : Undertaking a clinical trial is not an easy affair. It costs considerable amount of specialized manpower, finances, equipment and dedicated efforts. It is therefore advisable that before one starts thinking of a clinical trial one should carefully assess whether it is really necessary to undertake a clinical trial. Firstly, a detailed review of literature should be undertaken to see whether the question has already been answered by some other workers and whether the findings can be adopted by us for our patients. Meta - analysis of published and even unpublished papers are also advisable because that may answer the issue without actually undertaking the clinical trial (68).

**Look into the Ethical Aspects of the Clinical Trial** : Ask yourself whether the trial is ethical (69 - 75)? The details of ethics in epidemiology and medical research are given subsequently in an exclusive chapter and readers are advised to go through the same.

**Step 2 - Clearly state the research question and the variables of study** : The research question should be developed after lot of reading and deliberations with experts. At times, the researcher may have more than one research question. In such cases one should clearly define out the *primary question* - this is one in which the investigators are most interested. The main statistical issues including the sample size calculation would revolve around the primary question. The *secondary questions* are subsidiary to the primary question; or else, sometimes, the data collected for the primary question may also be used for answering the secondary question. Having clearly defined the research question, the investigator should clearly list out as to what all “variables” will be studied to answer the research question. Broadly, there are four categories of variables that need to be enunciated :

**The exposure variable** : This means the “intervention” under study. The complete details including the dosage, method of administration etc. should be clearly defined.

**Co - Interventions** : Often co - interventions may be studied in addition to the primary intervention. Co - interventions should be as clearly defined as primary exposure variable.

**The outcome variable** : The outcome variable is the end point that is of utmost importance to the investigator. Care should be taken to clearly define one “primary outcome” or the “major endpoint” variable which is of most interest to the researcher and around which the analysis and sample size calculations would revolve. In addition, “secondary outcome” or the “other endpoint” variables can be defined.

**The confounder variables** : Ideally (at least theoretically), there should be no need to measure the confounder variables in a clinical trial, once randomization has been done, since randomization is itself a very powerful tool for controlling confounding. However, in small size trials, randomization may not have that much effect. Secondly it may also be worthwhile to do a baseline comparison between the intervention and the control group in respect of important confounding variables to show that randomization has been effective. It is therefore advisable, rather necessary, to collect data on major confounding variables i.e. those which are directly related to both the exposure and the outcome variables.

**Step 3 - Enumerate the inclusion and exclusion criteria**: Clearly define the characteristics of patients who would be eligible for entry into the trial, by specifying the “inclusion criteria” - based on demographic and clinical characteristics, to specify the patients or subjects who will be eligible to be included in the study. The more important aspect is the “exclusion criteria” - those who will not be eligible to be included in the study. More the exclusion criteria, more precise will be the findings and lesser will be the requirement of sample size. However, more the exclusion criteria, more difficult will be for you to find the particular type of subjects, and the generalizability of your study will be restricted.

**Step 4 - Defining the populations** : In the first sub - step we would define the reference population, also called the “universe” or the “target population”. This is the very large collection of patients or subjects to whom the results of the study would be generalized. For instance, if we wanted to do a clinical trial on whether Tamoxifen prevents recurrence of breast cancer, as an ICMR research project, we could define our reference population as “Wives of serving / retired central government personnel dependant on CGHS health care system, aged 40 to 70 yrs having at least one breast intact, not having history of venous thromboembolism, not taking oestrogen, mentally alert and who agree to participate”. The reference population is very large, scattered and difficult to delimit, and hence we cannot directly draw a representative sample from it. For this reason we often specify a well defined subset of the reference population from where we actually draw the sample of subjects. For instance, in our example we may define the actual study population as all the women of the type defined in the reference population “who are staying in Delhi”. It is from this actual study population that we finally draw our required sample. Specifying the actual study population is more of a matter of administrative convenience but we must be convinced that the actual study population is a reasonably representative subset of the reference population.

**Step 5 - Sample Size Calculation** : Sample size, is a major issue in clinical trials. Too small a sample would produce insignificant results and would be a waste of efforts. With a

small sample the chances are very high that the result would be statistically insignificant. Hence an adequately large sample is important. At the same time we must remember that every subject in a clinical trial costs tremendous amount of money, so even one additional subject may mean poor financial management. The details of calculation of sample size are dealt with in the section on biostatistics.

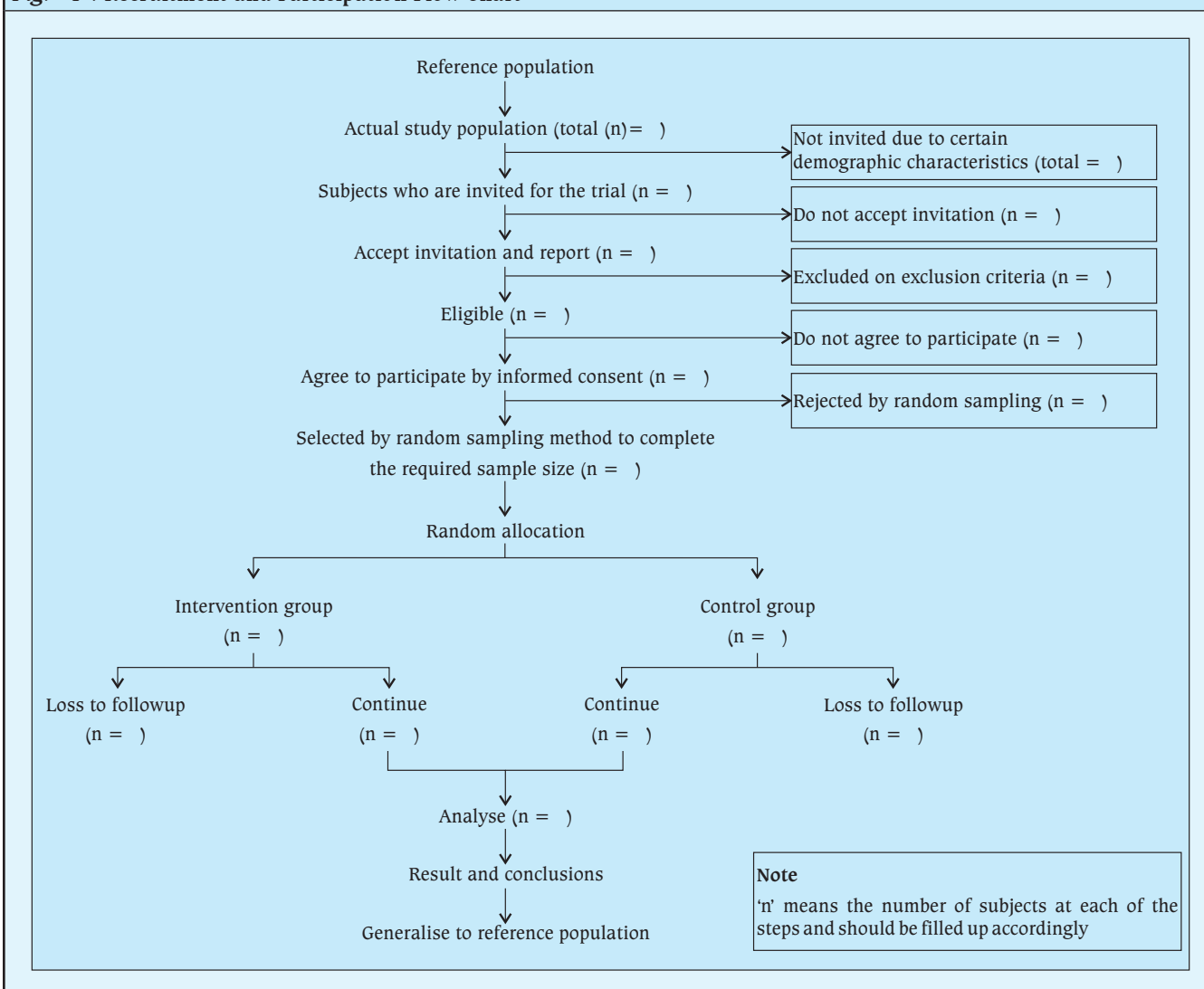
**Step 6 - Detailed Descriptions of Measurement Protocols :** The most important facet of clinical trials is to ensure that the measurement process is accurate. So, at the stage, develop the detailed protocols of clinical procedures, laboratory investigative procedures, as well as the details of questionnaire and interview protocols. For each and every variable (intervention, co - intervention, confounders and major and minor outcome variables), write down very clearly and explicitly, as regards Who will make the measurement ? When will it be made ? What equipment / instrument will be used ? What technique will be used ? How the equipment, techniques and personnel

be standardized and validated ?

**Step 7 - Enrolling the Participants :** Once the minimum sample size has been calculated the next step is to enroll a representative sample of the patients from the actual study population. In fact, during the planning and conduct of a clinical trial as well as during writing your research paper, it is important to present the “ Recruitment and Participation Flow Chart” giving the numbers ('n') at each step, as per format in Fig. - 1.

**Step 8 - Randomisation :** The basic dictum of any research is that the groups being compared should be absolutely similar to each other except for the factor which is being studied. In methodological terms, it means that all confounder variables must be controlled. There are various methods of control of confounding. When it comes to clinical trials the method is randomization or random allocation. So essential is randomization that the other name of this design is “RCT - Randomized Control Trial”. The procedure is quite simple. Random number tables available in any book on statistics or

**Fig. - 1 : Recruitment and Participation Flow Chart**





computer statistical packages are used to generate random numbers. Accordingly the subjects are allocated to either, receiving treatment A (the intervention under trial) or else treatment B (the control modality). The power of randomization is such that, the two groups so formed consequent to randomization, are absolutely similar to each other. However, there is a note of caution. Randomization works well to create 2 similar groups only when the sample is adequately large. In a small sample, the effect diminishes and may become erratic.

**Step 9 - Introduce the Intervention and Placebo Control Modalities** : Having created the two groups by random allocation, the investigator now needs to intervene with the trial modality in one group, and the control or the baseline modality in the other group. Certain aspects to be ensured at this stage are :

- Ensure ways and means to bring about compliance in both the groups. Give adequate amount of medicines to all the subjects in both the groups and instruct them clearly on the dose, mode of administration, frequency of intake, etc.
- Develop procedures for checking compliance as, for example, checking the count of balance pills, testing the urine/ other excretions for metabolites and so on.
- Brief both the groups clearly about co - interventions in the trial, if there are any.
- Ensure a placebo control, so that the control group who are not getting the trial intervention cannot make out that they are not getting it. Ensure that they get the placebo drug in the same shape, colour, size and taste and is also administered using similar procedures.

**Step 10 - Ensure Blinding** : What if the subjects know they are getting a new drug? They may start feeling better just because of this knowledge! They may report improvement just to please their Doctor! And those not getting the new treatment may not feel relieved thinking that they have been deprived of some new, good treatment. And may be, just because of this awareness, some of them may quietly start taking the new regimen or some other co - intervention. More bias may be introduced if the investigator is aware of the status of the subjects. The investigator may differentially probe or investigate more in one group or less in the other group.

To overcome these biases in the standard clinical trial, Blinding is used as an essential requirement. In single blinding, the subject is not aware of his status but the investigator is aware. The ideal standard of course is double blinding, in which neither the investigator nor the subject is aware as to which group a particular subject belongs to. Only the codes are given and these codes are handled by the data manager. The gold - standard in contemporary times for clinical trials is double blinding. Double blinding may sound difficult but can be implemented even in testing situations.

In surgical trials, double blinding may become difficult at times. In such situations, we may ensure that the surgeons who evaluate the outcome, should be independent of the research group and preferably different from the surgeon who operated. The operating surgeon may, however, keep monitoring the patients for purpose of management, not for research. We may also make the outcome criteria as objective as possible.

**Step 11 - Follow Up and Assessment** : The last but one step in the conduct of clinical trial is to follow up the subjects till the end point, or the period of trial, whichever is earlier and to make ascertainment. The key issue in follow up is to avoid losses to follow up, which may otherwise seriously bias the study results as seen in the following example : "A trial of nasal calcitonin spray to reduce the risk of osteoporotic fractures reported that the treatment reduced the risk of fractures by 36%". However, critical evaluation revealed that 60% of those who were originally randomized were lost to follow up and it was not known whether fractures had occurred among those who were lost to follow up. Because the overall number of fractures was small, even a few fractures among participants who were lost to follow up could have altered the results of the trial. This uncertainty diminished the credibility of the findings. It is therefore imperative that actions be taken right from the planning stage to retrieve those getting lost to follow up. The following general steps are worthwhile :

- At the very start, inform the participants of the scope of trial, and the time and place where they should report for follow up.
- Exclude, in the beginning itself, those who have a very low probability of continuing.
- Note down the detailed telephone numbers and addresses of the participants, their close friends, relatives and employers and their permanent home addresses to retrieve them.
- Treat them properly when they come for follow up; don't make them wait too long.
- Every time they come for follow up, talk to them about their condition and also about the progress of the trial to keep their interest alive.
- Even if some participants violate the study protocol or discontinue the trial intervention, they should still be followed up so that their outcomes could be used in "Intention to treat Analysis"

Finally during the follow up stage, keep the "Stoppage Rules" open. In brief there can be two reasons for prematurely stopping a trial :

- Evidence comes up in between against the intervention modality.
- Evidence of clearly high mortality or complication in the intervention group comes up.

**Step 12 - Statistical Analysis** : Statistical analysis is indeed a very important aspect of any research design, clinical trials included. Let us start with an example of a clinical trial which has been published in one of the recent issues of Lancet (86). The DREAM Project was a clinical trial to evaluate whether Rosiglitazone, a Thiazolidinedione drug said to improve insulin sensitivity can prevent diabetes type 2 among subjects who were having IGT or Impaired Fasting Glucose (IFG). 5,629 subjects with IFG were randomly allocated to either receive Rosiglitazone 8 mg per day (2,635 subjects) or a placebo (2,634 subjects) for a follow up period of 3 years. The primary clinical end point was development of diabetes. Those who did not develop diabetes were taken to have achieved the outcome. The final data is summarized in Table - 1.



Table - 1 : The DREAM Project			
Exposure	Outcome		Total
	O+ (Did not develop Diabetes)	O - (Developed Diabetes)	
E+ (Given RG)	2329 (89%)	306 (11%)	2635 (100%)
E - (Given Placebo)	1948 (74%)	686 (26%)	2634 (100%)
Total	4277 (81%)	992 (19%)	5269 (100%)

The data shows that as much as 88.4 % of the exposed group, i.e. given Rosiglitazone, remained free as compared to much lesser 73.45 among the placebo group.

An important decision to be taken at this point is whether we want to undertake an “*Intention to Treat Analysis*” or else a “*Per - protocol*” analysis. In the former, which is being often undertaken these days, the outcome is analyzed among subjects according to the group into which they were originally randomized (“analyse as you randomize”). Thus, even if participants assigned to the original intervention group may have discontinued or even crossed over or some of the placebo control group may have finally ended up taking the intervention modality, the analysis will be as per the subjects’ original randomization plan. On the other hand, the per - protocol analysis will include only those participants in both groups who undertook at least 80% of the assigned study medication, completed a certain percentage of their expected follow - up visits, and had no other protocol violation.

The first thing in undertaking statistical analysis of a clinical trial is to present the participant’s recruitment and flow chart, giving the actual data at each step, as explained in one of the earlier steps. The next step is to give a table showing baseline comparison between the interventional group and the placebo group as we have described earlier in the step of randomization. The next step is now to clearly visualize what are your primary exposure and outcome variables and what is meant by exposure present or exposure absent and by outcome achieved or outcome not achieved. Now, make a 2X2 table and place your data in the 2X2 table exactly as per the specifications for cells a, b, c and d that we have already discussed. Same is shown in Table - 2.

Table - 2 : DREAM Project			
Exposure (intervention)	Achieved Outcome (Did not become Diabetic)/ (O+)	Not achieved Outcome (became Diabetic)/ (O - )	Total
Given RG (E+)	2329(89%) a	306(11%) b	2635(100%)
Given Placebo (E - )	1948(74%) c	686(26%) d	2634 (100%)
Total	4277(81%)	992(19%)	5269(100%)

In the DREAM clinical trial, out of 2,365 who were exposed to RG, 2,329 achieved the defined outcome while in the non exposed (Placebo) group 1,948 out of 2,634 achieved the outcome. Please do take care to indicate both the numbers and percentages in the cells. Now, having placed the data in the 2x2 table, calculate the incidence of outcome in the exposed and non exposed group as :  $I_E = a/a+b = 2339/2635 = 89\%$  and  $I_{NE} = c/c+d = 1948/2634 = 74\%$ . And, as the next step, calculate the risk ratio (RR) i.e. the “effect” of the intervention as :  $RR(\text{Effect}) = I_E/I_{NE} = 89/74 = 1.20$ . This calculation of the effect size is an simple but extremely important parameter which you must calculate. In our example, it means that patients of IFG who got Rosiglitazone will be 1.2 times more likely to remain free of diabetes as compared to those on placebo, over 3 years.

In the next step, calculate the 95% CI of RR. In the DREAM trial example, the RR was 1.20 and its 95% CI was 1.16 to 1.23. The interpretation is like this : “Our sample results show that the effect of Rosiglitazone is to bring about 1.2 times more improvement”. We do not know what the real effect would be in the 2 large populations but we are 95% confident that the real effect in the two large population would be an improvement between 1.16 times to 1.23 times improvement as compared to placebo.

And, in the basic presentation, finally calculate the numbers needed to treat as :  $NNT = 1/(I_E - I_{NE})$  (where  $I_E$  and  $I_{NE}$  are measured as proportions out of 1) (87). In our example, it works out as :  $100/(0.89 - 0.74) = 1 / 0.15 = 7$ . It means that we will need to treat 7 patients with Rosiglitazone to get one additional case of cure (prevented diabetes) as compared to placebo.

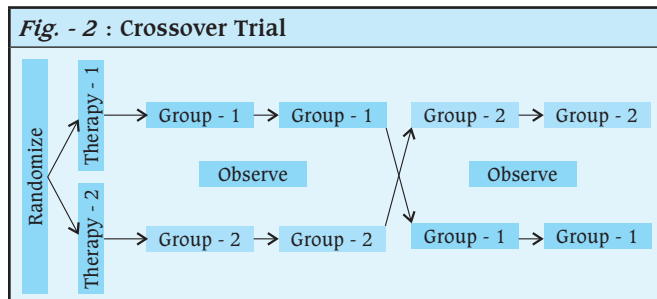
Having presented the basic statistics, the next step in statistical analysis is to undertake probability testing procedures. The details have been discussed at length in the section on biostatistics.

### Certain Variants in the Design of Clinical Trials

The details mentioned in the foregoing paragraphs of this chapter pertain to the classical randomised, concurrent placebo controlled, blinded trial. However, at times two of the variants in the methodology can be meaningfully utilized, as follows :

**Crossover Trial** : Let us assume that we are trying out the efficacy of new antihypertensive drug as compared to one of the standard ACE inhibitor drug. Let us say we decided to study 50 subjects in each group. We took 100 subjects of hypertension, randomised them into two groups of 50 each and gave the trial drug to group ‘A’ and Ramipril to group ‘B’. After treating the two groups for the decided period of 3 months, we measured the BP levels. We now stopped the drugs in both the groups for 1 month, so that the effect of the drugs is “washed off” and the patients returned to the baseline. Now, we gave Ramipril to group ‘A’ and the trial drug to group ‘B’ and followed up for another 3 months. This is an example of the “cross - over” design. Thus in a cross - over design, subjects are initially randomly allocated into therapy ‘A’ or therapy ‘B’ and after being observed for a certain period of time, and giving a period of “wash - out” to remove the existing effects of therapy, the subjects are switched over to the other therapy (i.e. cross over) and are thereafter again followed up for another relevant

period of time. The flowchart for the Cross Over Trial is shown in Fig. - 2.



Cross - over designs have certain advantages. Firstly, each subject serves as his or her own control, thus holding constant the variations between individuals as regards many characteristics that could potentially confound the comparison between two groups. Secondly, for the same reason, the requirement of sample size would be considerably reduced. It improves on the ethical considerations since all subjects are exposed to both therapies, thus nobody is denied of the potential advantages of a particular therapy.

At the same time, cross - over designs have certain disadvantages. Firstly, there is, most of the times, a requirement of giving a period of wash out to remove the residual effects of each therapy, before cross over can be effected. This prolongs the duration of the trial, especially if the period of wash out required is long. Second, it may be at times very difficult to ensure blinding or placebo control, for example if one of the therapy is oral medication while the other modality is parenterally administered. Thirdly, the order in which therapies are given may elicit psychological response; e.g. patients may react differently to the first therapy given in a study, as a result of enthusiasm that often happens at the start of the study, and which decreases over time. Finally, if either of the therapy cures the disease in toto (as an antibiotic for infectious disease) then, naturally, no cross over can be done.

The classical, 'planned cross over design' as described above, should be differentiated from the "unplanned cross - overs" as sometimes may happen in classical RCT. For example, in a trial to assess the efficacy of surgical versus medical treatment in IHD, some patients initially randomly allocated to surgical or medical options, may start having second thoughts and may decide to finally take the other form of therapy to which they were originally not allocated; or some patients initially allocated to medical group may deteriorate and may then be given surgery. Such crossovers may lead to serious objections as regards the validity of the trial.

**Factorial Design** : Let us take the example of the physicians health study, in which it was envisaged to study the efficacy of aspirin for primary prevention of cardiovascular disease and beta - carotene for primary prevention of cancer. In this trial, each physician was randomly allocated to receive one of the four treatments, viz., both aspirin (A) and beta - carotene (B), only aspirin (A), only beta - carotene (B) and neither of the two (0). The resulting design can be set out in the 2X2 table (Table - 3).

Table - 3 : Physician's Health Study		
Treatment 'A'	Treatment 'B'	
	Given	Not Given
Given	(Both A & B) (1)	Only A (2)
Not Given	Only B (3)	Neither A nor B (4)

The above is an example of the "factorial design" in which the two or more modalities are tested as per factors (both given, either one given, none given). This design is done when the anticipated outcomes for the two regimens are different and their modes of action are also different, one can economically use the same study population for testing both the regimens. We would evaluate the effects of treatment 'A' by comparing the results in cells (1+2) to the results in cells (3+4). Similarly, the results for treatment 'B' can be evaluated by comparing the results in cells (1+3) to the results of cells (2+4).

In case it becomes necessary to terminate the study on the effects of one of the regime (say, 'A'), this design permits continuing the study to determine the effects of treatment 'B'. For example, in the physicians health study quoted above, the aspirin part of the study was terminated earlier, because evidence of protective effect of aspirin on acute MI had already come in by then. The randomised beta carotene versus no beta carotene trial continued till the originally scheduled time line of 12 years and final results did not show any protective effect on cancers.

## Summary

In an experimental design, the epidemiologist excludes at the outset, all those who either have the outcome of interest or exposure of interest, from his study sample. He then "randomizes" (i.e. randomly allocates) this group into two, such that every subject has similar chance of coming in either of the two groups. By random allocation or randomization, the two groups formed will be absolutely similar to each other. So essential is randomization that the other name of this design is "RCT - Randomized Control Trial". He now gives the "exposure" of interest to one group (trial or intervention group (O - E+) and a 'placebo' only to the other group (control group) (O - E - ) and follows them up for a relevant period of time, at the end of which he compares the two groups as regards the development of the outcome of interest, by comparing the incidence of outcome in the exposed with that in the non - exposed group. Thus, in the experimental design it is the investigator who intervenes actively, deciding, in a random fashion, as to who will get the exposure and who will not. The experimental design is the method of choice when studying the efficacy of a therapeutic or else a preventive procedure.

Experimental studies can be of various types like Clinical (Therapeutic) Trial, Preventive Trial, Risk factor Trial, Community intervention Trial, Health Services Evaluation Trial and the Cessation Experiment. Randomized Controlled Trial (RCT; Clinical trial) is the classical setting of an intervention design, in which random allocation is done at the level of individual subjects. In community intervention trials, randomization is done at the level of "communities" or "clusters of humans",

rather than individuals, though the unit of assessment still remains the individual subjects.

Ideally, an experimental design should have the three essential elements of “Randomization”; Controls (usually placebo - control); and Blinding. This is what is called the “Randomized, Controlled, and Blinded Trial” (RCT). Such ideal conduct on the basis of RCT may not be always possible. Such circumstances, when an “intervention” has been given to one group of subjects and not given to another group, but the procedure of “random allocation” or “placebo” control has not been enforced for various reasons of practicability or ethics, are called as “Quasi - experimental” studies. Quasi - experimental studies can be in the form of Non randomized “concurrent” trials or else, Before and after trial using “historical” controls.

There are four phases in clinical trials, viz. Phase I to IV. Before phase I is undertaken, the new drug or treatment modality should have proved its effect and safety in the animal and laboratory. Phase I is dose finding studies undertaken on a small number of patients or healthy volunteer. Phase - II can be called as pharmacokinetic and pharmacodynamic studies, undertaken on a small number of patients with the target disorder. Phase - III is the actual, classical stage of clinical trial which is also known as the Randomised Controlled Trial (RCT). Following phase III, the drug is marketed and simultaneously phase IV also starts. Phase IV is also called as “Post Marketing Surveillance”.

Before starting a clinical trial, it is important to decide whether clinical trial is really required, by undertaking detailed review of literature, and by the procedure of Meta analysis of published and even unpublished papers. Once it has been decided to go ahead with a clinical trial, at the first step, decide whether it is feasible or not and one should also look into the ethical issue. Second step is to clearly state the research question and variables of study. At times, the researcher may have more than one research question, in which case one should clearly define the primary question and secondary questions. Having clearly defined the research question, the investigator should clearly list out as to what all “variables” will be studied to answer the research question. Broadly, there are four categories of variables that need to be enunciated : Exposure variable, Outcome variable, Co - interventions and Confounding variables. Care should be taken to clearly define one “primary outcome” or the “major endpoint” variable which is of most interest to the researcher. In addition, “secondary outcome” or the “other endpoint” variables can be defined. Baseline data about common confounding variable like age, sex should be collected and compared in the two groups, to show that randomization has been effective. Next, clearly enumerate the inclusion and exclusion criteria based on the characteristics of patients who would be eligible for entry into the trial - based on demographic and clinical characteristics. Now we define our actual study population and the reference or total population. Sample size is a major issue in clinical trials. Before calculating sample size we must not only specify the type 1 error, type 2 error and power of the study, but also, the expected proportion of the outcome in the Non - exposed (control) group ( $P_o$ ) and amount of effect due to intervention modality you would consider clinically significant. In the next

step, develop the detailed protocols of clinical procedures, laboratory investigative procedures, as well as the details of questionnaire and interview protocols.

Next step is enrolling the participants in the study. First of all make the list of all eligible participants based on inclusion and exclusion criteria. Now these eligible participants will be informed of the details of the study and asked to participate under informed consent. Those who agree to participate, are randomly allocated into two groups - one group which will be given intervention and other group which will not receive any intervention.

Having created the two groups, the investigator now intervenes with the trial modality in one group, and the control or the baseline modality in the other group. One must ensure ways and means to bring about compliance and develop procedures for checking compliance in both the groups. It should be ensured that the control group subjects get the placebo drug in the same shape, colour, size and taste and is administered using similar procedures. The next, extremely important step is to ensure blinding. In single blinding, the subject is not aware of his status (whether he belongs to the intervention or the placebo control group) but the investigator is aware. Double blinding is taken as gold standard, in which neither the subject nor the investigator is aware of the status of individual. Double blinding removes both respondent's bias and observer's bias.

The next step is to follow up the subjects till the end point, or the period of trial, whichever is earlier and to make ascertainment. The key issue in follow up is to avoid losses to follow up, which may otherwise seriously bias the study results. Steps should be taken in planning steps itself to prevent the losses to follow up, by informing the participants of the scope of trial, time and place for follow up; excluding in beginning itself those who have a very low probability of continuing; noting down the detailed telephone numbers and addresses of the participants, their close friends, relatives and employers and their permanent home addresses to retrieve them. Note that even if some participants violate the study protocol or discontinue the trial intervention, they should still be followed up so that their outcomes could be used in “Intention to treat Analysis”. Do ensure in follow up that subjects, irrespective of their trial status, are treated equally in every aspect of examination. And, finally during the follow up stage, keep the “Stoppage Rules” open. Reasons for premature stoppage of trial can be firstly, if evidence comes up in between against the intervention modality; secondly, evidence of clearly high mortality or complication in the intervention group comes up and thirdly, if Statistical, Methodological or Sample size assumptions are proved wrong.

Last step consists of statistical analysis. The first thing in undertaking statistical analysis of a clinical trial is to present the participant's recruitment and flow chart, giving the actual data at each step, followed by a table showing baseline comparison between the interventional group and the placebo group. The next step is to make a 2X2 table and calculating the incidence in exposed ( $I_E$ ) and incidence among non - exposed ( $I_{NE}$ ) and calculating the relative risk. Also calculate NNT (number needed to treat) as :  $NNT = 1 / (I_E - I_{NE})$ . Having presented the basic statistics, the next step in statistical analysis is to undertake probability testing procedures which will depend on

scales of measurements of exposure and outcome variables.

### Study Exercises

**Long Question :** Discuss the stepwise planning, design, conduct and analysis of a trial to assess the efficacy of “Deltamethrin Insecticide Treated Bed Nets” in reducing the incidence of malaria, in a Primary health Centre (PHC) area with a population of 30,000 spread over 30 villages, located in high malaria transmission area especially during June to October.

**Short Notes :** (1) Phases of a clinical trial (2) Quasi - experimental design (3) Randomisation (4) Blinding (5) Potential Biases in a clinical trial (6) Numbers needed to treat (7) Intention to treat analysis (8) Cross - over design.

#### MCQs

1. In which of the following study, randomization is done? (a) Case control study (b) Cohort Study (c) Experimental study (d) Cross sectional study
2. Which is the ideal (most scientific) setting for epidemiological study? (a) Case control study (b) Cohort Study (c) Experimental study (d) Cross sectional study

3. Experimental study can be used in following setting except (a) Study of risk factors (b) Preventive trial (c) Therapeutic trial (d) Health system evaluation trial
4. Phase IV of clinical trial is (a) Post marketing surveillance (b) Clinical trial (c) Animal studies (d) None of the above
5. Cessation experiment is a type of (a) Cohort study (b) Experimental study (c) Case control study (d) Cross sectional study
6. In single blinding, \_\_\_\_\_ is unaware of the status of the subject? (a) Analyzer (b) Observer (c) Subject (d) All of the above
7. While conducting experimental study, arrange the following steps in sequential manner 1) Randomization 2) Blinding 3) Statistical analysis 4) Enumerate the inclusion and exclusion criteria (a) 4, 1, 2, 3 (b) 4, 2, 1, 3 (c) 2, 1, 3, 4 (d) 2, 1, 4, 3
8. What is the tool for control of confounder in experimental design? (a) Blinding (b) Statistical analysis (c) Randomization (d) None of the above

**Answers :** (1) c; (2) c; (3) a; (4) a; (5) b; (6) c; (7) a; (8) c.

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### Studying the Diagnostic Tests

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In every area of clinical and public health practice, “diagnosis” becomes the central issue. The process of making diagnosis involves the use of certain tests, laboratory procedures or a constellation of signs and symptoms. The common settings of use of diagnostic tests can be, pathological, radiological, clinical or public health (e.g. mammography for mass screening for breast CA). Apparently, whenever we use any “diagnostic test” (including clinical signs), at the very outset we have to accept the fact that we will never get 100% accurate results. Some deviation on either side (i.e. the test is positive but disease is really absent or the test is negative but the disease is really present), is always likely to occur. The basic aim of any study on the evaluation of diagnostic test is, therefore, to assess and quantify the extent to which we may go wrong.

#### Essential Requirements of a Diagnostic Test Study

In any diagnostic test assessment, with the above mentioned broad aim in mind, there would be, three essential things required :

- (a) The diagnostic test, which is to be evaluated.
- (b) A ‘gold standard’ criteria of diagnosis. This ‘gold standard’ is that diagnostic criteria, as per current knowledge, can be assumed to be 100 percent accurate in diagnosis. For

example, while evaluating “Resting ECG” as a diagnostic test for Ischaemic Heart Disease, we may keep coronary angiography as the gold standard.

- (c) A group of subjects, *each of whom should be subjected to both the tests* - the test under evaluation and the gold standard test.

#### Parameters on which a Diagnostic Test is evaluated

Any diagnostic test should be evaluated in terms of these parameters :

**1. Reliability :** (Syn : Precision, Reproducibility, Repeatability). This denotes the ability of the test to give consistent results when repeated applications are made.

**2. Validity :** (Syn : Accuracy). This is the ability of the test to correctly diagnose the condition which it is meant to diagnose; in other words, it is the extent to which it correctly identifies those who do have the disease as well as excludes those who really do not have it, against the gold standard.

**3. Economicity :** (Syn : Efficiency). This is the extent to which the expenditures on the test in clinical and public health practice commensurate with the results. We would describe each of these 3 aspects in the succeeding paragraphs.

#### Reliability

The ability of any diagnostic test to give consistent results on repeated applications is reliability. It would be affected by variations which can occur due to observers, subjects, instruments or techniques, as per details already discussed in the chapter on validity and confounding. The methods for



improving reliability have also been mentioned in the same chapter and the readers are advised to go through the same. As discussed earlier in the chapter on confounding, reliability can be statistically assessed by estimating the degree of agreement between two measurements.

Consider a study on pulmonary TB, with AFB positivity on sputum smear as the method of measurement. We use laboratory technicians to examine the sputum slides after training them by microbiologist. For assessing the inter - observer reliability, (between the microbiologist and Lab technician), we took 320 stained slides and each slide was examined by both of them. The results are given in Table - 1.

Table - 1 : Results			
	Microbiologist's Diagnosis		
Technician's Diagnosis	Positive	Negative	Total
Positive	21 (a)	(b) 11	(p1) 32
Negative	37 (c)	(d) 251	(q1) 288
Total	58 (p2)	(q2) 262	(n) 320

Now, the observed agreement (O)

$$= \frac{\text{Where both agree at Yes} + \text{where both agree at No}}{\text{Total Subjects}}$$

$$= \frac{a + d}{n} = \frac{21 + 251}{320} = 0.85$$

And, agreement which was, in any case expected due to 'chance' (E)

$$= \frac{(p1 \times p2) + (q1 \times q2)}{(n \times n)}$$

$$= \frac{(32 \times 58) + (288 \times 262)}{320 \times 320} = 0.754$$

Now, Kappa Coefficient (K)

$$= \frac{O - E}{1 - E} = \frac{0.85 - 0.754}{1 - 0.754} = 0.388 \text{ (or 38.8 \%)}$$

The value of Kappa coefficient (K) will be between 0 and 1 (in our example it is 0.388). If it is 0, it means that the two measurements agree simply because of chance, while if it is 1 it means that the two measurements agree perfectly, irrespective of chance. In the above example, we would conclude that the observed agreement between the 2 observers of assessing AFB positivity is 38.8% of the way between a coincidental agreement purely by chance and a 'perfect agreement'. Nearer the Kappa coefficient is to 1 (or 100%), better the agreement between two observers, or methods of measurement, is likely to be. *Usually, values of kappa of upto 25% indicate mild agreement, 26 to 50% moderately strong agreement, 51 to 75% strong agreement and more than 75% indicate very strong or excellent agreement.*

### Validity

Let us consider the following 2x2 table (Table - 2) :

Table - 2			
Result of Diagnostic Test under Evaluation	Result of Gold Standard Test		Total
	Positive	Negative	
Positive	True positives (TP) (a)	False Positives (FP) (b)	a + b = Total +ve by test
Negative	False Negatives (FN) (c)	True Negatives (TN) (d)	c + d = Total - ve by test
Total	Total +ve by gold standard a + c	Total - ve by gold standard b + d	a + b + c + d = n = Total subjects studied
	Total Truly Diseased	Total Truly Not - diseased	

Let us say we studied a total of 'n' subjects; each subject was given both the diagnostic test, as well as the gold standard test for final diagnosis. The notations in the above table can be explained as follows :

- Cell 'a' represents those subjects who were diagnosed as diseased by the gold standard as well as called positive by the test being evaluated. They are thus the "True Positives" (TP).
- 'b' are those subjects who were called positive by our test but were not really diseased, as revealed by gold standard. They are thus the "False Positives" (FP).
- 'c' are those subjects who were actually diseased (as diagnosed by gold standard) but our test could not identify them and called them negative. These are the "False Negatives" (FN).
- 'd' are those subjects who were not diseased (called negative by gold standard) and the test also correctly called them negative. These are the "True Negatives" (TN).
- (a+b) are the total number of subjects who were called positive by the test, whether they had the disease or not; thus it is sum of TP and FP.
- (c+d) are the total number of subjects who were called negative by the test, whether they had the disease or not; thus it is the sum of FN and TN.
- (a+c) are the total subjects who were really diseased (gold standard diagnosis) irrespective of whether they were identified as positive by our test or not; thus it is the sum of TP and FN.
- (b+d) are the total number of subjects who were in reality not diseased, as diagnosed by gold standard, irrespective of whether our test called them negative or positive; thus it is the sum of FP and TN.

Let us assume we were evaluating the performance of ELISA as a diagnostic test for HIV infection and the gold standard that we used was PCR. We took 1,00,000 subjects and subjected each and every one of them to both, the ELISA as well as the PCR tests. The hypothetical results are presented in the 2x2 table (Table - 3) :

Table - 3			
ELISA	Gold Standard Test (PCR)		Total
	Positive	Negative	
+ve	TP (a) 990	FP (b) 9900	a+b = Total +ve by test 10890
- ve	FN (c) 10	TN (d) 89100	c+d = Total - ve by test 89110
Total	a+c 1000 (actually +ve for HIV)	b+d 99000 (actually - ve for HIV)	a+b+c+d = n 1,00,000

### Measures of Validity

**(a) Sensitivity :** This is defined as the ability of the test to call positive those who really have the disease. Thus, sensitivity

$$= \frac{\text{Positive by test}}{\text{Total diseased}} = \frac{(TP)}{(TP + FN)} \text{ or } \frac{a}{a + c}$$

It is also called "Positivity in Disease" (PID)

In our above example, sensitivity of ELISA = 990/1000 = 0.99, or 99%.

**(b) Specificity :** This is the ability of the test to call negative those who do not have the disease; thus it is also called as "Negativity in Health" (NIH). Thus, specificity

$$= \frac{\text{Negative by test}}{\text{Actually not diseased}} = \frac{(TN)}{(FP + TN)} \text{ or } \frac{d}{b + d}$$

In our example, specificity = 89100/99000 = 0.9 = 90%

**The problems with sensitivity and specificity :** Sensitivity and specificity of any diagnostic tests are the basic parameters of validity. They are 'fixed' parameters, i.e. the sensitivity and specificity of any test will not change in different type of settings. However, as doctors, our interest is truly not in sensitivity or specificity, e.g. in the above example, our interest will not be that the ability of the test (ELISA) is 99% in calling positive those who will have the disease. Our interest is to know if one of our patients has tested positive on ELISA, what are his chances of really having HIV infection? Or if he has tested negative, what are the chances that he really does not have the infection? These questions clearly can not be answered by sensitivity and specificity but by a different set of parameters - the predictive values.

**(a) Positive Predictive Value (PPV, PV+, post test probability):** This is the probability that if a person has tested positive on a test he will really have the disease. Thus, PPV

$$= \frac{\text{Total true +Ve}}{\text{Total +Ve on test}} = \frac{(TP)}{(TP + FP)} \text{ or } \frac{a}{a + b}$$

In our above example, PPV = 990/10890 = 9.1%

Thus, if our patient (of course, one coming from this particular type of population - we will explain this aspect shortly) has tested positive on ELISA there are only 9% chances that he will really be having the HIV infection !

**(b) Negative Predictive Value (NPV, PV-) :** This is the probability that a person who has tested negative really does not have the disease. Thus, negative predictive value

$$= \frac{\text{True Negatives}}{\text{Total Negatives on test}} = \frac{(TN)}{(FN + TN)} \text{ or } \frac{d}{c + d}$$

In our above example, NPV = 89100/89110 = 99.9%

**The difficulties with the predictive values :** The difficulty with the positive and negative predictive values is that while the sensitivity and specificity of a test are constant, the predictive values are largely dependent on the prevalence of the disease in the population in which the diagnostic test is being applied. Let us consider the following example :

The sensitivity and specificity of ELISA in diagnosing HIV infection is 99% and 90% respectively, as worked out earlier. Now, let us say, we applied the test in a population with very low prevalence of the disease (HIV positivity), e.g. healthy blood donors (in which the prevalence is known to be about 1%). Let us assume that we took 1 lakh healthy blood donors in this study.

Now, since prevalence of disease = 1%.

Therefore, total who will be truly positive = (1/100) X 1,00,000 = 1,000.

And total truly negative = 1,00,000 - 1,000 = 99,000.

Since, sensitivity of ELISA is 99%, it will correctly identify (99 / 100) x 1000 = 990 of those 1000 who have the infection; thus, 1000 - 990 = 10 will be called negative.

Again, since specificity is 90%, it will correctly call, as negative, 90% of 99000 who do not have the disease, i.e. 89100. Hence 99000 - 89100 = 9900 will be called positive by ELISA though they do not have the infection. We can now complete the 2x2 table as shown in Table - 4.

Table - 4			
ELISA	Healthy blood donors		Total
	Having HIV Infection	Not Having HIV Infection	
+ ve	990	9900	10890
- ve	10	89100	89110
Total	1000	99000	100000
Now, PPV = 990 / 10890 = 0.091, or 9.1%			
NPV = 89100 / 89110 = 0.9999, or 99.99%			

Thus, if the prevalence of the disease in the target population is low, the PPV will be low. So, if a healthy blood donor tests positive on first ELISA, the probability that he really has HIV infection is only 9% (This may sound interesting but is a fact. Leading text books of medicine authentically say that, of the healthy blood donors who test positive on first ELISA screen test, only about 13% will finally be confirmed to have the infection. The reason for this is explained above).

Now, let us say - we apply the same ELISA in another population with a very high prevalence of HIV infection; say, commercial sex workers (CSWs) in whom the prevalence is known to be about

50%. Assume that we subjected 1,00,000 CSWs to ELISA test. Now, since the prevalence is 50%, a total of 50,000 CSWs would be having HIV infection out of the 1,00,000 being studied. With a sensitivity and specificity of 99% and 90%, ELISA will give us 49,500 True Positives (99% of 50,000 diseased) and 45,000 True Negatives (90% of 50,000 not infected). The 2x2 table can now be constructed as shown in Table - 5.

<b>Table - 5</b>			
<b>ELISA</b>	<b>Commercial Sex Workers</b>		<b>Total</b>
	<b>Having HIV Infection</b>	<b>Not Having HIV Infection</b>	
+ ve	49500	5000	54500
- ve	500	45000	45500
Total	50000	50000	100000
Now, PPV = 49500 / 54500 = 0.91, or 91%			
And, NPV = 45000 / 45500 = 0.989, or 98.9%			

Thus, if the prevalence is high, the PPV is very high. In other words, if a CSW tests positive on first ELISA, the probability that she really has HIV infection is very high - more than 90%.

**Clinical implications of prevalence and PPV :** The above description of how a test, with a given sensitivity and specificity (which are constant parameters) can give very different positive predictive values depending upon the prevalence of the disease in the target population, has important clinical and public health implications :

(a) Most of the diagnostics tests, after their development, are validated in tertiary care settings, where the prevalence of the disease condition, as such, is very high and hence the PPV in such settings will be high. However, the same test (with the same sensitivity and specificity) will have a hopelessly poor PPV, if applied in the primary health care settings where the prevalence of the disease is low. Let us take a common example:

If we validate Resting ECG as a diagnostic test for diagnosing IHD in a cardiology center, on males more than 35 years age, the prevalence of IHD in this "population" (i.e. males more than 35years age attending a cardiology center) is likely to be substantial (say, at least 15% to 20%). Now let us say, validation studies in these settings indicate that the sensitivity and specificity of Resting ECG in diagnosing IHD is 95% and 80% respectively. Impressed with this sensitivity and specificity, we start applying resting ECG as a screening test for IHD in healthy young males of more than 35 years age, say, sportsmen. Now the prevalence of IHD in this target population is very low, say 1 in 1,000. Let us say we put 1,00,000 healthy sportsmen aged > 35 years to this screening test. Now, since the prevalence is 1 in 1,000, 100 out of the 1,00,000 will actually have IHD and 99,900 will not have IHD. With a sensitivity of 95%, 95 of these 100 will be called "True positive" by Resting ECG; and with a specificity of 85%, 84,915 of the 99,900 non diseased will be correctly called non diseased (TN) by Resting ECG; Hence 99,900 - 84,915, i.e. 14,985 will be False positives. The resulting 2x2 table is shown as Table - 6.

<b>Table - 6</b>			
<b>Resting ECG Result</b>	<b>TRUTH</b>		
	<b>Have IHD</b>	<b>Do not have IHD</b>	<b>Total</b>
Positive	95	14985	15080
Negative	5	84915	84920
Total	100	99900	100000
PPV = 95/15080 = 0.0063 or 0.63%			

In other words, a young healthy sportsman aged >35 years who turns positive on resting ECG has even less than 1% chances of really having IHD. The implications can be serious. The 15,080 which are called positive by Resting ECG, will have to be subjected to confirmatory test, leading to excessive expenditure, which could have been diverted to some other fruitful activity and finally not even 1% of these will turn out to be having IHD. Secondly, the adverse psychological impact ("labeling effect") on the 14,985 who really do not have IHD but are called positive by Resting ECG can be tremendous. The clinician, epidemiologist as well as health administrator must keep themselves aware of such phenomena.

(b) Most of the diagnostic tests and equipment which are marketed describe the sensitivity and specificity (which are likely to be quite high), to impress the clinician and health administrators. However, these do not describe the settings in which the validation studies have been carried out. We should therefore, specifically ask them (the manufacturers or promoters) about the "settings" in which such validation studies are done by them and see if our settings of proposed application of the test are the same as the ones in which the test was validated.

(c) We can improve the PPV by bringing the subjects from a population of low prevalence to one of a high prevalence by certain artificial measures. Let us work on an example to see how this can be done. In our example on ELISA done on healthy blood donors, after the first test the 2x2 table (Table - 4) showed that in all, 10,890 persons out of a total 1,00,000 had tested positive.

Now, after doing this first ELISA, let us pick up all the 10,890 who tested positive (these would include 990 who truly have HIV infection and 9,900 who do not have HIV infection but have tested positive, i.e. FP & TP). Now, let us subject these 10,890 to second ELISA test. The results of this second ELISA (again with sensitivity and specificity of 99% and 90% respectively) would be somewhat like Table - 7.

<b>Table - 7</b>			
<b>Second ELISA</b>	<b>Healthy blood donors who tested positive with ELISA on first test</b>		<b>Total</b>
	<b>Having HIV Infection</b>	<b>Not Having HIV Infection</b>	
+ ve	980	990	1970
- ve	10	8910	8920
Total	990	9900	10890

Since there were 990 who actually had HIV infection and the sensitivity of ELISA is 99%, 980 of these 990 will be called correctly positive (TP). Again, with a specificity of 90%, 8910 of the 9900 non infected will be called negative while (9900 - 8910). i.e. 990 of the non infected will be called positive (FP). Thus, the PPV would now be  $990 / (990 + 980) = 0.498$ . i.e. 49.8%. Thus, after the first test the PPV was only 9%; after second test it is almost 50%.

How could this happen ? This occurred because during the first test the prevalence was 1,000/1,00,000, i.e. 1% which was very low. However, during the second test, the prevalence was 990 / 10,890, i.e. 9% (you may like to calculate for yourself what the PPV would be if we pick up all those 1,970 who have tested positive on second ELISA and give them a third ELISA test ? Well, it will be 91% this time - quite high. Thus if a healthy blood donor tests repeatedly positive (3 or more times) on ELISA, you would be more than 90% sure that he does suffer from HIV infection. Even in our everyday clinical practice, we do this exercise, though often unknowingly. If a young athlete walks to our office and complains of 'chest pain' we do not straightaway order for an ECG, because he represents a "population" (of young athletes having chest pain) in which the prevalence of IHD would be very low and hence the PPV of ECG in such a population would be poor. What we do is that we ask him two more question "Does it occur on exertion?" "Does it radiate to left arm? If his answers are yes, we now order for an ECG; because now he represents another "population" (of young athletes with chest pain occurring on exertion and radiating to the left arm) in which the prevalence of IHD is high and hence the PPV of ECG would be high.

**When to use a highly sensitive test :** A test which has very high sensitivity (though at the cost of low specificity) will identify, as positive, almost all of those who have the disease (i.e. high TP rate) through in the bargain it will also identify a large number of those who do not have the disease (high FP). In other words, the number of false negatives will be low; it means that, if a person comes negative on a highly sensitive test, then we are almost sure that he does not have the disease (if test result is positive, however, then we are not very sure that the person really has the disease because 'FP' will be very high).

It follows, therefore, that a highly sensitive test is of value, clinically, when it is "negative", and in this situation, it helps in "ruling out" the disease; e.g. ELISA is a highly sensitive test for HIV infection (sensitivity 99%); thus, if a person is negative on ELISA, we are pretty sure that he does not have HIV infection, i.e. we rule out the diagnosis. This is also called as "Negativity in Health". However, if ELISA is positive, we are not so sure that the person really has HIV infection and hence we put him to a confirmatory test like Western Blot (or repeated ELISA tests using different systems). It also follows, therefore, that a highly sensitive test would be ideal as an initial screening test.

**When to use a highly specific test :** On the same reasoning used for a highly sensitive test, a highly specific test will have a large number of True Negatives and a very small (almost minimal) False Positives; however, the price one will pay will be a large number of False Negatives coming in. Because the

False Positives are almost nil in a highly specific test, if such a test is positive we are very sure that the person does have the disease; however, if the test is negative, it will not have much value since it will give a large number of false negative results. Thus, a highly specific test is of value when it is positive; and a positive result from a highly specific test "rules in" the diagnosis (Positivity in Disease). An example is Western Blot Test for HIV infection which is a highly specific test (specificity 99% or more). Once Western Blot is positive we are sure that the individual does have HIV infection. It also follows, therefore, that a highly specific test is best used as a "confirmatory test".

This discussion on highly sensitive or highly specific tests is because a test which is highly sensitive is likely to lose on specificity and vice versa. You possibly cannot have a test which is both highly specific as well as highly sensitive (because, if it is so, it will itself become the 'gold standard').

**The Likelihood Ratios :** From the foregoing narration it would be clear that the interest of the clinician or the public health specialist is, truly speaking, in the PPV and not the sensitivity or specificity. However, as we have seen, PPV depends on the prevalence of the target condition in the population, which is more often a matter of guesswork. To overcome these problems, the concept of likelihood ratios has been developed.

**Likelihood Ratio (Positive) (LR +, LRP) :** This is calculated by the following equation :

$$LR+ = \frac{\text{Sensitivity}}{(1 - \text{Specificity})}$$

For example, if the sensitivity of ELISA is 99% (i.e. 0.99 and specificity is 90% (i.e. 0.90), then

$$LR+ = \frac{0.99}{(1-0.90)} = \frac{0.99}{0.1} = 9.9$$

The interpretation is "A positive result on ELISA for HIV is 9.9 times (say, roughly 10 times) more likely to occur in a subject with HIV infection as compared to a subject who does not have HIV infection".

**Negative Likelihood Ratio (LR-, LRN) :** This is calculated by the equation :

$$LR- = \frac{(1 - \text{Sensitivity})}{\text{Specificity}}$$

In our above example on ELISA,

$$LR- = \frac{(1 - 0.99)}{0.90} = \frac{0.01}{0.9} = 0.011 = 1.1\%$$

The interpretation is that a negative result is only one hundredth times likely to occur in a person who really has HIV infection as compared to a person who does not have HIV infection. Apparently, for ELISA as diagnostic test for HIV infection, the LR minus is quite high (of the magnitude of 100 times) as compared to LR+ (of the magnitude of 10 times). Thus, it is the negative result of ELISA which is more important (a negative result would "rule out" the diagnosis), but not so much importance could be given to a positive result (a positive result of ELISA does not rule in the diagnosis; we have to



further confirm).

### The Other Scenario : When the Diagnostic Test Makes Measurements on a “Continuous Scale”

The discussion till now was in settings when the results of diagnostic test are recorded in either of the two categories - “Positive” and “Negative” (i.e. a categorical, “dichotomous” scale). Let us take the following hypothetical example.

We undertook : a study to evaluate Alanine Aminotransferase (ALT) as a screening test for chronic parenchymal liver disease. 500 patients attending a gastroenterology center with symptoms of liver disease were subjected to both, an assay of serum ALT levels as well as a diagnostic liver biopsy which was taken as the gold standard in this case. The results are presented in Table - 8.

Now, the instant question which would come up in any such situation is “what should be the optimum cut - off point for serum ALT by which we have the best probability of diagnosing Chronic Liver disease; i.e. what is that cut - off point at which we could correctly identify, as many as possible of those who have the disease (i.e. high sensitivity) and, at the same time, correctly leave out maximum number of those who do not have the disease (i.e. high specificity)”.

Table - 8				
Serum ALT Levels	Chronic parenchymal liver disease (As diagnosed by Liver Biopsy)		Total	Situation
	Present	Absent		
Units / Litre				
≤ 20	0	120	120	
21 - 40	20	150	170	(1)
41 - 60	40	15	55	(2)
61 - 80	40	12	52	(3)
81 - 100	40	3	43	(4)
> 100	60	0	60	(5)
Total	200	300	500	

Now let us see what happens if we place the cut - off point at 20 U/Litre (situation no. 1), and specify that we will diagnose any body who has ALT levels >20 U/L as having chronic liver disease. If this be the situation then we will diagnose all the 200 real patients as having liver disease; but at the same time we would also diagnose 180 non diseased persons (150 + 15 + 12 + 3 + 0) as having Chr. Liver disease. The 2x2 table would appear as Table - 9.

Table - 9		
Diagnosed Using ALT Level of >20	Chr. Parenchymal liver disease by Gold Standard	
	Present	Absent
Present	200	180
Absent	0	120
Total	200	300

And, in such situation, the sensitivity would be  $200/200 = 100\%$ , but the specificity would be  $120/300$ , i.e. 40% only.

Now, let us say we decide to place the cut - off point at >100, specifying that if we find anybody with ALT level >100 U/L, we would diagnose chronic liver disease, otherwise not. The 2x2 table in such case would be like Table - 10.

Table - 10		
Diagnosis based on ALT >100	Gold Standard Diagnosis	
	Present	Absent
Present	60	0
Absent	140	300
Total	200	300

In this instance, sensitivity =  $60/200 = 30\%$  (0.3)

And, specificity =  $300/300 = 100\%$  (1.0)

In fact we can work out the sensitivity and specificity for each level of cut - off point and put the same as shown in Table - 11.

Table - 11			
Cut off level	Sensitivity	Specificity	1 - Specificity*
> 100	0.30	1.00	0
> 80	0.50	0.99	0.01
> 60	0.70	0.95	0.05
> 40	0.90	0.90	0.10
> 20	1.00	0.40	0.60
* We shall discuss the significance of the column (“1 - specificity”) a little later.			

The straight conclusion which the above table gives us is that nowhere we would find a cut - off point where both sensitivity and specificity are 100%. If we lower our cut - off point (i.e. make the diagnostic criteria less strict), there will be an improvement in sensitivity from (0% at >100 to 100% at >20 units), but this will be obtained at a corresponding decline in specificity (from 100% at >100 units to 40% at >20); and contrarily as we keep raising the cut - off point (i.e. make the diagnostic criteria more strict) our specificity will keep increasing but at a corresponding decline in sensitivity.

The next question which comes to us, now, is what should be the “optimum cut - off point, i.e. how do we decide the cut off point which gives us the best combination of specificity and sensitivity. For doing this, we undertake the exercise of constructing the “Receiver - Operating - Characteristics curve” (ROC curve). Interested readers may refer to the list given in further suggested readings, for details of ROC curve analysis.

### Steps in Planning a Study on Diagnostic Test Evaluation

The following steps can be used as a checklist when planning a study on diagnostic test evaluation :

(a) Clearly define your research question and its background significance

- How your new diagnostic test, being evaluated, will help in better public health care / improved patient management.
- How is it going to be better than the existing tests (in terms of cost, ease of administration, technical ease, higher accuracy or better precision).

(b) *Specify the Variables* : Clearly specify the definition of the disease being diagnosed (as HIV), the variables being studied (as ALT, positivity to ELISA etc.) and the “scales” on which these variables are going to be measured (whether dichotomous or continuous etc.).

(c) *Give a clear description of the following “settings” of your study* :

- The type of hospital where you are going to do the study (e.g. specialized centre; secondary level care hospital etc.).
  - The demographic profile of the subjects (age, sex, race, education, economic status etc.).
  - The “referral filter” that your subjects have passed through before coming to your hospital; e.g. Whether they have come directly or passed through a referral filter of primary health centre, district hospital etc.
  - The “spectrum of disease” that you are including - whether only the severe forms or all the forms, i.e. mild, moderate and severe.
- (d) *As far as possible, include the complete spectrum of disease in your study* - the mild, moderate and severe forms : the typical as well as atypical forms; and also those disorders which are likely to be confused with the target disease.
- (e) *Give a clear description of the “Gold standard” of diagnosis in your study*, the reason as to why you are adopting it as a gold standard, and a clear description of the technique of undertaking the Gold standard test.
- (f) *Give a clear and detailed description of the technique of doing the diagnostic test under study* so that your colleagues who read your research paper can also undertake it on their patients.
- (g) *Clearly mention the Replicability* (reliability) of your diagnostic test in terms of variations that may occur due to Observers (inter and intra observer), Subjects (inter and intra subject) and instruments and techniques.
- (h) *Give a clear description of methods to improve precision*, i.e. to reduce variability when applying this test, in terms of Standardization of instruments, Standardization of techniques, Training and certification of observers (workers) and Quality control procedures.
- (j) *Calculate the sample size* - The sample size in a diagnostic test study is done in two stages :
- 1) *First, specify the expected “sensitivity” of the test* - just a rough estimate as you have seen earlier during sample size calculations; and specify the “acceptable deviation” from this sensitivity on either side of the expected sensitivity. Then,

$$a = \frac{\text{Sens} \times (1 - \text{Sens})}{(\text{Deviation})^2}$$

Let us say, we are validating ELISA test for HIV infection. Our rough estimate is that the sensitivity would be 95% (i.e. 0.95) and we accept a deviation of 3% on either side

(i.e. acceptable range of sensitivity to be detected by the present study sample = 92% to 98%); thus  $d = 3\%$  (i.e. 0.03).

$$a = \frac{0.95 \times (1 - 0.95)}{(0.03)^2} = 53$$

2) *Now, the actual sample size ‘N’ is calculated by the formula*

$$N = \frac{a}{\text{Prevalence}}$$

Let us say the expected prevalence of HIV infection in the population we are doing our study (say, professional blood donors) is 5% (i.e. 0.05)

Thus,

$$N = \frac{53}{0.05} = 1060$$

Thus, we should take a sample of 1060 subjects from the given population of professional blood donors. (note that if sensitivity is used as a fraction out of 1, then prevalence should also be in fraction form). In our example, we have therefore, taken both, the sensitivity (0.95) as well as prevalence (0.05) in fraction form.

k) And the last, but the most important point during the conduct of a diagnostic test study (which is often forgotten) is “*Put each and every subject of your study to BOTH, the diagnostic test under study as well as the Gold Standard test*”. If this is not done (e.g. only those who come positive on diagnostic test are put to Gold Standard test), it does not remain a diagnostic test study at all.

## Summary

For evaluating a diagnostic test, which could be a new pathological or radiological procedure, or even a clinical algorithm, we assess its ability to correctly diagnose a disease as compared to some ‘gold standard’ which would have diagnosed the disease in an absolutely perfect manner. Thus, any diagnostic test should be evaluated in terms of three types of parameters. These are Reliability, validity and Economicity. Reliability : (Syn : Precision, Reproducibility, Repeatability) is the ability of the test to give consistent results when repeated applications are made. Reliability is affected by variations which can occur due to observers, variations due to subjects and variations due to instruments and techniques (Different physical instruments, reagents etc. may give different results). Reliability can be minimized by standardization of definitions of the disease being diagnosed, using standard techniques of measurement, using standardized instruments, training of workers, continued supervision, establishing a quality control system, and by using good quality instruments and reagents.

Validity is the ability of the test to correctly diagnose what it actually intended to diagnose, as compared to the gold standard test. This has two broad components, viz., the ability of the test to correctly call positive those who really have the disease; this is known as sensitivity and is calculated by the number of actually diseased persons called correctly positive by the

test under study (true positives) divided by the sum of true positives and false negatives (people who actually have the disease as per gold standard but our test calls them negative). The second parameter is 'specificity' which is the ability of the test to correctly call negative those who do not have the disease and is calculated by dividing the true negatives by the sum of true negatives and false positives (persons who actually do not have the disease according to gold standard but our test has called them positive).

In addition to sensitivity and specificity, equally important are the 'predictive values' of a test, which are also of two types. The positive predictive value gives the probability that a person who has a positive result from our test will actually have the disease and is calculated by dividing the true positives by the sum of true positives and false positives. The negative predictive value gives the probability that a person with a negative result from our test really does not have the disease and is calculated by dividing the true negatives by the sum of true negatives and false negatives. A particular issue with the predictive values to be noted is that they are quite dependant on the prevalence of the disease being studied; if the prevalence of the disease is high, the positive predictive value will be high and vice versa. This problem may be overcome by calculation of "likelihood ratios" (positive and negative).

When the diagnostic test is recorded on continuous scale, there is no cut - off which will give 100% specificity and 100% sensitivity. If cut off is lowered, the test will have higher sensitivity value & low specificity; if the cut - off level is raised, it will result in high specificity and low sensitivity. To get the optimum cut off, which gives us the best combination of specificity and sensitivity, we construct the "Receiver - Operating - Characteristics curve" (ROC curve), by plotting the values of sensitivities against the corresponding values of (1 - specificity) at the various cut - off levels.

Before planning diagnostic test evaluation clearly define research question and its background significance and specify the variables. Then give a clear description of your settings in term of type of hospital, demographic profile of the subjects, referral filter and spectrum of diseases. As far as possible take the complete spectrum of disease. Give a description of gold standard test and the technique of undertaking it. Similarly give clear and detailed description of the technique of undertaking the diagnostic test being evaluated. Give considerations to the Replicability (reliability) of your diagnostic test in terms of variations that may occur due to Observers (inter and intra observer), Subjects (inter and intra subject), Instruments and techniques. Give a clear description of methods to improve precision, i.e. to reduce variability when applying this test, in terms of Standardization of instruments, Standardization of techniques, training and certification of workers and Quality control procedures. Finally, ensure that each and every subject of your study is subjected to both, the diagnostic test under study as well as the Gold Standard test. Analyse the results by calculating the sensitivity, specificity, predictive values and likelihood ratios.

## Study Exercises

**Long Question :** Most often, young children are at high risk of death or complications if they develop lower respiratory tract infections, usually with *Streptococcus pneumoniae*. Early institution of oral antibiotics by the paramedical health workers, at domiciliary level may be life saving. The gold standard accepted method of diagnosing this infection, is a combination of chest X - ray and sputum culture. A health policy maker wants to find out the extent to which a combination of fever and tachypnoea (respiratory rate > 40 per mt) can diagnose the condition; if the validity is high, a paramedical worker can be trained to start early antibiotics in the home settings. Forward your plan of undertaking this study.

**Short Notes :** (1) Validity of a diagnostic test (2) ROC curve analysis (3) Reliability of a diagnostic test (4) Kappa coefficient.

### MCQs & Exercises

1. The ability of the test to call positive those who really have the disease is known as : (a) sensitivity (b) validity (c) specificity (d) none of the above
2. The ability of the test to call negative those who do not have the disease is known as (a) sensitivity (b) validity (c) specificity (d) none of the above
3. Essential requirements of diagnostics test are (a) diagnostic test (b) subjects (c) gold standard test (d) all of the above
4. Parameters on which a diagnostic test is evaluated are all except (a) reliability (b) efficiency (c) validity (d) strength of association
5. What is plotted along the Y - axis in ROC curve (a) sensitivity (b) prevalence (c) specificity (d) predictive values
6. In diagnostic evaluation test, (a) only those subjects who are positive on diagnostic test are subjected to gold standard test (b) All subjects are subjected to both the test ; (c) only those subjects who are negative on gold standard test are subjected to diagnostic test. ; (d) None of the above.
7. Prevalence will affect the \_\_\_\_\_ of a test (a) Sensitivity (b) Predictive values (c) Specificity (d) Validity
8. Pap smear examination is often used as a screening test for cervical cancer. In developing countries, where resources are scanty, a public health manager wants to find out as to how well "Visual inspection (VI)" can be used as a screening test, when histopathology is taken as the gold standard. For finding this, the investigator took subjects from clinics catering to the rich, affluent socio - economic class. 5000 women who were established to be having cervical dysplasia on biopsy and 10,000 age and parity matched women who were not having cervical cancer were subjected to VI, which was positive in 3600 of the dysplasia subjects and in 1600 of the non - dysplasia group. Answer the following : (a) What is the sensitivity of VI (b) What is the specificity (c) What is the PPV (d) If VI is applied to CSWs, what will happen to these three parameters?
9. Two radiologists were asked to independently read 100 USG of bladder area and classify them as normal or abnormal.

Their results are as follows. Answer the questions (a) to (d) below based on this information :

Radiologist - 1	Radiologist - 2		Total
	Abnormal	Normal	
Abnormal	40	20	60
Normal	10	30	40
Total	50	50	100

(a) What was the simple, overall percent agreement between the two radiologists (b) If the USGs which both read as normal are removed, then what was the overall percentage agreement between the two (c) What is the value of Kappa Coefficient

(d) This value of Kappa represents what grade of agreement.

**Answers :** (1) a; (2) c; (3) d; (4) d; (5) a; (6) b; (7) b; (8) (a) 72% (b) 84% (c) 69.2% (d) sensitivity and specificity will remain the same but PPV is likely to go up, since CSWs are likely to have much higher prevalence of cervical CA as compared to women from high economic status, in which the test was initially assessed. (9) (a) 70% (b) 57% (c) 0.40 or 40% (d) Moderately strong agreement.

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## Epidemiologic and Public Health Basis of Screening for Diseases

RajVir Bhalwar

One of the priority duties, not only of a public health physician but for all medical personnel is to ensure an early diagnosis and treatment, through "screening for diseases".

**Definition :** Screening has been defined by the commission on chronic illnesses (88, 89) as "*the presumptive identification of unrecognized defect or disease by the application of tests, examinations or procedures which can be applied rapidly, to sort out apparently well persons who probably have a disease, from those who probably do not*". A screening test is not intended to be diagnostic. Persons with positive or suspicious findings must be referred to the physicians for diagnosis and necessary treatment.

The various objectives for which screening is undertaken are shown in Box - 1.

### Box - 1 : Objectives of Screening

#### Screening in community health care is undertaken with the following broad objectives

- To ensure early detection of a disease among individuals, so that prompt treatment may be instituted; e.g. screening for cervical cancer, breast cancer, hypertension etc. This is also called "Prescriptive Screening".
- To protect the community from disease that the person being screened has, also called "Prospective Screening"; e.g. screening the blood units for HIV.
- For entry into certain forms of occupations (armed services, industries, etc.) with a view to "weed out" those who are unfit or whose existing health status may be adversely affected by occupational conditions.

## Requirements of Tests used for Screening

A Screening test should be :

**Valid :** It should be "accurate", i.e. should measure correctly what it intends to. It should have high sensitivity, specificity, and positive & negative predictive values.

**Reliable (Precise) :** It should give consistent results when repeated applications are made.

**Yield :** It should give enough number of cases to commensurate with the expenditure and inputs involved. Yield will depend on Sensitivity of the test, Prevalence of the disease (If screening is applied to a high risk group, the yield will be better) and availability of medical care (if medical care has not been available to the community being screened, a large number of people with the disease will be diagnosed).

**Practical :** The test should be easily administered by even persons with ordinary training, should be innocuous, acceptable and should give fairly quick results.

**Efficient :** The amount of inputs (in terms of expenses and time) should result in reasonable amount of outputs in terms of improved health & satisfaction.

We have already had a detailed discussion on the various aspects of validity (sensitivity, specificity, etc.) and reliability in an earlier chapter on diagnostic test evaluation studies and the readers are suggested to recapitulate the contents of that chapter. Ideally a test should be both highly specific as well as highly sensitive, so as to get the maximum numbers of True Positives (TP) and True negatives (TN). However, in practice this is not possible and some trade off, depending on the disease under consideration is required. If a disease has serious implications if not treated early and has adequate treatment available, then our aim would be to not leave out any "false negative", even at the expense of getting many false positives; in such instance we would go up for highly sensitive test.

For a screening test in which the result is measured on a continuous scale, the decision regarding cut off point would



need consideration by experienced clinicians and public health administrators. For example, if tonometry is being used as a screening test for glaucoma, the results (18, 18.5, 22, 26.8 mm etc.) would be measured on a continuous scale. Now, possibly most of the eyes with intra ocular pressure upto 22 may be, in fact, non - glaucomatous while most of the eyes with intra ocular pressure more then 26 mm will be, in fact, really glaucomatous. The main problem will be the eyes having ocular pressure between 22 and 26 mm Hg, i.e. the area of overlap between glaucomatous and non glaucomatous eyes. If we keep the cut - off point low, say at 22 mm Hg, we will correctly identify nearly all the glaucomatous eyes (high TP) but will also identify a number of normal eyes as glaucomatous (large numbers of False Positives (FP)). On the other hand, if we keep the cut off at 26 mm Hg, we would correctly identify nearly all the normal eyes (high TN) but would miss out a large number of glaucomatous eyes who have mild rise of pressure (large numbers of False Negatives (FN)). In the former instance, when we have a low cut off point (i.e. less stringent criteria) we have, thus, higher sensitivity but lower specificity. On the other hand, in the latter instance, when we have a higher cut - off point (i.e. more strict criteria) we get a higher specificity at the cost of a lower sensitivity. In practice, the public health decision regarding the level of cut off is done based on the potential for treatment following early detection, the actual availability of treatment and the "labeling effect of having a disease", if any. In such cases, advanced statistical techniques in the form of "Receiver Operator Characteristics (ROC) curve analysis" are available to scientifically work out the optimum cut off point, which gives the best trade off between specificity and false - Positives (i.e. 1 - Specificity), as has been already described in the previous chapter.

As we have also explained at length in that same chapter, sensitivity and specificity of any diagnostic test are fixed, i.e. they will not change. However, our interest in screening is not only the sensitivity or specificity but rather the predictive values; i.e. if an individual has tested positive on a screening test, what are the chances that he really does have the disease. This is called the Positive Predictive Value (PPV or PV+). Unfortunately, predictive values are highly dependent on the prevalence of that disease in the population being screened. The same test with the same levels of sensitivity and specificity will give a very high PPV if the prevalence of disease is high but a very low PPV if prevalence is low. The optimum prevalence to get a very high PPV as well as NPV is between 30 - 60%. Thus, the health administrator should aim at getting the population to be screened in such a way that prevalence of the condition for which screening is being undertaken, is between 30% to 60% (90).

### Serial (Sequential) and Parallel (Simultaneous) Screening Tests

Two screening tests can be applied in serial (sequentially) one after the other, by taking people who test positive on the first test for the second test. In fact the same test (e.g. ELISA for HIV) can also be done two times in serial. This procedure will greatly increase the specificity and positive predictive value, but lead to decline in net sensitivity. Similarly two tests can be applied in parallel (simultaneously) and the person can be considered

as +ve if any one or both of the tests are +ve which leads to an increase in net sensitivity but a decline in net specificity.

### Considerations before Launching a Screening Programme (After Wilson & Jugner) (91)

Screening in public health settings should only be launched after carefully considering various aspects, as summarized in Box - 2. Detection of cancer of uterine cervix using "pap test" is a procedure which meets all these 10 criteria. The test is based on the assumptions that, firstly, a high proportion of cancer cervix detected in situ would progress to invasive cancer over time; secondly, most cancers remain in situ long enough for screening at reasonable intervals to detect a high proportion of cancer cases; and, thirdly, carcinoma in situ is highly curable.

Other diseases which are amenable to screening include breast cancer, Hypertension, Anaemia during pregnancy, Diabetes Mellitus, growth screening in children, CHD screening in high risk groups, phenylketonuria among new born etc.

#### Box - 2 : Considerations for a screening programme (source: 91)

- The condition should be an important health problem.
- There should be an acceptable and effective treatment.
- Facilities for confirming the diagnosis and for treatment should be available.
- There should be recognizable latent / early symptomatic stage.
- There should be a suitable screening test or examination available.
- The test should be acceptable.
- The natural history of the condition, including development from latent to apparent disease, should be adequately understood.
- There should be an agreed policy regarding whom to treat as patients.
- The cost of case finding (including final diagnosis and treatment) should be economically balanced vis - a - vis the expenditure on medical care as a whole.
- Case finding should be a continuing process and not "once and for all" project.

### Evaluation of Screening Programmes

Contemporary medical evidence strongly recommends that the effectiveness and impact of screening programmes must be evaluated by Randomised Controlled Trials (RCTs) by comparing the outcome measures between the screened and unscreened groups.

#### Biases in Screening Programmes (92 - 95)

**Lead time bias** : Lead time is defined as the interval between the point a condition is detected through screening and the time it would normally have been detected due to appearance and reporting of signs and symptoms. If early detection has no effect on the course of disease then it will be like giving the patient a few more years of sickness and apprehension rather than health! (e.g. HIV detection).

In such cases, it is possible that screening, through earlier detection, will advance the time of diagnosis without delaying

time of death, thereby increasing the “diagnosis - to - death - time” and tend to show “increased survival” among the screened group as compared to the group not given screening test, though in reality there would be no increase in survival.

**Length bias** : It has been observed that cases detected through periodic, early detection programs, tend to have longer preclinical stages than those missed out by screening but self detected between examinations. This preclinical stage is defined as the interval between the time a screening test is capable of detecting disease and the time the patient seeks care as a result of experiencing symptom detected patients. Thus, the length bias tends to spuriously show a better survival among screen detected cases.

**Self selection bias** : If the groups which are offered (and the other which is not offered the screening) are not constituted by random allocation but rather on the basis of self selection (volunteers), it is possible that such volunteers may be more health conscious, educated and more likely to give up associated risk factors; hence survival in such a screened group is likely to be better, not due to screening but because of associated factors.

### **Public Health Officer's Check List while Planning a Screening Programme**

In the past, many screening programmes have been launched simply due to over enthusiasm, without any consideration to the epidemiological facets of proper health planning. The result has been often quite adverse, creating unnecessary public aversion towards screening programmes (due to lack of proper diagnostic test or treatment), and wastage of resources. It is therefore necessary that the Public Health Officer in charge of Community health care should check the following list sequentially, while launching a screening programme.

**Do a “situational analysis”** : Undertake a quick collection of information, by going through existing records of health institutions and other governmental/non governmental agencies, or else, collect information by a quick survey, in respect of the community to be screened about the :

- Demographic profile;
- Attitudes towards utilization of existing health services;
- Knowledge & practices about disease(s) proposed to be screened;
- Prevalence of important diseases with special reference to the diseases proposed to be screened;
- Expected load of population likely to come up for screening, in respect of the community to be screened.
- **Resource analysis** : Available medical and paramedical personnel, buildings, vehicles, equipment (for screening and final diagnosis), etc. What additional resources in terms of men, money and material will be required to smoothly undertake the screening test (and the final diagnostic test for those who are positive on screening)? Are adequate treatment facilities available?
- Reports on previous screening programmes which were undertaken in the same community earlier and the “weak areas” noticed.

**Decide whether it is worthwhile and feasible to screen for the disease(s) in question** : These considerations are

very important before launching a screening programme. The important questions that you must ask yourself at this stage are :

- Is the disease proposed to be screened an important health problem?
- What are the high risk groups for the disease?
- What is the prevalence in these groups?
- Is a screening test available and can be administered to the subjects at a place near their home (say within 5 kilometers)?
- Will the screening test be acceptable to the clientele?
- Have the “diagnostic characteristics” (sensitivity, specificity etc.) of the screening test been worked out authentically?
- Is a confirmatory test available? Will you be able to administer it to all those who are positive on screening test?
- If the confirmatory test is to be given in a specialised centre, will that centre entertain your referred subjects? Will the subjects be able to afford the travel and stay at the place of final diagnostic test?
- Are you sure that there is a proper, proved modality of treatment for the disease you are going to screen?
- Will those finally diagnosed be able to “afford” this treatment? Or will you be able to provide treatment out of governmental funds?
- Are you sure that the disease you are screening for does not carry an over - riding “labeling” effect?

**Identify the high risk groups** : As we know, the prevalence will be high in high risk groups and hence the PPV and yield will be high; e.g. for screening for cervical cancer, “women > 35 years from lower socioeconomic status” may be identified as the high risk groups.

**Collect your logistics together** : Remember, not to start a screening programme, in anticipation of the resources - you may cut a sorry figure and cause adverse publicity. First get all your required personnel, equipment, reagents, and other logistics ready.

**“Standardize” your personnel, instruments and techniques**: The only method of ensuring a high repeatability of screening test is to centrally train your observers/ technicians, pretest and certify them, standardize your equipment and reagents, and establish quality control procedures.

**Ensure community participation** : Remember, a good epidemiologist never takes her community for granted. Your finest screening camp may not draw even a few subjects, simply because community participation had not been ensured. Contact the community leaders, peer groups and other members of the community who may matter, right in the planning stage itself. Explain to them the importance of the disease to be screened, and the usefulness of screening and early treatment. Emphasise on them that *you need their active participation*. Take their opinion as regards how they would like to get the camp organized.

**Give proper publicity** : Make sure that at least 2 to 3 rounds of wide publicity have been undertaken, with an additional round of publicity for the high risk groups. The last round should ideally be undertaken 2 to 3 days before the start of screening camp. Ensure that those living in the remote, cut - off areas

are covered well with your publicity - they are usually the ones who will benefit most by your screening programmes but are generally missed out by publicity campaigns.

**Conduct the screening programme** : Do not leave things to chance. Be there yourself at the site, or at least ensure that one of your senior subordinates is there to address the “unforeseen” problems.

**Evaluate the screening programme** : Set up your “criteria of evaluation well in advance. Write down your evaluation report at an early date while things are still fresh in the mind - this will serve as a good reference document for subsequent screening programmes.

## Summary

Screening is defined as “the presumptive identification of unrecognized defect or disease by the application of tests, examinations or procedures which can be applied rapidly, to sort out apparently well persons who probably have a disease, from those who probably do not”. Persons with positive or suspicious findings must be referred to the physicians for confirmation of diagnosis and necessary treatment”. A screening test should be valid (should measure correctly what it intends to), reliable (should give consistent results when repeated applications are made), and should give good yield. Yield will depend on Sensitivity of the test, Prevalence of the disease and availability of medical care. Besides, a screening test should be practical and efficient. The screening test being used should be as highly specific and sensitive as possible. Besides sensitivity and specificity, predictive values are also important (positive predictive values and negative predictive values). The optimum prevalence to get a very high PPV as well as NPV is between 30 - 60%. Two screening tests when applied in series one after the other increase the positive predictive value. Similarly two tests can be applied in parallel and the person can be considered as +ve if any one of the test is +ve (increase in sensitivity) or he may be considered +ve if both the tests are +ve (increase in specificity). Various factors are taken into consideration before launching a screening program, viz., the disease should be an important health problem, facilities for confirming the diagnosis and for effective and acceptable treatment should be available, there should be a suitable and acceptable screening test, the natural history of the disease should be well understood and there should be a recognizable latent / early symptomatic stage in disease history. The effectiveness and impact of screening programmes must be evaluated by Randomised Controlled Trials (RCTs) by comparing the outcome measures between the screened and unscreened groups. The common biases that may occur in screening programmes are lead time bias, length bias and self selection bias. Lead time is defined as the interval between the point a condition is detected through screening and the time it would normally have been detected due to appearance and reporting of signs and symptoms. If early detection has no effect on the course of disease then it will be like giving the patient a few more years of sickness and apprehension rather than health! Length bias refers to the observation that cases detected through periodic, early detection programs, tend to have longer preclinical stages than those missed out by screening but self detected between

examinations. Thus, the length bias tends to spuriously show a better survival among screen detected cases. If the groups which are offered (and the other which is not offered the screening) are not constituted by random allocation but rather on the basis of self selection (volunteers), it is possible that such volunteers may be more health conscious, educated and more likely to give up associated risk factors; hence survival in such a screened group is likely to be better, not due to screening but because of associated factors (self selection bias).

While launching a screening programme, at the outset, one must undertake a situational analysis of the community in which the screening programme is proposed to be launched, by collecting information about demographic profile, prevalence of important diseases with special reference to the diseases proposed to be screened, and the expected load of population likely to come up for screening. This should be followed by a resource analysis. Next step is to identify the high risk groups, as the prevalence and hence the PPV and yield will be high in these groups. Collect logistics together, get all your required personnel, equipment, reagents, and other logistics ready. Next step is to Standardize” personnel, instruments and techniques and training of observer to ensure high repeatability of screening. Ensure community participation by making contact with the community leaders, peer groups and other members of the community who may matter, right in the planning stage itself and explaining to them the importance of the disease to be screened, and the usefulness of screening and early treatment. Emphasise on them that you need their active participation. Give proper publicity to the programme; ensure that those living in the remote, cut - off areas are covered well with your publicity. Make sure that you have catered for providing the final confirmatory test to those who are found positive on screening test and that facilities for treatment have been catered for those who will be found finally positive. Next step is conducting the program itself and lastly evaluate the programme.

## Study Exercises

**Long Question** : Give a draft plan for planning, conducting and evaluating a cervical cancer screening programme in a CHC area covering a rural population of approximately 1 lac.

**Short Notes** : (1) Biases in screening (2) Requirements of a screening test (3) Criteria for undertaking screening for diseases in a population

### MCQs and Exercises

1. A cervical cancer screening programme was conducted in a rural area using pap smear procedure, in the year 2000. Out of the women who participated, Mrs 'A' was diagnosed to be having cervical cancer; however she could not be offered surgery because no gynaecologist was available. She died of cervical cancer in 2005. Out of the women who did not participate, Mrs 'B' developed symptoms of cervical cancer and was diagnosed in 2002. She also died in 2005. This occurrence represents : (a) Successful increase in years lived by Mrs 'A' (b) Length time bias (c) Lead time bias (d) self selection bias.
2. In a screening program for colonic cancer, the test used is stool test for occult blood among middle aged persons.



The camp was undertaken in a semiurban area with an estimated prevalence of colonic cancer of 1% in this age group. If the test has a sensitivity of 70% and specificity of 80%, what would be the PPV?

3. In the above question, if the test was negative, no other test was done. However, if the test was positive, one more test was given and persons who tested positive on the second test also were sent for confirmatory colonoscopy. If this procedure was applied, what would have happened : (a) Net sensitivity and net specificity are both increased (b) Net sensitivity is decreased but net specificity is increased (c) Net sensitivity remains the same and net specificity is increased (d) Net sensitivity is increased and net specificity is decreased
4. If a screening test is used in series twice, which parameter will increase? : (a) Sensitivity (b) Positive predictive value (c) Specificity (d) None of the above
5. What is the denominator in calculating the sensitivity of a test? : (a) True positive (b) True negative (c) False positive (d) False negative
6. What is the denominator for calculating the specificity of a test? : (a) True positive (b) True negative (c) False positive (d) False negative

7. For ruling in of the disease which test is preferred? (a) Highly sensitive test (b) Low specific test (c) Highly specific test (d) None of the above
8. For ruling out of the disease which test is preferred? (a) Highly sensitive test (b) Low sensitive test (c) Highly specific test (d) None of the above
9. Which of the following is a fixed parameter of screening test? (a) Sensitivity (b) Negative predictive value (c) Positive predictive value (d) None of the above
10. Predictive value of screening test depends on (a) Prevalence (b) Sensitivity (c) Health worker (d) None of the above
11. The optimum prevalence to get a very high PPV is (a) 30 - 60% (b) 5 - 30% (c) 60 - 90% (d) none of the above
12. The following consideration is NOT required to be taken while doing a screening programme (a) The disease should be a public health problem (b) The disease should be vaccine preventable (c) There should be an acceptable and effective treatment (d) Facilities for confirming the diagnosis and for treatment should be available.

**Answers :** (1) c; (2) 3.5% approx; (3) b; (4) b; (5) a; (6) b; (7) c; (8) a; (9) a (10) a; (11) a; (12) b

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### Planning, Design and Conduct of Epidemiological Surveys

*RajVir Bhalwar*

At times, information of the required nature may not be available to the public health specialist from the various sources of secondary data that have been discussed in detail in an earlier chapter. In such instances, the public health specialist would need to collect primary data by studying all or a sample of the community members, to generate information about the health status and related aspects, in the population under her health care, by means of a survey. However, as said earlier, surveys require money, material and manpower as well as time to conduct and analyse them before an answer can be given to the public health question. Hence, surveys should, in general, be undertaken only when we are convinced that the requisite information is not available from any other source of data.

Of course, surveys have certain distinct advantages over secondary data. Firstly, the data so generated is primary data, obtained to comprehensively answer the issue at hand and will therefore contain information about all the variables, which may not be the case with secondary data. Secondly, the data is likely to be more accurate in case it is a primary data, since various quality control measures are undertaken as part of survey methodology.

**What do we mean by "Survey"?** : A survey can be defined as an epidemiological investigation undertaken to examine certain selected features of a community, with a view to work out the frequency (either incidence or prevalence), of one or more diseases or health related phenomena, and often their distribution according to selected person, place and time related variables, by obtaining information from a sample drawn from the population of interest.

In public health, surveys may be undertaken in two broad settings. Firstly, the local public health specialist or health manager at district or Community Health Centre (CHC) level may need a survey to answer some issues related to planning her health care for the community, for example an immunization coverage survey. More often, however, surveys are undertaken by the CHC or district health team as a part of larger survey ordered by the Central or State Govt. (e.g. national tuberculosis survey or NFHS, etc.). Common reasons for undertaking epidemiological surveys in public health are :

- Provide general socio - demographic and basic health data for planning and organizing the health services or to make a community diagnosis.
- To estimate the frequency (incidence or prevalence) of important diseases, as HIV, malaria, tuberculosis, diarrhoeal disease, etc. and the important socio - demographic factors according to which these diseases are distributed.
- To assess the availability and locations of health care facilities (infrastructure, manpower, equipment) in relation to the distribution of the community.



- To assess local beliefs, behaviour patterns, customs and awareness about health / risk factors as well as attitudes towards health services.
- To evaluate the effectiveness of a health program, as immunization program.

### Types of Epidemiological Surveys in Public Health Practice

There are three main methodological types of surveys :

**(a) Cross sectional Surveys** : All subjects are examined only once for the variables of interest, and the results refer to a given point of time (though, as clarified earlier in the chapter on incidence and prevalence, the actual survey may take a lot of time depending on the number of subjects and the number of variables being studied). A cross sectional survey would therefore give “prevalence” of the condition being studied. These surveys have the advantages that they give quick results and are less resource intensive. Most of the public health issues related to planning and evaluation of health services can be answered by cross - sectional surveys. The disadvantage is that they do not measure incidence, and may not accurately answer issues related to cause and effect relationship. They are also not appropriate if the disease being examined is either a rare disease or else it lasts for a very short duration because in such exigencies, most cases of the disease may not be noticed by a cross - sectional survey.

**(b) Longitudinal surveys** : The essential feature which differentiates longitudinal survey with a cross sectional one is that each subject is examined at least twice, to see the “change” that has occurred as regards the phenomena of interest over a period of time. These surveys measure the “incidence” and give a better insight into “cause and effect relationship”. The major disadvantage is the requirement of considerable resources as well the time required to follow up, before we can answer an issue.

**(c) Hybrid surveys** : These can often be used to obtain the advantages of both the cross - sectional as well as longitudinal surveys. A very good example is “repeated cross - sectional surveys” which can give an approximate idea of the incidence. For example, if a cross sectional survey in the year 1990 indicates that the prevalence of cervical cancer among women of reproductive age group is 1%, while another cross - sectional survey in the same population, in 2000, indicates the prevalence in the same population to be 2%, it may give a rough idea that the incidence of cervical cancer is  $(2 - 1) = 1\%$  over 10 years; however, it should be remembered that this gives only an approximate idea of incidence but is actually not the incidence.

### Whether to do a “Hospital based” or else a “Community based” survey?

For most of the health care providers, hospital is a very important point of contact with the community and hence, the desire to use the data available in the hospitals, to work out the health status and needs of the community. The population which, in general, utilizes the services of a hospital is called as its “catchment” population. It should be noted that hospital data has its own strengths and drawbacks. Detailed discussion on these aspects has been undertaken in an earlier chapter on

sources of health information and you are advised to refer to the same. In short, the advantages are that hospital data, either from OPD or indoor admitted patients, is quite economical to be obtained, the data is easily available, can be obtained and compiled quickly, and has diagnostic accuracy. On the other hand, the following are the inherent disadvantages :

- Often, all people who are having a given disease may not be admitted to a particular hospital or even to any of the hospitals in that area.
- It is often quite difficult to work out frequency measures (incidence or prevalence) from hospital data unless one is quite sure that all persons from the catchment area (and none other than the catchment area) fully utilize the hospital for the particular disease(s) which are being studied.

On the other hand, in a community based survey, a representative sample of the entire population is examined and hence the above disadvantages are taken care of. This advantage however, comes at much higher cost, more logistic effort, extra time and, possibly, not - so - accurate diagnosis of the disease. In general, if we are doing an *initial assessment* of community resources or undertaking an *initial planning* for health care and if logistics are available, a community based survey would be definitely preferable. However, if the requirements are of a periodic nature, quick results are required, the hospital adequately draws nearly all the population from the catchment area and adequate resources for undertaking full - fledged community based survey are not available, we may prefer utilizing the hospital data.

### Steps in Organising and Conducting an Epidemiological Survey

#### Step 1 - Clearly define the question that is to be answered :

At the outset, one needs to be very clear about the issue that we are to examine. As said, conducting a community based survey in a valid manner is not an easy task and hence one should be very clear as regards the question for which we are thinking to carry out a survey.

**Step 2 - Decide - is it required to do a survey?** : A survey takes time and plenty of logistic efforts. Therefore, after having clearly spelt out the issue to be answered, we should examine whether answer to this issue has already been given by some other survey, or can be obtained by some other secondary data source. Thorough reading, discussion with experts and examining all available records / sources of data may be worthwhile at this stage.

#### Step 3 - Ensure involvement and participation of the community and the administrative machinery and obtain the required sanctions :

This must be the first step. Even the most scientifically planned survey would be a failure, if the community has not been contacted and educated in detail well before the survey and their co - operation has not been solicited. In particular, communicate with the local peers, leaders, and those who are in a position to guide community opinion. Explain to them the need for the survey, how it is going to be beneficial to them and how it is going to be conducted. Solicit, not only their support but also their advice as to how best to actually execute the survey. Similarly, contact the local

government officials and the influential non - governmental bodies for the requisite administrative sanctions and support.

**Step 4 - Get an idea of the socio - demographic and geographical distribution of the community and the local seasons of the area in which the survey is proposed:**

Undertake a preliminary appraisal of the area and the population proposed to be surveyed. Obtain information about the age and sex profile, major occupations, education, income, roads and communications, attitudes and beliefs, from the local governmental and non - governmental organizations. Find out as to where are the major residential and work areas and how are they approached. You will realize that this knowledge would make a considerable difference for planning your field work and for organizing your logistics. Some of this information would be available in the local government offices but in addition, spend time in walking / driving around the area and meeting local people formally as well as informally. Study the local climatic and seasonal patterns and work out the best times of the year to undertake the survey.

**Step 5 - Assess the resources :** Based on the broad research question, the type of resources can be technical personnel, administrative personnel, diagnostic and other clinical equipment and expendables, transport, computers, tents, accommodation, finances, etc. Assess availability of these resources.

**Step 6 - Define the survey objectives :** It will be the research question, which, if clearly stated, will give us an idea of the population to be studied and the various variables to be studied. The entire planning of the survey will depend on this decision. An example could be "What is the prevalence of anaemia among the community served by my CHC"? This clearly stated research question gives an idea that the reference population for this survey would be all community members of all ages and sexes in the CHC area and that the major variable of study will be haemoglobin estimation.

**Step 7 - Define the variables of study :** In a survey, having specified the research question and objectives of the survey, we would list out all the variables on which measurements would be made. Specify the variable which is of maximum interest. This is known as "primary outcome variable" or "major endpoint". The primary outcome variable is important since issues like sample size calculation and subsequent analysis hinges around this primary variable. One should be sure to study all the variables in the proposed survey. But each additional variable costs money and effort for its measurement; at the same time if we do not include any particular variable and realize later on that we actually required that data, nothing can be done at that later stage. Hence, survey objectives must be discussed with experts before finalizing.

**Step 8 - Write down the process of measurement for each of the variables :** Measurement of any variable should have two characteristics validity and reliability. It is also pertinent to define the "case".

Write down, for each variable, the measurement technique which is "ideal" (i.e. gold standard). Thereafter, write down what is the process that is do - able and satisfactory enough. Measurement modalities must also be worked out.

**Step 9 - Develop the survey questionnaire and the interview technique :**

Remember that "questionnaires" which are greatly used in surveys are also a type of instrument and recording of data, using this questionnaire, also requires a scientific technique by itself. Even issues like measurement of "age", though seemingly trivial, may become pretty difficult; for instance in an illiterate population, subjects may not be able to tell their date of birth but rather relate it to some natural calamity that had occurred in the past. Hence, give utmost attention to developing the questionnaires and on the interview techniques, as has been discussed in detail in earlier chapters.

**Step 10 - Describe the reference and actual (study) populations :**

As discussed in detail in an earlier chapter, reference population (also called as universe or target population) is the large collection of humanity to which the findings of the survey will be generalized. On the other hand, actual study population is that subset of the reference population from where the actual study sample is drawn. For example, while doing a survey on prevalence of anaemia, the reference population could be defined as "all the people living in rural areas of the state", while the actual study population could be hypothetically defined as "all people living in the Community Development Block No.45". It is important to explicitly write down the reference and the study populations for the survey.

**Step 11 - Calculate the sample size :** Studying an adequate sample size is important to ensure precision, by reducing the random error and to undertake optimum statistical analysis. The details of sample size calculation are discussed in the relevant chapter in the section on biostatistics. What is important is that the epidemiologist should be prepared to give certain specifications to the statistician, namely the approximate expected value of the major outcome variable (as the percentage of people likely to be having anaemia or the approximate expected mean haemoglobin level, in the reference population), the deviation from this expected value that the investigator is ready to accept in this particular survey, and the level of confidence (usually kept at 95% level of confidence). It is always worthwhile to include about 10% to 20% additional subjects over and above the calculated sample size, to cater for unforeseen refusals.

**Step 12 - Select the method of sampling :** The sample should be so selected that every person in the study population should have an equal chance of being selected (random sampling technique). The details of probability sample selection are given in the chapter on "sampling methods" in the section on biostatistics. We should decide as to what would be the "sampling unit", i.e. whether the selection would be of individual persons or of households etc. A list of all these sampling units in the actual study population should be made - this is known as the "sampling frame". Divide the number of units in the sampling frame by the sample size actually required to be studied, to get the "sampling ratio". Select out the units to be actually studied from the sampling frame, using one of the probability methods described in the chapter on sampling methods. In most of the community based surveys, particularly when the disease being studied is not a rare one and prevalence (not incidence) is being studied, the methods of "multi - stage random sampling" or

else, the 'cluster sampling' (usually 30 clusters, 7 units in a cluster) is reasonably good enough.

**Step 13 - Organise the Logistics and become Administratively Viable** : Men, money and material are important for surveys. Write down the fine details of your requirements of :

- Technical personnel, as data collectors, interviewers, entomological workers, laboratory assistants, nurses, general duty doctors, and specialist doctors. Do not forget to include female attendants if you are likely to interview or examine female subjects during the survey.
- Administrative personnel as clerks, computer operators, drivers, cooks and messing staff, ancillary workers, etc.
- Technical Material (as equipments, reagents, diagnostic items, survey forms and questionnaires, computer items). A useful method is to make a check list of items required for each and every technical procedure and then make an overall checklist of various items and equipment that will be required for the survey.
- Logistic material (as vehicles, petrol, tentages, stationery).
- Finances (money for purchasing technical and logistic material, salaries, incidentals, etc.).

Develop a written document specifying the job description of each category of workers, and to make a chart showing the hierarchy of command of the various personnel showing who will be responsible to whom and for what jobs.

**Step 14 - Organise technically for the survey** : Get your instruments, equipment, disposables and reagents and print your questionnaires. Standardise your equipment against standard equipment. Train your field workers centrally, test them for reliability and certify them. Finally, if possible, develop a detailed "operations manual" which spells out in detail as regards each aspect of how sample will be drawn, how various measurements will be made, how quality control procedures will be established etc.

**Step 15 - Examine the ethical issues and cater to them in your proposed survey** : In community based surveys, which by definition do not involve intervention and trial of a treatment/preventive procedure, the ethical issues may become less rigorous as compared to a clinical or preventive trial, but nonetheless, should be well examined. As far as possible, the possible ethical concerns should also be discussed with the local community and clearance from the local / institutional ethical committee should be taken if applicable.

In community based epidemiological surveys, the major concerns from ethical point of view pertain to : Firstly, protection of confidentiality as regards the information which has been given by the individual subjects and Secondly, obtaining informed consent from individual subjects for participating in the survey, after they have been informed in detail about the survey.

Thirdly, an important issue is the moral (if not truly legal) need of providing some health care along with the survey. A good old dictum is "no survey without service". For instance while doing a survey for anaemia, it would be quite desirable that Iron and Folic Acid tablets (and possibly anti - helminthics) be given to those who have been found to be having anaemia or

ancylostomiasis; at least some sort of referral to a health care facility may be organised for those who have been found to be having the disease being surveyed.

Fourthly, if medical records of patients are being used as source of data, one must examine the ethical as well legal issues, obtain proper sanctions from the competent authority for using the records and ensure protection of confidentiality of information.

**Step 16 - Make an "Action - Plan" showing the time line for various activities** : Make a chart and note down your various activities which you will undertake sequentially, in the first column. Thereafter, indicate with horizontal bars or lines, the point of start and completion of each activity. This will greatly help you in your execution of the survey. An example is shown in Table - 1.

**Step 17 - Do a Pilot testing** : The importance of pilot testing needs no emphasis. It is an essential part of any survey, wherein all methods and techniques, including interview technique, clinical measurements, laboratory and other diagnostic procedures are conducted on a small sample of subjects. The sample of subjects is usually a convenience sample of the strength of about 5% (if final sample size required is >200) to 10% (if final sample size to be studied is upto 200). Each and every procedure is watched for its replicability and validity and the findings are noted. If any defects are noted, the same should be rectified by way of re - training of workers or required improvements in the equipment. If major flaws are noticed, it may be worthwhile to carry out a second round of pilot testing, after proper rectifications. If major changes are made in the methodology following the pilot study, then the subjects studied in pilot testing should not be kept in the final analysis of data.

**Step 18 - Inform the Community About the Survey** : Success of a survey is quite dependant on how well all members of the community to be surveyed have been informed about the scope, time and place of the survey. Utilize all local resources as community meetings, prayer meetings, local radio broadcasts, school teachers, postman, and even person to person communications, for achieving this end.

**Step 19 - Organize and execute the fieldwork** : Actual fieldwork in a survey may be by home (or work place) visit method, wherein subjects selected by the sampling procedures are visited at their residence or workplace / school. The second is the "survey centre" method in which a centrally located building as community centre or school is utilized and all the selected subjects come to this place.

When using the household (or workplace) visit method, be judicious in calculating the number of households that can be interviewed by a worker. For an interview and clinical examination which may take about 45 minutes for one household, an interviewer can collect data on maximum 6 to 7 households in a day. Male investigators must be accompanied by female attendants or a local female social worker if female subjects are to be interviewed. Invasive / traumatic procedures (as blood sample collection) should be kept towards the end.

If using the survey centre approach, a "line of flow" should be made. 5 to 7 "stations" should be made. For instance, station



1 could be utilized for recording the general information about the subject, station 2 for oral questionnaire, station - 3 for anthropometry and other clinical measurements, station - 4 for non invasive diagnostic procedures as ultrasound or ECG, station - 5 for invasive procedures as drawing blood sample, station - 6 for dispensing required medications if any, and station - 7 for final checking of the completeness of the form and for providing basic health education. The sequence of headings in the form should conform to the sequence of various work stations as per line of flow. Readers are advised to refer to standard WHO guidelines for organizing the field work and survey centres while doing a survey, as mentioned in "further suggested readings" at the end of this section.

**Step 20 - Undertake Quality Control Procedures While the Survey is on :** Keep regularly visiting the community and supervising the field workers. Undertake an independent cross check by collecting information of 1 in 10 to 1 in 20 forms filled up by the field workers and see if there are discrepancies. Similarly, develop and undertake quality control procedures for the laboratory and other diagnostic procedures. The dictum is "when field work is on, be there yourself to see that everything is being done correctly".

**Step 21 - Analyse the data :** As the field work and data collection is going on, it would be prudent to enter the data into the computer software (preferably a database package). It would be further desirable to also keep a hard copy in the form of a "master chart" of the data. Simultaneous computer / manual entry into the database or manual chart will help identify the missing data points or the ones which are apparently erroneous and one could get back to the original subject before it is too late.

Analysis of data in a survey should be very simple and meaningful. Remember that the main users of analysed results would be the non - medical administrator and the community themselves, hence the analysis should be kept very simple, interesting, and meaningful, while at the same time not omitting any detail. The simplest and best is to make 2 X 2 tables, bar charts, line diagrams and spot maps. Do not make large tables, definitely avoid any table larger than 4 X 4 since it becomes very confusing and uninteresting for a layman. Give proper headings and legends to the tables and figures and always indicate the percentages in the tables.

**In general, the following parameters are analysed in a survey and findings are presented accordingly :**

- A map of the area, showing major landmarks, streets, residential and work areas and the area under survey.
- Socio - demographic profile showing numbers & percentages, in respect of major variables as age structure, sex, occupation, education, place of residence, place of work.
- The variable of principal interest according to total numbers and percentage and its 95% Confidence limits (CL), (or mean and SD if it was a qualitative variable).
- Other variables depicted as numbers and percentages and their 95% CL or mean & SD.
- Distribution of the major interest variable and other variables according to important socio - demographic variables as age, sex, place of residence and other variables studied, clearly showing the percentages in each table.
- Maps showing the percentage of the major variable according to various places, and line diagram showing the same at different points of time.

**Step 22 - Writing the survey report :** While the epidemiologist would have put her entire heart and soul into the planning, organizing, conduct and analysis of the survey, it is the report which is actually read by all and hence great care should be exercised while writing the report. The general guidelines have been given in a separate chapter dealing with how to write a research paper and the same should be consulted. One should also remember that there are 4 different categories of people who will be interested in your report, and the language, contents and illustrations contained in the report should commensurate with the target audience. These 4 categories of people are :

- The standard medical journals where the report may be sent as a research article and the medical fraternity who would be reading that article.
- The local health care providers.
- The local administrators and political leaders.
- The general members of the community.

## Summary

A survey can be defined as an epidemiological investigation undertaken to examine certain selected features of a community, with a view to work out the frequency (either

Table - 1 : Action plan																
Month >	September				October				November				December			
Week >	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
ACTIVITIES & TIME-LINE																
Decision on survey objectives																
Preparing of questionnaires																
Obtain staff & equipment																
Training of workers																
Pilot testing																
Data collection																
Data analysis																
Final report writing																



incidence or prevalence), of one or more diseases or health related phenomena, and often their distribution according to selected person, place and time related variables, by obtaining information from a sample drawn from the population of interest. Surveys are generally undertaken only when we are convinced that the requisite information is not available from any other source of data. In public health, surveys may be undertaken in two broad settings either to get answers related to health - planning activity at local level or as part of larger survey ordered by the Central or State Govt.

There are three main methodological types of surveys; cross - sectional surveys, wherein all subjects are examined only once for the variables of interest, and the results refer to a given point of time - these surveys give an estimate of prevalence; longitudinal surveys, wherein each subject is examined at least twice - these surveys give an estimate of incidence; and hybrid surveys - that can be used to obtain the advantages of both the cross - sectional as well as longitudinal surveys - these surveys give an approximate estimate of incidence.

The decision on whether to utilize hospital based data or else to go in for a full - fledged community based survey must be taken after the following considerations : In general, if we are doing an initial assessment of community resources or undertaking an initial planning for health care and if logistics are available, a community based survey would be definitely preferable. However, if the requirements are of a periodic nature, quick results are required, the hospital adequately draws nearly all the population from the catchment area and adequate resources for undertaking full - fledged community based survey are not available, we may prefer utilizing the hospital data.

The first step in a survey would be to ensure involvement and participation of the community and the administrative machinery and obtain the required sanctions - this would necessitate involvement of local peer leaders, government officials and NGOs. Subsequently, it would be prudent to get an idea of the socio - demographic and geographical distribution of the community and the local seasons of the area in which the survey is proposed. The next step would be to define the question that is to be answered, in clear, lucid and unambiguous terms. Subsequently, a decision on whether it is at all required to do a survey, has to be made, based on discussion with experts and scrutiny of available data.

Subsequent to this, we would proceed on to assess the resources and decide whether it is feasible to do the survey, keeping in mind the balance between what the survey aims at on one hand & the resources at our disposal on the other. The next step would be to define the survey objectives clearly and unambiguously. Thereafter, we proceed to define the variables of study, in which due emphasis needs to be laid on definition and selection of the "primary outcome variable", which would be crucial to the survey outcome. Also the other associated variables of interest need to be mentioned at this stage. Subsequently, the process of measurement for each of the variables is to be written down. Developing the survey questionnaire and the interview technique would be the next step - it would be prudent to select a scientifically sound and validated procedure which should be tailor - made for the specific study in question. Thereafter, we move on to describe the reference population i.e. the population

on which the results of the study are going to be generalized; and actual (study) population i.e. that subset of the reference population from where the actual study sample is drawn. After this is accomplished, calculation of sample size would form the next step. In this step, the important points to remember would be to scientifically calculate the sample size, and to include about 10% to 20% additional subjects over and above the calculated sample size, to cater for unforeseen exigencies and refusals.

Selecting the method of sampling would require specifications of sampling unit, sampling frame & sampling ratio need to be made. The next step thereon would be to organize the logistics and become administratively viable. An issue which needs to be specially dealt with at this stage is to develop a written document specifying the job description of each and every category of workers, and to make a chart showing the hierarchy of command and control of the various personnel. Subsequently, we need to organize technically for the survey, which would include standardization of equipment, training of field workers and if possible, development of an Operational manual. Thereafter, we need to proceed to examine the ethical issues and cater to them in the proposed survey - the most critical ones would include confidentiality, informed consent, proper sanction from relevant authority and provision of some health care along with the survey.

An "Action - Plan" showing the time line for various activities needs to be formulated subsequently. The next step would be to do a Pilot testing, having a convenience sample of the strength of about 5% to 10% of the total estimated sample size. Thereafter, informing the Community about the Survey would be imperative - which could be achieved by making optimal use of local resources. Organizing and executing the fieldwork would form the next major step. This can be performed by either of the following two modalities (or a combination of both), namely, the home (or work place) visit method or the survey centre method.

Even while the survey is under way, it would be wise to undertake Quality Control Procedures, which includes independent cross - checking of questionnaires etc. Analysis of data would be the penultimate step, wherein simple and meaningful inferences need to be drawn. The final step in this entire process would be writing the survey report in a manner which is well understood by the target audience.

## Study Exercises

**Long Question :** It is proposed to establish an obstetric unit at a Community Health Centre (CHC) which will serve as a First Referral Unit (FRU) for a population of one lakh, which is already being served by a total of 4 PHCs. Describe the conduct of an epidemiological survey which will be undertaken to generate information for the planning and design of this FRU.

**Short Notes :** (1) Longitudinal versus cross - sectional survey (2) Advantages and disadvantages of hospital based versus community based surveys (3) Line of flow in a survey centre

## MCQs and Exercises

1. Among the following, which type of survey provides an exact estimate of Incidence (a) Hospital - based survey

- (b) Hybrid Survey (c) Cross - sectional survey (d) Longitudinal survey.
- If we are doing an initial assessment of community resources or undertaking an initial planning for health care and if logistics are available, a hospital - based survey would be definitely preferable. Yes/ No
  - Arrange the following steps in Organization and conduct of an epidemiological survey, in the sequential & ideal order : (a) Analyse the data (b) Clearly define the question that is to be answered (c) Define the variables of study (d) Make an "Action - Plan" showing the time line for various activities (e) Calculate the sample size.
  - What type of survey is a Hybrid Survey (a) Repeated cross - sectional survey (b) Hospital - based survey (c) Community - based survey (d) Longitudinal surveys
  - In estimation of number of subjects for doing a pilot survey, if the final sample size to be studied is upto 200, the sample of subjects is usually a convenience sample of the strength of the following % of the total sample (a) 10% (b) 20% (c) 30% (d) 40%
  - A list of all the sampling units (persons or households) in the actual study population is known as the (a) cluster sample (b) sampling ratio (c) sampling rate (d) sampling frame
  - A minimum sample size of 30 persons is almost always good enough for epidemiological studies. Yes/ No
  - The large collection of humanity to which the findings of the survey will be generalized is called (a) Study population (b) Sample population (c) Universe (d) Common population
  - It would always be worthwhile to include how many additional subjects over and above the calculated sample size, to cater for unforeseen exigencies and refusals (a) 5 - 10% (b) 10 - 20% (c) 20 - 25% (d) 30 - 40%
  - All of the following are important ethical issues that need to be addressed in a proposed survey, except (a) Provision of cash benefit (b) Provision of health care benefit (c) Confidentiality (d) Informed consent
  - An "Action - Plan" is being prepared in the conduct of an epidemiological survey, showing the time line for various activities. Arrange the steps in the ideal and sequential order, from the ones given below : (a) Decision on survey objectives (b) Pilot testing (c) Data analysis (d) Preparing of questionnaires (e) Training of workers
  - While organizing & executing the field work in conduct of a epidemiological survey, in which method is a "line of flow" (i.e. creation of different stations for different activities) needed to be made : (a) Home visit method (b) Work place method (c) Survey centre method (d) Multi - centric method.
  - "As part of Quality control during conduct of an epidemiological survey, generally what proportion of forms filled by field workers is independently cross - checked to see for any discrepancies? (a) 1 in 2 to 1 in 5 forms (b) 1 in 5 to 1 in 10 forms (c) 1 in 10 to 1 in 20 forms (d) 1 in 20 to 1 in 25 forms
  - The primary target audience towards whom the findings of a survey are to be commensurate with, and towards whom the report language is to be directed at, would include all of the following groups of people, except : (a) local administrators (b) local political leaders (c) local health care providers (d) urban elite
  - Survey and Surveillance are essentially one and the same. Yes/ No

**Answers :** (1) d; (2) No; (3) b - c - e - d - a; (4) a; (5) a; (6) d; (7) No; (8) c; (9) b; (10) a; (11) a - d - e - b - c; (12) c; (13) c; (14) d; (15) No.

Epidemiological Surveillance is a major function of Public Health. The genesis of modern surveillance can be traced back to 1662, when John Gaunt was the first to quantitatively study the patterns of human disease and its possible causes. However, it was only after almost 200 years, when William Farr, in 1838, while working in the office of Registrar General, UK, created a modern surveillance system; he is aptly called the founder of "Epidemiological Surveillance" (105). Twentieth century saw a rapid growth in the scientific concepts and data collection / analytic procedures. By now, public health surveillance activities have widely proliferated, encompassing

a large gamut of communicable as well as non - communicable diseases and many countries also have regularly collected and reported data on important diseases covered by their respective national health programmes. In India, a comprehensive "Integrated Disease Surveillance Programme" (IDSP) has been launched since 2005.

**Definition :** (Suggested by Alexander Langmuir and adopted by WHO in 1968) : "Surveillance, when applied to a disease, means the *continued watchfulness* over the distribution, and trends of the incidence, through the systematic collection, consolidation and evaluation of morbidity, mortality and other health relevant data, as well as regular dissemination of interpretations to all who have contributed and to all those who are in a position to take action". In a nutshell, surveillance means "information for action". In addition, surveillance is *distinguished by methods having practicability, uniformity and rapidity, rather than by*

complete accuracy (106 - 110).

**Surveillance Vs Monitoring** : The term 'Surveillance' and 'Monitoring' are often used interchangeably but they are, in fact, distinct. Monitoring refers to ongoing measurements of health services or a health programme with a view to 'evaluate' the particular programme / service or intervention, with constant adjustment of performance in relation to the results. In addition, surveillance concerns general populations while monitoring applies to specific target groups (e.g. vaccinated infants).

### The Objectives of Public Health Surveillance

The specific objectives with which surveillance systems are established, are one or more of the following (111) :

**To study the trends of disease** : Changes in the frequency over short term or long term periods help in identifying as to whether significant rising or falling trends are present and to predict the future course of the disease.

**Early warning of epidemics** : Constant analysis of surveillance data of a disease would identify any upward trend, at a very early stage. This is, in fact, the commonest reason for which surveillance systems are established.

**To provide quantitative estimates of magnitude of health problem** : By providing data on incidence and prevalence and further descriptions of incidence/ prevalence according to various socio - demographic characteristics, surveillance helps in identifying the priority (i.e. high risk) groups.

**To study the natural history of disease** : Surveillance of AIDS during the last decade has added significantly to our knowledge regarding the natural history of HIV infection and AIDS.

**Demonstrating the spread of a disease in time and place** : Description of surveillance data using time and space combinations can demonstrate the spread of a disease and identify the possible vehicles and routes of spread.

**To develop epidemiologic research questions** : Sensible interpretations of surveillance data can open up interesting research questions; e.g. increase in the sales of pentamidine noted by CDC Atlanta, in 1981, led to generation of research questions and finally "AIDS" was recognised.

**To test epidemiologic hypothesis** : Sometimes surveillance data can be used to test hypothesis; e.g. in 1973, a particular insecticide was suspected of being related to birth defects. However surveillance data for 1970 - 73 showed decrease in total birth defects even though there was five fold increase in insecticide sales during the same period, thus acquitting the particular insecticide.

**Evaluation of control and preventive measures** : Surveillance data on poliomyelitis during 1950's in USA showed a dramatic decline in disease incidence, thereby confirming the efficacy of polio vaccination campaign.

**Monitoring of change in infectious agent** : Development of antibiotic resistant gonococci have been identified with the help of surveillance data.

**Detecting changes in health practices** : Surveillance of delivery practices has shown that caesarian deliveries increased

from 5% to 25% in developed countries.

### Criteria for Identifying High Priority Areas for Establishing Surveillance Activities

Surveillance activities are costly and hence should not be launched inadvertently. Careful consideration should be made beforehand as to whether the particular disease is a high priority area from public health point of view. This includes review of the data on *Frequency of the disease* (in terms of incidence of mortality, and incidence/prevalence of morbidity, due to the disease); *Severity* (in terms of case fatality ratio, proportionate mortality ratio, hospitalization rates due to the disease and disability rates); *Economic impact* (in terms of direct costs that accrue due to medical treatment for the disease and indirect costs due to reduction in productivity); Preventability ; and, *Public interest* (community attitudes towards the disease and political will).

### Organization and Structure of a Surveillance System

The essential components of a surveillance system are :

- An overall organization : Consisting of personnel, finances, logistics and administrative back up.
- The originators of data : This would include the sources of data, data collectors and data collecting mechanisms.
- The transmission of data to the surveillance centre, with specification of the mode of transmission and frequency of such transmission.
- Data management and analysis : This includes manual / computerized data files, and statistical analysis procedures.
- The sensible interpretation of results : Including their consolidation and preparation of reports.
- A system of feed back of results : To the originators of data and to those who are in a position to enforce preventive steps.
- A system to periodically evaluate the surveillance system itself.

### Steps in Establishing a Surveillance System

#### Step 1 - Is it justifiable to Establish a Surveillance System:

It must be analysed whether it is really required to initiate a surveillance system by confirming if the disease is of public health importance (see criteria above) and whether prevention/ control measures are available. It needs to be appreciated that every country, state or district will have some system of its own of collecting routine health information and reporting it from the peripheral health care facilities (as PHC) to the central level (as District or state headquarters). Such information is generally collected at the peripheral health care facilities and is recorded in various ways. Unfortunately, often this information recorded at the periphery may be inaccurate or incomplete; moreover, the information may keep lying at the central headquarters and analysed only after many months, without any feedback information to either the originators of the data, thus reducing the efficacy of this data for surveillance.

More often the need is to improve an existing source of data collection and ensure its prompt analysis and feedback rather than to start up a completely new surveillance system. It should also be noted that emphasis should be on collection of



minimum amount of inescapable data, in a very simple manner, particularly at the primary care level. Secondly, controlling the quality of collected data is of vital significance and requires frequent checks and quality control measures. One way of ensuring this is by developing the forms in a way that they are directly useful to the health workers at the primary level also, thus helping the health workers at PHC, CHC and district level to plan and evaluate their own programmes.

**Step 2 - Spell out the objectives of surveillance system :** The following issues should be addressed :

- Clearly specify the disease (s) proposed to be brought under surveillance.
- *Specify* : Who needs what information, for what purpose? (e.g. whether a rapid case count for epidemic warning is required by the District Health Officer or detailed information to identify temporal trends is required by the state ministry?)
- *The target population* : e.g. whether it is “mothers and children” or “blood donors” or “all population living in the hilly areas of the state”.
- *The health problem* : e.g. whether only Acute MI or entire spectrum of IHD is to be put to surveillance ?
- *Nature of control programmes* : e.g. if it is a rare disease or a disease moving towards eradication, a fine surveillance will be needed; on the other hand if it is a common disease, a crude surveillance would suffice.

**Step 3 - Specify the organization and structure of the surveillance :** At the planning stage, clear specifications should be made as to “who will do what, how, and will be responsible to whom”.

**Step 4 - Clearly define the disease(s) being considered for surveillance :** Case definitions should be meticulously worked out after detailed consultation with experts. They should be adequately inclusive (i.e. sensitive) as well as adequately exclusive (i.e. specific). All those involved in the collection of data should be well trained in the use of these case definitions/ diagnostic methods. Case definitions/ diagnostic procedures should be simple enough so as to be understood and used by all those on which the system depends for reporting. It would be desirable to report the cases under three different diagnostic categories, viz., confirmed / probable / suspect, with clear definitions for each category stipulated. Some sample case definitions as per these three levels are given in the chapter on investigations of an epidemic.

**Step 5 - Specify the Details of Collection of Information :** Collection of data is the most costly and difficult component of a surveillance system. The quality of a surveillance system is as good as the quality of the data collected. The epidemiologist will therefore have to make the following specifications :

**(a) Select the proper sources of data :** Various sources of secondary data are available (109) as described in an earlier chapter on sources of information in epidemiology. It would require an intelligent thought by the surveillance officer as to what all sources would be optimum. These include Registration of deaths and death certificates; Reports on various sickness / diseases; Field investigations of epidemics; Public health laboratory reports; Clinical Laboratory reports; Individual case

investigations from hospitals / health centres; Consolidated Hospital statistics; Reports of Health surveys; Studies on Insect vectors and animal populations; Utilisation of drugs and other biological products; Socio - demographic and environmental data about the population; Panels of cooperating physicians who agree to report specific diseases; Data on absenteeism from workplace / schools; and newspapers and news broadcasts.

**(b) Specify the method of data collection :** Available methods can be :

**Passive surveillance :** In passive surveillance, the data recipient has to wait for the data providers to report, (e.g. various district headquarters wait for malaria forms to be raised by hospitals / PHCs). Passive surveillance is the most common method of data collection. All the passive surveillance agencies that are required to report should be sensitized and trained. The frequency of reporting should be clearly laid down and a system of issuing prompt reminders established.

**Active Surveillance :** In certain circumstances, data must be obtained by searching for cases (e.g. health workers go into the community, search for cases of fever and take their blood slide for malarial parasite), and also by periodically contacting those who may know of cases, as GPs, etc. For rare disease, or disease on way to eradication, or during outbreaks, active surveillance is necessary, so that cases which could have been otherwise missed, are promptly identified. Since it is expensive, active surveillance is usually limited to specific diseases, and for specific situation as enumerated above.

**Sentinel Surveillance :** Data is obtained from selected hospitals who agree to report all cases of the disease.

**Special Surveillance teams :** Sometimes, special surveillance teams may be formed for carrying out surveys or epidemic investigations and to undertake clinical examinations and laboratory, entomological and environmental assessments.

**(c) The forms that will be used :** The forms should be *simple* and *as brief as possible*. The question should be clear cut, preferably with closed - ended answer categories and pre - coded for computer data entry. A suggested sample form which can be used for sending information from PHC or CHC level to the next higher level can be as shown in Box - 1.

**(d) What time/place of diagnosis will be entered :** One has to specify as to what time/place of the three i.e. the actual diagnosis, origin of infection or else first appearance of symptoms is to be recorded. Strict and standardized criteria must be ensured and they should not fluctuate from case to case. It is preferable to ask for time / place when the case actually got the infection and the time / place when first symptoms appeared.

**(e) What will be the frequency of reporting? :** For a disease like cholera and food poisoning it would be daily (or at the most weekly) report; for malaria, a weekly report would be optimum; for HIV infection a monthly report would be reasonable while for cancer, a quarterly or even half yearly report would be required.

**(f) Decide the method of transmission of reports :** The simplest is a letter. For diseases that may cause public alarm (plague, JE etc.), reports by telegram/ telephone may be stipulated. The data originators should give due consideration



to possible postal delays that may occur, especially in developing countries or in rural areas and originate the report in time. E - mail can be a good alternative if computer network exists. The central surveillance node should keep a centralized cross - checking mechanism and issue a reminder if timely report is not received from a particular reporting unit.

**(g) Central Collection of Data :** At the central level all the data received from the peripheral reporting units, should be entered without any delay into a central register. Even if a electronic data registry is available at the central level, it would be still advisable to have a “hard” (register) method of storing the data. The individual forms should also be meticulously filed. The headings in this central register could be as shown in Box - 2.

#### Step 7 - The Organization and procedures of data Analysis:

The ideal is to have a computerized system, with back - up hard copies on central register. Computerized data should be maintained on a “Database” programme (as ACCESS or Foxpro) or else on a worksheet as EXCEL. For Statistical analysis, the software “EPI - 2002” developed by WHO and CDC Atlanta is quite good. Details are given in a subsequent section. It is better to maintain 2 sets of data bases - one provisional and another final. The statistical analysis will include :

**Simple display of data :** Data can be displayed through histograms/ bar diagrams/ line diagrams describing the data according to various characteristics of person, place and time. For depiction of “time trends”, line diagrams and histograms are the best. (refer to section on Biostatistics for details).

**Descriptive statistics :** Give the “Summary statistics” (Incidence rates / prevalence / proportions / Mean / Median) along with the measures of dispersion (SD) and the 95% confidence intervals. This should be done in respect of the important and relevant variables related to person (age, sex, occupation etc.), place (differences in geographical distributions, distributions according to place of contracting the infection, etc.) and distribution according to time. The tables should be small (ideally a 2 x 2 or maximum 2 x 4 table) and should be accompanied by descriptive notes. An example of tabular display of data for age and sex (person related variables), place of residence and time of onset can be shown as in Tables - 1, 2 and 3.

Table - 1 : Distribution of cases according to age & sex					
Disease :			Reporting period :		
Sex	Age Group (Years)				
	0 - 4	5 - 14	15 - 44	≥45	Total
Males					
Females					
Total					

Table - 2 : Distribution of cases according to place of residence				
Disease :		Reporting period :		
Number of cases according to Villages				
Village - 1	Village - 2	Village - 3	Village - 4	Total

(Note : The above information can be still better displayed in form of a spot map)

Table - 3 : Distribution of cases according to weekly time periods				
Disease :		Reporting period :		
Number of cases according to weeks				
Week - 1	Week - 2	Week - 3	Week - 4	Total

(Note : The above information can be better displayed in form of a line diagram)

**Inferential statistics :** Analytic procedures usually are based on comparing the current incidence against the “Upper and Lower Control Limits” (UCL & LCL).

*{A quick method of calculating the UCL and LCL is  $UCL \text{ or } LCL = R + 1.023 \times A$  ; (Where R = Average of Incidence rate per 1000 population for the corresponding period for the past 3 years and A is the average of “ranges” for the past 3 years. The resulting UCL and LCL will encompass 99%*

Box - 1 : Suggested form for weekly or monthly reporting from PHC or CHC to next higher health care level							
Period covered by the report : From (Date) : _____ To (Date) : _____							
Name and address of health facility :							
Sl No	Name	Address	Age	Sex	Diagnosis	Level of Diagnostic certainty (suspected/ probable/confirmed)	Date of onset
1.							
2.							
3.							
4.							
5.							
Name				Designation :			
Date				Signature :			

confidence interval)).

**Analysing Time (temporal) trends :** The comparisons are made between the rates during present period with the rates during the corresponding periods of the last 3 to 5 years; or between the rates or No. of cases reported during current week (or month) with the immediately preceding 4 weeks (or 4 months). For long term secular trends and cyclical trends, the most simple and suitable method is to present a line graph or histogram, indicating the occurrence of disease according to calendar years. More rigorous procedures as “test for linear trends for categorical data” and “time - series analysis” are available, which can be referred from advanced texts (see list at end of this chapter).

**Place (Spatial) data :** This analysis is important to identify the ‘places’ where significant number of cases are occurring; it may also reveal localized outbreaks. It is always desirable to plot the ‘spot maps’ according to ‘place of contracting the infection’ as well as according to the place of reporting.

#### Step 8 - Making Scientific interpretations out of the results:

It is not really in the analysis of the data but rather in making sensible interpretations that the skill of epidemiologist lies. Consider whether the apparent, statistically significant, increases or decreases in the disease incidence at a given place and time represent true changes. Fallacious increase or decrease may be due to changes affecting the numerator as improvement in diagnostic procedures, duplicate reporting, or enhanced reporting; or else may be due to changes affecting the denominator as increase in population size. Secondly, one must carefully consider the biases that could have occurred in detecting and reporting at various levels. The cases reported MAY NOT be always truly representative of the total target population under surveillance. A verification must be done by studying the characteristics of the population and comparing with the characteristics of cases reported.

**Step 9 - Ensure proper feedback to all concerned :** It is extremely important to provide regular (usually monthly) feedback reports to all those who are in a position to take action on the surveillance data (as, secretaries and directors of health department as well as other department concerned with human development, district collector panchayat office, etc.) and not to forget, all those who have provided the data (MO i/c of various PHCs and CHCs, pathologists and other specialist

in the hospital, etc.). This will go a long way in keeping their interest alive.

#### Step 10 - Periodically evaluate / review the surveillance system :

See whether the case definitions need a change? Are there some problems in the timely and accurate reporting and how can it be improved? Periodic evaluation is important to identify defects and reorient the methodology. At the functional level a surveillance system should be periodically evaluated for at least two issues - its completeness and accuracy. Let us illustrate this with an example of a hypothetical surveillance system we have launched in our CHC area covering a population of 1 lac. There are 102 villages each with 200 houses and the average family members in each house is 4.9 persons per household. The total households were thus 20,400. Suppose our surveillance system reported 136 cases of Dengue, which were reported based on visits by the health worker to each household, using the criteria “did any person in your household suffer from fever with severe retro - orbital headache and severe myalgia / backache which lasted for 2 to 5 days, anytime during previous 1 month”.

To evaluate the completeness of the surveillance system, we did a sample survey. The sample consisted of 30 randomly selected villages. In each of the selected villages, a house was randomly selected and this and the next 6 houses were visited. This gave a random sample of 210 houses in the 30 selected villages, giving an estimated population of  $4.9 \times 210 = 1029$  persons. Well trained workers visited these households and using the same case definition as used by the surveillance workers, they found that 7 persons gave the history of Dengue fever (DF) in past one month; thus the incidence rate was 7 per 1029 or roughly, 7 per 1000 population.

Now the estimated incidence of DF for all the households for the one month period would be

$$\frac{(\text{No. of cases of DF detected by surveillance} \times \text{Total households in CHC})}{\text{No. of households in the sample studied}} = \frac{(7 \times 20400)}{210} = 680$$

Now, our surveillance system had actually reported only 100 cases from the entire CHC area during the same period during

Box - 2 : Suggested headings for the central register for recording details of individual diseases									
Register Page No.:					Name of the Disease with ICD code :				
Reporting period : From :					To :				
Sl No	Name	Address	Age	Sex	Reporting PHC / CHC	Date of onset	Level of Certainty	Died or survived	Remarks
Entries made by (Name & Date) :						Checked and verified by (Name & Date) :			

the same month. Hence our completeness of reporting is  $(136 \times 100) / 680 = 20\%$  only. Thus only one in 5 cases of DF are being actually reported by our surveillance system. We should therefore enquire as to why this under-reporting is occurring, starting from the grass-root levels of reporting and examining all the steps in the surveillance system, to rectify this under-reporting.

### Check - List for Assessing an Established Surveillance System

At times the Public health Specialist may be asked to assess and comment upon an already existing surveillance system in her own CHC or district, or as an independent evaluator for a system functioning in another district or CHC. A suggested checklist for carrying out such assessment is as follows :

1. What are the broad goals & objectives with which the surveillance system has been established? Is it fulfilling those objectives?
2. Is it adequately staffed for meeting the stated objectives? Are personnel adequately trained?
3. What are the diseases which are under surveillance? What are the diagnostic criteria and case - definitions for these diseases? Are the case definitions adequately sensitive & specific? If strict diagnostic criteria are being used, are facilities for diagnosing available?
4. What are the sources of information for reporting the diseases? Who are the persons who are reporting and how frequently? Are they proficient in asking and recording the case definitions? Are the forms adequately feasible to use by the peripheral workers?
5. Has the information been reported from the periphery well within time? How much is the delay for information before it reaches the central surveillance office from the day of occurrence of the case?
6. How much is the under - or over - reporting?
7. Are central registers, manual files and automated files well maintained in the central office? Is a well trained surveillance officer and staff available at the central office?
8. What is the time lag between receipt of reports and generation of analysed feedback reports, by the central surveillance office? What are the reasons for delay, if any?
9. Are the feedback reports generated in simple and presentable form? Are they forwarded to all concerned, including local and regional health and administrative offices as well as to the originators of data?
10. Has the surveillance information been actually used in planning or evaluation of health programmes at district or CHC level?
11. Is the surveillance system periodically evaluated for its completeness, accuracy, process and adequacy? What remedial measures have been taken on recommendations?

### Summary

Surveillance is defined as the continued watchfulness over the distribution, and trends of the incidence, through the systematic collection, consolidation and evaluation of morbidity, mortality and other health relevant data, as well as regular dissemination

of interpretations to all who have contributed and to all those who are in a position to take action. It has to be differentiated from Monitoring, which refers to ongoing measurements of health services or a health programme with a view to 'evaluate' the particular programme/service or intervention, with constant adjustment of performance in relation to the results.

The objectives of Public Health Surveillance are manifold and include : to study the trends of disease, for providing early warning of epidemics, to provide quantitative estimates of magnitude of health problems, to study the natural history of disease, for demonstrating the spread of a disease in time and place, to develop epidemiologic research questions, to test epidemiologic hypothesis, in evaluation of control and preventive measures, monitoring of changes in infectious agents and to detect changes in health practices. If properly implemented and utilized, these will also become the uses of a surveillance system.

In the process of identifying high priority areas for establishing surveillance activities, careful consideration should be made beforehand as to whether the particular disease is a high priority area from public health point of view. The essential components of a surveillance system are : An overall organization, the originators of information, transmission, management, analysis of data and sensible interpretation of results; A system of feed back of results and actions to periodically evaluate the surveillance system itself, are also important.

The first step in establishing a Surveillance System is to consider and evaluate whether it is justifiable to establish a surveillance system. This can be accomplished by asking whether the disease is of public health importance and whether prevention / control measures are available; emphasis should be on collection of minimum amount of inescapable data, in a very simple manner, particularly at the primary care level. The next step would be to spell out the objectives of surveillance system clearly, taking care to address issues such as target population, health problem etc. Thereafter, specifying the organization and structure of the surveillance becomes imperative. Subsequently, we would clearly define the disease(s) being considered for surveillance - emphasise on simple, scientifically sound case definitions. The next step would be to specify the details of collection of information ; with regard to selecting the proper sources of data, specifying the method of data collection (whether Passive Surveillance, Active Surveillance or Sentinel Surveillance); also, specifications have to be made as to the forms that will be used (should be simple & brief), time/place of diagnosis to be entered, and the frequency of reporting. The method of transmission of reports also needs to be decided upon.

The succeeding step would be organization and procedures of data analysis. Under its purview, simple display of data would be essential, in which descriptive statistics (e.g. Distribution of cases according to age, sex etc.) would be worked out, followed by Inferential statistics, wherein the current incidence would be compared against the "Upper and Lower Control Limits" (UCL & LCL). Time (temporal) trends and spatial (place) trends need to be also analysed at this juncture.

Making Scientific interpretations out of the results would be the next step - sensible interpretations of available data are

essential. Proper feedback to all concerned - especially to those who are in a position to take appropriate action - is to be ensured. The final step that needs to be put in place would be to Periodically evaluate / review the surveillance system, by various survey methods. An ideal Check - list for assessing an established surveillance system would include, among other things, the broad goals & objectives, diseases which are under surveillance, under - or over - reporting and so on.

## Study Exercises

**Long Question :** You are working as the MO i/c of a CHC, covering a population of one lac, in an area endemic for malaria and where malaria control program is being undertaken. Discuss the steps that you will undertake to launch a surveillance system for malaria in your area of jurisdiction.

**Short Notes :** (1) Early warning of epidemics (2) Uses of surveillance (3) Sentinel surveillance (4) Active versus passive surveillance (5) Control limits

## MCQs & Exercises

1. All of the following diseases are included in the WHO programme for research in tropical diseases, except (a) Tuberculosis (b) Leishmaniasis (c) Schistosomiasis (d) Trypanosomiasis
2. Surveillance concerns specific target groups while monitoring applies to general populations. Yes/ No
3. Arrange the following steps in developing a surveillance system, in the sequential order : (a) Specify clear - cut case definitions (b) Do a pilot run (c) Define the sources of information (d) Clearly define the target population
4. All of the following are the uses of surveillance except (a) To develop epidemiologic research questions (b) To develop registries (c) To test epidemiologic hypothesis (d) To study the natural history of disease
5. Frequency of reporting (for purposes of surveillance) for diseases like cholera and food poisoning would be (a) Biweekly (b) On alternate days (c) Daily (d) Weekly
6. The comparisons made between the disease rates during present period with the rates during the corresponding

periods of the last 3 to 5 years to derive which type of trends (a) Spatial trends (b) Temporal trends (c) Personal trends (d) Disease trends

7. Spot maps come in handy while analyzing what aspect of data? (a) Spatial (b) Temporal (c) Secular (d) Cyclical
8. For what two issues should a surveillance system be periodically evaluated at the functional level (a) Incidence and prevalence (b) Relevance and repeatability (c) Completeness and accuracy (d) Sensitivity and specificity
9. Health workers going into the community in search of cases is an example of (a) Sentinel surveillance (b) Passive surveillance (c) Mass surveillance (d) Active surveillance
10. A crude surveillance would suffice if the disease in question is a common one. Yes/ No
11. Prior to setting up a surveillance system, careful consideration needs to be given to all the following aspects of the disease/ health event in question, except (a) Economic impact (b) Public interest (c) Academic interest (d) Preventability
12. During data analysis (Inferential statistics), analytic procedures usually are based on comparing the current incidence against the (a) Mean & Standard deviation (b) Upper and Lower Control Limits (c) Standard Error of mean and proportion (d) Co - efficient of variation.
13. For long term secular trends and cyclical trends, the most simple and suitable method is to present a (a) Stem and leaf plot (b) Bar diagram (c) Box and whisker plot (d) Line graph.
14. Inclusiveness, while developing case definitions for purposes of surveillance, would mean that the definition should be adequately (a) Sensitive (b) Specific (c) Have high positive predictive value (d) None of the above
15. Who is called the founder of Epidemiological Surveillance (a) Ramazzini (b) John Graunt (c) William Farr (d) John Snow

**Answers :** (1) a; (2) No; (3) d - a - c - b; (4) b; (5) a; (6) b; (7) a; (8) c; (9) d; (10) Yes; (11) c; (12) b; (13) d; (14) a; (15) c.

## 32 Investigations of an Epidemic

*RajVir Bhalwar*

Investigations of an epidemic is one of the most important duties of not only the epidemiologists but for all health care providers concerned with public health. Investigating an epidemic involves a series of steps, as narrated in the succeeding paragraphs. These steps are not necessary to be undertaken in the same sequence. In fact, often, at any given point of time

during the course of an investigation, it is quite possible that a number of steps may be addressed simultaneously (112 - 114). In this chapter, we will explain the various steps in detail, along with a hypothetical example of an epidemic, based on a real life episode (See Box - 1).

**Step 1 - Verification of the diagnosis :** The earliest report regarding an outbreak is often obtained from a non medical or paramedical person. Often the initial report is not in the form of particular diagnosis but rather in the form of a "syndromic" constellation of symptoms and signs (e.g. outbreak of diarrhoea and vomiting, or fever and skin rash).



**Box - 1 : Hypothetical Example**

Dr. 'X', was appointed as Medical officer of Health (MOH) in a large township. In the evening of 10th May, the medical officer of a large working women's hostel rang up to inform him that 2 cases of diarrhoea and vomiting with mild dehydration had occurred and she was referring them for admission to the district hospital. The Working Women's Hostel (WWH) was meant to provide accommodation and messing to almost one thousand working, single ladies, working in various companies and business establishments located at various places in the city. There were four "messes" with dining halls (named 'A', 'B', 'C', and 'D' mess) to provide for meals, besides a canteen run by a contractor to provide snacks. These women used to leave early morning in municipal buses or by their own two - wheelers for their respective offices, after breakfast and used to carry packed lunch. They used to come back in late evening from their respective offices and have their dinner in the hostel, before going to bed. At times, at irregular occasions, some of these women would also eat their lunch or dinner outside in local restaurants. Another about 300 personnel who were employees of the hostel, were staying with families in family quarters located in close vicinity of the hostel and shared the same general piped water supply and sewerage system (from municipal sources). These family members of these employees also used to go to the work or schools, located at various places in the city, while the women members of these worked as employees in the hostel. There was a small market nearby with all daily requirements available.

It is therefore essential to verify the diagnosis of the condition that one is dealing with in epidemic form. This also helps in developing the epidemiological case sheet and planning the laboratory, environmental and entomological procedures for investigations, as we shall see later on. At this point, talk in detail with the patients (cases), about their signs / symptoms, about their movements, about the possible exposures and what they think could have caused their present illness, and whether they know of similar cases in their neighbourhood, workplace or among friends. Recording as much details at this point of time may be of great value later when hypotheses are being developed. Verification of the diagnosis is usually made on clinical, laboratory and epidemiological parameters. Most important are the clinical parameters. In real life situations, it may not be necessary to confirm 100% cases by lab parameters; a 20% to 30% random sample, if confirmed by lab tests to be having similar disease should be adequate. At this point it is also very wise to describe the distribution of various signs / symptoms according to frequency distributions, which greatly helps in suggesting the diagnosis and also in developing the case definitions (See Box - 2) .

Guidelines for syndromic diagnosis for common epidemic prone diseases are given in Box - 3.

**Step 2 - Confirm the existence of an epidemic :** An epidemic is defined as "occurrence of a disease in a frequency which is clearly in excess of the normal expectations". Thus, having verified the diagnosis, one must work out the incidence rate, by dividing the total cases by the population at risk.

**Box - 2 : Continuing with the Hypothetical Example**

To start with, a "syndromic" diagnosis of "gastroenteritis, without fever & with moderate dehydration" was made. The possibilities which were kept within this tentative diagnosis were food poisoning (due to either of *S aureus*, non - typhoid *salmonella*, *C perfringens*, *B cereus*); cholera; ET EC gastroenteritis; and, algid malaria. The patients were contacted by the MOH at the hospital in the night itself and a quick clinical history and examination was done, and cases were discussed with the Physician and Pathologist. Both the patients were young unmarried women working in the same office and dining in the same ('B') mess. They had 1 - 2 bouts of vomiting in the afternoon, followed by 4 - 6 watery loose motions and felt "weak". There was no fever or tenesmus or blood / mucous in the stools. Except for moderate dehydration, physical examination was non - contributory. The MOH requested the pathologist for undertaking a GBP, PBS for MP, and stool examination for microscopy, hanging drop and culture for enteropathogenic organisms.

This rate is compared with the rate occurring in the same population, during the corresponding period of the past three years. Often, the decision as to whether the present rate is clearly in excess of the normal expectations (based on past three years' rates) is taken on the basis of informed and experienced judgment, though various statistical procedures for calculation of "control limits" are available to further assist in such decision (see previous Chapter on "surveillance" in this section for details). Quite often, in such situations, it is difficult to calculate rates in such an emergency and hence numbers may be compared. Usually, comparison is done of the present rates (or number of cases) with those of corresponding time period of preceding three years. For finding out as to what is the "normal" expectation during the period being compared with, we use the existing data based on records of hospital admission and discharge data and if these are not available, find out from various physicians in the community whether they have been observing more number of cases with the given set of symptoms recently; or lastly, undertake a survey of the community to get an idea of the baseline (historical) data. Ultimately pragmatic considerations are also important as to whether to investigate or not. There could also be situations when a single case of a disease may be enough to call for investigations, e.g. a suspected case of plague, or in many of the day to day situations, even a single case of cholera (See Box - 4).

**Step 3 - Develop an Initial (Rough) "Line - listing" of cases :**

A line list is like a nominal roll of the cases which have already been reported to the various health care establishments (like dispensaries, general practitioners or admitted to the hospitals) till now. Line listing of the cases is a major help in initial definition of the disease / syndrome that has occurred in epidemic form, in delineating the population at risk, and in preliminary definition of the transmission dynamics of the epidemic according to place and time. A line list is a serial, chronological listing of all the known cases till now, as per the headings shown in Table - 1.

**Box - 3 : General guidelines for “syndromic approach” to “common epidemic prone” diseases**

Quite often, reporting of epidemic is often in the form of a “syndrome”. Moreover, laboratory diagnostic results may take time to be available and till then the epidemiologist has to proceed with some tentative diagnosis, to give some direction to his investigations. The following list is intended to provide a general reference for the epidemiologist in the field, till definitive results are available.

**Syndrome of Fever without Rash**

- Usual manifestations : Sudden or insidious onset with fever of continuous, biphasic or recurrent type; frequently headache, myalgias, arthralgias; sometimes GIT manifestations, polyadenopathy or hepato - splenomegaly;
- NO specific localizing sign.
- Common Diseases : Vivax Malaria; Enteric fever; Leptospirosis; Uncomplicated Dengue fever (without haemorrhages or shock; Chikungunya (without haemorrhages); Brucellosis.

**Syndrome of Fever with Rash**

- Usual manifestations : Onset with fever and systemic symptoms; macular, papular, vesicular or pustular eruptions, either generalized or localized to certain parts of skin or mucous membranes; eruptions are NOT haemorrhagic.
- Common Diseases : Chickenpox; Measles; Rubella; Typhus group of fevers (scrub, louse borne, murine and tick borne typhus); Meningococcal bacteraemia.

**Syndrome of Haemorrhagic Fever**

- Usual Manifestations : Onset with fever and systemic symptoms; often a second phase of fever after 3 to 5 days with cutaneous haemorrhages (petechiae, ecchymosis or puncture oozing); sometimes internal bleeding (haemetemesis, malena, haematuria, vaginal bleeding); sometimes jaundice with or without terminal shock syndrome.
- Common Diseases : Dengue Haemorrhagic Fever or DSS; Kyasanur Forest Disease; Lassa Fever; Chikungunya (very few patients would have haemorrhagic phenomena.

**Fever & Respiratory Manifestations**

- Usual manifestations : Onset with fever and often fatiguability; sometimes systemic manifestations; cough; dyspnoea; chest pain; persistent or blood stained sputum.
- Common Diseases :
  - URTI : Pertussis; Influenza; Acute bacterial or viral pharyngitis.
  - LRTI : Streptococcal pneumonia; Pneumonic plague; Influenza, SARS, Avian influenza; Pulmonary anthrax (keep possibility of bio - terrorism).

**Syndrome of “Afebrile” Illness**

- Afebrile neurological disease : Convulsions, shock or GB syndrome (search for common vaccination history); botulinum food poisoning; Organophosphate Insecticide poisoning (food borne or after spray); mushroom poisoning.
- Afebrile GIT illness : Cholera (epidemic ‘O’ Gp); Food poisoning due to *S aureus*, *C perfringens*, *B cereus* or *V parahaemolyticus*; giardiasis (common - vehicle - food - borne).
- Afebrile Conjunctivitis : bacterial or adenoviral.
- Afebrile rash : Swimming pool associated dermatitis.
- Afebrile genito - urinary syndrome : Gonorrhoea, Chancroid, HSV

**Syndrome of Fever & Neurological Manifestations**

- Usual manifestations : Onset with fever and systemic manifestations; signs of meningitis or encephalitis or paralysis of central or peripheral type.
- Common Diseases :
  - Mainly paralysis : Paralytic poliomyelitis.
  - Mainly meningitis : Meningococcal meningitis
  - Mainly encephalitis : Japanese encephalitis

**Syndrome of Fever & Lymphadenopathy**

- Usual Manifestations : Onset with fever and systemic symptoms; Lymphadenopathy (generalized or localized; suppurative or non - suppurative)
- Common Diseases : Bubonic plague; kala azar; hyperendemic filariasis.

**Fever with G.I.T. Manifestations**

- Usual manifestations : Fever; nausea / vomiting; diarrhoea with or without blood or mucous; abdominal cramps; systemic manifestations usually mild or absent; sometimes neurological manifestations or rash may follow.
- Common Diseases : Non - typhoid *Salmonella* food poisoning; *Shigella* dysentery; Enteroinvasive / Enteropathogenic *E coli* diarrhoea; Rotaviral enteritis especially in children; Giardiasis; Amoebiasis; *Yersinia* or *Campylobacter* food poisoning.

**Syndrome of Fever with Jaundice**

- Usual manifestations : Initial phase with only fever and systemic symptoms; sometimes there may be no such initial phase; jaundice; sometimes haemorrhages.
- Common diseases : Viral Hepatitis ‘A’, and ‘E’; Viral hepatitis ‘B’ (due to common parenteral experience); sometimes Leptospirosis.

**Step 4 - Define the population at risk** : By knowing the general population from where the cases have been coming, as evident from the initial line listing and subsequently from the details of cases as recorded on the epidemiological case sheet (see below), one can define, in a demarcating manner, the source population. For example, the population at risk may be defined as “Markandeya Housing society”, or “people living in Gulwadi slum” or “all people working in the main office of Infotech Pvt Ltd”, etc. The more clearly such source population is defined, better the results of investigation would be (Box- 5).

#### Box - 4 : Continuing with the Hypothetical Example

With 2 cases out of 1000 women staying in the hostel, the rough incidence was worked out as 2 per 1000. Daily epidemiological surveillance system available with the district hospital indicated that maximum of one case of gastro - enteritis with dehydration could be expected in a day during that part of the year, in that general area of the township in which the hostel was located. Moreover, since “cholera” was also one of the possibilities, it was decided to tentatively consider the situation as one of “epidemic”. The Chief Medical Officer of the district and the manager of the hostel were informed and asked for their permission to investigate and their administrative & technical help was sought.

#### Box - 5 : Continuing with the Hypothetical Example

Urgent telephonic calls were made to the various government dispensaries and private hospitals in the city whether similar cases of gastroenteritis were seen by them on that day. The Duty Medical Officer of the district hospital was asked whether any other case (other than the two in question) with similar symptoms were also admitted to the hospital that day. Since there were no other cases, these two were taken as the initial cases and their details were noted on a line list as per format already discussed above. Since both these cases were from a single place, “people living in that particular hostel” were defined as the “population at risk”.

**Step 5 - Develop valid case definition** : Often the search for additional cases would involve a number of medical officers / paramedical personnel. It is therefore important that the investigator develops case definitions which are adequately sensitive (i.e. include all those who are having the target disease, though this may entail including many who do not really have the disease) as well as adequately specific (include all those who do not have the target disease, though many mild or equivocal cases of the disease may also be missed out). Apparently, the case definitions should be developed in a way that there is adequate trade - off between both sensitivity and specificity. Development of proper, standardised case definitions is important to ensure uniformity during the investigations. For practical purposes, it is better to have cases in three categories, viz., definite, probable and suspect. Initially during the investigations, while formulating the hypotheses, it may be desirable to have more sensitive definitions, and later, as the hypotheses are being refined / tested, the definitions may

be made more specific by removing the “suspect” category (See Box - 6).

#### Box - 6 : Continuing with the Hypothetical Example

The case definitions were developed as : *Suspect case* (for use by the paramedical nursing / health assistants) : any person with at least one vomiting and 2 episodes of watery loose motions in a day; *Probable case* (for use by GPs and Dispensary Medical Offrs) : suspect case criteria plus no fever, no tenesmus, and no blood in stools; *Confirmed case* (for use by MOH for investigating the epidemic) : probable case criteria plus laboratory demonstration of ETEC / *V cholerae* / *Salmonella sp* / *Shigella sp* / *Giardia* / *Entamoeba* from stools.

**Step 6 - Develop the epidemiological case sheet** : The epidemiological case sheet is an extension of the clinical case sheet on which, for each and every subject, the personal and clinical details are filled up. In addition, the details of all factors which are relevant to the mode of transmission for a period which is equal to the *range* of incubation period of the disease, going back from the date / time of onset of symptoms, are also recorded. For example, in an outbreak of cholera, the epidemiological case sheet would include the personal particulars, clinical features, laboratory investigation results, and details of all meals, casual meals, snacks, sources of water supply, drinks, soft - drink etc., consumed by the person between 1 day to 5 days prior to the onset of symptoms. Thus, if the patient had onset of first symptoms of cholera on 10 Aug, we will record all these relevant factors for the period of 06 to 09 Aug. In addition, it will also include details of his movements in time and place during one day to five days prior to the onset of symptoms i.e. the range of incubation period of cholera (See Box - 7).

#### Box - 7 : Continuing with the Hypothetical Example

Dr ‘X’, as the MOH, had been undertaking regular visits to the various areas in the township, including the women’s hostel, to assess various aspects of hygiene & sanitation, during the past one year, since she had joined. She could identify that the disease being investigated would have come from either drinking water being provided through water coolers placed in each of the mess and each building; or from food which was prepared in the various messes; or from some snacks / Lassi consumed at the local canteen; or from water consumed from coolers or some snacks consumed at workplace; or from one of the two sugar - cane - juice stalls or a sweet - meat shop in the nearby market; or a party which was held in the hostel on 8th May. These various possible factors which could have led to the transmission were specifically kept in the epidemiological case sheet. By now, the hospital laboratory had intimated that organisms with darting motility were seen on hanging drop exam from the two patients; hence the diagnosis was finalized as “cholera” and it was decided to record the history of exposure to these various transmission factors as enumerated above, for a period of 1 to 5 days, retrospectively from the date of onset of symptoms.



**Table - 1 : Line listing**

Sr No	Name	Age	Sex	Residential address	Work - place address	Date / time of onset of symptoms	Main symptoms/ signs			Name / address of medical facility with date of admission or reporting
							1	2	3	

**Step 7 - Organise the laboratory (including Entomological and public health lab) work** : A very important step in epidemic investigations is laboratory work. This would include collection, storage and dispatch of body samples (blood, CSF, stool, throat swabs, rectal swabs etc.), environmental samples (water, food items), entomological samples (as mosquito adults and larvae etc.), and animal samples. It would be extremely desirable to consider what all items would be required for such laboratory procedures keeping in view the possible disease which is being investigated. Close liaison with the local hospital laboratory and with the pathologist / microbiologist needs no emphasis (See Box - 8).

**Box - 8 : Continuing with the Hypothetical Example**

Dr 'X' had kept her small laboratory in the MOH office, in a state of constant readiness to deal with any such public health emergency. However, she once again had detailed discussions with the hospital pathologist as regards various samples to be taken and their method of dispatch to the lab. She quickly organised a portable container having gloves, rectal swabs, rectal catheters, sterile Winchester bottles, specimen vials having Cary - Blair transport medium, sterile vials, centrifuge, and personal protective equipment. She decided to collect and dispatch stool samples / rectal swabs, food samples, water samples and serum for immunology.

**Step 8 - Contact administrative and engineering authorities and establish rapport** : It is extremely important to explain the objectives and requirements to the local leaders and administrative authorities of the affected community, establish close rapport with them and allay their apprehensions. This way, a lot of information can be obtained without any resistance. Similarly, it is also desirable to establish close rapport with the public health engineering authorities since a substantial part of investigations is likely to be directed towards public health engineering systems like water supply, excreta disposal etc. The layout maps of water supply and sewerage system should be obtained from the engineering and administrative authorities (See Box - 9).

**Step 9 - Collection of Information** : Having undertaken the preliminary steps, the investigator proceeds to collect information, recording the details on the epidemiological case sheet for each subject. Information is collected in respect of all possible modes of transmission which are relevant to the disease being investigated, and going back for a period which is equal to the "range" (difference between maximum and minimum) incubation period of the disease, going back from the time of onset of first symptom. For example, in an epidemic of hepatitis A, we would ask for details of sources of regular meals, casual meals, water, milk, sweets, snacks, and

**Box - 9 : Continuing with the Hypothetical Example**

Dr 'X' had kept "spot maps" showing hygiene and sanitation of various areas under her health cover, and constantly updated them after her regular visits to locations. She had also liaised with Public Works Dept (PWD) authorities and kept updated maps of water supply and sewage disposal systems. However, she once again contacted the PWD authorities and asked for their assistance in conducting the investigations. She also sought the sanction of the District magistrate and the CMO, to undertake the investigations. Thereafter she contacted the manager of the affected hotel, took him into confidence and discussed the details as to how the investigations would be undertaken. Finally, she had discussions with lower level PWD functionaries, with the junior functionaries of the affected hostel (canteen owner, cook house in-charge, etc.) and with the paramedical members of her investigative team.

so on, from the date of onset of symptoms and going back for a period of two to 6 weeks. The information is collected from the following sources :

(a) **From the cases** : The persons who have already reported to the health care facility by now (as indicated in the line list) or who report subsequent to the initiation of investigations are the straightway available source of information.

(b) **Search for additional cases and make the final "line - list"** : The cases who have reported to the health care facility may not represent the entirety of epidemic. Many cases may be lying hidden in the community, being mild cases, or those who may have reported to some other agency for treatment. It is therefore mandatory to search for additional cases so that the complete picture of the epidemic may be obtained. Using the standardised case definition, an extensive search is made using door to door survey in the entire population defined to be at risk. In case of very large populations, a random sample (usually a systematic sample) can be taken. The population must be informed well in advance about the search, through mass - media, announcement systems, fixing hand - bills describing the symptoms and requesting the people to report the disease. Apparently, assistance of administrative authorities would go a long way in this process. In addition, other health sources like other hospitals and General Practitioners (GPs) in the area may also be contacted to find out additional cases. In addition to clinical and epidemiological information, laboratory specimen, as applicable, should also be obtained in the field, from suspected cases. Fill up the epidemiological case sheet for cases detected during the search.

A final line list is made. It would include a list of all cases, including those detected on search for additional cases, in a chronological order as they occurred, showing their personal



particulars, date of onset, place of stay, place of work and all exposure histories that are relevant to the disease (e.g. sources of meals and water in case of an epidemic of oro - faecal disease). A review of the line listing of cases will give important clues as regards the various possible sources of exposure - these would be those exposures which are commonly shared by the cases, as seen in the line listing (See Box - 10).

**(c) Environmental information:** Besides clinico-epidemiological information from cases, a detailed environmental assessment is made of the area, depending on the disease one is investigating. Thus, while investigating an epidemic of cholera, one would make a detailed assessment of water supply system, nightsoil disposal system, cook houses and other eating/drinking establishments in the area where the defined population is staying. Similarly, in a suspected epidemic of dengue, one would make a detailed environmental assessment of vector breeding areas. In addition, various environmental samples (e.g. water, food, etc.) and entomological samples (e.g. larval and adult mosquitoes) would also be collected as required (See Box - 11).

#### Box - 10 : Continuing with the Hypothetical Example

By now a total of 7 cases had been admitted with same presentation. All were from the same hostel and all showed growth of *V. cholerae* Biotype 01, serotype Ogawa from stool samples. The line list was accordingly revised. All cases were interviewed personally by Dr 'X' and detailed information about various transmission factors was recorded on the epidemiological case sheet for the retrospective period of 1 to 5 days from date of onset. Cases were also asked in detail about any other factor which could have led to the transmission and which might not have been included in the epidemiological case sheet. In this regards, 5 of the cases said that they had also been often going to a kiosk selling "fruit - chaat" (mainly water melons) which had come up in the local market recently; accordingly, this was also included in the epidemiological case sheet.

All the local newspapers as well as the local radio and television were asked to announce the "suspect case definition" and inform any person member having such symptoms to come to the MO i/c of local govt. dispensary. The MOs i/c were asked to refer any person or family fitting into "probable case definition" to the district hospital for admission and also inform the MOH. The Health Assistants & Lab Assistants of MOH went "door to door" in the affected area, including their family quarters and asked if any person had suffered with symptoms fitting into "probable" case definition; if yes, their details were recorded on the epidemiological case - sheet and stool samples were taken and dispatched to the hospital lab.

**(d) Information from those who did not suffer from the disease :** This is a very important step which is often overlooked. While search for additional cases is going on, one must record the information regarding possible exposures (e.g. movements, sources of meals, casual meals, snacks, water, drinks etc.) not only from those who suffered from the disease symptoms, but also from those who were a part of the population at risk but did not suffer (i.e. the controls). This information from controls

is of vital importance in the later part of investigations, when hypothesis regarding various suspected exposures are to be analysed by comparing cases and controls.

**Step 10 - Describe the epidemic :** Once the information has been obtained, an epidemiological description of the epidemic is prepared. This description is vital for developing hypotheses regarding various possible sources of exposures that could

#### Box - 11 : Continuing with the Hypothetical Example

A team of the MOH and PWD staff conducted a detailed physical, on - ground check of water distribution and chlorination system and sewage pipe lines was rapidly undertaken. Water and food samples were taken from all messes, water coolers, eating joints in the market and water taps in work - places. These samples were dispatched to hospital lab. Water supply pumps in the affected unit were run for continuous 3 hours by PWD, while the ground was being observed. At one place, there was apparent moistness on the ground overlying a major water pipeline. The affected ground was dug open and it was noticed that there was a break in the water pipe line at that spot; this water pipe line was running approx. 5 feet above a sewage pipe which was also slightly damaged. These were immediately repaired. However, this particular water pipe was a main trunk, which was supplying water to the entire affected unit as well as the adjoining family quarters and not to any single mess.

No other case could be confirmed despite extensive search for cases. Hence information was recorded on the epidemiological case sheet from the seven cases. In addition, 50 healthy people (who did not even fit in the definition of even suspect or probable case), from the same affected military unit were selected from the list of personnel supplied by the unit authorities, by systematic random sampling and all information about various transmission factors as recorded from cases was also recorded from these "controls".

have caused this outbreak. The description of epidemic would include :

**(a) Developing the overall attack rates :** Using the cases (reported to health care facility plus found during additional search) as the numerator and the population defined to be at the risk as the denominator.

**(b) Describing the clinico - epidemiological profile :** This would include a percentage wise distribution of major clinical signs and symptoms among the cases, a description of the mild/moderate/severe forms, and fatalities.

**(c) Describe the cases according to distribution of person related variables :** This step involves development of proportional distribution of cases according to relevant, person related variables like age, sex occupation, source of water supply etc. The detailed line list described in the preceding paragraph is used to describe the cases according to all possible exposures. For example, in an epidemic of cholera, description of cases according to person related variables will include their distribution according to age groups, sex, occupation, place of regular meals, sources of drinking water, sources of casual meals / snacks, etc. (See Box - 12).

**Box - 12 : Continuing with the Hypothetical Example**

The following was the description of the 7 cases, according to history of major transmission factors as were recorded in epidemiological case sheet

Living in hostel dormitories	7 (100%)	Age < 35 yrs	6 (85%)	Took sugar cane juice from kiosk No. 1	5 (72%)
Living with family	0	Female sex	7 (100%)	Took fruit chaat from market	6 (85%)
Eating in 'A' mess	0	Took water from workplace No. 1	4 (58%)	Ate during party on 8th May	6 (85%)
Eating in 'B' mess	6 (85%)	Took water from workplace No. 2	2 (28%)	Had snacks / Lassi from local canteen	5 (72%)
Eating in 'C' mess	0	Took water from workplace No. 3	1 (14%)	Ate sweet - meat from a particular shop in market	2 (28%)
Eating in 'D' mess	1 (15%)	Age > 35 years	6 (85%)	Ate snacks at workplace	2 (28%)

**(d) Describe the epidemic according to time :** An epidemic is described according to time by plotting an epidemic curve. This curve is developed by plotting the attack rate along the vertical (Y) axis and unit of time along the horizontal (X) axis. The unit of time would depend on the disease; in food poisoning epidemic it would be in hours, in days for cholera and in weeks for Hepatitis A or E outbreaks. Often, it may not be possible to compute the attack rates according to time; in such instances, the epidemic curve may be prepared by plotting the actual number of cases along the vertical axis, instead of attack rates. The shape of the epidemic curve give us important leads as regards the cause. For details of the shapes of various epidemic curves and their interpretation, refer to the chapter on descriptive epidemiology.

**(e) Describe the epidemic according to place :** Description of the epidemic according to place is given by making the spot map of the area on which the frequency of the disease is plotted as coloured dots. Often, instead of plotting the frequency, only the actual number of cases are plotted and this may be simple and effective method too. Sometimes, different spot maps may have to be developed, e.g. separate spot maps for place of residence, place of work etc., depending on the possible places where exposure to disease could have occurred. For example, in a suspected epidemic of scrub typhus, we may have to prepare separate spot maps for cases, according to places of residence, place of work, places visited while camping as a part of holidaying - all for a period equal to the range of incubation period of the disease, going back from the day of onset of signs / symptoms. Spot map also gives important insight in to the possible causes of the diseases. One would be inclined to develop possible hypothesis regarding the cause of the outbreak, considering those places where the local concentration of cases in high (See Box - 13).

**(f) Describe the environmental conditions just before and during the outbreak :** A clear description of the findings of environmental and entomological assessment is given. For example, details of damaged water supply lines, cross - connections with sewer lines, unhygienic conditions in cook house, vector breeding and densities are described and efforts made to correlate these finding with description of epidemic according to line listing and distribution according to person,

place and time, thus developing various hypotheses regarding possible causes of the outbreak. It is often worthwhile to superimpose these environmental findings on the spot map for a quick visual evaluation.

**Box - 13 : Continuing with the Hypothetical Example**

2 cases had onset on 10th May, 3 on 11th and 1 each on 12 and 13th May. There was no case thereafter. The 7 cases were plotted according to the date of onset of their symptoms. The resultant curve showed a sharp rise, a sharp peak and an abrupt fall, indicating a "common vehicle, single exposure (point source)" transmission. It indicated that all these cases had probably got infected at a common source which existed only for a brief period of time, as can occur when a particular meal or drink gets contaminated, or a water storage cistern gets contaminated for a small time till the water is used, or when an infected food handler who is an "incubatory carrier" contaminates a food or drink for a brief period of time, before himself coming down with symptoms.

3 different spot maps were made - according to workplace, place of staying and place of routine eating and drinking, and cases were plotted as coloured dots on these maps. A clear - cut "clustering" was seen in all the three maps - in mess No. 'B', at workplace No. 1 and in Living dormitories No. 4 and 5. Further assessment indicated that large majority of these cases were staying in dormitory No. 4 or 5, as well as eating in Mess 'B' and working in workplace No. 1.

**Step 11 - Developing various alternative hypotheses regarding the cause of outbreak :** Once the epidemic has been described according to its clinico - epidemiological profile, line - list, and distribution according to person, place and time, various hypotheses are developed regarding possible cause(s) of the outbreak. The basis of developing these hypothesis is to start with the descriptions of cases according to various person, place and time related variables and see as to what are the possible exposures which are very common among cases. If the investigations have been done rightly till now, a large number of hypotheses will be developed (See Box - 14).

**Box - 14 : Continuing with the Hypothetical Example**

The factors which were very commonly found in a large proportion of cases were female sex, staying without family, age < 35 years, eating meals in mess 'B' or drinking water from its water cooler, drinking water from water cooler of work - place No.1, staying in barrack No. 4 or 5, having lassi or snacks from local canteen, eating in the party on 8th May, consumption of sugarcane juice from kiosk No. 1, and eating fruit - chaat from the market. These were kept as possibilities which could have transmitted the organism (hypotheses). On the other hand, eating snacks at work - place, eating sweetmeats from a particular shop, eating / drinking in messes Nos. 'A', 'C', or 'D' or drinking water from workplaces No. 2 and 3, were very uncommon among cases and hence not kept as "hypotheses" requiring further exploration.

**Step 12 - Testing the hypotheses - Comparisons using analytical epidemiology** : This step is the backbone of epidemic investigations. A comparison is made between the cases, and those who did not suffer, though being a part of same source population (controls), in respect of each and every possible hypotheses developed in the previous step. The Odds Ratios for each of these exposures are calculated and their statistical significance is seen by a chi square test. Thus, out of the various hypothesized exposures, one would find out one particular exposure in which the cases and controls differ significantly and this is, then, the likely source of the outbreak (See Box - 15).

**Step 13 - Further search for environmental and other possibly causative factors** : Further exhaustive search is now made, based on the indications given by the preceding step, to explore in detail as to what could have been the reason for transmission of the organism (See Box - 16).

**Step 14 - Final Laboratory proof of cause and effect relationship** : This is a difficult proposition, but if done, can give the final proof of the cause and effect relationship. For example, if the same organism that is isolated from the food handler, who has also been incriminated by analytical epidemiology (case control step above), is also isolated from the cases, then the link is finally proved.

However, it is not necessary that this step must always be completed, though best efforts should be made. In most of the real life situations, description of epidemic and test of hypotheses based on analytical epidemiological are enough proof of the cause (See Box - 17).

**Box - 16 : Continuing with the Hypothetical Example**

Once the results of hypothesis testing step focused the suspicion on 'B' mess, the conditions in 'B' mess that existed at the time of the outbreak were further evaluated. Extensive study of hygiene and sanitation of cook house and dining halls, drinking water storage and handling, health state of food handlers and cooking / food serving practices were evaluated. It was noticed that the tap of the water cooler was not functioning and hence drinking water was drawn manually by mess waiters, by immersing a "jug" into the cooler. Water samples were dispatched for bacteriological exam. There were total of 9 food handlers in 'B' mess, including 2 cooks, 2 cleaners and 5 waiters. 1 of the waiters (named herewith as waiter No. 'Q') had not reported for duty because of "upset stomach" from 10th may to 13th May. Clinical exam of all these food handlers was undertaken and rectal swabs of all 9 were dispatched to the laboratory

**Box - 17 : Continuing With the Hypothetical Example**

Water samples from water cooler showed very high coliform count of 180 per 100 ml but no *E. coli*. Rectal swab of the food handler 'Q' grew *V. cholerae* O1 Ogawa, i.e. the same biotype and serotype as was isolated from the 7 cases.

**Control and Prevention**

Steps for immediate control measures and long term prevention should not wait for the final proof of the cause of epidemic but should start immediately and continue concurrently as the investigations proceed. The following broad categories of steps are to be undertaken :

**(a) Measures directed towards the source of infection** : These would include detection and treatment of cases and carriers, isolation if required, notification, and control of zoonotic reservoir if applicable.

**(b) Actions directed towards channels of transmission** : These would include measures like protection of water supply and food hygiene, vector control, proper disposal of night soil and solid waste, various disinfection procedures, etc., depending on the disease.

**(c) Protection of susceptible population** : This includes steps like immunization, immunoprophylaxis, chemoprophylaxis, personal protective measures etc.

**Box - 15 : Continuing with the Hypothetical Example**

comparison of the 7 cases and 50 controls as regards the 6 different hypothesized factors indicated following

Hypothesized factor	Cases	Controls	Statistical results	Hypothesized factor	Cases	Controls	Statistical Results
Eating in 'B' mess	6 (85%)	11 (22%)	p < 0.001	Fruit Chaat	6 (85%)	39 (78%)	p > 0.05
Water from workplace no. 1	4 (58%)	32 (64%)	p > 0.05	Eating in party	6 (85%)	44 (88%)	p > 0.05
Sugar cane juice	5 (72%)	38 (76%)	p > 0.05	Lassi / snacks from canteen	5 (72%)	35 (70%)	p > 0.05

(Large majority of cases compared to statistically much smaller % of controls were eating / drinking in 'B' mess. For other factors, there was no difference)



(d) **Developing a long term early warning system** : A proper epidemiological and public health surveillance system should be developed and launched, so as to give ongoing data regarding the frequency of disease and changes in various environmental risk factors, with a view to give early warning of impending outbreaks (See Box - 18). Details of surveillance are discussed in an earlier chapter.

**Box - 18 : Continuing With the Hypothetical Example**

Super - chlorination of water supplies to bring the level of free residual chlorine at consumer end point at 1 ppm was ensured from the very first day the epidemic was reported and was periodically checked by sanitary staff. As investigations proceeded, the damaged water pipe lines and sewage lines were promptly repaired. The food handler 'Q' was removed from duty for 5 days and treated with oral tetracyclines at the district hospital; all other food handlers, though not found infective were given a presumptive dose of oral Doxycycline. The damaged tap of the water cooler in 'B' mess was repaired and the top lid was closed and locked. Local medical officer of the hostel was provided guidance to launch a daily surveillance system for diarrhoeal diseases and their reporting to the MOH. The in - charges of cook - houses were trained to undertake regular, daily medical surveillance of all food handlers.

## Investigating an Outbreak of Food Poisoning

Investigations of an outbreak of food poisoning takes the same general approach as any other epidemic, as has been outlined earlier. However, there are certain differences in approach, viz the details often described in other textbooks. In the usual situations, as in the case of individual families, where generally all people live and eat as a family group and not in the form of community feeding, the "common" meal (as a banquet, religious get - together, picnic etc.) can be easily identified and the details of food histories of that meal can be obtained. On the other hand, in some other settings as a hostel, the fact that all the inmates live and eat all meals together, every meal is a common meal, and hence identification of the common meal which caused the episode of food poisoning may not be as simple a common - sense conclusion. For instance, if 25 inmates out of 100 staying in a hostel, eating from a common cook house, are admitted with symptoms of gastro - enteritis between 9 a.m. and 3 p.m. on 10 May, which meal do we investigate - whether breakfast of 10 May, or dinner of 9th May or lunch of 9th May? Secondly, the idea of investigations is not simply to incriminate a given food stuff. The goal is to trace back the entire history of that food item to find out why contamination occurred so that the episode does not repeat. We shall deliberate on the steps to be undertaken for investigating an outbreak of food poisoning, illustrating it with a hypothetical example based on a real life episode (See Box - 1a).

**Step 1 - Confirm whether it is an outbreak?** : An outbreak of food poisoning has three characteristics - Firstly, the symptomatology should be usually referable to gastrointestinal tract (and sometimes systemic in case of mushroom or organophosphate etiology or neurological in botulinum

etiology). Secondly, *a large number of cases should occur in a small period of time*. Thirdly, the cases should have some history of sharing at least one common meal. If these three criteria are fulfilled, we would say that it is an outbreak of food poisoning.

**Step 2 - Verifying the Diagnosis & Deciding Which Meal to Investigate?** : In a food poisoning episode one has to decide as to which meal is to be investigated and this is done by making a "tentative" verification of diagnosis mainly on clinical grounds. While microbiological diagnosis is always desirable, for all practical purposes it is extremely difficult to establish lab diagnosis quickly because the procedures are highly specialized, available only at specialized centres and

**Box - 1a : Hypothetical Example**

On 8th March, Dr 'X', the Medical Officer of Health (MOH) got the information that yesterday, i.e. 7th March, an episode of gastroenteritis had occurred in the same working women's hostel, in which she had earlier investigated an epidemic of cholera. Out of 1000 working women in this hostel, 87 were eating in 'B' mess and out of these, 36 developed symptoms and have been detained for observation and treatment at the dispensary at the hostel. Since the incident was concerning, the CMO of the district directed Dr 'X' to move to the affected site and investigate. She left immediately and reached the location at 2 p.m. on 8th Mar. Preliminary investigations revealed that out of the 36 patients, all the cases (100%) had 6 to 8 watery loose motions, 100% had abdominal cramps, 3% had nausea / vomiting, none had fever or blood / mucous in stools. No case had dehydration or any complications. The first 3 cases had onset of symptoms at 7 a.m. on 7th March, 7 between 7 and 8 am, and similarly, 9, 5, 4, 3, 2, 2 and 1 had onset between 8 and 9 am and similar hourly periods; the last case had onset at 3 pm. The peak of the epidemic was reached at 9 a.m. by which time, 19 cases had onset. No food sample of any meal had been kept since the entire episode was not visualized and the hostel had no such procedure of preserving the food samples.

The epidemic curve plotted with the above data showed a classical "common vehicle point exposure" curve typical of food poisoning. As evident from clinical profile, the entire epidemic was clearly due to either *C perfringens* or *B cereus* type - 2. Going by the median and range of incubation periods of these organisms, the suspicion converged to some meal which was eaten at about 9 p.m on 6th March.

take time; more important, the food samples are themselves usually not available due to ignorance or deliberation on the part of food handlers. For example, lab confirmation of *C perfringens* food poisoning requires demonstration of  $10^7$  spores per gram of faeces from patients or food handlers and *S aureus* or mushroom poisoning requires toxin assays available only at few centres in our country.

The mainstay is therefore to see the "clinico - epidemiological" profile of the outbreak by quickly analyzing the frequency of symptoms in the present outbreak and comparing this profile with what is expected during outbreaks caused by common etiological causes of food poisoning, as shown in Table - 2.



Table - 2

Etiologic agent	Median incubation (range)	Nausea / Vomiting	Loose motions	Abdominal Cramps	Fever	Blood / Mucous in stools	Neuro-muscular symptoms
<i>Staph aureus</i> & <i>B cereus</i> - 1	2 hr (1 - 6)	+++	+	+	-	-	-
<i>C perfringens</i> & <i>B cereus</i> - 2	13 ( 10 - 18)	+	+++	+++	-	-	-
<i>Salmonella spp</i>	18 (16 - 24)	++	+++	++	+++	-	-
<i>Shigella spp</i>	24 (12 - 96)	+++	+++	+++	+++	+++	-
Insecticides / mushroom	Few mts.	++	+	-	-	-	+++
<i>C botulinum</i>	24 (18 - 36)	+	-	-	-	-	+++

( Legend :- +++ = occurs in 80 to 100% patients; ++ = 40 to 60%; + = 20 to 30%; - = 0 to 5% patients show this manifestation)

The first thing is to work out the % of various signs / symptoms in the present outbreak (besides taking all available samples as food samples, water samples, stool samples of cases and food handlers). Ascertain as to, with which etiologic symptomatology (as shown in Table - 2) does the present outbreak match and make a tentative diagnosis of the cause of the present outbreak.

Draw an epidemic curve, plotting the number of cases along the vertical axis and the time according to hourly period (i.e. 9 a.m., 10 a.m. etc.). The peak of epidemic curve must be noted. Also note the first case and the last case. Go back in time, from the peak of the curve, by the known median incubation period of the suspected etiologic agent (as shown in Table - 2) as also the minimum and maximum incubation periods from the first and last case respectively. The meal which was consumed where all these three time periods converge gives the meal which was most probably contaminated and needs to be further investigated (See Box 1a).

**Step 3 - Getting the Food Histories about the Suspected Meal :** Once the meal which was most probably associated with the epidemic has been identified, a list of *each and every dish* (including even chapattis, rice and water / drinks) which was served during that meal is made. Now, *each and every person* who attended that meal is interviewed and asked about the *history of consumption of each and every food item* that was served during that meal. The information is recorded as per the following work - sheet, which, in fact, is nothing but the line - list, as shown in Table - 3 (Also see Box 2a).

**Step 4 - Consolidating the food histories and sickness histories :** The details recorded on the above line list are now consolidated into a summary - table as shown in Table - 4.

Now, the food item which shows the maximum Attributable Risk is the food item which most probably was involved in the transmission of the epidemic (See Box - 3a).

[Sometimes all persons who ate the suspected meal may not be available for interrogation. In such instances, the "cases" and a "random sample" of those who ate the meal but did not become ill (controls) are interrogated about the food histories.

This is the case - control approach, wherein we would calculate the Odds ratio (OR) and not the Attributable risk. The food item showing highest OR would be taken as the suspect item].

#### Box - 2a : Continuing with the Hypothetical Example

Dr 'X' made a list of each and every item which was served during the dinner on 6th March. These items were Mutton Curry, *Matar - Paneer*, *Moong Daal*, *Chapati* and *Rice*. She then interviewed each and every of the 87 ladies who had eaten that dinner in their 'B' mess dining hall and asked them whether they developed any symptom. If they had developed symptoms, details of each symptoms were enquired. Details were also taken about each and every of these 5 food items - whether eaten or not eaten, irrespective of whether the lady developed sickness or not.

**Step 5 - Undertake an extensive assessment of the sanitary history and food hygiene of each constituent of the suspected food item :** The objective of investigations is to find out why a particular food item got contaminated so that recurrences are prevented in future. Therefore, once a particular dish has been identified as per details given in previous step, all its constituents (including condiments and water) should be noted and detailed history of every constituent should be taken :

- From where they were procured;
- What were the hygienic conditions at the point of procurement;
- How they were stored in the cook house;
- Sanitary conditions at the time of cooking;
- What temperature did the initial cooking achieve;
- Whether the cooked food was eaten hot and freshly cooked or else stored;
- If stored, at what temperature and under what hygienic conditions was it stored;
- If stored, was it adequately re-heated before consumption. (Refer Box - 4a.)

<b>Table - 3</b>											
Serial No.	Name & Personal particulars	Whether developed illness (Yes or No)	If ill, Presence of symptoms (Yes / No)				History of eating various food items served during the suspected meal				
			Nausea / Vomitting	Watery Diarrhoea	Abdominal Cramps	Fever	Matar Paneer	Mutton Curry	Kheer	Item No. 4	Item No. 5
1.	ABCD	No	-	-	-	-	Yes	No	Yes	Yes	Yes
87.	XXYZ	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No

<b>Table - 4</b>										
Food Item	Those who ate the item				Those who did not eat the item				Relative Risk	Attributable Risk
	Became Sick	Did not Become sick	Total	Incidence among those who ate the item ( $I_E$ )	Became Sick	Did not Become sick	Total	Incidence among those who did not eat the item ( $I_{NE}$ )		
(a)	(b)	(c)	(d)	(e) (b ÷ d)	(f)	(g)	(h)	(i) (f ÷ g)	(j) (e ÷ i)	(k) (e - i)
Item - 1	31	9	40	78%	5	42	47	22%	3.6	66%
Item - 2										
Item - 3										

<b>Box - 3a : Continuing with the Hypothetical Example</b>										
Dr 'X' now consolidated the line list that she had made into a summary table as follows										
Food Item	Those who ate the item				Those who did not eat the item				Relative Risk	Attributable Risk
	Became Sick	Did not Become sick	Total	Incidence among those who ate the item ( $I_E$ )	Became Sick	Did not Become sick	Total	Incidence among those who did not eat the item ( $I_{NE}$ )		
(a)	(b)	(c)	(d)	(e) (b ÷ d)	(f)	(g)	(h)	(i) (f ÷ g)	(j) (e ÷ i)	(k) (e - i)
Mutton Curry	31	9	40	78%	5	42	47	22%	3.6	66%
Mutter Paneer	30	31	61	49%	6	20	26	23%	1.19	7%
Dal Moong	27	24	51	53%	9	27	36	25%	2.1	28%
Chappati	32	43	75	42.7%	4	8	12	33.3%	1.27	14.4%
Rice	34	46	80	42.5%	2	5	7	28.6%	1.5	13.1%

#### Box - 4a : Continuing With the Hypothetical Example

Once mutton curry was identified as the possibly contaminated dish, the suspicion became strong regarding *C perfringens* etiology, since *B cereus* is more likely to be conveyed through rice dish while *C perfringens* is more likely through a meat dish. Dr 'X' quickly made out a detailed list of all items used in making the mutton curry, including condiments, vegetables and water. She thereafter took a detailed sanitary history of each and every item, starting from the point of procurement till the final cooking and subsequent storage / serving of the cooked dish. She also verified the details by personally observing the hygienic conditions on ground.

She noticed some peculiar and interesting findings. The cook house and dining hall were properly constructed, with adequate sanitary standards. The various dry raw edibles as wheat, rice, pulse, condiments, etc. were bought by the catering in-charge from the nearby market, while the vegetables, fruits and meat was supplied by a local contractor on a contract basis. The contractor used to get mutton from a local butchery. On visiting the butchery it was found that the conditions were grossly unhygienic. The floor was cracked and there was no arrangement for washing the floor nor there were arrangements of hygienic disposal of excreta of slaughtered animals. There was no system of starving the animals prior to slaughtering. Animal excreta (which is a rich source of *C perfringens* spores) was seen lying all over the floor of the butchery and the raw meat was apparently getting mixed up with the excreta.

On 6th March, the contractor reached the hostel cook house, with mutton and other fresh items by around 1 p.m. In the 'A', 'C' and 'D' messes, the raw mutton was stored on ice till 6 p.m. and cooking started at about 6 p.m. and was completed by 7 p.m. However, in 'B' mess, since there were lesser cooks, cooking of mutton curry started at about 3 p.m. and was completed by about 4 p.m. Thereafter, this cooked mutton curry was stored in the large utensil, which was kept on a table, since there was no arrangements of a fridge. This dish was therefore kept at an environmental temperature of about 30°C for almost 4 hours, till 8 pm, giving optimum time and temperature for the heat - shocked *C perfringens* spores in the mutton to germinate and produce large amount of toxin. At 8 pm, the mutton dish was "warmed" (to about 40°C) (and not reheated thoroughly which could have inactivated the preformed perfringens toxin) and served for dinner starting at about 8.15 pm till 10 pm.

**Step 6 - Make focused recommendations based on the findings of investigations** : Make specific and "do - able" recommendations, based on the actual findings and develop a system of keeping a check that these recommendations are being adhered to (See Box - 5a).

#### Box - 5a : Continuing with the Hypothetical Example

Based on her findings, Dr 'X' made the following do - able recommendations :

- Meat should not be taken from the particular butchery, since it was difficult to have adequate sanitary control on it.
- An alternative butchery to be identified for supply of meat and should be properly inspected for sanitary conditions by a public health officer.
- After receipt from the contractor raw meat should be stored in a deep freeze.
- Meat dish should be the last one to be cooked for dinner. Cooking of meat dish should start after 6 p.m. so that it is completely ready by about 7 p.m.
- All meals should be served freshly cooked and hot.
- No cooked food item should be stored, unless operationally essential.
- If cooked item is to be stored, the storage should be in a deep freeze or on ice, in ice box and storage should not be more than 4 hours.
- Cooked food item, if stored (even on ice), should be thoroughly reheated to > 60°C before serving.
- In - charge of the catering arrangements of the hostel to check implementation of these recommendations.

#### Summary

Investigation of an epidemic is one of the most important duties of the health care provider, as well as the epidemiologist. It involves a series of steps. These steps are not necessary to be undertaken in the same sequence, some of them may even be undertaken simultaneously.

The first and foremost step would be verification of the diagnosis of the condition that one is dealing with in epidemic form. For this purpose, it may be adequate to confirm by lab tests, a 20% to 30% random sample to be having similar disease. The next step is to confirm the existence of an epidemic. This is done by comparing the current incidence rate with the rate occurring in the same population, during the corresponding period of the past three years. After this step, an Initial (Rough) "Line - listing" of cases is developed - i.e. a nominal roll of the cases which have already been reported to the various health care establishments.

The next step would be to define the population at risk - the source population. Developing valid case definitions would be the subsequent step. The case definitions should be a fine balance between sensitivity and specificity. Subsequently, an Epidemiological case sheet is to be developed - it is an extension of the clinical case sheet on which, for each and every subject, the personal and clinical details are filled up as well as details of all possible exposures that could have led to this infection, recorded for a range of time equal to the maximum and minimum incubation period, going retrospectively from the date of onset of the disease.

After this is accomplished, it would be advisable to organize the laboratory (including Entomological and public health lab) work, which would include collection, storage and dispatch of body samples, entomological samples, environmental samples

and animal samples. The next step would be to contact administrative and engineering authorities and establish rapport. Thereafter, collection of information from the cases and through environmental information should be carried out. Also, additional cases need to be searched for and thereafter, the final "line - list" is made. Information for those who did not suffer from the disease also needs to be included.

The next step would be to describe the epidemic - by developing the overall attack rates, describing the clinico - epidemiological profile, describing the cases according to distribution of person, time and place related variables. Description of the environmental conditions just before and during the outbreak would be appropriate at this juncture of investigating an epidemic.

Various alternative hypotheses regarding the cause of outbreak have to be developed thereafter. Using analytical epidemiology, each of these hypothesis is tested and compared. Thus, out of the various hypothesized exposures, one would find out one particular exposure in which the cases and controls differ significantly and this is, then, the likely source of the outbreak. Final Laboratory proof of cause and effect relationship is not mandatory, but can be performed if facilities are available and will further strengthen the results.

Steps for immediate control measures and long term prevention should not wait for the final proof of the cause of epidemic but should start immediately and continue concurrently as the investigations proceed. These measures are generally directed towards the source of infection, towards channels of transmission, protection of susceptible population and for developing a long term early warning system.

As an example, investigations of an outbreak of food poisoning can be taken and the general steps outlined above may be instituted appropriately. A point in case here would be to deduce the probable meal to be incriminated, by making necessary calculations using time - points along the epidemic curve and knowledge of incubation period of specific agents causing food poisoning. Also to keep in mind would be to get clear food histories and sickness histories.

## Study Exercises

### Long Questions :

1. You are the medical Officer in charge of a PHC. You have received a message on 10th August 2008 from your Health Assistant of one of the subcentres that there have been unusually large number of patients of jaundice have been reporting at the subcentre during the past one week. Describe as to how will you proceed to investigate this occurrence.
2. You are the Medical Officer in charge of a PHC. From 1 a.m. onwards on 17th June 2008, a number of patients have started coming to the PHC from a local village with complaints of nausea, vomiting, abdominal cramps and occasional watery loose motion. There is no fever or blood in stools. All these patients belong to a "Barat" (marriage party) which came in the evening of 17 June along with the bridegroom, for solemnizing a marriage. Describe as to how you will proceed to investigate this occurrence.

**Short Notes :** (1) Epidemiological case sheet (2) Line listing (3) Describing an epidemic (4) Hypothesis testing in an epidemic.

### MCQs & Exercises

1. The very first step in investigation of an epidemic is (a) Confirmation of existence of an epidemic (b) Verification of diagnosis (c) Develop epidemiological case sheet (d) Formulation of hypothesis.
2. A nominal roll of the cases which have already been reported to the various health care establishments (like dispensaries, general practitioners or admitted to the hospitals) till the present moment would form (a) Line list (b) Epidemiological list (c) Case summary (d) Secondary data.
3. Arrange the following steps in investigation of an epidemic, in the sequential & ideal order (a) Develop the epidemiological case sheet (b) Testing the hypotheses (c) Confirm the existence of an epidemic (d) Develop an Initial (Rough) "Line - listing" of cases (e) Develop valid case definition.
4. For purposes of terming a health - related event as an epidemic, the incidence rate computed is compared with the rate occurring in the same population, during the corresponding period of the past (a) 01 year (b) 03 years (c) 10 years (d) No specific time frame is laid down.
5. As a general rule, to avoid the danger of food poisoning, cooked food item, if stored (even on ice), should be thoroughly reheated to what temperature before serving (a) 60°C (b) 80°C (c) 100°C (d) 120°C.
6. Match the following; While plotting the epidemic curve of a common - source, single exposure epidemic (say, an outbreak of food poisoning), which time period needs to be deducted/ subtracted (i.e. column B) from the given time points along the curve (in column A) so as to draw an inference regarding the most probable meal to be incriminated and its timing

Column A	Column B
A) Peak of epidemic	I) Minimum Incubation period
B) Occurrence of First case	II) Maximum Incubation Period
C) Occurrence of last case	III) Median Incubation Period

7. All of the following categories are to be defined in developing valid case definitions of diseases, except (a) Suspect (b) Fatal (c) Probable (d) Confirmed.
8. While developing an epidemiological case sheet in investigation of an epidemic, it would be prudent to go back by what time period from the onset of the first symptom, so as to get an idea of the agent to be incriminated (a) Maximum Incubation period (b) Minimum incubation period (c) Latent period (d) Range of Incubation period.
9. While investigating an epidemic, the document which is made after including the cases that were earlier missed out, i.e. after inclusion of additional cases,, is known as (a) Final line list (b) Optimal line list (c) Active line list (d) Passive line list.
10. In case of large populations, while looking out for additional cases to complete the line list when investigating an epidemic, which type of sample should be ideally taken



- (a) Cluster sample (b) Multi - stage sample (c) Systematic random sample (d) Stratified random sample.
11. An epidemic is described in all of the following ways/parameters, except (a) According to time characteristics (b) According to space characteristics (c) According to person characteristics (d) According to place characteristics.
  12. Which measure is to be used while making comparisons using analytical techniques, between those who suffered, and those who did not suffer, though being a part of same source population, for testing the hypothesis in investigation of an epidemic (a) Odds ratio (b) Relative risk (c) Attributable risk percent (d) Population Attributable risk.
  13. Which test of significance is to be used while making comparisons using analytical techniques, between those who suffered, and those who did not suffer, though being a part of same source population, for testing the hypothesis in investigation of an epidemic (a) Paired 't' test (b) Unpaired 't' test (c) 'Z' test (d) Chi - square test.
  14. All of the following are measures directed towards control and prevention of the source of infection, in an epidemic, once identified, except (a) Vector control measures (b) Notification (c) Isolation if required (d) Detection and treatment of cases and carriers.
  15. All of the following are measures directed towards protection of susceptible population, in an epidemic, once identified, except (a) Immunization (b) Chemo - prophylaxis (c) Personal protective measures (d) Quarantine.
- Answers :** (1) b; (2) a; (3) c - d - e - a - b; (4) b; (5) a; (6) A - III, B - I, C - II; (7) b; (8) d; (9) a; (10) c; (11) b; (12) a; (13) d; (14)a; (15) d.

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## Writing the Research Findings

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While the researcher would have put her entire heart and soul into the planning, organizing, conduct and analysis of the research work, it is the report (often called as the "paper" in research parlance), which is actually read by all and hence great care should be exercised while writing the same. The discussion in the present chapter is intended to serve as general guidelines for writing a research paper or dissertation. The researcher is advised to also obtain a copy of specific guidelines from the journal to which he or she intends sending the article (or the academic council or research body in case of a thesis or project report) and adhere to the finer details provided in such instructions. All leading medical journals publish guidelines for authors, as specific for their journal, in all their issues, or at least once a year, and the same should be checked.

### The General Sequence of Presentation in an Original Research Paper or Thesis is usually as follows :

1. Title 2. Abstract (Summary in case of thesis) 3. Key words 4. Introduction 5. Aim and objectives 6. Review of literature 7. Material and Method 8. Findings (Results) 9. Discussion 10. Conclusion 11. Recommendations 12. References 13. Annexures 14. Other Enclosures.

All or most of these headings should be sequentially covered up, whether you are preparing an original research article or a thesis, keeping one major difference in mind, that in a thesis or project report, the various aspects are dealt with in great detail while in a research article, these are condensed. As a general guideline, try and restrict your research paper to 10 to

12 double spaced A - 4 sized typed pages and your dissertation/ project report within 125 to 150 pages.

**Title :** A large majority of the readers of medical journals generally browse through the list of contents and tend to select the article whose title attracts attention. The take home message is that you must select the words in the title in such a way that it attracts attention. Do not keep the title either too long or too short. A good method is to write down a few titles, revise and modify them a number of times till you get the one which appears to be the best. The optimum number of words in a title should be between 10 and 15. The title should be, in fact, a very short, "telegraphic summary" of your objectives. In addition, the title may also give a very brief indication of the place and general settings of the study and the type of study design; e.g. "A Randomized Controlled Clinical Trial (i.e. the "design") of the effectiveness of acetazolamide in preventing Acute Mountain Sickness (i.e. the *research question*) among young healthy tourists inducted to high altitude in Northern Himalayas" (i.e. the *general settings*).

**Abstract :** In a research paper, the title is followed by the Abstract. In case of a dissertation or project report, there is an additional page giving the Index (list of contents) interspersed between title page and the "Summary". In a dissertation/ project report you would write a Summary which occupies approximately 5% to 7% of the total pages that are present in the report. The abstract is a short, crisp summary of your entire research paper. Usually, it should be limited to 200 to 300 words (about one typed page in double spacing). Most of the standard journals want the Abstract section to be further subdivided into four sub - headings - Background significance, Material and Method, Results and Conclusion. The abstract should start with a sentence or two on the background of

the research question, including its importance, followed by your actual research question (i.e. objectives) summarised in a sentence or two. Thereafter the salient features of methodology are summarised in about three or four sentences, so as to give an idea of the general settings, the reference population, the sample size, sampling method, type of design, the methods used in making measurements / obtaining information from the subjects and the intervention procedure if any. This is followed by the salient findings (giving the measures of effect like OR and p value in brackets) and finally the main conclusions drawn from the study. In case of summary of a thesis or project report, the above aspects are explained in slightly greater detail, paragraph wise, in about seven to ten typed pages. Avoid including aspects pertaining to "Review of literature" or "Discussion" in the abstract or summary.

**Key words :** After the Abstract, indicate four or five key words that will help "indexing" your article in Index Medicus or on the internet / computer based databases.

**Introduction :** Keep it brief, but, at the same time, as clear as possible. The optimum space for introduction is about half page in your typed manuscript; in a thesis/project report the optimum space is 3 to 4 pages. The Introduction should bring out, systematically, the definition of the disease/health problem that you have studied, its "magnitude" in terms of morbidity, mortality and suffering, a brief note on what is already known in this area and finally the facets where gaps exist in the present body of knowledge and which have prompted you to take up the present research work.

**Aim and Objectives :** In a research article, aim and objectives are usually covered in the last one or two sentences of introduction, without giving any separate heading. In a thesis/project report, a separate heading must be given and the aim and objectives should be spelt out in detail.

**Material & Methods :** This section is the "backbone" of your entire study. Write your methodology with great care and accuracy. It would be worthwhile devoting upto one complete page to material and methods in a research paper, and up to 12 to 15 pages in your thesis/project report to this aspect. Coverage of all the headings described in material and method section of the next chapter (on research proposal) must be ensured, in detail when writing a thesis and in a summarised form when writing a research paper. (Go through the next chapter for details).

**Review of Literature :** A review of literature is not required in a research paper. On the other hand it is a must for thesis/project report, wherein it should be a detailed review of recent literature (generally covering the past 5 years). In a dissertation/ project report the review of literature may generally occupy 30 to 40 pages. The order of proceeding with the review of literature usually takes the following sequence :

- Definition(s) of the condition(s) of interest in the present research.
- Historical review of the condition of interest.
- Magnitude of the problem due to the condition of interest, in terms of mortality, morbidity and suffering.
- Major risk factors for the condition.
- Other (minor or possible) risk factors for the condition.
- Review of diagnostic/therapeutic strategies (in case of a

study addressing issues of "therapy" or "diagnosis") Or Review of preventive strategies (in case of study addressing issue of "prevention" or "risk").

**Findings (Results) and Discussion :** In general, findings and discussion should be in two separate headings. The findings should be "grouped" into broad headings, commensurate with the study objectives. Graphical presentations should be made using appropriate types of figures (diagrams) or tables. Each figure should be appropriately referred to in the text. Each table should have a table number, usually in Arabic numerals, which should be clearly referred to at the appropriate place in the text. The table number should be followed by a clear but concise heading, and the actual findings. It is always a good practice to indicate the percentages along with the numbers. Do not forget to indicate 100% besides or below the number out of which you have calculated the percentage. Also make sure that the totals of the columns as well as the rows have been presented. Following the table, the abbreviated statistical findings as "t = 3. 21, df = 28, p < 0. 05 (significant)" must be given. An example is given as Table - 1.

<b>Table - 1 : Comparison of cases of IHD and controls regarding smoking</b>			
<b>Smoking History</b>	<b>Cases</b>	<b>Controls</b>	<b>Total</b>
	<b>No. (%)</b>	<b>No. (%)</b>	
Present	67 (76. 1%)	54 (42. 5%)	121
Absent	21 (23. 9%)	73 (57. 5%)	94
Total	88 (100%)	127 (100%)	215
<b>X<sup>2</sup> = 23. 9, df = 1, p &lt; 0. 001 (very highly significant)</b>			
<b>(OR = 4. 3; 95% CI of OR = 2. 4 to 7. 7)</b>			

Following the table, describe your own findings in two or three sentences. Do not leave it on your examiner or the reader to make interpretations from the tables. Having given an overview of your findings, discuss them by first bringing out such studies which have given similar findings. Next, give a brief account of studies which have obtained findings that are dissimilar from your findings, and "reason out" the possible causes as to why your findings could be different from theirs. Finally, in a sentence or two, summarise the overall findings and how your findings would affect the clinical or preventive policy.

**Conclusions and Recommendations :** A point which needs to be emphasised is that the conclusion should be drawn from the premises of your study and not from possible factors which you have not studied. Similarly, while making your recommendations, make sure that they are based on facts which you have studied and not simply a repetition of standard recommendations given in some text book or by some other author. Moreover, the recommendations should be "do - able" (practicable).

**Annexures and Enclosures :** In general, the annexures that are attached in a thesis/project report are the same as have been explained subsequently in the chapter on writing a research proposal. In addition, if necessary and possible, in a thesis/project report, interesting ECG tracings, Skiagrams etc. may be attached as separate enclosures. Annexures and

enclosures should be properly referred to at appropriate places in the text.

**References :** The references should be serially numbered in Arabic numerals, in a chronological order, as they appear in the text. Do make sure that a particular reference number should appear in the text for the first time, only after the immediately preceding reference number has appeared in the text at least once. For example, reference number 9 should appear in the text only after reference number 8 has appeared in the text at least once. The style of writing the reference should conform to the one used in *Index Medicus*, which is as per the Vancouver system. For example, for writing a reference of an article published in a journal, the format is as follows : "*Reference No. Name of author(s). Title of article. Name of journal & Year; Volume : Pages from - to*". (A hypothetical example is as follows - "18. Singh BB, Kumaran R. Epidemiological study of murine typhus in a rural area. *Indian Jr Biology* 1968; 37 : 368 - 73". ). If there are up to 6 authors, then give the names of all; if more than six, give the names of first three, followed by "et al".

## Summary

Great care should be exercised while writing the Report or "paper" as it is actually read by all. A copy of specific guidelines from the journal to which researcher intends sending the article must be obtained and one must adhere to the finer details provided in such instructions. These are generally published once a year. In a thesis or project report, the various aspects are dealt with in great detail while in a research article, these are condensed. Restrict research paper to 10 to 12 double spaced A - 4 sized typed pages and dissertation/project report within 125 to 150 pages. The general sequence of presentation in an original research paper or thesis is usually the Title followed by Abstract (Summary in case of thesis), Key words, Introduction, Aim and objectives, Review of literature, Material and Method, Findings (Results), Discussion, Conclusion, Recommendations, References and finally Annexures and other Enclosures.

The words in the title must attract attention; the optimum number of words in a title should be between 10 and 15. A suitable title can be written by writing few possible titles and modifying them till a suitable title is arrived at. It should bring out the research question, design and the setting of the study. The abstract is a short, crisp summary of your entire research paper, limited to 200 to 300 words. Abstract section may be further subdivided into four sub - headings - Background significance, Material and Method, Results and Conclusion. Do not include aspects pertaining to "Review of Literature" or "Discussion" in the abstract or summary. Four or five key words must be given to facilitate the indexing. Introduction is a brief note on what is already known, what are the gaps in the existing body of knowledge and why this present work was taken up. It should combine brevity and clarity. Methodology must be written with great care and accuracy. A detailed review of recent literature must generally cover the past 5 years. In a dissertation / project report the review of literature may generally occupy 30 to 40 pages. It consists of Definition(s) of the condition(s) of interest in the present research, Historical review of the condition of interest, Magnitude of the problem due to the condition of interest, in terms of mortality, morbidity

and suffering, Major risk factors for the condition, Other (minor or possible) risk factors for the condition, Review of diagnostic/therapeutic strategies (in case of a study addressing issues of "therapy" or "diagnosis") Or Review of preventive strategies (in case of study addressing issue of "prevention" or "risk").

The findings should be "grouped" into broad headings, commensurate with the study objectives. It should use graphs, charts and tables to lucidly present the findings. They should be properly referred to in the text. Conclusion should be drawn only from the premises of study. Recommendations made should be fact based and "do - able" i.e. practical and feasible. Interesting and relevant documents should be placed at annexure. References, annexures and enclosures should be serially numbered and properly referred to in the paper.

## Study Exercises

### MCQs

1. As a general guideline, research paper should be restricted to \_\_\_\_\_? (a) 10 to 12 double spaced A - 4 sized typed pages (b) 5 to 6 double spaced A - 4 sized typed pages (c) 18 to 20 double spaced A - 4 sized typed pages (d) 1 to 2 double spaced A - 4 sized typed pages.
2. As a general guideline, dissertation/project report should be restricted to \_\_\_\_\_? (a) 60 to 70 pages (b) 100 to 110 pages (c) 150 to 170 pages (d) 125 to 150 pages.
3. What is the optimum number of words in a title? (a) Between 15 and 20 (b) Between 20 and 25 (c) Between 10 and 15 (d) Between 25 and 30.
4. In a dissertation/project report, Summary which occupies approximately \_\_\_\_\_ of the total pages that are present in the report ; (a) 5% to 7% (b) 7% to 10 % (c) 1% to 2% (d) 11% to 13% .
5. The abstract is a short, crisp summary of your entire research paper of \_\_\_\_\_ words. (a) 100 to 150 words (b) 150 to 170 words (c) 300 to 350 words (d) 200 to 300 words.
6. Background significance, Material and Method, Results and Conclusion all are four sub - headings of which part of research paper? : (a) Abstract (b) Summary (c) Introduction (d) Review of literature.
7. What is the recommended number of keywords for indexing of an article in *Index Medicus* or on the internet / computer based databases? : (a) Eight to ten (b) Twelve to fifteen (c) Nine to twelve (d) Four to five.
8. Which section of research paper is also called "Backbone" of the study? (a) Background significance (b) Material and Method (c) Results and Conclusion (d) Summary.
9. In a research paper \_\_\_\_\_ is not required, while it is a must for thesis/project report? (a) A review of literature (b) Summary (c) Abstract (d) References.
10. In a table showing the results, it is a good practice to indicate the \_\_\_\_\_ along with the numbers. (a) Decimal (b) Fractions (c) Percentages (d) Rates.
11. The style of writing the reference should conform to the one used in *Index Medicus*, which is as per the \_\_\_\_\_ system. (a) Verdana (b) New York (c) British (d) Vancouver

**Answers :** (1) a; (2) d; (3) c; (4) a; (5) d; (6) a; (7) d; (8) b; (9) a; (10) c; (11) d.



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This chapter lays down the general guidelines for writing a research proposal. Apparently, researchers should also abide by the format which are specifically laid down by the respective funding agencies as ICMR, or by the concerned University.

**Introduction** : This the first group heading. In a nutshell, the introduction should give a good overview of two aspects - firstly, the *background importance* about the area of study and secondly the *relevance* of the proposed work. The introduction should generally be limited to within 400 to 600 words (2 to 3 double spaced A - 4 size typed pages). The introduction should have specific paragraphs which should logically and sequentially bring out the following aspects :

- Definition of the problem in which the research is going to be undertaken.
- Magnitude of the problem in terms of morbidity, mortality, disability, suffering and socioeconomic consequences.
- A brief statement of what is already known about the condition, depending on the review of literature.
- A statement on what is not known, or areas where gaps in knowledge still exist and which need to be filled.
- What is the research question to be answered in this proposed study. This will include a paragraph giving general statement, enunciating the broad issue of the study.
- A final paragraph should be written on how the study findings will contribute to the existing knowledge, and help in improving the health care or clinical practice.

**Aim and objectives** : The AIM is a general statement about the research question. The OBJECTIVES are very specific issues through which the aim is going to be achieved. Be very careful while writing down your objectives, since any funding agency will examine them very closely. Secondly, you are also expected to fulfill these objectives at the end of your research and hence, do not keep such objectives which you are doubtful that you will be able to complete them at all.

**Review of Literature** : Brief review of literature of 3 to 4 double spaced typed pages should be given. The review should generally be of the "recent literature" (i.e. past 5 years or so). The review should bring out the definition of the condition of interest, the magnitude of the problem, a review of what is already known about the topic of research and finally a review of the gaps which exist in the present body of knowledge as far as it pertains to the proposed research.

**Material and Method** : This is the "heart" of the research protocol. Great care should be exercised while writing this part. In general, the following aspects should be clarified in adequate detail, point wise.

**General settings and time line** : Define the general settings, i.e. whether the study will be done in a hospital or in general community, the type of hospital (primary / Secondary / Tertiary level or OPD), or the community (Urban, Slums, Rural) etc., and the time - line.

**Study design** : Specify the exact study design (e.g. "cross - sectional analytical study"). In a few lines, describe as to why this particular study design is being used as compared to the other available study designs.

**Reference and Study (Actual) population** : Define the reference (total) population on which the study results will be generalised. Next, define the actual (study) population from which the study sample will be drawn. Add a line to justify that the actual (study) population is a reasonably representative subset of the total (reference) population.

**Sample size** : Clearly specify the statistical procedure that you have followed for calculating the sample size. Do consult a epidemiologist or statistician since this heading is quite thoroughly scrutinized by various research bodies.

**Sampling method** : Describe as to what will be the sampling ratio, how the "sampling frame" will be developed and by which particular sampling method (simple random, systematic random, multistage, cluster, stratified random, etc.) will the sample be drawn from the actual (study) population.

**Exclusion criteria** : If you are having "exclusion criteria", then be very specific in defining them; e.g. "all cases who have undergone hysterectomy will not be included in this study".

**Specify the variables** : Specify the variables of interest under the headings of Exposure variable(s) of main interest, Other exposure variables, Outcome variables (Primary outcome variable and secondary ones, if applicable) and the Potential Confounding Variables.

**Instruments** : Give a clear description of all instruments that will be used to collect the data. This should include the physical instruments (e.g. sphygmomanometer), or laboratory instruments (e.g. stereoscopic microscope) or special instruments (e.g. portable 12 lead ECG machine) and the Questionnaire (remember, Questionnaire is also an instrument).

**Techniques** : Give a clear description of the technique of using the instruments and making the measurements. In addition, give a description of who will collect the data (e.g. by the principal worker, trained interviewers, trained laboratory technicians etc.). Finally, make a mention as to how training in data collection will be imparted and how testing and certification of the data collectors will be done.

**Details of randomization, blinding and Intervention** : If the study involves any intervention (e.g. drug, vaccine, program, therapeutic procedure, etc.), then give a very clear and detailed description of the process of Random allocation, the details of blinding (single / double) and the "intervention" which is going to be studied (who will do what to whom, how and how frequently). Even minor points like dose, formulation and frequency of administration of the drug or details of operative procedure must be mentioned. Similarly, details of "Placebo" in case of a clinical trial should be mentioned.

**Follow up procedures** : In a cohort study as well as a experimental design, mention the details as to how the follow up of the two groups will be done, including details as who will be ascertaining the final and interim outcomes, when and where. In addition, give a clear description of modalities of "retrieving" those who are getting lost to follow up.



**Description of gold standard test in diagnostic test study :** In a study proposing to evaluate the performance of a diagnostic test, including clinical algorithms, a detailed description of the “gold standard” against which the current test under study will be evaluated, should be given.

**Pilot study :** In case a pilot study would be done to refine the material and methods, then give a clear description of how many subjects will be required for the pilot study, how will they be sampled, and whether the pilot study subjects are likely to be included in the main study or not, going a brief justification for the same.

**Issues of analysis :** A general description must be given in the protocol as to what statistical procedures will be used for the basic analysis or for advanced issues like control of confounding. In case the help and guidance of a research methodologist or biostatistician will be taken for handling issues of advanced analysis, then the same should be mentioned. In addition, if data management by computerisation is planned, then a brief description of computer packages should be given. In clinical trials, details of stoppage rules and “intention to treat analysis” if applicable, should be clearly brought out.

**Ethical issues :** Most research bodies now need the proposal to be cleared by the Institutional Ethical Committee and this should be ensured and, for animal experiments, separate clearance by Institutional Animal Experiments Ethical committee.

**Financial Details :** This paragraph is mandatory for any study which seeks “funding” from any Governmental or Non Governmental organisation. A detailed description of financial requirements, according to instruments, reagents, drugs, salaries, office contingencies etc. should be made, phase - wise or financial year wise. Work out the financial requirements meticulously, catering to the inflation rates. Contact the various dealers and make an on - ground estimate of prices as well as availability of the equipment, reagents etc. Remember, do not simply go by guess works or estimates made by some other workers or in the past; such an action has been a cause of major embarrassment for many workers.

**References :** This is the last section. The details of writing the references have already been presented in earlier chapter on writing a research paper.

**Annexures :** Annexures may be attached to clarify in greater detail, the following

- A particular aspect which has not been clarified adequately in the “Material and Method” section because the same would have become unnecessary voluminous.
- Detailed description of terms and phrases.
- Detailed techniques of making clinical measurements and protocols.
- Minute details of the intervention measure to be used in the proposed study.
- The questionnaire or schedule for recording the data.
- Clearance certificate from ethical committee.
- Minute details of expenses or equipment, instruments etc.

## Summary

Introduction to a research proposal should give a good overview of the background importance about the area of study and the

relevance of the proposed work. It should be limited to 400 to 600 words. It should elaborate upon definition, magnitude of the problem, what is already known and not known about the condition, and the research question to be answered in the proposed study. A final paragraph should be written on how the study findings will contribute to the existing knowledge, and help in improving the health care or clinical practice.

Aim and objective of the research proposal must be lucid and achievable so as to stand scrutiny of journal or funding organization. Material and Method should cover General Settings and Time Line of the study, Study design, Reference and Study (Actual) population, Sample size, Sampling method, Exclusion criteria, Variables of study, Instruments, Details of randomization, blinding and intervention, Follow up procedures (if applicable), Description of gold standard test in diagnostic test study, Pilot study and issues of analysis (statistical procedures, computer based data management etc.).

Ethical clearance of the research proposal from institutional Ethical Committee must be taken. For animal experiments, separate clearance by Institutional Animal Experiments Ethical committee is required. A study requiring funding must clearly spell out realistic financial requirements catering to inflation. Details of planned expenditure should be given phase wise or financial year wise and must cater for inflation to avoid hardships at later date.

Last section consists of references. Serially numbered references may be given. For additional details, annexures may be attached containing detailed description of terms and phrases, details of techniques of making clinical measurements, protocols, the questionnaire or schedule for recording the data and clearance certificate from ethical committee. A particular aspect which has not been clarified adequately in the “Material and Method” section because the same would have become unnecessary voluminous may be elaborated in an Annexure.

## Study Exercises

**Long Question :** You are desirous of undertaking a research work in a community development block area among married women aged 19 to 45 years on the usage, acceptance and factors associated with the acceptance and discontinuation of IUD and oral contraceptive usage. You want to approach the ICMR for funding and support to this research project. Give an outline of the proposal that you will write with this background.

### MCQs & Exercises

1. The introduction of a research proposal should generally be limited to (a) Within 100 to 200 words (b) Within 300 to 500 words (c) Within 300 to 400 words (d) Within 400 to 600 words.
2. The following is a general statement about the research question : (a) Aim (b) Indicator (c) Target (d) Objective.
3. What are those are very specific issues through which the aim is going to be achieved : (a) Targets (b) Goals (c) Purpose (d) Objectives.
4. Read the following statement : “A researcher should be very careful while writing down objectives, because (A) Any funding agency will examine them very closely (B) He is expected to fulfill these objectives at the end of research and hence must not keep such objectives which

he is doubtful that he will be able to complete them at all". Now, based on above statement, choose the correct option among following : (a) Both A & B are true (b) A is true, B is false (c) B is true, A is false (d) Both A and B are false.

5. What is the "heart" of the research protocol? : (a) Aim and objectives (b) Review of literature (c) Statistical procedures applied (d) Material and Method.
6. Questionnaire is an instrument - True or False?
7. Details of "Placebo" in case of a clinical trial should be mentioned - True or False?
8. Choose the incorrect match : (a) Financial requirements : The inflation rates; (b) Review of literature : Past five years or so; (c) Study design : Gold standard test; (d) Issues of

analysis : Computer packages.

9. A particular aspect which has not been clarified adequately in the "Material and Method" section because the same would have become unnecessary voluminous may be elaborated in : (a) Annexure (b) Analysis (c) References (d) Review of Literature.
10. Clearance certificate from ethical committee may be attached in which of the following sections : (a) Materials and method (b) References (c) Annexure (d) Review of literature.

**Answers :** (1) d; (2) a; (3) d; (4) a; (5) d; (6) True; (7) True; (8) c; (9) a; (10) c.

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### Critical Appraisal of a Published Article

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The issue of critical appraisal of a published article in a journal is of much importance to every Public health specialist as well as for the clinician. As Post - Graduate students in the respective specialities, we have periodic "journal clubs" during which research articles are critically evaluated. As practising Doctors, we need to advance our knowledge constantly, by reading the various articles. Similarly, as public health functionaries and senior level health care administrators, we have to keep abreast regarding the contemporary practices in health care administration, therapies, equipment, diagnostics and the financial implications. From the research methodologist's perspective, reading a journal needs a series of well planned sequential steps. The following is a check list proforma :

#### Step 1 : Deciding whether I should Read this Article

- (a) Look at the title : Is it interesting ?; Likely to be useful in your practice? Yes/No.
- (b) Look at the Abstract : Will the conclusions (if valid), likely to be useful to you, in your area of clinical practice or research areas ? Yes / No.
- (c) Quickly browse through the 'Materials and Methods' section. See if the 'settings' are similar to your own settings of practice (may be dissimilar because of different facilities, different technological availability, grossly different demographic profile of patients, or the level of medical care in which the study was done) - Yes/No

If answers to 1 (a), (b) & (c) are Yes for two or more question, go ahead and start reading the article. Keep giving your comments on a separate paper, as per the general check - list presented in the subsequent paragraphs :

#### Step 2 : Assess the Research Question of the Authors

- (a) Is there a well defined, clear cut and specific research question?
- (b) Was it feasible for the authors to study this question, given their technical expertise, available facilities, etc.
- (c) Does the research question has some element of novelty (is likely to add to existing knowledge rather than reconfirming the already well established facts).

#### Step 3 : Assess the Issues of Internal / External Validity, Bias and Methodology in the Study

- (a) Have the authors made a mention (explicit or at least, implicitly) of the -
  - (i) Total (Whole; Reference) Population ?
  - (ii) Actual (study) Population ?
- (b) Is the actual (study) population from which sample was drawn likely to be a "representative subset" of the total population (If no, then external validity / generalisability will be restricted)
- (c) Have the authors :
  - (i) Calculated the sample size ?
  - (ii) Whether they have specified the parameters like Type - I (alpha), Type - II (Beta) errors, OR or RR to be detected, expected Po, or Mean and SD, and acceptable deviation (as applicable to the study design), while calculating the sample size?
  - (iii) Are the above parameters, if specified, likely to be correct / realistic.
- (d) Have the authors :
  - (i) Described the method of sampling ?
  - (ii) Is the method of sampling based on some random (probability) method ?
- (e) Have the authors explicitly mentioned :
  - (i) The exposure variable(s) (only for an analytic design).
  - (ii) The outcome variable(s) (for all types of designs).

- (f) Have the authors clearly identified all the potential confounding factors (PCFs)?
- (g) Have they adequately covered for all PCFs by taking action during designing (Randomisation/ Restriction/ Matching) or during analysis (Standardisation / Stratified analysis/ Mathematical modelling) ?
- (h) What are those PCFs which have either not been considered at all, or else not controlled during design/ analysis ?
- (j) Have the authors clearly described the following items used by them in this study :
  - (i) Physical instruments and reagents ?
  - (ii) Questionnaire ?
  - (iii) Any other scales (e.g. psychological assessment scale).
  - (iv) Definitions of terms and diagnostic criteria for various diseases ?
  - (v) Techniques of using the instruments, questionnaires, scales, etc. ?
  - (vi) Are the techniques of measurement, the definitions of terms and diagnostic criteria used by the authors based on some accepted standards? Have they quoted the references?
- (k) Have the authors mentioned as to how they have standardized / validated :
  - (i) Physical instruments ?
  - (ii) Questionnaires ?
  - (iii) Any other “scales” used by them ?
  - (iv) Quality control procedures during the conduct of study?
- (l) Could any of the following biases have occurred in the study ?

Bias	Yes/ No/NA	If yes, briefly comment as to how
<b>Selection bias</b>		
Referral		
Self selection		
Berkson's		
Survivorship		
Healthy worker		
Exposure related		
<b>Information Bias</b>		
Recall / reporting		
Detection		
Observers'		
Cross over		
Contamination		
Co - intervention		
Loss to follow up		
<b>Note : NA stands for “Not Applicable”</b>		

#### Step 4 - Analysis

- (a) Has the data been presented in a simple, intelligible

form?

- (b) Are the statistical tests “correct” for the type of variables being analysed?
- (c) Have the authors worked out the measures of ‘effect’ (i.e. RR or OR) (as applicable to the research question) ?
- (d) Have the authors worked out the 95% CI of the various estimates?
- (e) Have the authors correctly controlled for confounders, in analysis, and worked out the independent, adjusted estimates (e.g. by stratified analysis or by regression analysis).
- (f) Have the authors assessed effect modification?

#### Step 5 - Conclusions

- (a) If the findings are ‘statistically significant’, are they also of clinical/ public health significance/relevance?
- (b) If the findings are ‘statistically non significant’ is it possible that a real effect may have been missed due to “low study power” as consequence of low sample size (Have the authors back calculated the study power; alternatively calculate it yourself)?
- (c) Are the conclusions drawn by the authors based on the actual findings of the study?
- (d) Do you think the study results can be gainfully utilized in your own clinical / preventive / public health practice?

#### Step 6 - Additional Actions for Specific Situations

Check the following special points depending on the type of study objective.

##### (a) For a study assessing the efficacy of a therapeutic or preventive procedure :

- Was allocation to the intervention and control groups done by ‘Randomisation’ ?
- Were the 2 groups similar on baseline comparison ?
- Were all the clinical/health relevant outcomes (good as well as bad) considered ?
- Has the therapeutic / preventive procedure studied, been described in adequate detail?
- What was the level of control? : Placebo control/Non placebo control/ Uncontrolled.
- What was the level of blinding? : Triple / Double/ Single blinding / Unblinded.
- Was the trial ethical?
- Were all the subjects who entered the study accounted for in the final analysis?
- What was the proportion of “lost to follow up” ?

##### (b) For a study assessing the role of a risk factor / causal factors

- What was the strength of the design itself, as per following hierarchy? :

Very strong	Moderately strong	Minimal strength	Weak
Experimental	Cohort	Cross sectional analytic, Case control	Ecological

- What is the strength of association (as seen by RR or OR)?

- Is the association significant (as seen by test of significance and 95% CI of RR) ?
- Is the temporal relationship (cause or exposure definitely preceded the effect or outcome) definitely demonstrated ?
- Does the association stand to reasoning ?
- Is there a dose response relationship ?

**(c) For a study dealing with clinical course and prognostic factors**

- Was an 'inception cohort' assembled ?

(subjects should be identified at an early and uniform point (inception) in the course of their disease, such as when they develop unambiguous symptoms or receive their first definitive therapy)

- Was the "referral filter" of the subjects to the health care facility, where the study was done, adequately described?
- Was clinical status of all patients who entered the study accounted for in, the end?
- Were the prognostic outcomes clearly defined ?
- Was the outcome assessment done by physicians who were 'blinded' to the other features of patients ?

**(d) For a study on evaluation of a diagnostic test**

- Was a proper 'Gold Standard' of diagnosis described and used?
- Was the test or clinical rule being studied clearly described?
- Were ALL subjects subjected to BOTH, the test under study as well as the gold standard test?
- Was the evaluation of test results done by observers who were 'blinded' to the results of Gold Standard test?
- Did the subject sample contain an appropriate 'spectrum' of the target disease? (mild, moderate, severe, atypical, other closely related diagnoses).
- Were the "settings" of study adequately described?
- Was the "referral filter" through which subjects passed before reaching the settings of present study adequately defined?
- Was the reproducibility of test (the range of variations due to observers, subjects, instruments and techniques) adequately studied and defined?
- Were the techniques of carrying out the test under study adequately described?
- Was the "utility" of the test determined? (i.e. whether the authors went beyond the issues of validity and reliability to describe the consequences of the test - whether it really contributed to better patient management or favourably changed the disease outcome for which the test is designed).

## Summary

The issue of critical appraisal of a published article in a journal is of immense importance to every Public health specialist and health administrator to keep abreast regarding the contemporary practices in health care administration, therapies, equipment, diagnostics and the financial implications. It is equally useful for the clinicians who need to advance their knowledge constantly by reading various articles.

Reading a journal needs a series of well planned sequential steps beginning with decision whether one should read this

article at all. It is judged by the title, abstract, materials and methods. Next step is to assess the research question - whether it is clear cut, feasible and novel. Readers should also assess the issues of Internal / external validity, bias and methodology in the study. It should be seen if description is made of Reference Population and Actual (study) Population. Make a note whether issues pertaining to sample size, specifying of Type - I and Type - II error and exposure and outcome variables have been made. Note whether potential confounding factors have been identified and controlled for. Standardization and validation of various instruments including questionnaire, and the possibility of various forms of selection and measurement etc. should also be looked into.

Next step is to check the analysis of the research paper. Examine the mode of data presentation, statistical tests applied, measures of 'effect' and control of confounders. Finally, see if results are statistically significant and if not, is it due to effects of low power study consequent to a small sample. Also confirm the utility of the findings in clinical or public health practice.

Additional points should be seen in specific situations; for example, in a study assessing the efficacy of a therapeutic or preventive procedure, specifically check for randomisation, baseline comparison, outcome measures and placebo control. Examine if double or single blinding was done or it was an unblinded trial. Reader must check issues of ethics and loss to follow up which may have lead to vitiation of study results. For a study assessing the role of a risk factor / causal factors one should examine strength of the study design, strength and significance of association, temporal relationship, logical reasoning and dose response relationship. In a study dealing with clinical course and prognostic factors, one must check for inception cohort, referral filter, and prognostic outcomes.

For a study on evaluation of a diagnostic test, readers should examine the Gold Standard of diagnosis and whether all subjects were subjected to both tests. Check if study population had appropriate 'spectrum' of the target disease in form of mild, moderate, severe, atypical, and other closely related diagnoses. Also check the "settings" of study, referral filter, and reproducibility of the test under study. An important component is "utility" of the test i.e. whether it really contributed to better patient management or favourably changed the disease outcome for which the test is designed.

## Study Exercises

### MCQs

1. Read the following two statements : (i) For a practicing Doctor critical appraisal of a journal article is useful. (ii) It advances his knowledge constantly. Based on above, choose the correct option : (a) Both (i) and (ii) are true (b) Both (i) and (ii) are false (c) (i) is true and (ii) is false (d) (i) is false and (ii) is true.
2. For a study assessing the role of an exposure in leading to an outcome, what is the correct hierarchy as per strength of the design : (a) Experimental > Cohort > Cross sectional analytic and Case control > Ecological (b) Ecological > Experimental > Cohort > Cross sectional analytic and Case control (c) Experimental > Cross sectional analytic and Case control > Cohort > Ecological (d) Cohort > Experimental >



Cross sectional analytic and Case control > Ecological.

3. Which of the following should be examined to decide whether one should further read a particular article in detail : (a) Title (b) Abstract (c) Material and Method (d) All of above.
4. What are available methods for a researcher to control for PCFs by taking action during design stage? : (a) Randomisation (b) Restriction (c) Matching (d) All of above.
5. What are available methods for a researcher to control for PCFs during analysis? : (a) Standardisation (b) Stratified analysis (c) Mathematical modeling (d) All of above.
6. Referral, Self selection, Berkson's, Survivorship, Healthy worker, Exposure related are all which type of Bias : (a) Selection bias (b) Information bias (c) Both of above (d) None of above.
7. The strength of association is seen by : (a) RR (b) OR (c) Both of above (d) None of above.
8. To see whether a diagnostic test really contributed to better patient management or favourably changed the disease outcome for which the test is designed, which of the following parameter is used : (a) Validity (b) Reliability (c) utility (d) None of above.
9. Test of significance and 95% CI of RR are used to determine : (a) Statistical significance (b) Strength of association (c) Temporal relationship (d) Dose response relationship.
10. Stratified analysis or regression analysis is used to work out : (a) RR (b) OR (c) Controlling for confounding during analysis (d) None of above.
11. Randomisation is an important step for : (a) A study assessing the role of a risk factor / causal factors (b) A study dealing with clinical course and prognostic factors (c) A study on evaluation of a diagnostic test (d) A study assessing the efficacy of a therapeutic or preventive procedure.

**Answers :** (1) a; (2) a; (3) d; (4) d; (5) d; (6) a; (7) c; (8) c; (9) a; (10) c; (11) d.

## 36

### Ethical Issues in Epidemiology & Medical Research

*RajVir Bhalwar*

The issues of ethics in medical practice are being increasingly talked about, not simply in medical circles but even in legal, societal and similar “outside - the - medical - fraternity” echelons. Most of these issues naturally pertain to clinical practice, ranging from negligence to frank malpractice. While considerations for ethics in the individualised clinical practice are well understood, the question that arises is whether epidemiology and medical research should also be subject to ethical regulations? If yes, why?

First of all, let us define “Ethics”. It has been defined as “a set of principles of right conduct”. In the medical sense, it has also been defined as “the principles and norms of proper professional conduct concerning the rights and duties of health care professionals themselves and their conduct toward patients and fellow practitioners, including the actions taken in the care of patients and family members”.

Though the ethical practice of health dates back to ancient times, however, the concept of “bioethics” took birth due to the experiences of the Second World War and the atrocities conducted in the name of medical research by Nazis among inmates of concentration camps. As a result, a code of conduct for human research was established. In 1964, the World Medical Association Declaration of Helsinki took this process a step further and underscored certain basic principles for the conduct of human biomedical research (115). More recently, in our country, the ICMR has published detailed guidelines regarding ethics in biomedical research (116). The crux of the

Helsinki declaration is presented at the end of this chapter as an appendix.

**Is Epidemiology and Medical Research different from Clinical Practice as far as Ethical Reasons are concerned ?**

The answer is yes, it is different and it is so because of two reasons. Firstly, clinical practice is applied on a single individual, the patient, who directly bears the consequences of unethical practice of his or her physician, while epidemiology and medical research is undertaken on a large group of humans and any unethical practice would therefore affect these large numbers. Secondly, the results of epidemiological and medical research studies nearly always have policy implications which may be, at times, very far reaching and are applied on the entire community or nation (for example, when John Snow removed the handle of the broad street pump and showed that cholera is transmitted by contaminated water, it had deep policy implications). Compromise in ethics in any sequence of epidemiological or medical research study will therefore lead to a policy which may be unsound, even unethical!

**What are the Basic Principles of Ethics in Epidemiology and Medical Research**

The basic principles of ethics in epidemiology and medical research are, in fact, common - sense statements, as follows :

**Principle No. 1 :** No human being should be exposed to any form of intervention which is likely to be hazardous to human health, safety or well being, just because epidemiological or research principles dictate so. This principle becomes quite relevant in intervention (experimental) type of epidemiological studies. To satisfy this principle, no treatment or preventive procedure should be tried out in human research until its pharmacokinetics and pharmacodynamics have been adequately

studied and it has been clearly shown to be safe & free of toxicity, carcinogenicity, mutagenicity and teratogenicity, in animal studies. Only after these considerations have been met, should the human trials start as phase - 1 trials.

**Principle No. 2 :** No human being should be denied a treatment or such other intervention which is known to be effective for that particular disease, just because epidemiological or research principles dictate so. Once again, this principle is mainly concerned with experimental studies, since in the process of randomization, two groups will be formed, one of which will be offered the new intervention while the other will be offered the standard (existing) modality of treatment / prevention. Now, if the standard treatment is itself known to be very effective against the disease, then, naturally, the intervention group will be denied this modality. For example, we may be trying out a new antibiotic for treatment for streptococcal pneumonia against the standard treatment with penicillin. Now, penicillin is known to be an excellent treatment modality for this condition and the intervention group (which will get the new antibiotic) will naturally be denied this modality. This aspect should be an important consideration for Institutional Ethical Committees (IEC).

**Principle No. 3 :** Confidentiality of participants and of the information given by them should be protected. This is a very important issue for all types of epidemiological studies (observational as well as interventional) and becomes, at times, quite difficult to ensure. For instance, there could be occasions when the epidemiologist may be required by law to divulge the information. At times this divulgence may itself be an ethical requirement, if not legal. For example, if during a study on the blood donation practices of HIV infected persons, some of the HIV positive subjects, who have been found positive within the past few days, tell the investigator that they have donated blood, within the past 4 weeks ! Should the investigator go back to the respective blood banks and inform them to incinerate the blood units of these persons, though he has initially promised them confidentiality? However, notwithstanding these tricky issues, which would need to be decided by a consensus, the confidentiality of persons and the information given by them should be protected, as far as possible. The following steps may be utilized :

- Informed consent should be taken from all subjects and they should be clearly informed that their confidentiality would be protected and of the situations when the epidemiologist may need to divulge their personal identification or the information they have provided. Only after an informed consent has been taken after such briefing of the subjects, should the investigator proceed with collecting the data.
- If information is being obtained from medical or administrative records, the requirements of confidentiality as stipulated by the officer in charge of these records, should be followed.
- All data should be kept under lock and key under the personal custody of the investigator.
- Only "code numbers" should be mentioned on the data forms and no other personal identifier should be mentioned. The key for linking these code numbers with the original individual names should be kept separately

under a lock and key, under personal custody of the principal investigator.

- "Individual Identifying Information" should be destroyed at the end of the epidemiological / research study, unless there is specific justification for retaining this information; if so, this should be additionally permitted by the IEC.
- All results should be published only in the aggregate or group form, so that individual subjects are never identified in the final report.
- In general, individual identifying information should not be entered on computer files and individual identifiers should not be included in routine tabulations generated from computerized data.
- The importance of maintaining confidentiality should be regularly impressed upon the research staff.

**Principle No. 4 :** Any human being should participate in an epidemiological or medical research study only after he / she has been clearly informed of the scope of the research, and having been so informed, the subjects should consent to participate, of their own free will, without any force, coercion or undue motivation (this is the principle of 'informed consent'). Informed consent includes the following facets :

- The subjects should be clearly informed of the scope of the trial, the major advantages as well as adverse effects of all the modalities (both the intervention as well as control modality).
- They should be clearly told that they would get either of the new intervention modality or the control modality, purely decided by luck (as by drawing a lottery) and that getting the trial or control modality will not be based on their or the investigator's desire.
- No coercion, force, or undue motivation is undertaken for getting the subjects to agree to participate.
- That the subjects are in a fit state to decide for themselves whether they wish to participate or not.
- Having so informed, as above, the subjects agree to participate, of their own free will and accord.
- It is always desirable to have a written informed consent. It should be obtained from the participant or his / her legally authorized representative.

**Principle No. 5 :** No incentives or pressure should be there to force or lure the subjects into the study.

**Principle No. 6 :** In case of any harm resulting due to the research, on the health of a subject, there should be adequate treatment and compensation. The investigators should make available facilities for management of any side effect / complication that may occur in any subject as a result of participation in the trial; for permanent damages / disabilities, suitable compensation as decided by existent laws should be available.

**Principle No. 7 :** The people who are doing the research should be adequately qualified / competent to undertake the same and the research should be executed using sound research methods. This aspect should also be considered by the IEC and Institutional Review Boards (IRBs) since a research which lacks scientific rigour or does not conform to the laid down principles of research methodology, is as unethical as one which does not follow the other principles of ethics.

**Principle No. 8 :** (The principle of justice). This says that the benefits and burdens of research and epidemiology should be distributed fairly. To elaborate, this means that people living in poverty (as large populations of developing countries), those who have poor access to health care or who lack adequate capacity to make informed choice, may all seem very attractive to conduct research but as a principle, such populations should not be targeted if other populations could also be suitable participants.

**Principle No 9 :** The participants should be informed of the information which has resulted from the research, about themselves, as well as provided guidance regarding the future course of action they should undertake. For example, during the conduct of a survey, subjects who have found to be hypertensive, should be informed about the same and guided as regards lifestyle changes as well as further diagnosis and management if required.

**Principle No. 10 :** Research on animals should be undertaken only when it is absolutely essential and the animals should be treated/sacrificed in humane manner. It is advisable that any research involving animals should be deliberated upon & cleared by "Institutional ethical committee on animal research".

### Institutional Ethical Committee (IEC)

Every institution where health research is taking place should have an IEC, which should review and clear research proposals before they are actually launched. The details of IEC are given in the ICMR document (116) and readers are advised to go through the same. In general, the constitution may be as follows :

- The chairperson should be an eminent person with a well documented record in health research, and should be from outside the institution to give independence of judgement to the committee.
- The secretary should be from within the institution and should be a person with well documented track record in academics and health research.
- Eminent academicians and researchers from various specialities; it is suggested that at least the professor or advisor in one of the basic medical sciences, and from the departments of surgery, medicine, pathology, community medicine and pharmacology be members.
- One member from legal field.
- One independent member representative from the community, with track record in community work.
- Officer in charge of animal house.
- Any other member(s) depending on the type of research may be co-opted for particular meetings.

The IEC should develop detailed Standard Operative Procedures (SOPs) which should be circulated to all members. All research proposals should be scrutinized by the IEC, after giving adequate notice to all members. The copy of proposals to be considered should be sent to all members well in advance for study. The minimum quorum should be clearly defined. The IEC should meet regularly, at least once in a quarter and records of all meetings, duly signed by all members should be meticulously maintained.

### Conflicts of Interest

Conflict of interest occurs when researchers may have conflicting

interests that may impair their objectivity or make them biased towards or against a research work. Conflicts of interest occurs due to two main reasons :

**Financial conflicts of interest :** Studies of drugs or material / equipment for diagnostics / therapeutics are commonly funded by pharmaceutical industry / firms. If the investigator has some interest in the firm, they may reap large financial rewards if the treatment under study is shown to be beneficial.

**Conflicts of interest because the investigator is also the care provider :** An investigator may be also the health care provider of the eligible research participant. For this reason the patient may consent even if unwilling, or may give biased information.

### Methods to Resolve Conflicts of Interest

- The research proposal should be carefully scrutinized by the IEC and it should be obligatory on the researchers to declare any conflict, especially the possible sources of funding / sponsorship or incentives from any pharmaceutical firm.
- Ensuring rigorous randomization, blinding and placebo control during the trial.
- An independent "data safety monitoring board" whose members have no conflicts of interest regularly review the interim data and terminate the study if the data provide convincing evidence of benefit or harm.
- If the research is directly or indirectly funded by a pharmaceutical firm, the contract should give the investigators the control over the primary data, its statistical analysis and the freedom to publish the findings whether or not the investigational drug or equipment is found to be effective or ineffective.
- The investigators should disclose all possible conflicts of interest in their published article / report.

### Appendix : The Helsinki Declaration - Recommendations guiding doctors in clinical research

(Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964)

#### I. Basic Principles

1. Clinical research must conform to the moral and scientific principles that justify medical research and should be based on laboratory and animal experiments or other scientifically established facts.
2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.
3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.
5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.



## II. Clinical Research Combined With Professional Care

1. In the treatment of the sick person, the doctor must be free to use a new therapeutic measure, if in his judgment it offers hope of saving life, reestablishing health, or alleviating suffering. If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent, after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.
2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

## III. Non - Therapeutic Clinical Research

1. In the purely scientific application of clinical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.
2. The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.
- 3a. Clinical research on a human being cannot be undertaken without his free consent after he has been informed; if he is legally incompetent, the consent of the legal guardian should be procured.
- 3b. The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice.
- 3c. Consent should, as a rule, be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained.
- 4a. The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.
- 4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued.

The investigator or the investigating team should discontinue the research if in his or their judgment, it may, if continued, be harmful to the individual.

## Summary

"Ethics" has been defined as "a set of principles of right conduct". In the medical sense, it has also been defined as "the principles and norms of proper professional conduct concerning the rights and duties of health care professionals themselves and their conduct towards patients and fellow practitioners, including the actions taken in the care of patients and family members". Unlike clinical practice, epidemiology and medical research is undertaken on a large group of humans and any unethical practice would therefore affect these large numbers and also the results of epidemiological and medical research studies nearly always have policy implications.

The basic principles of ethics in epidemiology and medical research are :

- No human being should be exposed to any form of intervention which is likely to be hazardous to human health and no treatment or preventive procedure should be tried out in human research until its pharmacokinetics and pharmacodynamics have been adequately studied and it has been clearly shown to be safe & free of toxicity, carcinogenicity, mutagenicity and teratogenicity, in animal studies.
- No human being should be denied a treatment or such other intervention which is known to be effective for that particular disease, just because epidemiological or research principles dictate so.
- Confidentiality of participants and of the information given by them should be protected.
- Any human being should participate in an epidemiological or medical research study only after informed consent.
- No incentives or pressure should be there to force or lure the subjects into the study.
- In case of any harm resulting due to the research, on the health of a subject, there should be adequate treatment and compensation.
- The people who are doing the research should be adequately qualified / competent.
- The principle of justice says that the benefits and burdens of research and epidemiology should be distributed fairly.
- The participants should be informed of the information which has resulted from the research, about them, as well as provided guidance regarding the future course of action they should undertake.
- Research on animals should be undertaken only when it is absolutely essential and the animals should be treated/ sacrificed in a humane manner.

Every institution where health research is taking place should have an Institutional ethical committee (IEC), which should review and clear research proposals before they are actually launched. Conflicts of interest occur due to financial reasons and when the investigator is also the care provider. Few important methods to resolve these conflicts are scrutinizing research proposal carefully by the IEC, ensuring rigorous randomization, blinding & placebo control; by disclosing all possible conflicts in their published article/report & other methods.

## Study Exercises

**Short Notes :** (1) Basic principles of ethics in epidemiology and medical research (2) Institutional ethical committee

**MCQs :**

1. Which is false about Institutional ethical committee (a) The chairperson should be an eminent person with a well documented record in health research (b) The chairperson should be from within the institution (c) The secretary should be from within the institution (d) It reviews and clears research proposals before they are actually launched.
2. Method to resolve the conflicts of interest in a medical research is (a) Scrutinizing research proposal carefully by the IEC (b) Ensuring rigorous randomization, blinding and placebo control (c) By disclosing all possible conflicts in their published article (d) All the above.

**Answers :** (1) b; (2) d.



## 37 Qualitative Research : An Overview

Vijay K. Bhatti

Research in the field of bio-medicine has produced many significant achievements in the last century leading to a radical change in the experience of health and illness, however many problems of today cannot be solved or understood by biomedicine alone. This is primarily because of the fact that many of the health problems are fundamentally problems of interpretation and meaning; and a complex interplay of social factors. The following questions raise doubts about the adequacy of only quantitative research as a research method to answer various research questions in the field of health :

- “Why is it that people continue to smoke when the evidence about harmful effects of smoking is all around them and known to those who smoke?”
- “Why do people often not take the medicine prescribed for them?”
- “Why do many people not wear seat belts and helmets in spite of knowing that wearing them will save them if an accident occurs?”
- “What difference has the involvement of doctors in health management made to the management of health services?”
- “Why is that though we know clearly the biomedical understanding of how HIV/AIDS is transmitted, the problem continues to be.”

These are questions not easily answered by the quantitative research designs used commonly under the umbrella of hard - core epidemiology and research methodology. They are however the type of questions best answered by qualitative research methods instead, an area of research which has gained momentum and importance in recent years.

Quantitative research is concerned with counting and measuring things, producing estimates of averages and differences between groups (e.g. blood pressure of patients treated with two different drugs) whereas Qualitative research has its roots in social science and is more concerned with understanding why people behave as they do : their knowledge, attitudes, beliefs, fears, etc. Qualitative research allows the subjects being studied to give much ‘richer’ answers to questions put to them by the researcher, and may give valuable insights which might have been missed by any other method. It not only provides valuable information to certain research questions in its own right but it is used to complement quantitative research methods. If the area of interest has not been previously investigated, then qualitative research may be a vital forerunner to conducting any quantitative research; for example, it’s impossible to carry out a meaningful structured questionnaire survey on patient satisfaction with a service, if the important issues from the patients perspective, surrounding the provision of that service, are not known. At the other extreme qualitative research also helps one to understand the findings of quantitative research; for example, it is very easy to discover that some patients fail to keep appointments at outpatients clinics, but uncovering the reasons for this can be more difficult and conventional surveys

may miss some of the important factors.

Qualitative research is often done to answer the question *why* rather than *what*. Quantitative research on the other hand involves techniques to quantify distribution and association of certain variables in a study population, mostly to provide proof rather than discovery. Qualitative and quantitative methods are wrongly thought to be competing with each other whereas in reality they are complimentary to each other and skilful combination of both methods can maximize the quality of research and data and reduce chances of bias.

**Definition :** Qualitative research can be defined as a research that seeks the answer to the questions in the real world. It has a person centred perspective. Qualitative research is a form of social enquiry that focuses on the way people interpret and make sense of their experiences and the world in which they live.

**The characteristics and aims of qualitative research:** Different types of qualitative research have common characteristics and use similar procedures while differences in data collection and analysis do exist. The following are part of most qualitative approaches:

- (a) Researcher focuses on the everyday life of people in natural settings
- (b) The data have primacy; the theoretical framework is not predetermined but derives from the data.
- (c) Qualitative research is context bound - this means that the researcher has to be sensitive to the context of the research and immerse himself in the settings and the situation.
- (d) It focuses on the views of the people involved in the research and their perceptions, meanings and interpretations.
- (e) Data collection and analysis generally proceed together and interact with each other.
- (f) It uses open ended methods.
- (g) It involves respondents as active participants rather than subjects

The differences between qualitative and quantitative research are given in Table - 1.

### Qualitative Data Collection Techniques

Several methods exist for data collection in qualitative research, however there are three main methods of data collection, namely Participant Observation (Descriptive observations of verbal and non - verbal behaviour), Interactive interviewing (People asked to verbally describe their experiences of phenomenon), and written descriptions by participants (People asked to write descriptions of their experiences of phenomenon). In the succeeding paragraphs, we will discuss only the more important and commonly used techniques (in-depth techniques).

#### Participant Observation

Observation is one of the strategies in data collection. The researcher as observer looks at places and people in their natural settings. Qualitative researchers use the term ‘participant observation’, a term originally coined by Lindemann (1924).

Participant observation always takes place in community settings, in locations believed to have some relevance to the research questions. The method is distinctive because the researcher approaches participants in their own environment

rather than having the participants come to the researcher. Generally speaking, the researcher engaged in participant observation tries to learn what life is like for an “*insider*” while remaining, inevitably, an “*outsider*”. In the community setting, the researcher makes careful, objective notes about what he sees, recording all accounts and observations as field notes in a field notebook. Informal conversation and interaction with members of the study population are also important components of the method and should be recorded in the field notes, in as much detail as possible.

**Table 1 : Distinction between Qualitative and Quantitative Methods**

Qualitative Methods	Quantitative Methods
Provides depth of understanding	Measure level of confidence
Ask why?	Ask “how many?” “how often” ?
Study motivations/ intentions/reasons	Study action / manifested behaviour
Are subjective	Are objective
Enable discovery	Provide proof
Are exploratory	Are definite
Interpret	Describe
Instruments use more flexible, iterative style of eliciting and categorizing responses to questions	Instruments use more rigid style of eliciting and categorizing responses to questions
Use semi - structured methods such as in - depth interviews, focus groups, and participant observation	Use highly structured methods such as questionnaires, surveys, and structured observation
Describe and explain relationships	Predict causal relationships
Describe individual exp-eriences. Describe group norms	Describe characteristics of a population
Data format is Textual (obtained from audiotapes, videotapes, and field notes)	Data format is Numerical (obtained by assigning numerical values to responses)
Participant responses affect how and which questions researchers ask next	Participant responses do not influence or determine how and which questions researchers ask next
Study design is iterative, that is, data collection and research questions are adjusted according to what is learned	Study design is subject to statistical assumptions and conditions

It involves establishing a rapport in the community, learning to act so that people go about their work as usual, undisturbed

by the researcher’s presence. To be an efficient participant observer one needs to have the skills of knowing the native language of the researched, having explicit awareness of own behaviour, having a good memory, maintain consciously a naiveté (in order to genuinely know maximum possible about the researched). Refer Table - 2 & 3.

**Table - 2 : Strengths and weaknesses of participant observation**

Strengths	Weaknesses
Allows for insight into contexts, relationships, behaviour	Time - consuming
Can provide information previously unknown to researchers that is crucial for project design, data collection, and interpretation of other data	Documentation relies on memory, personal discipline, and diligence of researcher
	Requires conscious effort at objectivity because method is inherently subjective

### Questions to be Asked in the Observation

The ‘*who*’ questions - who all are in the setting, how many people are present ? What are their characteristics and roles?

The ‘*what*’ questions - what is happening in the setting, what are the actions and rules of behaviour/ what are the variations in the behaviour observed?

The ‘*where*’ questions - where do interactions occur? Where are people located in the physical space?

The ‘*when*’ questions - when do conversations and interactions take place? What is the timing of activities?

The ‘*why*’ questions - why do people in the setting act the way they do? Why are there variations in behaviour?

**Participant observation in action, an example :** In the early 1990s, sharing needles during injection drug use was a known risk factor for HIV acquisition in the United States. After educational campaigns informed injection drug users about the importance of using clean needles, surveys indicated that needle - sharing had declined. High rates of HIV transmission persisted among this population, however. An anthropologist’s observation of heroin users in one state confirmed that users were not sharing needles. In observing the preparation process leading up to injection, however, the anthropologist noticed numerous opportunities for cross - contamination of the instruments shared in cooking and distributing the heroin (such as cooking pots, cotton, and needles) and of the liquid heroin itself. Discovery of this phenomenon through participant observation, constituted an important contribution to understanding injection drug use behaviour as related to HIV acquisition. The phenomenon itself is now known as “indirect sharing.”

<b>Table - 3 : What to observe in participant observation</b>		
<b>Category</b>	<b>Includes</b>	<b>Observation to make</b>
<b>Appearance</b>	Clothing, age, gender, physical appearance	Anything that might indicate membership in groups or in sub - populations of interest to the study, such as profession, social status, socioeconomic class, religion, or ethnicity
<b>Verbal behaviour and interactions</b>	Who speaks to whom and for how long; who initiates interaction; languages or dialects spoken; tone of voice	Gender, age, ethnicity, and profession of speakers; dynamics of interaction
<b>Physical behaviour and gestures</b>	What people do, who does what, who interacts with whom, who is not interacting	How people use their bodies and voices to communicate different emotions; what individuals' behaviours indicate about their feelings toward one another, their social rank, or their profession
<b>Personal space</b>	How close people stand to one another	What individuals' preferences concerning personal space suggest about their relationships
<b>Human traffic</b>	People who enter, leave, and spend time at the observation site	Where people enter and exit; how long they stay; who they are (ethnicity, age, gender); whether they are alone or accompanied; number of people
<b>People who stand out</b>	Identification of people who receive a lot of attention from others	The characteristics of these individuals; what differentiates them from others; whether people consult them or they approach other people; whether they seem to be strangers or well known by others present

### **In - depth Interviews**

The qualitative in - depth interview is a favoured strategy of data collection in qualitative research and produces rich data. It is a 'conversation with a purpose' in which the interviewer aims to obtain the perspectives, feelings and perceptions from the participants in the research. The in - depth interview is a technique designed to elicit a vivid picture of the participant's perspective on the research topic. During in - depth interviews, the person being interviewed is considered the expert and

the interviewer is considered the student. The researcher's interviewing techniques are motivated by the desire to learn everything the participant can share about the research topic. Researchers engage with participants by posing questions in a neutral manner, listening attentively to participant's responses, and asking follow - up questions and probes based on those responses. They do not lead participants according to any preconceived notions, nor do they encourage participants to provide particular answers by expressing approval or disapproval of what they say. In - depth interviews are usually conducted face - to - face and involve one interviewer and one participant.

The details of conducting interviews have already been covered in detail in an earlier chapter and the readers are advised to go through the same.

### **Key Informant (KI) Interviews**

Key Informant interviews are qualitative, in - depth interviews of 10 to 20 people selected for their first - hand knowledge about a topic of interest. The interviews are loosely structured, relying on a list of issues to be discussed. Key informant interviews resemble a conversation among acquaintances, allowing a free flow of ideas and information. Interviewers frame questions spontaneously, probe for information and takes notes, which are elaborated on later. Key to a KI is selection of the key informant. The KI should be articulate, willing to participate, trustworthy and should have other personal attributes conducive of conducting detailed interviews. The KI is known as key because of his/her unique position in the community by the virtue of which he/she can impart a useful piece of information.

This method is useful in all phases of development activities identification, planning, implementation and evaluation. Specifically, it is useful in the following situations :

- When qualitative, descriptive information is sufficient for decision - making.
- When there is a need to understand motivation, behaviour, and perspectives of our clientele and health partners. For example, In - depth interviews of program planners and managers, service providers, host government officials, and beneficiaries concerning their attitudes and behaviours about a health program activity can help explain its successes and shortcomings.
- When the main purpose is to generate recommendations, Key informants can help formulate recommendations that can improve a program's performance.
- When preliminary information is needed to design a comprehensive quantitative study. Key informant interviews can help frame the issues before the survey is undertaken.

### **Focus Group Discussions (FGD)**

Focus groups discussion is a qualitative data collection method effective in helping researchers learn the social norms of a community or subgroup, as well as the range of perspectives that exist within that community or subgroup. Focus groups seek to illuminate group opinion. This method is especially well suited for socio - behavioural research that will be used to develop and measure health services that meet the needs of a



given population. An FGD requires the following :

- (a) 6 - 12 participants who are willing to talk about the issue under discussion.
- (b) These participants should be as homogenous as possible with respect to their background characteristics.
- (c) There is a moderator conducting the discussion but not leading the discussion.
- (d) There is a recorder who notes down the proceedings and draws the sociogram (a pictorial representation of the way the interactions have occurred between various participants).
- (e) There should be a predetermined FGD guide.
- (f) Recording equipment with a backup should be present.

A focus group discussion is a qualitative data collection method in which one or two researchers and several participants (6 - 12) meet as a group to discuss a given research topic. The discussion is in - depth and is guided by a moderator during which group members talk spontaneously and freely about a certain topic. The aim of the moderator is to use a predetermined pretested line of questioning to stimulate discussion among the participants in order to understand perceptions, interpretations and beliefs of a selected population to gain understanding of a particular issue from the perspective of the group's participants. These sessions are usually tape recorded, and sometimes videotaped. The moderator leads the discussion by asking participants to respond to open - ended questions - that is, questions that require an in - depth response rather than a single phrase or simple "yes" or "no" answer. A second researcher (the note - taker/recorder) takes detailed notes on the discussion. A principal advantage of focus groups is that they yield a large amount of information over a relatively short period of time. They are also effective for accessing a broad range of views on a specific topic, as opposed to achieving group consensus. Focus groups are not the best method for acquiring information on highly personal or socially sensitive topics; one - on - one interviews are better - suited for such topics. Focus groups are commonly used in the following areas :

- (a) Exploratory studies in health issues.
- (b) Testing ideas about acceptances of a new program.
- (c) Solving specific program problems.
- (d) Evaluating health programs.

Specific components of an FGD include *preparation, conduct of the session and decisions regarding number and duration of the sessions.*

#### **Preparation**

**(a) Recruitment of participants :** Participants should be homogenous with respect to the socio - economic group, sex, age and status. It is recommended that one to two FGD be held for each major group of participants.

**(b) Physical arrangements :** Physical arrangements in terms of a neutral, well lit and a quiet place are very essential for the participants to be able to discuss freely. Sitting arrangement should be semicircular so that each participant is in the view of the others.

**(c) Preparation of the FGD guide :** It is a written list of the topics that need to be discussed in the group and consists of a series of open ended questions. It should be prepared carefully

ensuring that it covers the most necessary issues and avoids the unnecessary ones. Topics should be arranged in a logical sequence and a thorough familiarisation with the topics is a must for the moderator and helps him/her to anticipate the range of issues that might come up during the FGD.

**Conduct of the session :** Moderating a focus group discussion is an art. The moderator must be vigilant about covering all the material in the focus group guide, while also ensuring that the entire group participates and that a wide range of perspectives has been solicited and expressed. The role requires you to be fully engaged in the discussion, yet refrain from participating too much in it. You must know how and when to interject and intervene, yet not interfere.

**Facilitating group discussion :** The following are the general guidelines

- *Open with a general comment* and wait for a response. For example, you might say, Family planning can be a complex issue ..." or "What do you think about the issue that has brought us here today?" Alternatively, you might address the first question to an individual who seems comfortable speaking in front of the group. The first question in the focus group guide is usually designed to engage participants in discussion and may not actually be intended to yield important data.
- *Invite a wide range of commentary* by asking participants for experiences, thoughts, and definitions. Also ask what others like them or others in their families think, say, or do that may be similar or different. If everyone appears to agree about a particular issue, verify this by inquiring, "Are there any other points of view?" or "Does anyone see it differently?"
- *Use silence to your advantage.* Give participants a chance to think about the questions, and do not be afraid to wait until someone speaks. In some cultures, people are comfortable with silence; in others, they are not. In the latter case, allowing for pauses could be advantageous, because eventually someone would feel compelled to speak to end the silence.
- *Limit your own participation* once the discussion begins. After going through the introductory material, set the stage by posing a question and then letting the participants react to it for a few minutes with limited direction from you. Do not provide commentary on each contribution or take on the role of counsellor or educator. The moderator's role is to elicit information, not dispense it.
- *Covering the material in the guide :* Moderators are responsible for asking all of the questions in the focus group guide. A good way to keep track of the questions addressed is to check them off in the guide. This is especially practical when you ask questions in a different order than they appear in the guide and when a response applies to a different or additional question than the one you initially presented. Checking off the questions also makes it easier to return to questions that were skipped in the natural progression of the discussion. Although the guide is designed to help the discussion flow easily, you usually do not have to follow the exact order of questions. Try to cover each question thoroughly, because each



question is designed to elicit specific information. Probe each topic as necessary to get sufficient information. Make notes in the discussion guide as a reminder to return to a question or address an issue further.

During the focus group discussion, moderators should not correct participants. It is important in qualitative data collection to elicit all the participants' perspectives, including misinformation. If inaccurate information is stated during the focus group, make a note to correct the misinformation but only after the focus group discussion is over. Afterwards, however, the moderator should provide correct factual information.

- **Encouraging maximum participation.** Try to include as many participants as possible in the discussion, keeping track of their participation by marking the seating chart each time individual participants contribute to the discussion. Techniques for encouraging full participation include referring back to a reticent participant's previous comments, if the current conversation relates it. For example, you might say, "What you are describing sounds very similar to (or different from) what Mr X was talking about earlier. What do you think about this, Mr X?" You might also direct one of the questions from the focus group guide to a particular participant. After he or she responds, ask whether others agree or disagree. Also, encourage participants to discuss the questions with each other rather than address the moderator. Finally, remain in charge. Do not allow a pattern to develop in which everyone orients toward one particular participant and his or her comments.

**Functions and qualities of a moderator :** He introduces the session, he introduces the recorder, participants and puts them at ease, encourages participation, discussion and involvement by all, he builds a rapport amongst all participants, he consciously avoids the role of an expert, ensures that the discussion does not lead away from the topics, he also ensures that no one participant dominates the discussion. At the end of the FGD, he summarizes and thanks all the participants. A good moderator shows flexibility, sensitivity, has a sense of humour, links ideas together and encourages participation from everyone. *A good moderator tries not to dictate* the course of discussion, lose control over the conversation, judge comments or be an "expert", not to inform or educate during the group and does not lead a question and answer session. He ensures that questions are not leading in nature.

**Function of the recorder or the note taker :** The recorder records the complete proceedings of the FGD, the date, time, place, name and characteristics of the participants, the general group dynamics i.e. level of participation, interest etc. Opinion of participants including their emotional reactions, their language, vocabulary etc. Tape recording and if possible, video recording of the FGD must be ensured.

**The number and duration of sessions :** A typical FGD should not last for more than an hour and a half. The number of sessions should be decided based on the nature of the project need, resources and whether the information coming is redundant or not. 2 to 3 FGDs are considered enough for each population subgroup.

## Sampling in Qualitative Research

In qualitative research, only a sample of a population is selected for any given study. The study's research objectives and the characteristics of the study population (size and diversity) will determine which and how many people to select. Qualitative Research uses non - probability sampling methods. Selection of the respondents is usually flexible and evolves as the study progresses. There are many approaches for selecting samples in qualitative research, the most commonly used is the purposive sampling.

The sample size in qualitative research is relatively small but consists of 'information rich' cases. Generally the chosen sample size is between four and forty participants (large studies may have upto 100). In qualitative research at times, the number of people in the sample is not known before the research starts; the sample undergoes change during the research in respect of size and type. Usually sampling goes on till *saturation* is achieved, that is until no new information is generated and *informational redundancy* occurs. This is the main principle of sampling in qualitative research completeness.

## Data Analysis in Qualitative Research

In quantitative analysis, numbers and what they stand for are the material of analysis. By contrast, qualitative analysis deals in words and is guided by fewer universal rules and standardized procedures, rather than statistical analysis.

In Qualitative research, the researcher captures the thoughts and experiences of individual people, and every set of qualitative data collected (from every participant observation event, interview, and focus Group) is distinct. In qualitative evaluation, data collection and data analysis are not temporally discrete stages : as soon as the first pieces of data are collected, the evaluator begins the process of making sense of the information. Qualitative analysis involves examining the assembled relevant data to determine how they answer the evaluation question(s) at hand. Qualitative data most often occur in more embedded and less easily reducible or distillable forms than quantitative data. For example, a relevant "piece" of qualitative data might be interspersed with portions of an interview transcript, multiple excerpts from a set of field notes, or a comment or set of comments from a focus group. Major phases of data analysis are data reduction, data display, and conclusion drawing and verification. Researcher needs to do the following to analyse the data of a qualitative study :

**(a) Description of sample population :** Qualitative data is derived from small samples, more information is needed to place the data in their context, e.g. who were the KI?, What were the factors that made them qualify as such? Who all took part in the FGDs? How representative were the participants of the population / group they represented? Who all were observed etc.

**(b) Data reduction (ordering and coding of data) :** Data reduction refers to the process of selecting, focusing, simplifying, abstracting, and transforming the data that appear in written up field notes or transcriptions. Not only do the data need to be condensed for the sake of manageability, they also have to be transformed so they can be made intelligible in terms of the issues being researched. Coding of data should be as per

topics of discussion guide or check list of observation or semi structured interviews.

**(c) Data display** : Data display goes a step beyond data reduction to provide “an organized, compressed assembly of information that permits conclusion drawing” A display can be an extended piece of text or a diagram, chart, or matrix that provides a new way of arranging and thinking about the more textually embedded data. Data displays, whether in word or diagrammatic form, allow the analyst to extrapolate from the data enough to begin to discern systematic patterns and interrelationships. By displaying data in form of a chart (matrix), a figure (flow chart) or other graphic forms, one is already analysing the data.

**(d) Conclusion drawing and verification** : Conclusion means what the analyzed data means and to assess the implications for the research issue at hand. Verification is integrally linked to conclusion drawing; it involves revisiting the data as many times as necessary to cross - check or verify the emergent conclusions. The meanings emerging from the data have to be tested for their plausibility, their sturdiness, their validity. Validity means something different in this context than in quantitative evaluation, where it is a technical term that refers quite specifically to whether a given construct measures what it purports to measure. Here validity encompasses a much broader concern for whether the conclusions being drawn from the data are credible, defensible, warranted, and able to withstand alternative explanations.

Unlike quantitative researchers, who need to explain away deviant or exceptional cases, qualitative analysts are also usually delighted when they encounter twists in their data that present fresh analytic insights or challenges. One needs to think about “checking the meaning of outliers” and “using extreme cases.” In qualitative analysis, deviant instances or cases that do not appear to fit the pattern or trend are not treated as outliers, as they would be in statistical, probability - based analysis. Rather, deviant or exceptional cases should be taken as a challenge to further elaboration and verification of an evolving conclusion. Triangulation of data is critical for validity of the study findings.

### Software Packages for Qualitative Analysis

Software packages that can be used to aid analysis of qualitative data have been developed in recent years. Most of these packages were reviewed by Weitzman and Miles (1995), who grouped them into six types : word processors, word retrievers, text base managers, code - and - retrieve programs, code - based theory builders, and conceptual network builders. All have strengths and weaknesses. Weitzman and Miles suggested that when selecting a given package, researchers should think about the amount, types, and sources of data to be analyzed and the types of analyses that will be performed.

There are two limitations with softwares used in qualitative research. First, computer software packages for qualitative data analysis essentially aid in the manipulation of relevant segments of text. While helpful in marking, coding and moving data segments more quickly and efficiently than can be done manually, the software cannot determine meaningful categories for coding and analysis or define salient themes or factors.

Software packages cannot and should not be used as a way of evading the hard intellectual labour of qualitative analysis. Second, it takes time and resources to become adept in utilizing a given software package and learning its peculiarities.

### Summary

Qualitative research can be defined as a research that seeks the answer to the questions in the real world. Quantitative research is concerned with counting and measuring things, producing estimates of averages and differences between groups whereas Qualitative research has its roots in social science and is more concerned with understanding why people behave as they do: their knowledge, attitudes, beliefs, fears, etc. It has a person centred perspective. It not only provides valuable information to certain research questions in its own right but it is used to complement quantitative research methods either as a vital forerunner or to understand the findings of quantitative research. The skilful combination of both Quantitative and Qualitative methods can maximize the quality of research and data and reduce chances of bias.

The characteristics of the qualitative approaches are : researcher focuses on the everyday life of people in natural settings; the data have primacy; it is context bound; it focuses on the views of the people involved in the research and their perceptions, meanings and interpretations; data collection and analysis generally proceed together and interact with each other; it uses open ended methods and it involves respondents as active participants rather than subjects.

In qualitative research, the three main methods of data collection are Participant Observation (Descriptive observations of verbal and non - verbal behaviour), Interactive interviewing (People asked to verbally describe their experiences of phenomenon), and written descriptions by participants (People asked to write descriptions of their experiences of phenomenon). Key Informant Interview and Focus Group Discussions are important types of interviewing methods. Key Informant interviews are qualitative, in - depth interviews of 10 to 20 people selected for their first - hand knowledge about a topic of interest. Focus group discussion is a qualitative data collection method, effective in helping researchers learn the social norms of a community or subgroup, as well as the range of perspectives that exist within that community or subgroup. Focus groups seek to illuminate group opinion. This method is especially well suited for socio - behavioural research that will be used to develop and measure health services that meet the needs of a given population.

Qualitative Research uses non - probability sampling methods. Selection of the respondents is usually flexible and evolves as the study progresses. There are many approaches for selecting samples in qualitative research, the most commonly used is the purposive sampling. The sample size in qualitative research is relatively small but consists of ‘information rich’ cases.

Qualitative analysis deals in words and is guided by fewer universal rules and standardized procedures, rather than statistical analysis. In Qualitative research, the researcher captures the thoughts and experiences of individual people. In qualitative evaluation, data collection and data analysis go simultaneously. Major phases of data analysis are

data reduction, data display, and conclusion drawing and verification.

Software packages that can be used to aid analysis of qualitative data have been developed in recent years. Most of these packages were reviewed by Weitzman and Miles.

## Study Exercises

**Short Notes :** (1) Differences between Qualitative and Quantitative research (2) Data collection method in Qualitative research (3) Analysis in Qualitative research (4) Focus group discussion.

**MCQs :**

1. Which of the following is not characteristic of Qualitative research? (a) Provides depth of understanding (b) Study motivations/intentions/reasons (c) Provide proof (d) Study design is iterative.
2. Which of the following is characteristic of Qualitative research? (a) Predict causal relationships (b) Are Objective (c) Measure level of confidence (d) Describe individual experiences.
3. Which of the following is not a method of Data collection in Qualitative research? (a) Participant Observation (b) Interactive interviewing (c) Written descriptions by participants (d) None.

4. The following is false regarding FGD : (a) 6 - 12 participants who are willing to talk (b) These participants should be as homogenous as possible with respect to their background characteristics (c) Moderator leads the discussion (d) There is a recorder who notes down the proceedings and draws the sociogram.
5. The following is false about Qualitative Research (a) Uses non - probability sampling methods (b) Selection of the respondents is usually not flexible and one - time event (c) The most commonly used approach is the purposive sampling (d) The sample size in qualitative research is relatively small.

**Answers :** (1) c; (2) d; (3) d; (4) c; (5) b.

## Further Suggested Reading

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Seema R. Patrikar

The origin of statistics roots from the Greek word 'Statis' which means state. In the early days the administration of the state required the collection of information regarding the population for the purpose of war. Around 2000 years ago, in India, we had this system of collecting administrative statistics. In the Mauryan regime the system of registration of vital events of births and deaths existed. Ain-i-Akbari is a collection of information gathered on various surveys conducted during the reign of Emperor Akbar.

The birth of statistics occurred in mid-17th century. A commoner, named John Graunt, began reviewing a weekly church publication issued by the local parish clerk that listed the number of births, christenings, and deaths in each parish. These so called Bills of Mortality also listed the causes of death. Graunt who was a shopkeeper organized this data, which was published as Natural and Political Observations made upon the Bills of Mortality. The seventeenth century contribution of theory of probability laid the foundation of modern statistical methods.

Today, statistics has become increasingly important with passing time. Statistical methods are fruitfully applied to any problem of decision making where the past information is available or can be made available. It helps to weigh the evidences and draw conclusions. Statistics finds its application in almost all the fields of science. We hardly find any science that does not make use of statistics.

### Definition of Statistics

Different authors have defined statistics differently. The best definition of statistics is given by Croxton and Cowden according to whom statistics may be defined as the science, which deals with collection, presentation, analysis and interpretation of numerical data.

### Definition of Biostatistics

Biostatistics may be defined as application of statistical methods to medical, biological and public health related problems. It is the scientific treatment given to the medical data derived from group of individuals or patients.

### Role of Statistics in Clinical Medicine

The main theory of statistics lies in the term variability. No two individuals are same. For example, blood pressure of person may vary from time to time as well as from person to person. We can also have instrumental variability as well as observers variability. Methods of statistical inference provide largely objective means for drawing conclusions from the data about the issue under study. Medical science is full of uncertainties and statistics deals with uncertainties. Statistical methods try to quantify the uncertainties present in medical science. It helps the researcher to arrive at a scientific judgment about a hypothesis. It has been argued that decision making is an integral part of a physician's work. Frequently, decision making is probability based.

### Role of Statistics in Public Health and Community Medicine

Statistics finds an extensive use in Public Health and Community Medicine. Statistical methods are foundations for public health administrators to understand what is happening to the population under their care at community level as well as individual level. If reliable information regarding the disease is available, the public health administrator is in a position to:

- Assess community needs
- Understand socio-economic determinants of health
- Plan experiment in health research
- Analyse their results
- Study diagnosis and prognosis of the disease for taking effective action
- Scientifically test the efficacy of new medicines and methods of treatment.

Statistics in public health is critical for calling attention to problems, identifying risk factors, and suggesting solutions, and ultimately for taking credit for our successes. The most important application of statistics in sociology is in the field of demography.

Statistics helps in developing sound methods of collecting data so as to draw valid inferences regarding the hypothesis. It helps us present the data in numerical form after simplifying the complex data by way of classification, tabulation and graphical presentation. Statistics can be used for comparison as well as to study the relationship between two or more factors. The use of such relationship further helps to predict one factor from the other. Statistics helps the researcher come to valid conclusions in answering their research questions.

Despite wide importance of the subject it is looked upon with suspicion. "Lies, damned lies, and statistics" is part of a phrase attributed to Benjamin Disraeli and popularized in the United States by Mark Twain: "There are three kinds of lies: lies, damned lies, and statistics." The semi-ironic statement refers to the persuasive power of numbers, and describes how even accurate statistics can be used to bolster inaccurate arguments. It is human psychology that when facts are supported by figures, they are easily believed. If wrong figures are used they are bound to give wrong conclusions and hence when statistical theories are applied the figures that are used are free of all types of biases and have been properly collected and scientifically analysed.

### Broad Categories of Statistics

Statistics can broadly be split into two categories *Descriptive Statistics* and *Inferential Statistics*. Descriptive statistics deals with the meaningful presentation of data such that its characteristics can be effectively observed. It encompasses the tabular, graphical or pictorial display of data, condensation of large data into tables, preparation of summary measures to give a concise description of complex information and also to exhibit pattern that may be found in data sets. Inferential statistics however refers to decisions. Medical research doesn't stop at just describing the characteristic of disease or situation. It tries to determine whether characteristics of a situation are unusual or if they have happened by chance. Because of this desire to generalize, the first step is to statistically analyse the

data.

In order to begin our analysis as to why statistics is necessary we must begin by addressing the nature of science and experimentation. The characteristic method used by researcher when he/she starts his/her experiment is to study a relatively small collection of subjects, as complete population based studies are time consuming, laborious, costly and resource intensive. The researcher draws a subset of the population called as “sample” and studies this sample in depth. But the conclusions drawn after analyzing the sample is not restricted to the sample but is extrapolated to the population i.e. people in general. Thus Statistics is the mathematical method by which the uncertainty inherent in the scientific method is rigorously quantified.

## Summary

In recent times, use of Statistics as a tool to describe various phenomena is increasing in biological sciences and health related fields so much so that irrespective of the sphere of investigation, a research worker has to plan his/her experiments in such a manner that the kind of conclusions which he/she intends to draw should become technically valid. Statistics comes to this aid at the stages of planning of experiment, collection of data, analysis and interpretation of measures computed during the analysis. Biostatistics is defined as application of statistical methods to medical, biological and public health related problems. Statistics is broadly categorized into descriptive statistics and inferential statistics. Descriptive statistics describes the data in meaningful tables or graphs so that the hidden pattern is brought out. Condensing the complex data into simple format and describing it with summary measures is part of the descriptive statistics. Inferential statistics on other hand, deals with drawing inferences and taking decision by studying a subset or sample from the population.

## Study Exercises

**Short Notes :** (1) Differentiate between descriptive and inferential statistics (2) Describe briefly various scales of measurement.

### MCQs & Exercises

1. An 85 year old man is rushed to the emergency department by ambulance during an episode of chest pain. The preliminary assessment of the condition of the man is performed by a nurse, who reports that the patients pain seems to be ‘severe’. The characterization of pain as ‘severe’ is (a) Dichotomous (b) Nominal (c) Quantitative (d) Qualitative
2. If we ask the patient attending OPD to evaluate his pain on a scale of 0 (no pain) to 5 (the worst pain), then this commonly applied scale is a (a) Dichotomous (b) Ratio scale (c) Continuous (d) Nominal
3. For each of the following variable indicate whether it is quantitative or qualitative and specify the measurement scale for each variable : (a) Blood Pressure (mmHg) (b) Cholesterol (mmol/l) (c) Diabetes (Yes/No) (d) Body Mass Index (Kg/m<sup>2</sup>) (e) Age (years) (f) Sex (female/male) (g) Employment (paid work/retired/housewife) (h) Smoking Status (smokers/non-smokers, ex-smokers) (i) Exercise (hours per week) (j) Drink alcohol (units per week) (k) Level of pain (mild/moderate/severe)

**Answers :** (1) d; (2) b; (3) (a) Quantitative continuous; (b) Quantitative continuous; (c) Qualitative dichotomous ; (d) Quantitative continuous; (e) Quantitative continuous; (f) Qualitative dichotomous; (g) Qualitative nominal ; (h) Qualitative nominal; (i) Quantitative discrete; (j) Quantitative discrete; (k) Qualitative ordinal.

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## Descriptive Statistics: Displaying the Data

*Seema R. Patrikar*

The observations made on the subjects one after the other is called *raw data*. Raw data are often little more than jumble of numbers and hence very difficult to handle. Data is collected by researcher so that they can give solutions to the research question that they started with. Raw data becomes useful only when they are arranged and organized in a manner that we can extract information from the data and communicate it to others. In other words data should be processed and subjected to further analysis. This is possible through data depiction, data summarization and data transformation.

The first step in handling the data, after it has been collected is to ‘reduce’ and summarise it, so that it can become understandable; then only meaningful conclusions can be drawn from it. Data can be displayed in either tabular form or graphical form. Tables are used to categorize and summarize data while graphs are used to provide an overall visual representation. To develop Graphs and diagrams, we need to first of all, condense the data in a table.

### Understanding as to how the Data have been Recorded

Before we start summarizing or further analyzing the data, we should be very clear as on which ‘scale’ it has been recorded (i.e. qualitative or quantitative; and, whether continuous, discrete, ordinal, polychotomous or dichotomous). The details have already been covered earlier in the chapter on variables and scales of measurement (section on epidemiology) and the

readers should quickly revise that chapter before proceeding.

### Ordered Data

When the data are organized in order of magnitude from the smallest value to the largest value it is called as ordered array. For example consider the ages of 11 subjects undergoing tobacco cessation programme (in years) 16, 27, 34, 41, 38, 53, 65, 52, 20, 26, 68. When we arrange these ages in increasing order of magnitude we get ordered array as follows: 16, 20, 26, 27, 34, 38, 41, 52, 53, 65, 68. After observing the ordered array we can quickly determine that the youngest person is of 16 years and oldest of 68 years. Also we can easily state that almost 55% of the subjects are below 40 years of age, and that the midway person is aged 38 years.

### Grouped Data - Frequency Table

Besides arranging the data in ordered array, grouping of data is yet another useful way of summarizing them. We classify the data in appropriate groups which are called “classes”. The basic purpose behind classification or grouping is to help comparison and also to accommodate a large number of observations into a few classes only, by condensation so that similarities and dissimilarities can be easily brought out. It also highlights important features and pinpoints the most significant ones at glance.

Table 1 shows a set of raw data obtained from a cross-sectional survey of a random sample of 100 children under one year of age for malnutrition status. Information regarding age and sex of the child was also collected. We will use this data to illustrate the construction of various tables. If we show the distribution of children as per age then it is called as simple table as only one variable is considered.

**Table - 1 : Raw data on malnutrition status (malnourished and normal) for 100 children below one year of age**

Child	Sex	Age (months)	Malnutrition Status
1	f	6	Normal
2	m	4	Malnourished
3	m	2	Malnourished
4	m	5	Normal
5	m	3	Normal
6	f	1	Normal
7	m	5	Normal
8	f	8	Normal
9	f	7	Normal
10	f	9	Normal
11	f	10	Normal
12	f	2	Normal
13	m	4	Malnourished
14	f	6	Normal
15	m	8	Normal
16	f	1	Malnourished

Child	Sex	Age (months)	Malnutrition Status
17	f	2	Normal
18	m	11	Normal
19	m	12	Normal
20	m	11	Malnourished
21	m	10	Normal
22	f	9	Normal
23	f	5	Normal
24	f	6	Normal
25	m	4	Normal
26	f	7	Normal
27	f	11	Normal
28	f	12	Normal
29	m	10	Malnourished
30	m	4	Normal
31	m	6	Normal
32	m	8	Normal
33	m	12	Malnourished
34	m	1	Malnourished
35	m	1	Normal
36	f	3	Normal
37	m	5	Normal
38	f	6	Normal
39	f	8	Normal
40	f	9	Normal
41	f	10	Malnourished
42	m	1	Normal
43	f	12	Malnourished
44	f	2	Malnourished
45	m	1	Normal
46	m	6	Normal
47	m	4	Normal
48	f	9	Normal
49	f	4	Normal
50	m	9	Normal
51	m	7	Normal
52	m	6	Normal
53	m	4	Normal
54	f	2	Normal
55	m	5	Normal
56	m	3	Normal
57	f	1	Normal
58	m	5	Normal



Child	Sex	Age (months)	Malnutrition Status
60	m	7	Malnourished
61	m	9	Normal
62	m	10	Normal
63	f	2	Normal
64	f	4	Normal
65	f	6	Normal
66	f	8	Normal
67	m	1	Normal
68	m	2	Normal
69	m	11	Normal
70	f	12	Normal
71	m	11	Normal
72	m	10	Malnourished
73	f	9	Normal
74	f	5	Normal
75	f	6	Normal
76	m	4	Normal
77	m	7	Normal
78	m	11	Normal
79	f	12	Normal
80	f	10	Normal
81	m	4	Normal
82	m	6	Malnourished
83	m	8	Normal
84	m	12	Normal
85	m	1	Normal
86	m	1	Normal
87	m	3	Normal
88	f	5	Normal
89	m	6	Normal
90	f	8	Normal
91	f	9	Normal
92	f	10	Normal
93	f	1	Normal
94	m	12	Normal
95	m	2	Normal
96	f	1	Normal
97	m	6	Normal
98	f	4	Malnourished
99	f	9	Malnourished
100	m	4	Normal

### Steps in Making a Summary Table for the Data

To group a set of observations we select a set of contiguous, non overlapping intervals such that each value in the set of observations can be placed in one and only one of the intervals. These intervals are usually referred to as *class intervals*. For example the above data can be grouped into different age groups of 1-4, 5-8 and 9-12. These are called class intervals. The class interval 1-4 includes the values 1, 2, 3 and 4. The smallest value 1 is called its *lower class limit* whereas the highest value 4 is called its *upper class limit*. The middle value of 1-4 i.e. 2.5 is called the *midpoint or class mark*. The number of subjects falling in the class interval 1-4 is called its class frequency. Such presentation of data in class intervals along with frequency is called frequency distribution. When both the limits are included in the range of values of the interval, the class interval are known as *inclusive type* of class intervals (e.g. 1-4, 5-8, 9-12, etc.) whereas when lower boundary is included but upper limit is excluded from the range of values, such class intervals are known as *exclusive type* of class intervals (e.g. 1-5, 5-9, 9-12 etc.) This type of class intervals is suitable for continuous variable. Tables can be formed for qualitative variables also.

Table - 2 and 3 display tabulation for quantitative as well as qualitative variable.

Table - 2 : Age distribution of the 100 children	
Age group (months)	Number of children
1-4	36
5-8	33
9-12	31
Total	100

Table - 3 : Distribution of malnourishment in 100 children	
Malnourishment Status	Number of children
Malnourished	17
Normal	83
Total	100

Such type of tabulation which takes only one variable for classification is called one way table. When two variables are involved the table is referred to as cross tabulation or two way table. For example Table - 4 displays age and sex distribution of the children and Table - 5 displays distribution of malnourishment status and sex of children.

Table - 4 : Age and sex distribution of 100 children			
Age group (months)	Female	Male	Total
1-4	14	22	36
5-8	15	18	33
9-12	16	15	31
Total	45	55	100

**Table - 5 : Malnourishment status and sex distribution of children**

Malnourishment Status	Female	Male	Total
Malnourished	6	11	17
Normal	39	44	83
Total	45	55	100

### How to Decide on the Number of Class Intervals?

When data are to be grouped it is required to decide upon the number of class intervals to be made. Too few class intervals would result in losing the information. On the other hand too many class intervals would not bring out the hidden pattern. The thumb rule is that we should not have less than 5 class intervals and no more than 15 class intervals. To be specific, experts have suggested a formula for approximate number of class intervals (k) as follows:

$K = 1 + 3.332 \log_{10} N$  rounded to the nearest integer, where N is the number of values or observations under consideration.

For example if  $N=25$  we have,  $K = 1 + 3.332 \log_{10} 25$  i.e. approximately 5 class intervals.

Having decided the number of class intervals the next step is to decide the width of the class interval. The width of the class interval is taken as :

$$\text{Width} = \frac{\text{Maximum observed value} - \text{Minimum observed value}}{\text{Number of class interval (k)}} \quad (= \text{Range})$$

The class limits should be preferably rounded figures and the class intervals should be non-overlapping and must include range of the observed data. As far as possible the percentages and totals should be calculated column wise.

### Graphical Presentation of Data

A tabular presentation discussed above shows distribution of subjects in various groups or classes. This tabular representation of the frequency distribution is useful for further analysis and conclusion. But it is difficult for a layman to understand complex distribution of data in tabular form. Graphical presentation of data is better understood and appreciated by humans. Graphical representation brings out the hidden pattern and trends of the complex data sets.

Thus the reason for displaying data graphically is two fold:

- 1) Investigators can have a better look at the information collected and the distribution of data and,
- 2) To communicate this information to others quickly

We shall discuss in detail some of the commonly used graphical presentations.

**Bar Charts** : Bar charts are used for qualitative type of variable in which the variable studied is plotted in the form of bar along the X-axis (horizontal) and the height of the bar is equal to the percentage or frequencies which are plotted along the Y-axis (vertical). The width of the bars is kept constant for all the categories and the space between the bars also remains constant throughout. The number of subjects along with

percentages in bracket may be written on the top of each bar. When we draw bar charts with only one variable or a single group it is called as simple bar chart and when two variables or two groups are considered it is called as multiple bar chart. In multiple bar chart the two bars representing two variables are drawn adjacent to each other and equal width of the bars is maintained. Third type of bar chart is the component bar chart wherein we have two qualitative variables which are further segregated into different categories or components. In this the total height of the bar corresponding to one variable is further sub-divided into different components or categories of the other variable. For example consider the following data (Table-6) which shows the findings of a hypothetical research work intended to describe the pattern of blood groups among patients of essential hypertension.

**Table - 6 : Distribution of blood group of patients of essential hypertension**

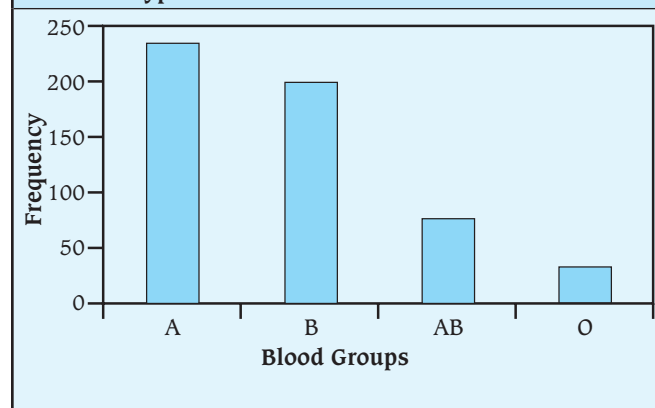
Blood Group	Number of patients (frequency)	Percentage
A	232	42.81
B	201	37.05
AB	76	14.02
O	33	6.09
Total	542	100.00

A simple bar chart in respect of the above data on blood groups among patients of essential hypertension is represented as in Fig. - 1.

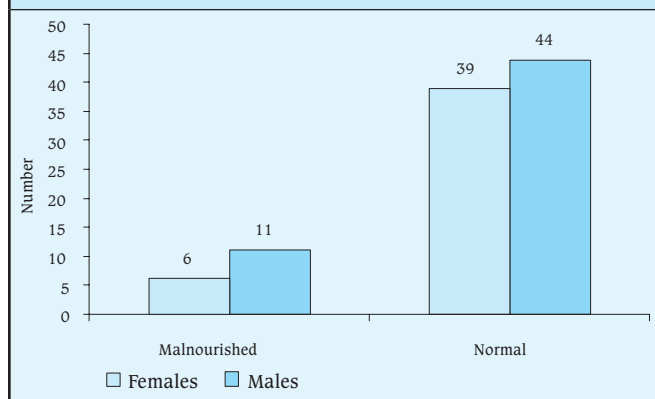
Similarly a multiple bar chart of the data represented in Table - 5 of the distribution of the malnourishment status among males and females is shown in Fig. - 2.

The same information can also be depicted in the form of component bar chart as in Fig. - 3.

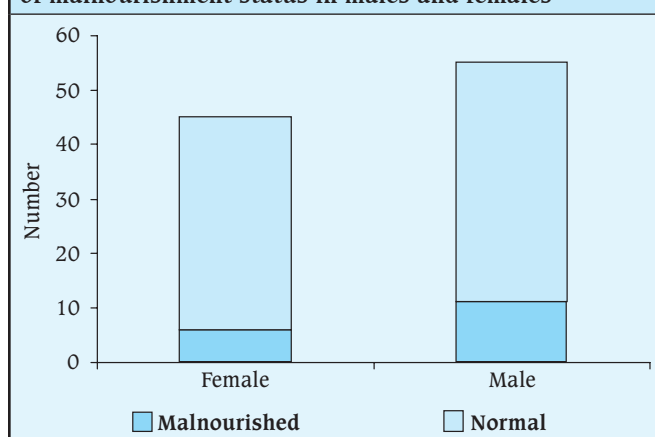
**Fig. - 1 : Distribution of blood groups of patients with essential hypertension**



**Fig. - 2 : Multiple Bar Chart showing the distribution of malnourishment status in males and females**



**Fig. - 3 : Component Bar Chart showing the distribution of malnourishment status in males and females**



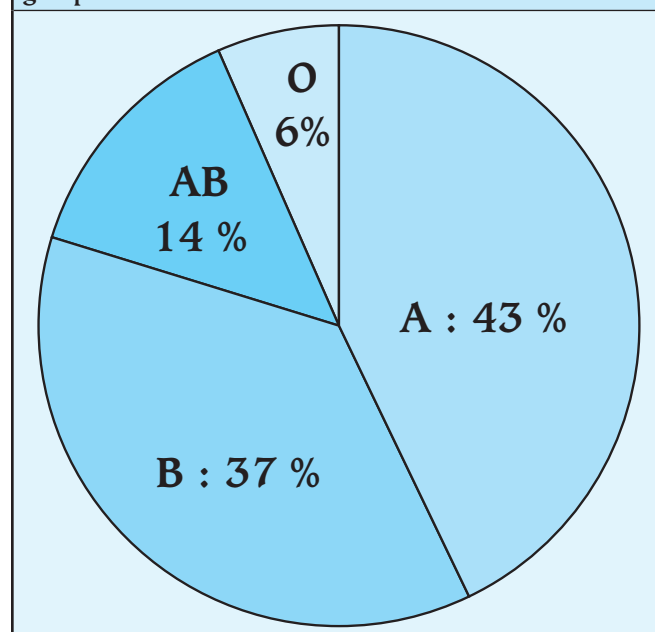
**Pie Chart :** Another interesting method of displaying categorical (qualitative) data is a pie diagram also called as circular diagram. A pie diagram is essentially a circle in which the angle at the center is equal to its proportion multiplied by 360 (or, more easily, its percentage multiplied by 360 and divided by 100). A pie diagram is best when the total categories are between 2 to 6. If there are more than 6 categories, try and reduce them by “clubbing”, otherwise the diagram becomes too overcrowded.

A pie diagram in respect of the data on blood groups among patients of essential hypertension is presented below after calculating the angles for the individual categories as in Fig. - 4 a, b.

**Frequency Curve and Polygon :** To construct a frequency curve and frequency polygon we plot the variable along the X-axis and the frequencies along the Y-axis. Observed values of the variable or the midpoints of the class intervals are plotted along with the corresponding frequency of that class interval. Then we construct a smooth freehand curve passing through these points. Such a curve is known as frequency curve. If instead of joining the midpoints by smooth curve, we join the consecutive

points by a straight line then it is called as frequency polygon. Conventionally, we consider one imaginary value immediately preceding the first value and one succeeding the last value and plot them with frequency = 0. An example is given in Table - 7 and Fig. - 5.

**Fig. - 4a : Distribution of patients according to blood group**



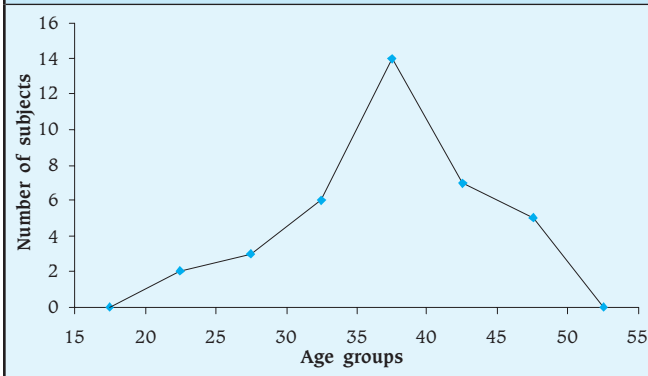
**Fig. - 4b**

$$\begin{aligned} \text{Blood group A} &= \frac{42.81}{100} \times 360 = 154 \text{ degrees} \\ \text{Blood group B} &= \frac{37.08}{100} \times 360 = 134 \text{ degrees} \\ \text{Blood group AB} &= \frac{14.02}{100} \times 360 = 50 \text{ degrees} \\ \text{Blood group O} &= \frac{6.09}{100} \times 360 = 22 \text{ degrees} \end{aligned}$$

**Table - 7: Distribution of subjects as per age groups**

Age	Midpoints	Number of subjects
20-25	22.5	2
25-30	27.5	3
30-35	32.5	6
35-40	37.5	14
40-45	42.5	7
45-50	47.5	5

**Fig. - 5 : Distribution of subjects in different age groups**



**Stem-and-leaf plots** : This presentation is used for quantitative type of data. To construct a stem-and-leaf plot, we divide each value into a stem component and leaf component. The digits in the tens-place becomes stem component and the digits in units-place becomes leaf components. It is of much utility in quickly assessing whether the data is following a “normal” distribution or not, by seeing whether the stem and leaf is showing a bell shape or not. For example consider a sample of 10 values of age in years : 21, 42, 05, 11, 30, 50, 28, 27, 24, 52. Here, 21 has a stem component of 2 and leaf component of 1. Similarly the second value 42 has a stem component of 4 and leaf component of 2 and so on. The stem values are listed in numerical order (ascending or descending) to form a vertical axis. A vertical line is drawn to outline a stem. If the stem value already exists then the leaf is placed on the right side of vertical line (Fig. - 6).

The value of each of the leaf is plotted in its appropriate location on the other side of vertical line as in Fig. - 7.

To describe the central location, spread and shape of the stem plot we rotate the stem plot by 90 degrees just to explain it more clearly as in Fig. - 8.

Roughly we can say that the spread of data is from 5 to 52 and the median value is between 27 and 28. Regarding the shape of the distribution though it will be difficult to make firm statements about shape when n is small, we can always determine (Fig. - 9) :

- Whether data are more or less symmetrical or are extremely skewed
- Whether there is a central cluster or mound
- Whether there are any outliers

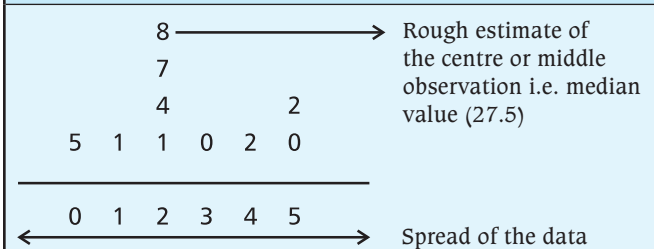
**Fig. - 6**

0	
1	
2	
3	
4	
5	

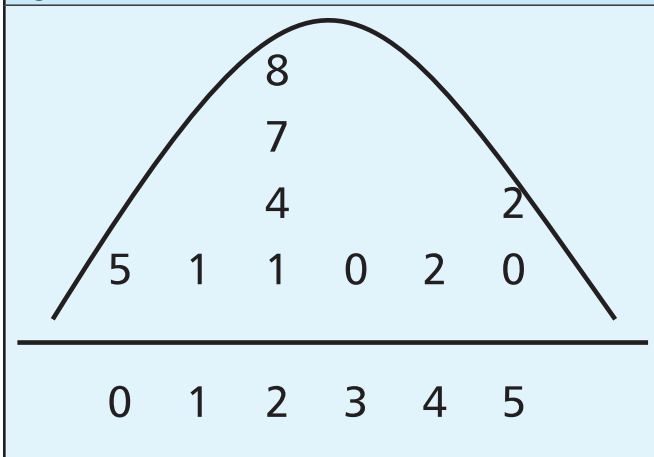
**Fig. - 7**

0	5
1	1
2	1 4 7 8
3	0
4	2
5	0 2

**Fig. - 8**



**Fig. - 9**



For the given example we notice the mound (heap) in the middle of the distribution. There are no outliers.

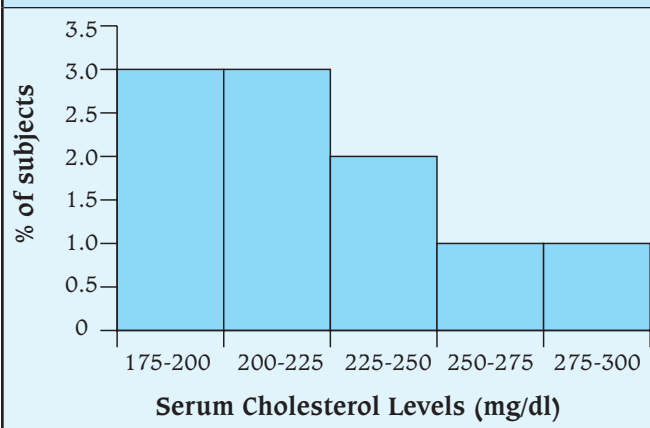
**Histogram** : The stem-and-leaf is a good way to explore distributions. A more traditional approach is to use histogram. A histogram is used for quantitative continuous type of data where, on the X-axis, we plot the quantitative exclusive type of class intervals and on the Y-axis we plot the frequencies. The difference between bar charts and histogram is that since histogram is the best representation for quantitative data measured on continuous scale, there are no gaps between the bars. Consider an example of the data on serum cholesterol of 10 subjects (Table - 8 & Fig. - 10)

**Table - 8 : Distribution of the subjects**

Serum cholesterol (mg/dl)	No of subjects	Percentage
175 – 200	3	30
200 – 225	3	30
225 – 250	2	20
250 – 275	1	10
275 – 300	1	10
Total	10	100%

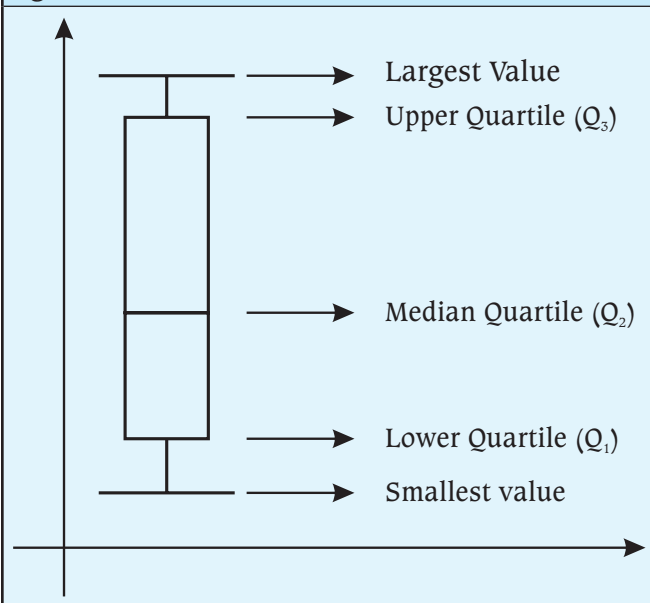


**Fig. - 10 : Distribution of subjects according to Serum Cholesterol Levels**



**Box-and-Whisker plot :** A box-and-whisker plot reveals maximum of the information to the audience. A box-and-whisker plot can be useful for handling many data values. They allow people to explore data and to draw informal conclusions when two or more variables are present. It shows only certain statistics rather than all the data. Five-number summary is another name for the visual representations of the box-and-whisker plot. The five-number summary consists of the median, the quartiles (lower quartile and upper quartile), and the smallest and greatest values in the distribution. Thus a box-and-whisker plot displays the center, the spread, and the overall range of distribution (Fig. - 11)

**Fig. - 11**

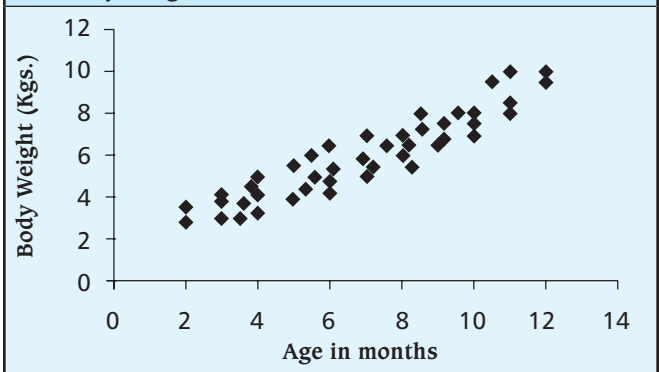


**Line chart:** Line chart is used for quantitative data. It is an excellent method of displaying the changes that occur in disease frequency over time. It thus helps in assessing “temporal trends” and helps displaying data on epidemics or localised outbreaks in the form of epidemic curve. In a line

diagram, the rate of disease are plotted along the vertical (y) axis. However, in localised outbreaks, with a well demarcated population that has been at risk (as sudden outbreaks of food poisoning) the actual numbers can be plotted on Y-axis, during quick investigations. The unit of time, as applicable to the disease in question, is plotted along the “X”-axis (horizontal). This unit of time would be hours-time in food poisoning, days (i.e, as per dates of the month) for cholera, weeks for typhoid, malaria or Hepatitis-A, months for Hepatitis-B and in years (or even decades) for IHD or Lung Cancer.

**Scatter Diagram :** A scatter diagram gives a quick visual display of the association between two variables, both of which are measured on numerical continuous or numerical discrete scale. An example of scatter plot between age (in months) and body weight (in kg) of infants is given in Fig. - 12.

**Fig. - 12 : Scatter Diagram of the association between Age and Body Weight of infants**



The scatter diagram in the above figure shows instant finding that weight and age are associated - as age increases, weight increases. Be careful to record the dependent variable along the vertical (Y) axis and the independent variable along the horizontal (X) axis. In this example weight is dependent on age (as age increases weight is likely to increase) but age is not dependent on weight (if weight increases, age will not necessarily increase). Thus, weight is the dependent variable, and has been plotted on Y axis while age is the independent variable, plotted along X axis.

## Summary

Raw information, which is just jumble of numbers, collected by the researcher needs to be presented and displayed in a manner that it makes sense and can be further processed. Data presented in an eye-catching way can highlight particular figures and situations, draw attention to specific information, highlight hidden pattern and important information and simplify complex information. Raw information can be presented either in table i.e. tabular presentation or in graphs and charts i.e. graphical presentation. A table consists of rows and columns. The data is condensed in homogenous groups called class intervals and the number of individuals falling in each class interval called frequency is displayed. A table is incomplete without a title. Clear title describing completely the data in concise form is written. Graphical presentation is used when data needs to be displayed in charts and graphs. A chart or diagram should have

a clear title describing the data depicted. The X-axis and the Y-axis should be properly defined along with the scale. Legend in case of more than one variable or group is necessary. An optional footnote giving the source of information may be present. Appropriate graphical presentation should be depicted depending on whether data is quantitative or qualitative. While dealing with quantitative data histograms, line chart, polygon, stem and leaf and box and whisker plots should be used whereas bar charts, pictograms and pie charts should be used when dealing with qualitative data.

## Study Exercises

**Long Question :** Discuss the art of effective presentation in the field of health, in respect of data and information; so as to convince the makers of decision.

**Short Notes:** (1) Discuss the need for graphical presentation of data (2) Differentiate between inclusive and exclusive type of class intervals (3) Box and Whisker Plot (4) Scatter diagram

### MCQs

- Which of the following is used for representing qualitative data (a) Histogram (b) Polygon (c) Pie chart (d) Line chart
- The scatter plot is used to display (a) Causality (b) Correlation (c) Power (d) Type II error
- Five summary plot consists of Quartiles and (a) Median (b) Mode (c) Mean (d) Range
- The appropriate method of displaying the changes that occur in disease frequency over time (a) Line chart (b) Bar chart (c) Histogram (d) Stem and leaf.
- Box and whisker plot is also known as (a) Magical box (b) Four summary plot (c) Five summary plot (d) None of the above
- The type of diagram useful to detect linear relationship between two variables is (a) Histogram (b) Line Chart (c) Scatter Plot (d) Bar Chart
- The following table shows the age distribution of cases of a certain disease reported during a year in a particular state. Which graphical presentation is appropriate to describe this data? (a) Pie chart (b) Line chart (c) Histogram (d) Pictogram

Age	Number of cases
5-14	5
15-24	10
25-34	120
35-44	22
45-54	13
55-64	5

- Which graphical presentation is best to describe the following data? (a) Multiple bar chart (b) Pie chart (c) Histogram (d) Box plot

Year	Exports (crores of rupees)	Imports (crores of rupees)
1960-61	610.3	624.65
1961-62	955.39	742.78
1962-63	660.65	578.36
1963-64	585.25	527.98

- Of the 140 children, 20 lived in owner occupied houses, 70 lived in council houses and 50 lived in private rented accommodation. Type of accommodation is a categorical variable. Appropriate graphical presentation will be (a) Line chart (b) Simple Bar chart (c) Histogram (d) Frequency Polygon
- A study was conducted to assess the awareness of phimosis in young infants and children up to 5 years of age. The awareness level with respect to the family income is as tabulated below. Which graphical presentation is best to describe the following data?

	<2000	2000 – 5000	5000 – 8000	>8000
Aware	50	62	77	70
Unaware	50	28	23	30

- (a) Stem & Leaf (b) Pie Chart (c) Multiple Bar Chart (d) Component Bar Chart
- Following is the frequency distribution of the serum levels of total cholesterol reported in a sample of 71 subjects. Which graphical presentation is best to describe the following data?

Serum cholesterol level	Frequency
<130	2
130-150	7
150-170	18
170-190	20
190-210	15
210-230	7
>230	2

- (a) Stem & Leaf (b) Pie (c) Histogram (d) Component Bar Chart
- Information from the Sports Committee member on representation in different games at the state level by gender is as given below. Which graphical presentation is best to describe the following data

Different Games	Females	Males
Long Jump	4	6
High Jump	2	4
Shot Put	9	11
Running	15	10
Swimming	5	4

- (a) Box plot (b) Histogram (c) Multiple Bar Chart (d) Pie chart
13. Which graphical presentation is best to describe the following data

Grade of malnutrition	Frequency
Normal	60
Grade I	30
Grade II	7
Grade III	2
Grade IV	1

- (a) Box Plot (b) Component Bar Chart (c) Histogram (d) Pie chart
- Answers : (1) c; (2) b; (3) a; (4) a; (5) c; (6) c; (7) c; (8) a; (9) b; (10) d; (11) c; (12) c; (13) d.

#### Statistical Exercise

1. Following is the population data in a locality, present the data in tabular form as well as using appropriate graphs.

S. No.	Age	S. No.	Age	S. No.	Age
1	11	11	8	21	16
2	15	12	12	22	17
3	6	13	22	23	19
4	17	14	24	24	8
5	18	15	16	25	9
6	7	16	19	26	10
7	25	17	20	27	24
8	32	18	9	28	31
9	12	19	21	29	32
10	34	20	31	30	37

40

### Summarising the Data: Measures of Central Tendency and Variability

Seema R. Patrikar

The huge raw information gathered by the researcher is organized and condensed in a table or graphical display. Compiling and presenting the data in tabular or graphical form will not give complete information of the data collected. We need to “summarise” the entire data in one figure, looking at which we can get overall idea of the data. Thus, the data set should be meaningfully described using summary measures. Summary measures provide description of data in terms of concentration of data and variability existing in data. Having described our data set we use these summary figures to draw certain conclusions about the reference population from which the sample data has been drawn. Thus data is described by two summary measures namely, measure of central tendency and measure of variability. Before we discuss in detail, the various measures we should understand the distribution of the data set.

#### Measures of Central Tendency

This gives the centrality measure of the data set i.e. where the observations are concentrated. There are numerous measures of central tendency. These are : Mean; Median; Mode; Geometric Mean; Harmonic Mean.

#### Mean (Arithmetic Mean) or Average

This is most appropriate measure for data following normal distribution but not for skewed distributions. It is calculated by

summing all the observations and then dividing by number of observations. It is generally denoted by  $\bar{X}$ . It is calculated as follows.

$$\text{Mean } (\bar{X}) = \frac{\text{Sum of the values of all observations}}{\text{Total number of observations, that is, the total number of subjects (denoted by "n")}}$$

Mathematically,

$$\bar{X} = \frac{\sum x_i}{n}$$

It is the simplest of the centrality measure but is influenced by extreme values and hence at times may give fallacious results. It depends on all values of the data set but is affected by the fluctuations of sampling.

Example : The serum cholesterol level (mg/dl) of 10 subjects were found to be as follows: 192 242 203 212 175 284 256 218 182 228

We observe that the above data set is of quantitative type.

To calculate mean the first step is to sum all the values. Thus,

$$\sum x_i = 192 + 242 + 203 + \dots + 228 = 2192$$

The second step is to divide this sum by total number of observation (n), which are 10 in our example. Thus,

$$\bar{X} = \frac{\sum x_i}{n} = 2192/10 = 219.2$$

Thus the average value of Serum cholesterol among the 10 subjects studied = 219.5 mg/dl. This summary value of mean describes our entire data in one value.

**Calculation of mean from grouped data :** For calculating the mean from a “grouped data” we should first find out the midpoint (class mark) of each class interval which we denote by  $x$ . (Mid point is calculated by adding the upper limit and the lower limit of the respective class intervals and dividing by 2). The next step is to multiply the midpoints by the frequency of that class interval. Summing all these multiplications and then dividing by total sample size yields us the mean value for grouped data.

Consider the following example on 10 subjects on serum cholesterol level (mg/dl), put in class interval (Table - 1).

Table - 1			
Serum cholesterol level (mg/dl) (a)	Midpoint (x) (b)	No. of subjects (f) (c)	$x \cdot f$ (bxc)
175-199	187	3	561
200-224	212	3	636
225-249	237	2	474
250-274	262	1	262
275-299	287	1	287
Total		$10 = \sum f$	$2220 = \sum x \cdot f$

The mean, then is calculated as

$$\bar{x} = \frac{\sum fx}{\sum f} = \frac{2220}{10} = 222$$

### Median

When the data is skewed, another measure of central tendency called median is used. *Median* is a locative measure which is the middlemost observation after all the values are arranged in ascending or descending order. In other words median is that -value which divides the entire data set into 2 equal parts, when the data set is ordered in an ascending (or descending) fashion. In case when there is odd number of observations we have a single most middle value which is the median value. In case when even number of observations is present there are two middle values and the median is calculated by taking the mean of these two middle observations. Thus,

$$\text{Median} = \begin{cases} \frac{n+1}{2} & ; \text{when } n \text{ is odd} \\ \text{mean of } \frac{n}{2}\text{-th \& } \left(\frac{n}{2}+1\right)\text{th obs} & ; \text{when } n \text{ is even} \end{cases}$$

Let us work on our example of serum cholesterol considered in calculation of mean for ungrouped data. In the first step, we will order the data set in an ascending order as follows :

175, 182, 192, 203, 212, 218, 228, 242, 256, 284

Since  $n$  is 10 (even) we have two middle most observations as 212 and 218 (i.e. the 5th and 6th value)

$$\frac{212 + 218}{2}$$

Therefore, median = ----- = 215

2

Like mean, median is also very easy to calculate. In fact if

the observations are less, median can be calculated by just inspection. Unlike mean, median can be calculated if the extreme observation is missing. It is less affected by fluctuations of sampling than mean.

### Mode

Mode is the most common value that repeats itself in the data set. Though mode is easy to calculate, at times it may be impossible to calculate mode if we do not have any value repeating itself in the data set. At other end it may so happen that we come across two or more values repeating themselves same number of times. In such cases the distribution are said to bimodal or multimodal.

### Geometric Mean

Geometric mean is defined as the  $n$ th root of the product of observations.

Mathematically,

$$\text{Geometric Mean} = \sqrt[n]{x_1 \cdot x_2 \cdot x_3 \cdot \dots \cdot x_n}$$

Thus if there are 3 observations in the data set, the first step would be to calculate the product of all the three observations. The second step would be to take cube root of this product. Similarly the geometric mean of 4 values would be the 4th root of the product of the four observations.

The merits of geometric mean are that it is based on all the observations. It is also not much affected by the fluctuations of sampling. The disadvantage is that it is not easy to calculate and finds limited use in medical research.

### Harmonic Mean

Harmonic mean of a set of values is the reciprocal of the arithmetic mean of the reciprocals of the values. Mathematically,

$$\text{Harmonic mean} = \frac{n}{\frac{1}{x_1} + \frac{1}{x_2} + \dots + \frac{1}{x_n}}$$

Thus if there are four values in the data set as 2, 4, 6 and 8, the harmonic mean is

$$\frac{4}{\frac{1}{2} + \frac{1}{4} + \frac{1}{6} + \frac{1}{8}} = 3.84$$

Though harmonic mean is based on all the values, it is not easy to understand and calculate. Like geometric mean this also finds limited use in medical research.

### Relationship between the Three Measures of Mean, Median and Mode

1. For symmetric curve  
Mean = Median = Mode
2. For symmetric curve  
Mean - Mode  $\approx$  3 (Mean - Median)
3. For positively skewed curve  
Mean > Median > Mode
4. For negatively skewed curve  
Mean < Median < Mode

### Choice of Central Tendency

We observe that each central tendency discussed above have some merits and demerits. No one average is good for all types



of research. The choice should depend on the type of information collected and the research question the investigator is trying to answer. If the collected data is of quantitative nature and symmetric or approximately symmetric data, generally the measure used is arithmetic mean. But if the values in the series are such that only one or two observations are very big or very small compared to other observations, arithmetic mean gives fallacious conclusions. In such cases (skewed data) median or mode would give better results. In social and psychological studies which deals with scored observations or data which are not capable of direct quantitative measurements like socio-economic status, intelligence or pain score etc., median or mode is better measure than mean. However, 'mode' is generally not used since it is not amenable to statistical analysis.

### Measures of Relative Position (Quantiles)

*Quantiles* are the values that divide a set numerical data arranged in increasing order into equal number of parts. *Quartiles* divide the numerical data arranged in increasing order into four equal parts of 25% each. Thus there are 3 quartiles Q1, Q2 and Q3 respectively. *Deciles* are values which divide the arranged data into ten equal parts of 10% each. Thus we have 9 deciles which divide the data in ten equal parts. *Percentiles* are the values that divide the arranged data into hundred equal parts of 1% each. Thus there are 99 percentiles. The 50th percentile, 5th decile and 2nd quartile are equal to median.

### Measures of Variability

Knowledge of central tendency alone is not sufficient for complete understanding of distribution. For example if we have three series having the same mean, then it alone does not throw light on the composition of the data, hence to supplement it we need a measure which will tell us regarding the spread of the data. In contrast to measures of central tendency which describes the center of the data set, measures of variability describes the variability or spreadness of the observation from the center of the data. Various measures of dispersion are as follows.

- Range
- Interquartile range
- Mean deviation
- Standard deviation
- Coefficient of variation

#### Range

One of the simplest measures of variability is range. *Range* is the difference between the two extremes i.e. the difference between the maximum and minimum observation.

Range = maximum observation - minimum observation

One of the drawbacks of range is that it uses only extreme observations and ignores the rest. This variability measure is easy to calculate but it is affected by the fluctuations of sampling. It gives rough idea of the dispersion of the data.

#### Interquartile Range

As in the case of range difference in extreme observations is found, similarly interquartile range is calculated by taking difference in the values of the two extreme quartiles.

Interquartile range = Q3 - Q1

Quartiles divide the total number of observations into 4 equal parts of 25% each. Thus there are three quartiles (Q1, Q2 and Q3) which divide the total observations in four equal parts. The second quartile Q2 is equivalent to the middle value i.e. median. The interquartile range gives the middle 50% values of the data set. Though interquartile range is easy to calculate it suffers from the same defects as that of range.

### Mean Deviation

Mean deviation is the mean of the difference from a constant 'A' which can be taken as mean, median, mode or any constant observation from the data. The formula for mean deviation is given as follows:

$$\text{Mean deviation} = \frac{\sum |x_i - A|}{n}$$

where A may be mean, median, mode or a constant;  $x_i$  is the value of individual observations; n is the total number of observations; and,  $\sum$  = is a sign indicating "sum of". The main drawback of this measure is that it ignores the algebraic signs and hence to overcome this drawback we have another measure of variability called as Variance.

### Standard Deviation

Variance is the average of the squared deviations of each of the individual value from the mean ( $\bar{x}$ ). It is mathematically given as follows:

$$\text{Variance} = \frac{\sum (x_i - \bar{x})^2}{n}$$

Most often we use the square root of the variance called *Standard Deviation* to describe the data as it is devoid of any errors. Variance squares the units and hence standard deviation by taking square root brings the measure back in the same units as original and hence is best measure of variability. It is given as follows:

$$\text{Standard Deviation (SD)} = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n}}$$

The larger the standard deviation the larger is the spread of the distribution.

Note: When n is less than 30, the denominator in variance and standard deviation formula changes to (n-1).

Let us demonstrate its calculations using our hypothetical data set on serum cholesterol (Table - 2).

$$\text{Standard Deviation (SD)} = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n - 1}}; \text{ since } n < 30$$

$$= \sqrt{\frac{(739.84 + 519.84 + \dots + 77.44)}{10 - 1}}$$

$$\text{Thus SD} = \sqrt{\frac{10543.6}{9}} = 34.227$$

Table - 2			
Sr. No	Serum cholesterol	$x_i - \bar{x}$ ( $\bar{x} = 219.2$ )	$(x_i - \bar{x})^2$
1	192	$192 - 219.2 = -27.2$	$(-27.2)^2 = 739.84$
2	242	$242 - 219.2 = 22.8$	$(22.8)^2 = 519.84$
3	203	-16.2	262.44
4	212	-7.2	51.84
5	175	-44.2	1953.64
6	284	64.8	4199.04
7	256	36.8	1354.24
8	218	-1.2	1.44
9	182	-37.2	1383.84
10	228	8.8	77.44
Total	2192		10543.6

**Calculation of Standard deviation in a grouped data :** For grouped data the calculation of standard deviation slightly changes. It is given by following formula.

$$SD = \sqrt{\frac{\sum f_i (x_i - \bar{x})^2}{\sum f_i = n}} \quad ; \text{replace } n \text{ by } n-1 \text{ if observations are less than } 30$$

where  $f_i$  is the frequency (i.e. number of subjects in that group) and is the overall mean. Suppose the data on serum cholesterol was grouped, as we had demonstrated earlier in this chapter for calculation of the mean for grouped data. We had calculated the mean as 222. Now in the same table, make more columns as in Table - 3.

Thus,

$$SD = \sqrt{\frac{\sum f_i (x_i - \bar{x})^2}{\sum f_i - 1 = n - 1}} = \sqrt{\frac{10250}{9}} = 33.74$$

### Coefficient of Variation

Besides the measures of variability discussed above, we have one more important measure called the *coefficient of variation* which compares the variability in two data sets. It measures the variability relative to the mean and is calculated as follows:

$$\text{Coefficient of Variation (CV)} = \frac{SD}{Mean} * 100$$

If the coefficient of variation is greater for one data set it suggests that the data set is more variable than the other data set.

Thus, any information that is collected by the researcher needs to be described by measures of central tendency and measures of variability. Both the measures together describe the data. Measures of central tendency alone will not give any idea about the data set without measure of variability. Descriptive Statistics is critical because it often suggests possible hypothesis for future investigation.

### Summary

Raw information is organized and condensed by using tabular and graphical presentations, but compiling and presenting the data in tabular or graphical form will not give complete information of the data collected. We need to "summarise" the entire data in one figure, looking at which we can get overall idea of the data. Thus, the data set should be meaningfully described using summary measures. Summary measures provide description of data in terms of concentration of data and variability existing in data. Having described our data set we use these summary figures to draw certain conclusions about the reference population from which the sample data has been drawn. Thus data is described by two summary measures namely, measures of central tendency and measures of variability. Measures of central tendency describe the centrality of the data set. In other words central tendency tells us where the data is concentrated. If the researcher is dealing with quantitative data, mean is the best centrality measure whereas in qualitative data median and mode describes the data appropriately. Measures of variability give the spreadness or the dispersion of the data. In other words it describes the scatter of the individual observations from the central value. The simplest of the variability measure is range which is difference between the two extreme observations. Various measures of dispersion are mean deviation, variance and standard deviation. Standard deviation is the most commonly used variability measure to describe quantitative data and is devoid of any errors. When commenting on the variability while dealing with two or more groups or techniques, special measure of variability called coefficient of variation is used. The group in which coefficient of variation is more is said to be

Table - 3					
Serum cholesterol level (mg/dl)	Midpoint (x)	No. of subjects (f)	$x_i - \bar{x}$	$(x_i - \bar{x})^2$	$f_i * (x_i - \bar{x})^2$
175-199	187	3	$(187-222) = -35$	$(-35)^2 = 1225$	$3*1225=3675$
200-224	212	3	$(212-222) = -10$	100	300
225-249	237	2	15	225	450
250-274	262	1	40	1600	1600
275-299	287	1	65	4225	4225
Total		$10 = \sum f$		7375	10250

more variable than the other. Both measures of central tendency and measures of variability together describe the data set and often suggest possible hypothesis for future investigation.

## Study Exercises

**Short Notes :** (1) Measures of central tendency (2) Measures of Variation

### MCQs

- Which of the Statistical average takes into account all the numbers equally? (a) Mean (b) Median (c) Mode (d) None of the above
- Which of the following is a measure of Spread (a) Variance, (b) Mean (c) p value (d) Mode
- Which of the following is a measure of location (a) Variance (b) Mode (c) p value (d) Median
- Which among the following is not a measure of variability: (a) Standard deviation (b) Range (c) Median (d) Coefficient of Variation
- For a positively skewed curve which measure of central tendency is largest (a) Mean (b) Mode (c) Median (d) All are equal
- Most common value that repeats itself in the data set is (a) Mean (b) Mode (c) Median (d) All of the above.
- Variance is square of (a) p value (b) Mean deviation (c) Standard deviation (d) Coefficient of variation.
- Percentiles divides the data into \_\_\_\_\_ equal parts (a) 100 (b) 50 (c) 10 (d) 25

- 10 babies are born in a hospital on same day. All weigh 2.8 Kg each; What would be the standard deviation (a) 0.28 (b) 1 (c) 2.8 (d) 0
- To compare the variability in two populations we use this measure (a) Range (b) Coefficient of Variation (c) Median (d) Standard deviation

**Answers :** (1) a; (2) a; (3) d; (4) c; (5) a; (6) b; (7) c; (8) a; (9) d; (10) b.

### Statistical Exercises

- A researcher wanted to know the weights in Kg of children of second standard collected the following information on 15 students: 10, 20, 11, 12, 12, 13, 11, 14, 13, 13, 15, 11, 16, 17, 18. What type of data is it? Calculate mean, median and mode from the above data. Calculate mean deviation and standard deviation. (Answer : Mean = 13.7, Median = 13, Mode = 11&13, Mean deviation = 2.34, Standard deviation = 2.9)
- If the height (cm) of the same students is 95, 110, 98, 100, 102, 102, 99, 103, 104, 103, 106, 99, 108, 108, 109. What type of data is it? What is the scale of measurement? Calculate mean, median and mode from the above data. Calculate mean deviation and standard deviation. Between height and weigh which is more variable and why? (Answer : Mean = 103.1, Median = 103, Mode = 99, 102, 103 & 108, Mean deviation = 3.55, Standard deviation = 4.4, Coefficient of variation of weight = 21.17, Coefficient of variation of height = 4.27 hence weight is more variable)

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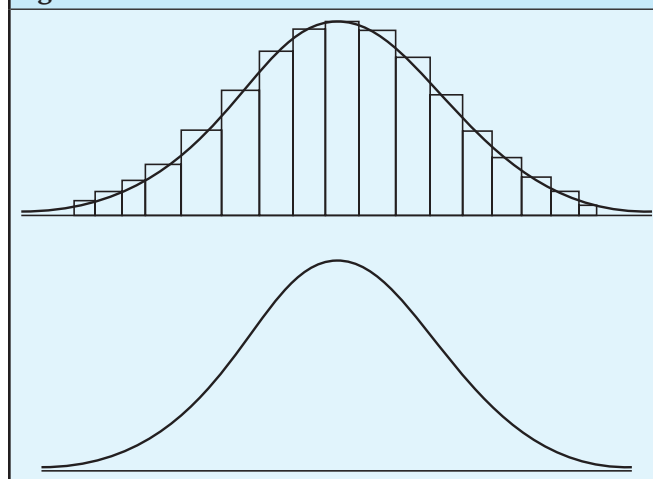
## Introducing Inferential Statistics : Gaussian Distribution and Central Limit Theorem

Seema R. Patrikar

### The Gaussian Distribution or Normal Curve

If we draw a smooth curve passing through the mid points of the bars of histogram and if the curve is bell shaped curve then the data is said to be roughly following a normal distribution. Many different types of data distributions are encountered in medicine. The *Gaussian* or “normal” distribution is among the most important. Its importance stems from the fact that the characteristics of this theoretical distribution underline many aspects of both descriptive and inferential statistics (Fig. - 1).

Fig. - 1



Gaussian distribution is one of the important distributions in statistics. Most of the data relating to social and physical sciences conform to the distribution for sufficiently large observations by virtue of central limit theorem.

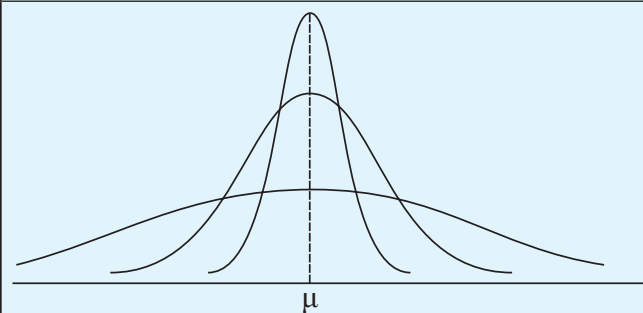
Normal distribution was first discovered by mathematician De-Moivre. Karl Gauss and Pierre-Simon Laplace used this distribution to describe error of measurement. Normal distribution is also called as 'Gaussian distribution'.

A normal curve is determined entirely by the mean and the standard deviation. Hence it is possible to have various normal curves with different standard deviations but same mean (Fig. - 2a) and various normal curves with different means but same standard deviation (Fig. - 2b).

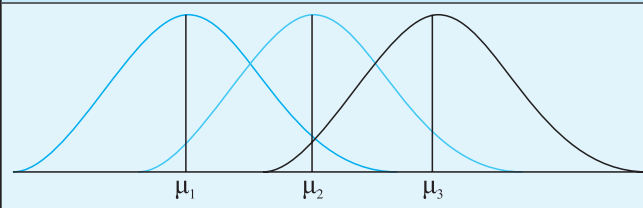
The normal curve possesses many important properties and is of extreme importance in the theory of errors. The normal distribution is defined by following characteristics:

- It is a *bell shaped symmetric* (about the mean) curve.
- The curve on either side of the mean is mirror image of the other side.
- The mean, median and mode coincide.

**Fig. - 2a: Normal curves with same mean but different standard deviations**



**Fig. 2b : Normal curves with same standard deviation but different means**



- Highest frequency (frequency means the number of observations for a particular value or in a particular class interval) is in the middle around the mean and lowest at both the extremes and frequency is decreasing smoothly on either side of the mean.
- The total area under the curve is equal to 1 or 100%.
- The most important relationship in the normal curve is the area relationship.

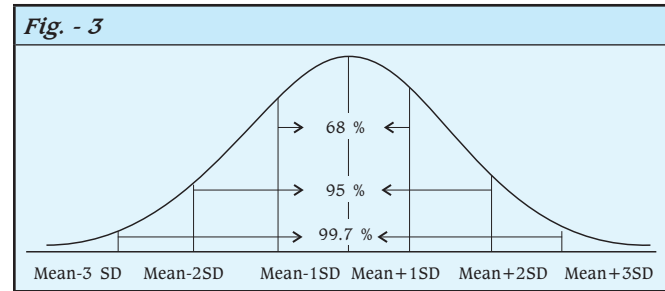
The proportional area enclosed between mean and multiples of SD is constant.

Mean  $\pm$  1 SD -----> 68% of the total area

Mean  $\pm$  2 SD -----> 95% of the total area

Mean  $\pm$  3 SD -----> 99% of the total area

Fig. 3 shows the area enclosed by 1, 2 and 3 SD from mean.



If these criteria are not met, then the distribution is not a Gaussian or normal distribution.

### Standard Normal Variate (SNV)

As already specified, a normal frequency curve can be described completely with the mean and standard deviation values. Even the same set of data would provide different value for the mean and SD, depending on the choice of measurement. For example, the same persons height can be expressed as 66 inches or 167.6 cms. An infant's birth weight can be recorded as 2500 gms or 5.5 pounds. Because the units of measurement differ, so do the numbers, although the true height and weight are the same. To eliminate the effect produced by the choice of units of measurement the data can be put in the unit free form or the data can be normalized. The first step to transform the original variable to normalized variable is to calculate the mean and SD. The normalized values are then calculated by subtracting mean from individual values and dividing by SD. These normalized values are also called the z values.

$$z = \frac{x - \mu}{\sigma}$$

(where  $x$  is the individual observation,  $\mu$  = mean and  $\sigma$  = standard deviation)

The distribution of  $z$  always follows normal distribution, with mean of 0 and standard deviation of 1. The  $z$  values are often called the 'Standard Normal Variate'.

### Central Limit Theorem (CLT)

The CLT is responsible for the following remarkable result:

*The distribution of an average tends to be Normal, even when the distribution from which the average is computed is non-Normal.*

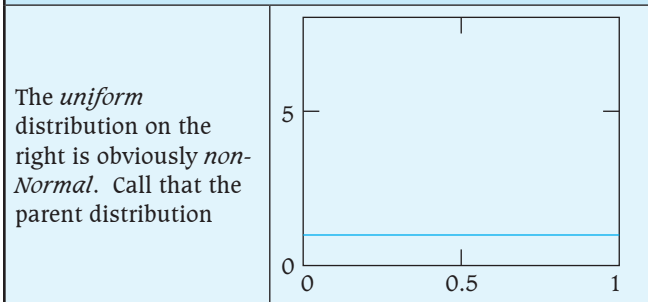
Furthermore, this normal distribution will have the *same mean* as the parent distribution, *AND*, variance equal to the variance of the parent distribution divided by the sample size ( $\sigma/n$ ).

The central limit theorem states that given a distribution with a mean  $\mu$  and variance  $\sigma^2$ , the sampling *distribution of the mean* approaches a *normal distribution* with a mean ( $\mu$ ) and a variance  $\sigma^2/N$  as  $N$ , the *sample size*, increases. The amazing and counter-intuitive thing about the central limit theorem is that no matter what the shape of the original distribution, the sampling distribution of the mean approaches a normal distribution. Furthermore, for most distributions, a normal distribution is approached very quickly as  $N$  increases. Thus, the Central Limit theorem is the foundation for many statistical procedures.

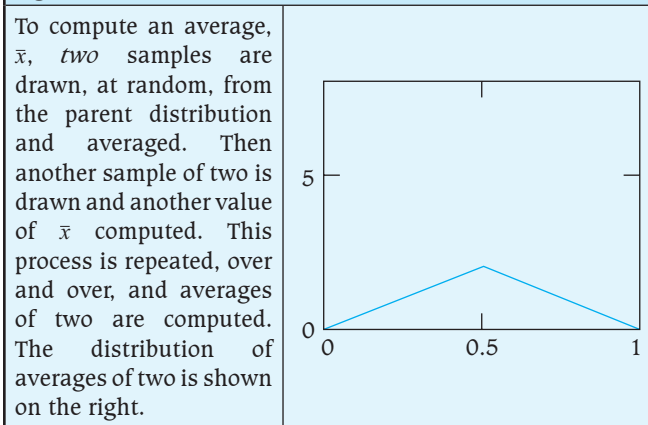


To understand the concept of central limit theorem in detail let us consider the following example (Fig. - 4a - g).

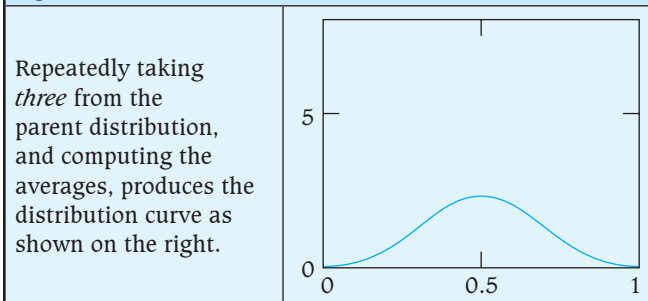
**Fig. 4a : Non Normal distribution of  $\bar{x}$**



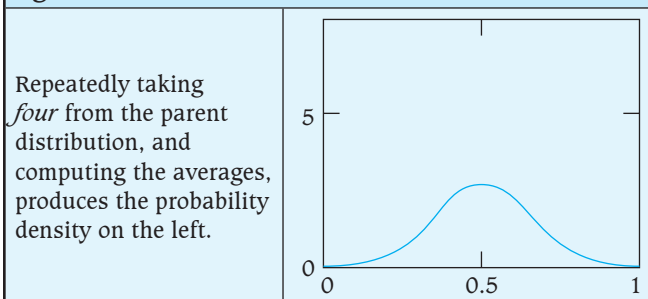
**Fig. - 4b : Distribution of  $\bar{x}$  when  $n=2$**



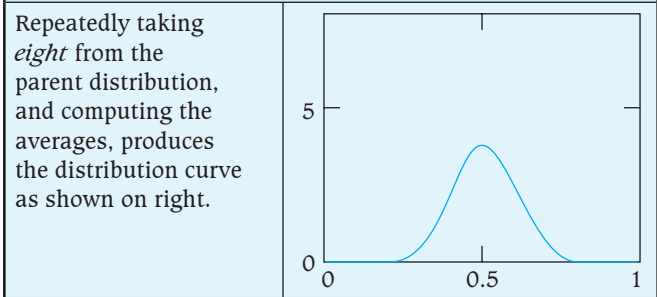
**Fig. - 4c : Distribution of  $\bar{x}$  when  $n=3$**



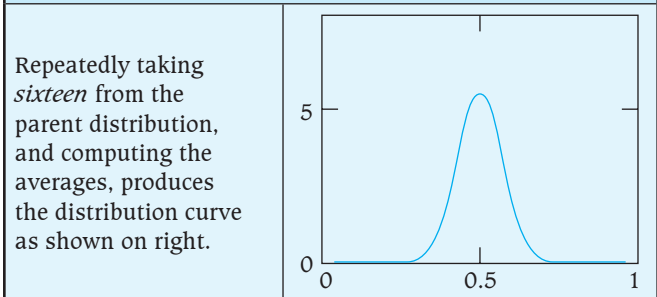
**Fig. - 4d : Distribution of  $\bar{x}$  when  $n=4$**



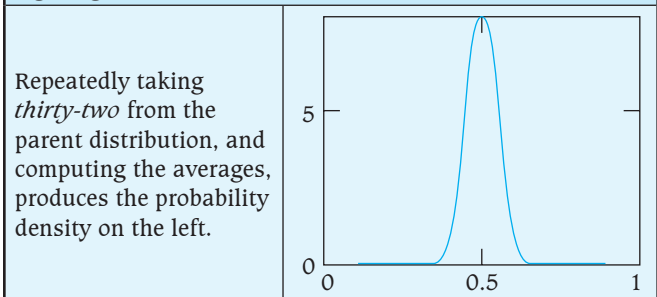
**Fig. - 4e : Distribution of  $\bar{x}$  when  $n=8$**



**Fig. - 4f : Distribution of  $\bar{x}$  when  $n=16$**



**Fig. - 4g : Distribution of  $\bar{x}$  when  $n=32$**



Thus we notice that when the sample size approaches a couple dozen, the distribution of the average is very nearly Normal, even though the parent distribution looks anything *but* Normal.

## Summary

Normal distribution was first discovered by mathematician De-Moivre. Karl Gauss and Pierre-Simon Laplace used this distribution to describe error of measurement. Normal distribution is also called as 'Gaussian distribution'. When the midpoints of the histograms are joined by smooth curve and if the curve resembles a bell shaped curve, the data is said to be approximately normal. The normal distribution is defined by certain characteristics. It is a bell shaped symmetric (about the mean) curve. The curve on either side of the mean is mirror image of the other side. The mean, median and mode coincide. Highest frequency is in the middle around the mean and lowest at both the extremes and frequency is decreasing smoothly on either side of the mean. The total area under the curve is equal to 1 or 100%. The most important relationship in the normal curve is the area relationship. The proportional area enclosed

between mean and multiples of SD is constant. Mean  $\pm$  1SD, Mean  $\pm$  2SD and Mean  $\pm$  3SD encompass 68%, 95% and 99% of the total area. Central limit theorem is an important theorem by virtue of which the distribution of an average tends to be Normal, even when the distribution from which the average is computed is non-Normal. In other words, the central limit theorem states that given a distribution with a mean  $\mu$  and variance  $\sigma^2$ , the sampling distribution of the mean approaches a normal distribution with a mean ( $\mu$ ) and a variance  $\sigma^2/N$  as  $N$ , the sample size, increases. This concept is used in most of the statistical analysis.

## Study Exercises

**Short Notes :** (1) Describe Gaussian (normal) distribution (2) Skewness and kurtosis in Gaussian curve (3) Central limit theorem

## MCQs

1. Characteristics of normal distribution curve includes all except (a) Bell shaped symmetrical curve (b) Mean, Mode, Median coincides (c) Area under the curve is 1 (d) Mean of all the curves is same.
2. Area enclosed in normal distribution curve between Mean  $\pm$  2 S.D. is (a) 90% (b) 95% (c) 99% (d) 20%
3. Mean of unit normal distribution is (a) One (b) Zero (c) Unknown (d) Hundred
4. Variance of unit normal distribution is (a) Zero (b) Two (c) One (d) Not known
5. Coefficient of kurtosis,  $\beta_1$  measures (a) Peakedness of distribution (b) Skewness of distribution (c) Spreadness of distribution (d) All of the above
6. All are true regarding Normal distribution curve except (a) One standard deviation includes 95% of values (b) Mean, Median, Mode coincides (c) Median is mid value (d) Area under the curve is one

Answers : (1) d; (2) b; (3) b; (4) c; (5) a; (6) a.

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## Inferential Statistics: Estimation and Hypothesis Testing

Seema R. Patrikar

Another important broad category for which statistics is used is Statistical Inference. We have already said that research most often is conducted using samples of individuals from larger populations. It is impractical if not impossible to study all people, so we select a sample of people for study. We collect data on these subjects, draw conclusions from the data and make inferences to the larger population. The collected data is of utility to us only if we are in a position to make interpretation and draw inferences. This process of making interpretation and drawing inferences is called as *inferential statistics*. Any researcher collects information with the aim to draw valid conclusions regarding the research question. The information collected is basically with the purpose of two broad things. The researcher is either interested in estimating a population parameter or testing a hypothesis concerned with population parameter.

**Estimation :** *An estimate is a numerical value which is used to estimate the corresponding population parameter.*

Consider following situation where an investigator is interested in finding out the mean duration of hospital stay by patients undergoing cesarean section. Ideally the investigator should go through the case details of all patients who have undergone cesarean section. But the investigator decides to examine a sample of these patients from which he computes the average

duration of hospital stay.

Consider another situation where an investigator is interested in assessing the proportion of patients recovering from a disease after administration of a new drug. Again ideally the investigator should select all the patients who suffer from that particular disease, but since it would be expensive and time consuming the investigator selects sample of patients having that disease and administer the new drug to assess its effect.

The first situation deals with mean parameter whereas the second situation deals with proportion parameter. In both the examples the investigator is interested in estimating the population mean and population proportion respectively. Similarly there may be situations when an investigator is studying two populations and is interested in estimating the difference between two means or difference between two proportions. For example, an investigator may be interested in estimating difference between the mean serum cholesterol levels in the males living in hot deserts and in temperate climates. Similarly an investigator may be interested in estimating the rate of complications by administration of two different drugs.

**Hypothesis Testing:** Hypothesis testing as against estimation deals with testing the statements dealing with population parameters. The researcher states a hypothesis to be tested, formulates an analysis plan, analyzes sample data according to the plan, and accepts or rejects the hypothesis, based on results of the analysis. There are two types of hypotheses-null hypothesis and alternate hypothesis. The concept is best understood by an example of a court decision in a crime case. When a case is presented before a court of law by the prosecution, the judge has to start with the presumption of

innocence. The prosecution has to present adequate evidence against the innocence of the person tried. If the evidence is not sufficient the person is acquitted, whether the crime was actually committed or not. Thus, the permutation and combination between the exact reality (or, truth) and our verdict (decision) can be presented in Table - 1 :

Table - 1		
Our judgment about Mr. X (based on evidence produced before us)	The reality about Mr.X	
	<i>Is not Guilty</i>	<i>Is Guilty</i>
Found guilty	Type I error Wrong decision	Correct decision
Found Not Guilty	Correct decision	Type II error Wrong decision

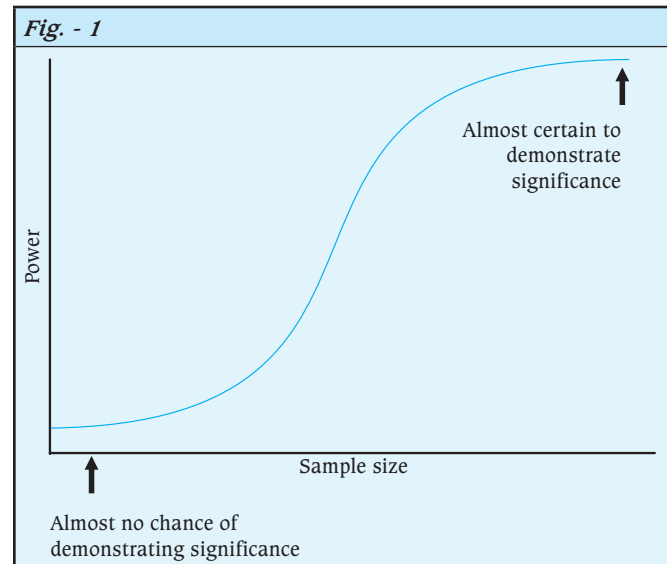
When we do medical research, we take a sample of people, representative of the study population we wish to do. For example, we may wish to study the effect of a new drug in reducing cholesterol levels. Any results we get from our research are only estimates of the true effect that medication will have in the population. The participants are our sample. Since we know our results are just estimates, we may be wrong in giving our conclusions. Statistically these are called as 'errors'. The research question is formally converted into a formal scientific hypothesis, which has two parts: the *null hypothesis* (denoted by  $H_0$ ) and the *alternative hypothesis* (denoted by  $H_1$ ). In case of statistical decision making, the assumption initially made unbiasedly is that the new medication is not effective in reducing cholesterol levels which is equivalent to the presumption of innocence in the judicial setting. In the settings where two treatments (new drug and placebo) are administered to two different samples, the null hypothesis would be that there is no difference between cholesterol levels in the two groups i.e. "Persons treated with new drug will have same cholesterol levels as persons not treated with new drug". If this null hypothesis gets rejected then the hypothesis that gets accepted is called as 'Alternate hypothesis'. Thus the alternative hypothesis is the assertion accepted when null hypothesis is rejected. The alternate hypothesis would be phrased as, "Persons treated with a new drug have different (higher or lower) cholesterol levels than persons not treated with new drug". This alternative hypothesis is called as a *two-tailed* hypothesis. If the alternative hypothesis would have been stated as "Persons treated with new drug have lower cholesterol levels than the persons not treated with new drug", then such an alternate hypothesis, which considers only one direction or effect (either lower or else higher), is called as '*one-tailed* alternative hypothesis'.

To prove the hypothesis stated by the researcher, he starts accumulating data from the selected sample. The values observed in the sample serve as evidence against  $H_0$ . The error of rejecting the true null hypothesis is equivalent to punishing an innocent person. This is serious type of error and is called as *Type I error*, denoted by  $\alpha$  and referred to as 'p-value'. Thus, p-value is probability that a true null hypothesis is wrongly

rejected. The maximum p-value allowed in a research problem is called the 'Level of significance or  $\alpha$ -level'. The type I error is the probability that we reject the hypothesis that there is no difference between the cholesterol levels in the two groups (i.e. we conclude that there is a difference), when actually there is no difference. In other words, these are false positive trials; that is, when there is no difference we conclude that there is difference, (An innocent person is hanged). Being serious, this error is kept at a very low level, mostly 5% or 0.05.

There may be other type of error in taking decision called as *Type II error* which is the probability that we accept a false null hypothesis. In other words, this is equivalent to letting a culprit go free. This error is denoted by  $\beta$ . In medical research this is equivalent to false negative trials i.e. though there is significant difference between the drugs we conclude that there is no difference and declare the new drug as ineffective. This error is not as serious as type I error. If today we are not able to prove that the new drug is effective someone else would prove it in some other trial tomorrow. The effect of type-II error is that it may delay the introduction of the new drug, though effective, in the market but not deny it. Type-I error is pre-decided before the research is undertaken. Depending on type-I error and the alternative hypothesis, the type-II error is calculated. Type-II error can occur when our sample size is too small to detect the difference that really exists between those treated and those not treated. This brings us to the concept of power.

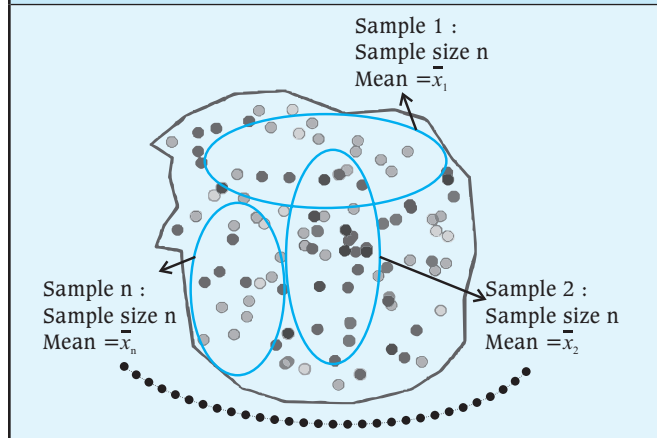
**Power** : The complimentary of Type II error is called 'Power' (Power =  $1 - \beta$ ). Thus, the power of a test is the probability of correctly rejecting  $H_0$  when it is false. In other words, power means that we readily detect true difference when it exists. Power of a test is high if it is able to detect a small difference and thus reject  $H_0$ . Power of the test is kept atleast at 80%. You will get more power with a larger sample size as in Fig. - 1.



**Standard Error of Mean** : Sampling errors are caused because we observe a sample instead of the whole population. When you take a sample from a population, you only have a subset of the population - a 'piece' of what you're trying to understand.

The SD is the variability within a sample that we select to study. The mean  $\pm 2$  SD would give the spread of 95% of the values within a sample. It does not tell us regarding the variability present in the reference population. However theoretically, if we take repeated samples from the same reference population and keep computing the average for each of the sample, then each sample will give us different mean from each other. We consider the set of all such means from all possible samples of specified size (Fig. - 2).

Fig. - 2



Thus, consider the set of different means from all possible samples.

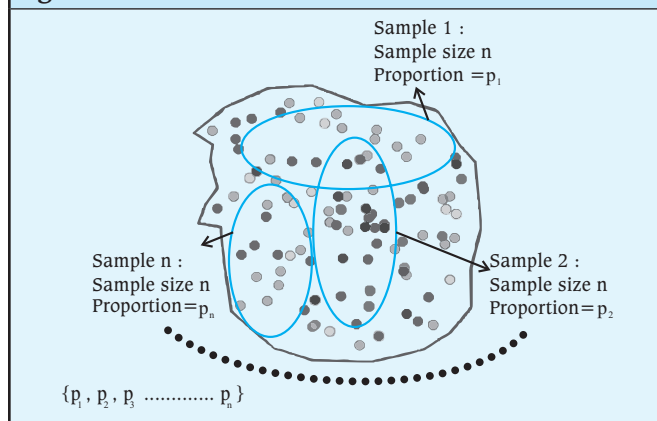
$$\{\bar{x}_1, \bar{x}_2, \bar{x}_3, \dots, \bar{x}_n\}$$

The mean of these mean would be 'Population mean' and the standard deviation of the sample means is called *standard error of mean* which is given by  $\frac{\sigma}{\sqrt{n}}$ . The frequency curve of

these means would give us the underlying distribution of these means which is approximately normal and is called *Sampling Distribution of Mean*.

**Standard Error of Proportion :** The second type of summary statistic besides means which the researcher may be interested in is 'proportion'. It is denoted by 'p'. On the same lines of mean, we consider the set of proportions from all possible samples of specified sample as depicted in Fig. - 3.

Fig. - 3



Thus we have set of all sample proportions as follows

$$\{p_1, p_2, p_3, \dots, p_n\}$$

The mean of these proportion would be 'Population proportion' and the standard deviation of the sample proportions is called *Standard Error of Proportion* which is given by  $\sqrt{\frac{p \cdot q}{n}}$ . The

frequency curve of these proportions would give us the underlying distribution of these proportions which is approximately normal and is called *Sampling Distribution of Proportion*.

**p-value :** p-value is calculated under the assumption that the null hypothesis is correct. R. A. Fisher first proposed the p-value in the 1920s. Fisher proposed this as an informal index to be used as a measure of discrepancy between the data and the null hypothesis. It is the probability of the test statistic (a function of sample values) as extreme as or more than one actually calculated. Since it is a probability, it lies between 0 and 1 (or, from 0% to 100%). If it is 0%, it implies that the chances of our having gone wrong from our study sample are absolutely nil and on the other hand, if it is 100%, it means that we are absolutely wrong in our conclusions. But how small should we consider the p-value is a difficult question to answer. The answer to this question will vary from one situation to the next, and will depend on many factors. If adopting a new drug would be very expensive, or expose patients to severe side effects, as compared to the already available cheap and low toxicity drugs, then one might demand a very high standard of evidence (that is very small p-value). On the other hand, the shortcoming to adopting the new treatment may be quite low, and may offer advantages over an existing treatment, in which case we may agree to even higher p-value for taking the decision. This could be the situation when we are trying out a vaccine against HIV infection against "no vaccine" against this frightening and potentially fatal condition. Thus, what we need therefore, is a rule to help us decide if a result is likely due to chance alone, meaning it is not statistically significant, or if it is unlikely due to chance alone, meaning it is statistically significant.

- Statistically significant = unlikely due to chance alone
- Not statistically significant = likely due to chance alone

To make a decision, you need a point such that any p-value larger than that point will lead to one conclusion and a p-value smaller than that point will lead to the opposite conclusion. That point is most often set at 0.05 and is called as 'alpha or Type I error'.

When alpha is = 0.05, a p-value of 0.10, for example, indicates the result of the study are not statistically significant and the conclusion will be that chance is a likely explanation for the observed results. The conclusion will be that the observed results are unlikely to represent real treatment differences.

When alpha is = 0.05, a p-value of 0.03, for example, indicates the result of the study are statistically significant and the conclusion will be that chance is an unlikely explanation for the observed results. The conclusion will be that the observed results are likely to represent real treatment differences.

The following provides a reasonable interpretation of p-values:



p-value	Interpretation
$p < 0.01$	Very strong evidence against null hypothesis ( $H_0$ )
Between 0.01 to 0.05	Moderate evidence against null hypothesis
Between 0.05 to 0.10	Suggestive evidence against null hypothesis
$p \geq 0.10$	Little or no real evidence against null hypothesis

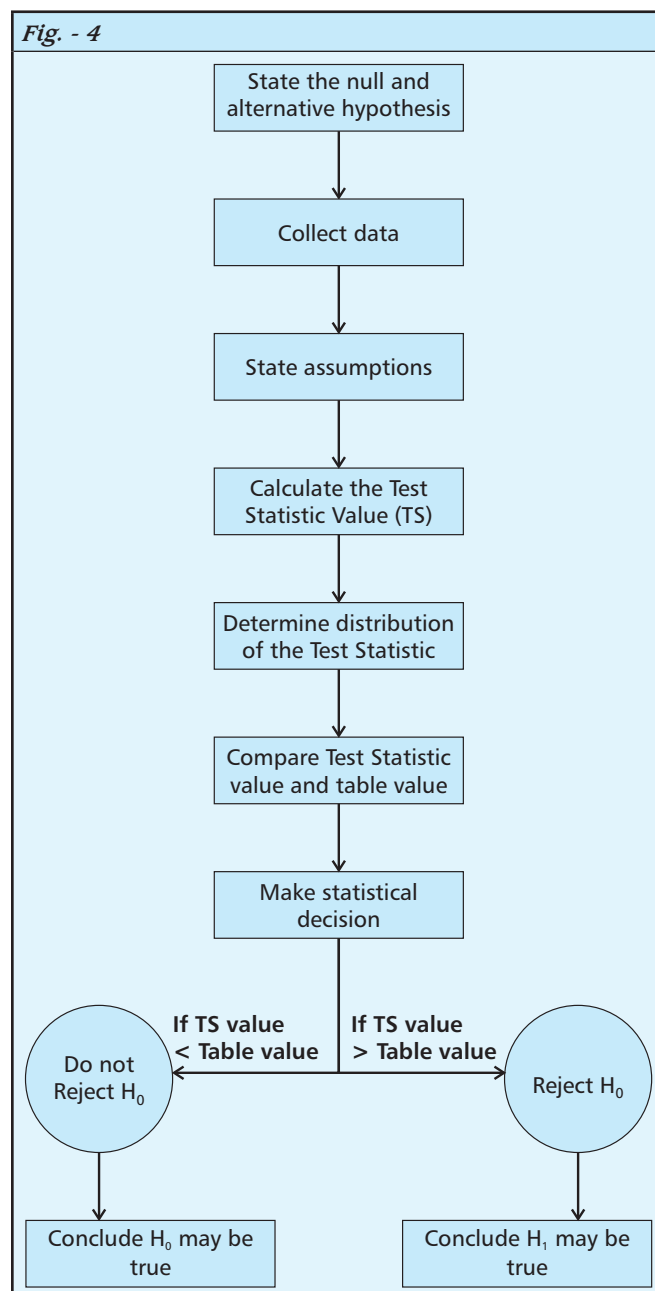
This interpretation is widely accepted, and many scientific journals routinely publish using such an interpretation for the result of test of hypothesis. However, our readers need to be cautioned at this point. Random error or chance which is estimated by p-value is just one type of error that can occur in research. One needs to be more cautious about the other 3 types of errors in research, i.e. error of basic measurement, systematic error (Bias) and Confounding error, all of which have been discussed in detail in the previous section on Research Methodology. Even the most highly significant p-value is of no avail if the data has flaws of measurement error, systematic error or confounding.

**Statistical Procedure in Hypothesis Testing :** Hypothesis testing aids the clinician and researcher in reaching a conclusion concerning a population by examining a sample from that population. Hypothesis testing assists the investigator to make decisions. At this point the difference between a statistically significant result and a clinically significant result must be thoroughly understood. Statistical decision should not be interpreted as definitive but it has to balance with the clinical and medical significance. Clinical significance relates to the magnitude of the observed effect while statistical significance answers the question of whether or not the results are due to chance alone or otherwise. The hypothesis testing procedure follows certain steps which are as listed below in the flow chart (Fig. - 4). We will see each step in detail in the next chapter.

## Summary

The process of making interpretation and drawing inferences from data is called as *inferential statistics*. The information collected is basically with the purpose of two broad objectives. The researcher is either interested in estimating a population parameter or testing a hypothesis concerned with population parameter. An estimate is a numerical value which is used to estimate the corresponding population parameter. Hence the researcher may be interested in estimating mean, proportion, difference between two means and difference between two proportions. Hypothesis testing as against estimation deals with testing the statements dealing with population parameters. There are two types of hypotheses-null hypothesis and alternate hypothesis. If the null hypothesis gets rejected then the hypothesis that gets accepted is called as alternate hypothesis which can be *two-tailed* or *one-tailed*. If the information on the direction of the hypothesis is known from review of literature one tailed alternative hypothesis is used whereas when no information is available unbiasedly two tailed hypothesis is considered. Since we deal with sample instead of population,

Fig. - 4



errors are bound to be present. The error of rejecting the true null hypothesis is called as *Type I error*, denoted by  $\alpha$  and referred to as p-value. Thus p-value is probability that a true null hypothesis is wrongly rejected. The maximum p-value allowed in a research problem is called the *Level of significance* or  $\alpha$ -level. Accepting a false null hypothesis is called as Type-II error. This error is denoted by  $\beta$ . Type-II error can occur when our sample size is too small to detect the difference that really exists between those treated and those not treated. The complimentary of Type II error is called *power* (Power =  $1 - \beta$ ). The power of a test is the probability of correctly rejecting  $H_0$  when it is false. Power of the test is kept atleast at 80%. Power increases with increasing sample size.

p-value is calculated under the assumption that the null

hypothesis is correct. Whether the results are statistically significant i.e. unlikely due to chance alone is decided by p value. If p value is less than 0.05, then it is said to be statistically significant otherwise the results are said to be statistically insignificant.

## Study Exercises

**Long Question :** Discuss the concepts “Hypothesis Testing” and “Estimation” as applied in the field of public health with suitable examples.

**Short Notes :** (1) Describe type I error and type II error in research (2) p value (3) Null Hypothesis (4) Standard error of mean and proportion

### MCQs

- Standard error of mean shows (a) Variation with in samples (b) Variation of sample means from population mean (c) Both of the above (d) None of the above.

- Type-1 error is (a) Rejecting true null hypothesis (b) Rejecting false null hypothesis (c) Accepting true null hypothesis (d) Accepting false null hypothesis
- Type-II error is (a) Rejecting true null hypothesis (b) Rejecting false null hypothesis (c) Accepting true null hypothesis (d) Accepting false null hypothesis
- Power is the ability to (a) Reject true null hypothesis (b) Reject false null hypothesis (c) Accept true null hypothesis (d) Accept false null hypothesis
- Statistically significant results mean that (a) Effect is due to chance (b) Effect is not due to chance alone (c) Findings are clinically significant (d) All of the above
- Type II error and \_\_\_\_\_ are complimentary (a) Type 1 error (b) p value (c) Power (d) None of the above
- What is the effect of increasing sample size on power? (a) It increases (b) It decreases (c) It remains same (d) None of the above

**Answers :** (1) b; (2) a; (3) d; (4) b; (5) b; (6) c; (7) a.

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## Inferences with Single Mean

Seema R. Patrikar

**Hypothesis Testing - A Single Population Mean :** Here we consider two situations about a population mean ( $\mu$ )

- When sampling is from *normally distributed population* and *population variance is known*. (Population may not be normally distributed but if sample size  $\geq 30$ , replace population variance by sample variance)
- When sampling is from *normally distributed population* but with *unknown population variance*.

**Situation 1 :** When sampling is from *normally distributed population* and *population variance is known*. (Population may not be normally distributed but sample size  $\geq 30$ , replace population variance by sample variance).

In the first situation the distribution of the test statistic under null hypothesis follows a standard normal distribution. The test statistic value which is a function of null hypothesis and the sampling distribution of the sample means (SE) is calculated as

$$z = \frac{\bar{x} - \mu_0}{\sigma / \sqrt{n}} \dots\dots\dots \text{(Equation 1)}$$

If the sample on which we base our hypothesis test about population mean comes from a population that is not normally distributed but if we have large sample drawn ( $n \geq 30$ ), then by virtue of central limit theorem we use the test statistic value as

$$z = \frac{\bar{x} - \mu_0}{s / \sqrt{n}} \dots\dots\dots 2)$$

where s is sample standard deviation, which under null hypothesis follows standard normal distribution.

Let us consider a hypothetical example. Researchers claim that the mean age of population having a certain disease 'A' is 35 years. To prove their claim, a researcher collected information from a random sample of 20 individuals drawn from population of interest. Population variance is known and is equal to  $\sigma^2 = 25$  and the study found that the mean age of 20 individuals is as 29.

**Hypotheses :** Null hypothesis is that the mean age of the population is equal to 35. The alternative hypothesis is that the mean age of the population is not equal to 35.

$H_0 : \mu = 35$  against  $H_1 : \mu \neq 35$

**Data :** From the sample the mean age was computed as  $\bar{X} = 29$ .

**Assumptions :** It is assumed that the parent population from which the sample is drawn follows a normal distribution. We also assume that  $\alpha = 5\%$  and population variance is known and is equal to  $\sigma^2 = 25$

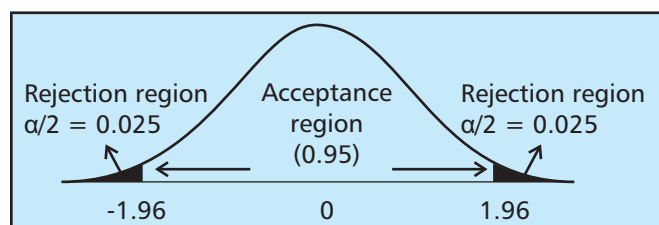
**Test Statistic :** Since we assume that population is normally distributed and since population variance is known, our statistic will be given by equation (1).

Thus,

$$z = \frac{\bar{x} - \mu_0}{\sigma / \sqrt{n}} = \frac{29 - 35}{5 / \sqrt{20}} = -5.36$$

**Distribution of test statistic** : The test statistic if  $H_0$  is true follows standard normal distribution with mean of 0 and variance of 1.

**Decision Rule** : The statistical decision is taken by comparing the calculated test statistic value with the table value of standard normal curve against predecided value of  $\alpha$  and type of the alternative hypothesis. If the alternative hypothesis is two tailed, then  $\alpha$  is divided in the two tails of the standard normal curve into equal parts of  $\alpha/2$  each. These areas are called as *Rejection areas*. The decision of rejecting the null hypothesis is taken if the calculated value of absolute test statistic falls in this area i.e. rejects  $H_0$  if calculated value of the absolute test statistic is  $\geq Z_{1-\alpha/2}$  or  $\leq Z_{\alpha/2}$



From the standard normal table for  $\alpha = 0.05$  two tailed, the table value is 1.96. Whereas for one tailed alternative hypothesis,  $\alpha = 0.05$ ,  $\mu < \mu_0$  type, the table value is -1.64 and for  $\mu > \mu_0$  type, the table value is 1.64. So we may reject  $H_0$  if calculated value of the test statistic is  $\geq 1.96$  or  $\leq -1.96$ , otherwise we do not reject  $H_0$ . In the given situation we take the statistical decision to reject the null hypothesis, since absolute value of test statistic (5.36) is greater than the table value (1.96). Tables of normal distribution are provided at the end of the section.

**Conclusion** : We conclude that the mean age of the population with a specific disease 'A' is not equal to 35 years ( $p < 0.05$ ).

**Situation 2** : When sampling is from *normally distributed population* but with *unknown population variance*.

In practice we rarely know the population variance. Quite often we face the situations where the sample size is less than 30 and population variance  $\sigma^2$  is not known. In such cases, we calculate the sample standard deviation ( $s$ ) and use this as an estimate of  $\sigma$ . This adds another element of uncertainty to our inference. Z statistics do not consider this additional uncertainty. Therefore, we use a modification of z procedures based on *Student's t distribution*. Student's 't' distribution was discovered by William Gosset who was working for Guinness brewing company. He was not allowed to publish scientific research, so he used the pseudonym "Student" to publish his work. t distributions are similar to z distribution, but have broader tails and less peaked at the center. As 'n' increases, t distribution approaches normal distribution. t tables are set up different than z tables. Each row is for a particular (df) degree of freedom. Columns show cumulative probabilities. (Tables are provided at the end of the section). When sampling is from normally distributed population but unknown population variance, the test statistic for testing  $H_0 : \mu = \mu_0$  is given as

$$t = \frac{\bar{x} - \mu_0}{s / \sqrt{n}} \dots\dots\dots (3)$$

which under  $H_0$  follows Student's t test with (n-1) degrees of freedom (df).

Consider a hypothetical situation. Suppose the researcher wants to know as to what extent the diabetics are over weight. He collects information on the body weight in terms of % of ideal body weight in 18 diabetics.

**Hypotheses** : We convert the claim to null hypothesis. Null hypothesis is that "Diabetics are *not* overweight". (Not overweight = 100% of ideal body weight). Therefore,

$H_0 : \mu = 100$  and alternative hypothesis can be  $H_1 : \mu \neq 100$  (*two-sided*)

Data => {107, 119, 99, 114, 120, 104, 88, 114, 124, 116, 101, 121, 152, 100, 125, 114, 95, 117}

We calculate sample mean  $\bar{X} = 112.78$  and sample standard deviation ( $s$ ) = 14.424

**Assumptions** : It is assumed that the parent population from which the sample is drawn follows approximate normal distribution. We also assume that  $\alpha = 5\%$  and population variance is unknown.

**Test Statistic**: Since the population variance is unknown and  $n < 30$ , the test statistic is given by equation (3). Thus substituting the values we get the calculated test statistic value as

$$t = \frac{\bar{x} - \mu_0}{s / \sqrt{n}} = \frac{112.78 - 100}{14.424 / \sqrt{18}} = 3.76$$

**Distribution of test statistic** : The test statistic if  $H_0$  is true follows student's t distribution with (n-1) df.

$$t_{n-1, 1-\alpha/2} = t_{18-1, 1-0.05/2} = t_{17, 0.975} = 2.11 \text{ (t table)}$$

**Decision Rule** : The statistical decision is taken by comparing the calculated test statistic value with the table value of student's 't' distribution. Since our calculated 't' value is more than table value at that particular df (17) and at that particular "two-tailed level of significance" (0.975), we reject the null hypothesis at 5% level of significance.

**Conclusion** : We have significant evidence against  $H_0$ . Hence we conclude that diabetics are not having the same weight as normals ( $p < 0.05$ ).

Consider another situation. We know from our background knowledge that the mean fasting blood sugar level of non pregnant young adult women is 88 mg/dl. With this background, we conducted a study on a sample of 100 ladies in 2nd / 3rd trimester of pregnancy, attending the obstetric department. We found that the mean fasting blood sugar of this sample of 100 ladies was 102 mg/dl with a standard deviation (SD) of 14. Apparently, our sample shows that the fasting blood sugar, on an average is higher by  $(102-88) = 14$  mg/dl among pregnant ladies, as compared to non pregnant ladies. We now want to see, statistically, whether this is a significant finding or simply a matter of chance, i.e, simply due to random (sample to sample) variations. To summarize, this is a situation in which we are studying only one sample and trying to compare the mean from this sample with a known population mean. This is the "single population mean" (or, one sample) situation. The statistical procedure is followed as mentioned

above. The test statistic is

$$t = \frac{\bar{x} - \mu_0}{s/\sqrt{n}} = \frac{102 - 88}{14/\sqrt{100}} = 10$$

The 't' value so calculated is compared with the 't' table value at degrees of freedom = (n-1)

$$df = (n - 1) = (100 - 1) = 99.$$

On looking at the 't' table, we find that the 't' table value at 0.05 level corresponding to df = 99 is approximately 1.98 and at 0.01 level it is 2.62. Since our calculated 't' value (10) is much higher than these values, we say that our results are highly significant ( $p < 0.01$ ); the higher average fasting blood sugar that we have seen among our sample of pregnant ladies is not likely to have come up simply because of "chance" (the probability of its having occurred simply by chance, i.e. random error is less than 1 in 100). We finally conclude, clinically, that pregnancy definitely leads to a rise in fasting blood sugar level.

## Summary

The statistical analysis in testing single population mean situation depends on whether the population variance is known or not. If population variance is known, the correct statistical analysis involves 'z' test, whereas when the population variance is unknown, students unpaired t test is used. Student's 't' distribution was discovered by William Gosset who was working for Guinness brewing company. He was not allowed to publish scientific research, so he used the pseudonym "Student" to publish his work. t distributions are similar to z distribution, but have broader tails and less peaked at the center. As 'n' increases, t distribution approaches normal distribution. Comparing the calculated test statistic value and the table value, the statistical decision is taken and accordingly conclusions are drawn. There are various situations which the researcher may be interested in like difference in proportions and means. Sometimes, in medical research, we may have either only one sample which gives us two sets of readings (before and after readings) or else, we may have two different samples which are very similar to each other excepting for the factor which is being studied. The statistical procedure in such situations is the "paired" 't' test where we first calculate the difference between pairs of observation i.e. difference ( $d_i$ ) between before and after value. The n sample differences then represent a sample from a normally distributed population.

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### Inferences with Single Population Proportion

Seema R. Patrikar

In clinical trials one may count the number of times an event occurs. For example number of successful outcomes, number of failures or number of patients recovered after administration of drug etc. This proportion may be compared with a hypothesized value or we may study a two sample problem in which trials are conducted in two independent study groups. Similarly patients in one group may receive new treatment drug and another independent group may receive existing conventional treatment. We may be interested in comparing the proportion of patients attacked by disease after administration of the treatment in the two populations. The population proportion is denoted by ' $\pi$ '.

The testing of hypothesis about population proportion is carried out in the same way as means.

#### Hypothesis Testing : A Single Population Proportion

In testing a single population proportion denoted by  $\pi$  against a hypothesized value of  $\pi_0$ , approximate normality assumptions holds true if the sample size is large.

The test statistic is given as

$$z = \frac{p - \pi_0}{\sqrt{\frac{\pi_0(1 - \pi_0)}{n}}} \dots\dots\dots 8)$$

Which when the null hypothesis is true follows a standard normal distribution. Here p is the sample proportion and  $\pi_0$  is the hypothesized population proportion.

Consider a hypothetical example. In clinical studies of an anti-allergy drug, 70 of 781 subjects experienced drowsiness. A competitor claims that 8% of users of his drug experience drowsiness. Use a 0.05 significance level to test this claim.

**Hypotheses** :  $H_0: \pi = \pi_0$  (0.08) against  $H_1: \pi \neq \pi_0$  (0.08)

**Data** : The data obtained on drug says 70 out of 781 subjects experienced drowsiness. Hence,

$$p = 70 / 781 = 0.089$$

**Assumptions** : The random sample is drawn from a normally distributed population and  $\alpha = 5\%$ .

**Test Statistic**: The test statistic is given by equation 8

$$z = \frac{p - \pi_0}{\sqrt{\frac{\pi_0(1 - \pi_0)}{n}}} = \frac{0.089 - 0.08}{\sqrt{\frac{0.08(1 - 0.08)}{781}}} = 0.99$$



**Distribution of test statistic** : The test statistic, if  $H_0$  is true, follows standard normal distribution with mean of 0 and variance of 1.

**Decision Rule** : For  $\alpha = 0.05$ , the standard normal table value is 1.96. Since our calculated test statistic value is less than the

table value, we fail to reject the null hypothesis.

**Conclusion** : There is not sufficient evidence to warrant rejection of the claim that drowsiness will be less among users of the competitors drug vis-à-vis the drug used by us ( $p > 0.05$ ).

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## Hypothesis Testing: The Difference between Two Population Means

Seema R. Patrikar

One of the commonest situations that a medical researcher faces while testing his/her hypothesis is when his/her interest is to see whether the two samples that he/she has drawn, differ significantly from each other as regards the “mean” of a particular variable of interest. Apparently, the above situation will be possible when we have recorded the data, in respect of that variable, on a “numerical discrete”, or on a “numerical continuous” scale. At this point, it would be worth emphasizing that in case the data has been recorded on a “numerical ordinal” scale (eg, dyspnoea scores, cancer grades etc.), we would NOT do testing for difference between “means”. This is for the simple reason, that though these figures (eg, dyspnoea score 1, 2, 3 etc.) obviously look like mathematical figures, they are not “mathematically meaningful” numbers. In such cases, we should use non-parametric tests for the differences between “medians”. In testing the hypothesis whether the means of the two populations differ significantly or not, we have one of the following hypotheses formulated for our research:

1.  $H_0: \mu_1 = \mu_2$  against  $H_1: \mu_1 \neq \mu_2$  which is equivalent to saying  $H_0: \mu_1 - \mu_2 = 0$  against  $H_1: \mu_1 - \mu_2 \neq 0$
2.  $H_0: \mu_1 - \mu_2 \geq 0$  against  $H_1: \mu_1 - \mu_2 < 0$
3.  $H_0: \mu_1 - \mu_2 \leq 0$  against  $H_1: \mu_1 - \mu_2 > 0$

Again we consider different situations about difference between two population means ( $\mu_1 - \mu_2$ )

- (1) When sampling is from *normally distributed population* and *population variance is known*. (Population may not be normally distributed but if sample size  $\geq 30$ , replace population variance by sample variance)
- (2) When sampling is from *normally distributed population* but with *unknown population variance*.

**Situation 1** : When sampling is from *normally distributed population* and *population variance is known*. (Population may not be normally distributed but sample size  $\geq 30$ , replace population variance by sample variance).

In the situation when both the samples follow normal

distribution and population variances are known, the distribution of the test statistic under null hypothesis follows a standard normal distribution. The test statistic in this case is calculated by the following equation.

$$z = \frac{(\bar{x}_1 - \bar{x}_2) - (\mu_1 - \mu_2)}{\sqrt{\frac{\sigma_1^2}{n_1} + \frac{\sigma_2^2}{n_2}}} \dots\dots\dots 4)$$

In the situation when the samples do not follow normal distribution but if the samples are large enough ( $\geq 30$ ), then the distribution of the test statistic under null hypothesis follows a standard normal distribution for assumed  $\alpha$ . The test statistic in this case is calculated by the following equation

$$z = \frac{(\bar{x}_1 - \bar{x}_2) - (\mu_1 - \mu_2)}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}} \dots\dots\dots 5)$$

**Situation 2** : When sampling is from *normally distributed population* but with *unknown population variance*.

In this situation the test statistic is calculated by first calculating the pooled variance given by  $s_p^2$ . The test statistic is then calculated by the following equation.

$$t = \frac{(\bar{x}_1 - \bar{x}_2) - (\mu_1 - \mu_2)}{\sqrt{\frac{s_p^2}{n_1} + \frac{s_p^2}{n_2}}} \dots\dots\dots 6)$$

$$\text{Where, } s_p^2 = \frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2}$$

Under the null hypothesis, the test statistic follows student's t distribution with  $(n_1 + n_2 - 2)$  dfs. Since under null hypotheses that there is no difference,  $\mu_1$  and  $\mu_2$  are assumed to be the same and hence  $\mu_1$  minus  $\mu_2$  becomes zero.

The following is a hypothetical data set of a research study to answer the question whether the serum cholesterol of healthy adult males, living in hot desert areas is, on an average, different (ie., significantly higher or lower) from the average serum cholesterol of healthy adult males living in temperate climates. The serum cholesterol values of 12 subjects from the deserts and 14 subjects from temperate climate are presented as :

**Serum Cholesterol Values (mg/dl) : Desert group** (Total = 12): 254, 218, 176, 242, 184, 239, 225, 256, 218, 182, 210, 191;  
**Temperate Climate Group** (Total = 14): 210, 176, 194, 250, 219, 207, 162, 154, 258, 166, 219, 200, 176, 182.

**Hypotheses** :  $H_0: \mu_1 = \mu_2$  against  $H_1: \mu_1 \neq \mu_2$  which is equivalent to saying

$H_0: \mu_1 - \mu_2 = 0$  against  $H_1: \mu_1 - \mu_2 \neq 0$

**Data** : As given above

**Assumptions** : Both the populations follow approximate normal distribution with unknown population variances and  $\alpha = 5\%$ .

**Test Statistic** : Since population variance is unknown we use equation 6 to calculate the test statistic value.

$$s_p^2 = \frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2}$$

$$= \frac{(12 - 1)(28.2)^2 + (14 - 1)(31.5)^2}{12 + 14 - 2} = 901.95$$

$$t = \frac{(\bar{x}_1 - \bar{x}_2) - (\mu_1 - \mu_2)}{\sqrt{\frac{s_p^2}{n_1} + \frac{s_p^2}{n_2}}}$$

$$= \frac{(216.25 - 198.07) - 0}{\sqrt{\frac{901.95}{12} + \frac{901.95}{14}}} = 1.53$$

**Distribution of test statistic** : If null hypothesis is true then the test statistic will follow student's t distribution with  $(n_1 + n_2 - 2)$ . From the t table we get the value against  $(12 + 14 - 2 = 24)$  dfs as 2.06.

**Statistical Decision** : Since the calculated test statistic value lies below the table value we do not reject the null hypothesis (accept  $H_0$ ).

**Conclusion** : Serum Cholesterol levels of healthy adult males, living in hot desert areas is, on an average, *not different* from the average serum cholesterol of healthy young males living in temperate climates ( $p > 0.05$ ).

## Paired Comparisons

The 't' test we have described above deals with situations in which there are two different samples whose means are to be compared. Sometimes, in medical research, we may have either only one sample which gives us two sets of readings (before and after readings) or else, we may have two different samples which are very similar to each other excepting for the factor which is being studied. Let us have a look at the following examples:

1. To study the efficacy of a drug in reducing the Serum Cholesterol level, we took 10 healthy adult males and measured their Serum Cholesterol levels. These 10 subjects are then given the drug for 1 month and the Serum Cholesterol levels were again measured thereafter.
2. For evaluating the skin irritant effect of an industrial chemical, we applied the chemical (in paste form, using paraffin jelly as the medium) on the right forearm of 10

subjects, while on the left forearm, only paraffin jelly was applied to serve as control. After 24 hours, we measured the maximum diameter of hyperaemia in millimeters on both the forearms.

3. For studying the effect of tobacco smoking during pregnancy on the birth weight of the child, we took a sample of 90 pregnant ladies who were tobacco users. For each such lady, we took another pregnant lady of same age, parity, income status and duration of pregnancy but who was a non smoker. In other words, we "pair - matched" each subject (pregnant smoker) with a control (pregnant non-smoker). We then followed up each of the 180 subjects till delivery and recorded the birth weight of the offspring in grams.

All the above three examples have very different objectives and settings; however, they have one thing in common - each data point of the first sample is related to a unique data point of the second sample. These are the situations of "paired samples". Such "paired samples" may represent two sets of measurements on the same subject in a "before and after" fashion (thus, each subject serving as his own control, vide example No. 1 above); or they may be two exactly similar anatomic or physiological points excepting for the factor under study (example No. 2 above); or, measurements on different people who are chosen on an individual basis using "matching criteria", so that they are very similar to each other, except for the factor under study (example No. 3 above).

The statistical procedure in such situations is the "paired" 't' test where we first calculate the difference between pairs of observation i.e. difference ( $d_i$ ) between before and after value. The n sample differences then represent a sample from a normally distributed population. The test statistic for testing the hypothesis that the mean difference between the before and after value = 0 ( $\mu_d = 0$ ) is as follows:

$$t = \frac{\bar{d} - \mu_d}{\frac{SD(\text{difference})}{\sqrt{n}}} \dots \dots \dots (7)$$

Where  $\bar{d}$  is the sample mean difference,  $\mu_d$  is hypothesized value of the population mean difference and SD is the standard deviation of the sample difference. The test statistic under null hypothesis follows a student's t distribution with  $(n-1)$  dfs.

Let us illustrate the calculation by taking following example. The Serum Cholesterol levels of the 10 subjects before giving the drug are mentioned in second column in Table - 1, while the cholesterol values of the same subjects after giving the drug for one month are given in the third column in Table - 1. The differences between these two cholesterol readings in respect of each and every subject are given in the last column.

**Hypotheses** :  $H_0: \mu_d = 0$  against  $H_1: \mu_d \neq 0$

**Data** : Now, the mean of the differences of the 10 observations  $(+26 + 12 + \dots - 1 - 10)$  comes out to + 9.7 and the standard deviation comes out to 12.96 thus.

$$\bar{d} = 9.7, SD(\text{difference}) = 12.96, n = 10.$$

Table - 1			
Subject No.	Serum Cholesterol mg/dl		Difference (d) (= d1 -d2)
	Before therapy d1	After therapy d2	
1	306	280	+ 26
2	254	242	+ 12
3	198	204	- 6
4	242	238	+ 4
5	236	228	+ 8
6	228	202	+ 26
7	286	264	+ 22
8	274	258	+ 16
9	208	209	- 1
10	188	198	- 10

**Assumptions** : The observed differences constitute a random sample from a normally distributed population and  $\alpha = 5\%$ .

**Test Statistic** : Using equation (7) for paired observation we get test statistic value as

$$t = \frac{\bar{d} - \mu_d}{\frac{SD(\text{difference})}{\sqrt{n}}} = \frac{9.7 - 0}{12.96/\sqrt{10}} = 2.37$$

$$df = (n - 1) = (10-1) = 9$$

**Statistical Decision** : Now, turning to the t table, we find the t table value at  $p$  or  $\alpha = 0.05$  and  $df = 9$  is 2.26. Since our calculated 't' value (2.37) is more than the table value (2.26), we conclude that our results are significant i.e. we reject our null hypothesis.

**Conclusion** : What we are in fact concluding is our sample of 10 subjects shows that there is a reduction on an average by 9.7 mg/dl due to the drug; and the "probability" that in the large reference population (of millions of persons who would be given the drug), the drug will not lead to a reduction in Serum Cholesterol is less than 5 in 100 chances; thus there are 95 in 100 chances that the drug will lead to a reduction in Serum cholesterol in the large reference population ( $p < 0.05$ ).

Once again, if we are using "numerical-ordinal" scales, then it should not be the "paired t-test" but rather a non parametric test (Wilcoxon's signed rank test) that should be used. For example, if we are comparing the "pain scores" (0,1,2,3 etc) before and after a drug then we should *not* use the paired t test as described above, but the Wilcoxon's signed rank test.

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## Hypothesis Testing: The Difference between Two Population Proportions

Seema R. Patrikar

This is the most common situation in medical research. We test the null hypothesis that the difference between the two proportions is zero or some other value. When the null hypothesis is stated as  $\pi_1 = \pi_2$  (two population proportions are same), it means that we are testing the hypothesis that  $\pi_1 - \pi_2 = 0$  (difference between two population proportions is zero).

The test statistic is given as

$$z = \frac{(p_1 - p_2) - (\pi_1 - \pi_2)}{SE_{p_1 - p_2}}, \dots\dots\dots(9)$$

Where  $p_1$  and  $p_2$  are sample proportion values

$$\text{where } SE_{p_1 - p_2} = \sqrt{\frac{\bar{p}(1 - \bar{p})}{n_1} + \frac{\bar{p}(1 - \bar{p})}{n_2}} \text{ and } \bar{p} = \frac{x_1 + x_2}{n_1 + n_2},$$

$x_1$  and  $x_2$  are numbers in the first and second samples possessing the characteristic of interest. The test statistic under null hypothesis follows standard normal distribution.

Consider a hypothetical example where we sampled 55 males in their adolescent ages. 24 of them were obese. Another sample of 149 females had 36 obese ladies. Can we conclude that in the sampled populations the proportion of obese males is higher than that of females ?

**Hypotheses** :  $H_0: \pi_1 \leq \pi_2$  or  $\pi_1 - \pi_2 \leq 0$  against

$$H_1: \pi_1 > \pi_2 \text{ or } \pi_1 - \pi_2 > 0$$

$\pi_1$  and  $\pi_2$  are proportions of obese in male and female populations respectively.

**Data** : The data gives the sample proportion values as  $p_1 = 24/55 = 0.44$  and  $p_2 = 36/149 = 0.24$ .  $\bar{p} = (24+36)/(55+149)$   
 $\bar{p} = 0.29$

**Assumptions :** The two independent simple random samples is drawn from a normally distributed population and  $\alpha = 5\%$ .

**Test Statistic :** The test statistic is given by equation 9

$$z = \frac{(p_1 - p_2) - (\pi_1 - \pi_2)}{SE_{p_1 - p_2}} = \frac{0.44 - 0.24}{\sqrt{\frac{0.29(1-0.29)}{55} + \frac{0.29(1-0.29)}{149}}} = 2.71$$

**Distribution of test statistic :** The test statistic, if  $H_0$  is true, follows standard normal distribution with mean of 0 and variance of 1.

**Decision Rule :** For  $\alpha = 0.05$ , the standard normal table value is 1.645 for one tailed hypothesis. So since the test statistic value is greater than the table value ( $2.71 > 1.645$ ), we reject the null hypothesis.

**Conclusion :** There is sufficient evidence that proportion of obese in males population is significantly higher than female population ( $p < 0.05$ )

## Study Exercises

**Short Notes :** (1) Unpaired 't' test (2) 't' test

### MCQs

- Twenty-five children are chosen randomly from a school playground. Their heights are measured when they first come into school the next morning, and again just before they go home that same evening. What statistical test could be used to test the hypothesis that their morning heights are no different from their evening heights? (a) Unpaired t-test (b) Paired t-test (c) Z-test (d) Regression
- To label a statistical test definitely significant, the p-value should be (a) Less than 0.05 (b) Less than 0.5 (c) Greater than 0.05 (d) Greater than 0.5
- The basic goal of Hypothesis testing is (a) To confirm the alternative hypothesis (b) To distinguish between random and meaningful differences in outcome (c) To establish the value of alpha (d) To establish the value of beta
- The value of alpha serves as protection against (a) False negative results (b) Inadequate sample size (c) Type I error (d) Type II error
- Six volunteers have gone on a cholesterol lowering diet for six months. The pretrial and the posttrial changes in the cholesterol levels are as given in the table. The appropriate test of statistical significance for this trial is (a) The critical ratio (b) Odds ratio (c) Paired t-test (d) Student's t test
- In the Testing of Hypothesis problems, we reject the null hypothesis. (a) If the Test Statistic value (calculated) is greater than the table value (b) If the Test Statistic value (calculated) is smaller than the table value (c) If the Test Statistic value (calculated) is equal to the table value (d) None of the above
- In comparing the difference between two population means, if value of p is 0.31. Then correct interpretation is (a) There is a significant difference between population means. (b) There is no significant difference between population means. (c) None of the above. (d) All of the above
- In a small sample survey on 7 male and 10 female students, the mean cholesterol levels were found to be 250 mg percent and 260 mg percent respectively. Which one of the following statistical tests is appropriate to find significance of the difference in this case (a) Chi-square test (b) Unpaired 't' test (c) Paired 't' test (d) z-test
- The statistical test used to analyze the difference between the mean values of hemoglobin of two independent samples (of 100 school children in each sample) drawn from normally distributed populations is (a) Paired 't' test (b) Unpaired 't' test (c) Chi-square test (d) z-test
- The minimum power of a study should be (a) 70% (b) 80% (c) 90% (d) None of the above
- Hb of 10 people was measured before and after giving them iron tablets for one month. Statistical test which can be used to measure the effect of iron on Hb is (a) Paired 't' test (b) Unpaired 't' test (c) Sign test (d) Chi-square test
- In hypothesis testing between two population means null hypothesis is (a)  $\mu_1 = \mu_2$  (b)  $\mu_1 = 0$  (c)  $\mu_1 = \mu_2 = 0$  (d)  $\mu_1 \neq \mu_2$
- Paired 't' test is used in all the following condition except (a) When only one sample gives two sets of readings (before and after readings) (b) When two different samples are similar to each (paired match) (c) When two different samples are similar to each (frequency match) (d) Independent samples are considered
- If numerical ordinal data for paired samples is used then the statistical test used is (a) Sign test (b) Wilcoxon sign test (c) Paired 't' test (d) Chi-square test
- Researcher's interest is to see whether the two samples that he/she has drawn, differ significantly from each other as regards the "mean" of a particular variable of interest the statistical procedure used is (a) Hypothesis testing of difference between two means (b) Hypothesis testing of single mean (c) Chi-Square test (d) All of the above
- While testing a hypolipidemic drug, serum lipids levels were tested both before and after its use. Which test is best suited for the statistical analysis of the results (a) Paired 't' test (b) Unpaired 't' test (c) Chi-square test

**Answers :** (1) b; (2) a; (3) b; (4) c; (5) c; (6) a; (7) b; (8) b; (9) d; (10) b; (11) a; (12) a; (13) c; (14) b; (15) a; (16) a.

### Statistical Exercises

- A researcher wants to estimate the mean Hb level of adult male population in Pune and studied 100 adult male. Previous studies shows that mean Hb level of Pune population is 12gm%. Average Hb level in 100 adult male is 11.5gm%. (i) Write the null hypothesis and the alternative hypothesis. (ii) What would be the test statistic value and its distribution (iii) Suppose in the above example sample size was 20, then which statistical test would be applied.
- A random sample of 100 subjects with family history of diabetes were selected and their mean fasting blood sugar was measured as 100mg/dl with standard deviation of 0.06mg/dl. It is known from previous study that mean fasting blood sugar level in persons without history of diabetes is 95mg/l. Can you conclude from the following data that mean fasting blood glucose level in subjects with



family history of diabetes is different from that of without family history ? let  $\alpha = 0.05$ . (T.S.=8.33, reject the null hypothesis)

19. A random sample of 52 subjects with family history of IHD were selected and their mean serum cholesterol level with standard deviation were measured as 220mg/dl and 10mg/dl respectively. It is known from the previous study that mean serum cholesterol level in subjects without family history of IHD was 200mg/dl. Can you conclude from these data that the mean serum cholesterol level in subjects with family history of IHD is different from that of without family history of IHD? Let  $\alpha = 0.05$ . (T.S.=14.4, reject the null hypothesis)

20. A researcher wants to study prevalence of anemia among rural pregnant ladies. Previous studies have shown prevalence to be 50%. She took 100 pregnant ladies from rural areas and took their hemoglobin readings and found 40% as anemic. Which statistical procedure will be used in this method. What would be the null hypothesis and the alternative hypothesis Can researcher conclude that prevalence of anemia in her study is different from previous studies? (T.S.=2, reject the null hypothesis)
21. A survey on 144 women respondents in India shows that 50% females are satisfied with their family life (n=144). Similar survey done globally showed that 45% of females are satisfied with their family life. Can you conclude from the data that females in India are more satisfied than at world level? let  $\alpha = 0.05$ . (T.S.=1.20, do not reject the null hypothesis)

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## Chisquare Test

Seema R. Patrikar

The previous section of hypothesis testing dealt with situations when we had discrete or continuous, i.e. “quantitative or numerical variables”, which could be measured. Apart from above mentioned situations many times medical research deals with situations involved with comparing two groups with the presence and absence of various diseases. Here the qualitative or categorical variables are measured in terms of “counts”. In other words, the researcher is interested in finding out the association or relationship between two qualitative variables. The statistical tests used for such variables which do not assume normality of the variable are specific and called as *nonparametric tests*. These are also called as *distribution free test*. These tests are weaker than parametric test and require fewer assumptions. For categorical data, the test used is called as chi-square test ( $\chi^2$  test). Since information is qualitative, it would be collected in counts. When the information is collected in counts, it is compiled and presented in a table called as *contingency table*. When both the qualitative variables are dichotomous, the tabular presentation takes the form of 2 x 2 contingency table (2 rows and 2 columns). In general we can have r x c contingency table where r is number of rows and c is number of columns. Under the null hypothesis, the test statistic follows a chi-square distribution with (r-1)x(c-1) degrees of freedom. The number of subjects falling in each category from our collected sample is called observed frequencies ( $O_{ij}$ ) and the numbers of subjects in our sample, that we would expect to observe, if null hypothesis is true are called the expected frequencies ( $E_{ij}$ ).

Chi-square tests have three applications.

1.  $\chi^2$  test for independence to test whether two or more characteristics are associated (independent) to each other.
2.  $\chi^2$  test for goodness of fit to study whether two or more independent populations are similar with respect to some characteristic.
3.  $\chi^2$  test for homogeneity to study whether two study groups independently drawn from two populations are homogenous with respect to some criteria of classification

In all the three situations, the test statistic takes the same formula given as follows

$$\chi^2 = \frac{\sum (O_{ij} - E_{ij})^2}{E_{ij}}$$

where  $O_{ij}$  and  $E_{ij}$  are observed and expected frequencies for  $i^{\text{th}}$  row and  $j^{\text{th}}$  column. The expected frequencies are calculated as follows

$$\text{Expected frequency} = \frac{(\text{marginal row total}) \times (\text{marginal column total})}{n}$$

The  $\chi^2$  test statistic value give details as to how close the observed and expected frequencies lie. When the null hypothesis is true, the test statistics follows a  $\chi^2$  distribution with (r-1)\*(c-1) degrees of freedom. The calculated  $\chi^2$  is compared with the  $\chi^2$  table value and the decision to reject  $H_0$  is taken if the calculated test statistic value is greater than the table value for specified value of  $\alpha$ .

Let us illustrate the procedure of Chi-square test using the hypothetical example on the association between maternal age and congenital malformations (Table-1). Let us say, we started with the research issue as to whether advanced maternal age (>35 years) is associated with congenital malformations among the children. We took a sample each, say, 500 pregnant ladies

aged > 35 years and another 1000 pregnant ladies aged upto 35 years and followed them till delivery. We found that out of the 500 children born to ladies > 35 years, 50 had congenital malformations, while out of 1000 ladies upto 35 years, there were again 50 children born with congenital malformations. We would thus proceed to test the research hypothesis that the age of mother and congenital malformations are associated. This research hypothesis would be tested against the "Null Hypothesis" which states "There is no association between congenital malformation and age of mother". (Age of mother and congenital malformation are independent to each other). The outcome variable of interest is dichotomous (either malformed child or normal child)

Table 1 : $\chi^2$ test for Independence			
Samples of ladies	Number of Children		Total
	Having Congenital malformations	Not having Congenital malformations	
>35 years	(O <sub>11</sub> )50 (10%) (a)	(O <sub>12</sub> )450 (90%) (b)	500 (100%) (a+b)
<35 years	(O <sub>21</sub> )50 (5%) (c)	(O <sub>22</sub> )950 (95%) (d)	1000 (100%) (c+d)
Total	100 (6.67%) (a+b)	1400 (93.33%) (b+d)	1500 (100%) (n)

O<sub>11</sub>, O<sub>12</sub>, O<sub>21</sub> and O<sub>22</sub> (Equivalent to a, b, c and d) are the observed frequencies in our sample. To calculate the chi-square test statistic value, we are first required to calculate the expected frequencies. Expected frequencies are the one that we expect if null hypothesis is true and is given by

$$\text{Expected frequency} = \frac{(\text{marginal row total}) \times (\text{marginal column total})}{n}$$

Thus for the above example we have expected frequencies for each cell as follows:

$$E_{11} = (500 \times 100) / 1500 = 33.33 \quad E_{12} = (500 \times 1400) / 1500 = 466.67$$

$$E_{21} = (1000 \times 100) / 1500 = 66.67 \quad E_{22} = (1000 \times 1400) / 1500 = 933.33$$

**Test Statistic:** Test Statistic for chi-square tests is given by

$$\chi^2 = \frac{\sum (O_{ij} - E_{ij})^2}{E_{ij}}$$

where O<sub>ij</sub> and E<sub>ij</sub> are observed and expected frequencies for i<sup>th</sup> row and j<sup>th</sup> column. Substituting the values from the above example we get

$$\chi^2 = \frac{(50 - 33.33)^2}{33.33} + \frac{(450 - 466.67)^2}{466.67} + \frac{(50 - 66.67)^2}{66.67} + \frac{(950 - 933.33)^2}{933.33}$$

$$\chi^2 = 13.39$$

**Distribution of the Test Statistic:** Under null hypothesis the test statistic follows a chi-square distribution with (row-

1)\*(column-1) degrees of freedom. For the above problem we have (2-1)\*(2-1) = 1 degree of freedom. For 1 df and assumed  $\alpha$  level of significance the chi-square table value is 3.84.

**Statistical Decision:** If the calculated test statistic value is greater than table value we reject the null hypothesis otherwise accept it. Since our calculated test statistic value = 13.39 > 3.84 we reject null hypothesis.

**Conclusion :** On the clinical front we conclude that there is a definite relationship between advanced maternal age (> 35 years) and congenital malformations in the offspring.

**Shortcut method for 2 x 2 contingency table :** When the data is cross tabulated in a 2 x 2 contingency table the  $\chi^2$  can be calculated using a shortcut formula given as follows.

$$\chi^2 = \frac{n(ad - bc)^2}{(a + c)(b + d)(a + b)(c + d)}$$

where a, b, c and d are observed frequencies in a 2 x 2 table and the denominator is the product of the marginal totals of the rows and columns. The  $\chi^2$  test statistic value always follows  $\chi^2$  distribution with 1 degree of freedom.

When 20% of the expected frequencies are less than 5 we apply Yates correction factoring in case of 2 x 2 table.  $\chi^2$  corrected formula is given as follows.

$$\chi^2 = \frac{n(|ad - bc| - 0.5n)^2}{(a + c)(b + d)(a + b)(c + d)}$$

where n is the total sample size.

## Summary

Many times medical research deals with situations involved with comparing two groups with the presence and absence of various diseases. Here the qualitative or categorical variables are measured in terms of "counts". In other words the researcher is interested in finding out the association or relationship between two qualitative variables. The statistical tests used for such variables which do not assume normality of the variable are specific. These tests are weaker than parametric test and require fewer assumptions. For categorical data the test used is called as chi-square test ( $\chi^2$  test). Since information is qualitative it would be collected in counts. When the information is collected in counts it is compiled and presented in a table called as contingency table. The number of subjects falling in each category from our collected sample is called observed frequencies (O<sub>ij</sub>) and the numbers of subjects in our sample that we would expect to observe if null hypothesis is true are called the expected frequencies (E<sub>ij</sub>). Under the null hypothesis the chi square test finds the difference between the observed and expected frequencies. Chi-square tests have three applications.  $\chi^2$  test for independence to test whether two or more characteristics are associated (independent) to each other.  $\chi^2$  test for goodness of fit to study whether two or more independent populations are similar with respect to some characteristic.  $\chi^2$  test for homogeneity to study whether two study groups independently drawn from two populations are homogenous with respect to some criteria of classification.

## Study Exercises

**Long Question :** What is test of significance? Discuss Chi-square test in detail.

**Short Notes:** Chi-square test

### MCQs

- In a study to determine relationship between presence of I.H.D and smoking, the appropriate Statistical test is :  
(a) z-test (b) Paired 't' test (c) Chi-square test (d) None of the above
- Which of the following is non-parametric test (a) z-test (b) 't' test (c) Chi-square test (d) None of the above
- Under the null hypothesis the test statistic follows a chi-square distribution with \_\_\_\_\_ degrees of freedom  
(a)  $(r-1) \times (c-1)$  (b)  $r \times c$  (c)  $n$  (d)  $n-1$
- All are application of chi-square test except (a)  $\chi^2$  test for independence (b)  $\chi^2$  test for goodness of fit (c)  $\chi^2$  test for homogeneity (d)  $\chi^2$  test for heterogeneity
- The number of degrees of freedom in a table of  $(4 \times 4)$  in Chi-square test is (a) 16 (b) 8 (c) 9 (d) 1.

**Answers :** (1) c; (2) c; (3) a; (4) d; (5) c.

## Statistical Exercises

- A researcher wanted to study association between exercise and survival from myocardial infarction he collected the following data

Exercise	Death	
	Yes	No
No	70	13
Mild	54	45
Moderate	30	50
Rigorous	15	70

Can we conclude from the following data that there is no association between exercise and death due to myocardial infarction? (Answer : T.S. = 80.37, reject null hypothesis)

- A cross sectional survey was carried out among women of age group 20-60 yrs to determine whether there is an association between history of multiple sexual partners and cervical cancer. Can you conclude from the survey results shown below that there is no association between the two?

History of Multiple sexual partner	Cervical cancer	
	Yes	No
Present	538	1125
Absent	112	1425

(Answer : T.S. = 300, reject null hypothesis)

- A cross-sectional survey was carried out to find out the relationship between sex and anemia and following data was collected

Sex	Anemia	
	Present	Absent
Male	15	150
Female	25	115

Can you conclude from the following data that there is no association between sex and anemia

(Answer : T.S. = 5.11, reject null hypothesis).

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## Confidence Interval

*Seema R. Patrikar*

As we have stated above, if an investigator is interested in estimating population mean ( $\mu$ ) or population proportion ( $\pi$ ), he draws a sample from population and compute the sample mean ( $\bar{X}$ ) or sample proportion ( $p$ ) as an estimate for population mean or population proportion. Since the investigator is studying a sample instead of population, error would always creep in. Most of the research results rely on the premise that what is true for the randomly selected sample from the population will be true for the population from which the sample is selected. But by all

logic we know that  $\bar{X}$  cannot be expected to be exactly equal to  $\mu$ . It would hence be required to estimate  $\mu$  by an interval that somehow communicates information regarding the true value of  $\mu$ . This reliability of the results obtained is addressed by Confidence Intervals (CIs). A CI is the range of values that encompass the actual or true population value. They provide information about how precise the estimate is. Wider CIs indicate lesser precision and narrower CIs indicate greater precision. Also p value and CIs are related to each other. When p value is less than 5%, the 95% confidence interval will exclude the hypothesized null value. Hence confidence intervals can also tell you whether null hypothesis is rejected or not.

### Confidence Interval for Population Mean

To calculate confidence interval we make use of the knowledge

of sampling distributions. We have already studied the sampling distribution of mean and proportion in the estimation and hypothesis chapter. From one of the important property of area relationship in a normal curve, we know that approximate 95% of the data value lies within 2 standard deviation from mean ( $\mu \pm 2 \sigma_{\bar{x}}$ ). Now if we consider all possible samples and calculate the mean for each sample we get  $\{\bar{x}_1, \bar{x}_2, \bar{x}_3, \dots, \bar{x}_n\}$ . From the sampling distribution of mean we know that the mean of these means would be population mean and the standard deviation of the sample means also called standard error of mean is given by  $\sigma_{\bar{x}} = \sigma / \sqrt{n}$ . If we construct intervals about every possible value of  $\bar{x}$  computed from all possible samples of size n we would have a large number of intervals of the form  $\bar{x} \pm 2\sigma_{\bar{x}}$ . Approximately 95% of these intervals would constitute the population mean value.

Thus a confidence interval gives an estimated range of values which is likely to include an unknown population parameter, the estimated range being calculated from a given set of sample data. It is interpreted as follows.

When sampling is from a normally distributed population with known standard deviation, we are  $100(1-\alpha)$  percent confident that the computed interval  $\bar{x} \pm z_{1-\alpha/2} \sigma_{\bar{x}}$  contains the population mean  $\mu$ . This interval is called a confidence interval for  $\mu$ .

Confidence intervals are usually calculated at 95%, but we can produce 90% or even 99% confidence intervals for the unknown parameter. The width of the confidence interval gives us some idea about how uncertain we are about the unknown parameter. A very wide interval may indicate that more data should be collected before anything very definite can be said about the parameter. Confidence intervals are more informative than the simple results of hypothesis tests (where we decide “reject  $H_0$ ” or “don't reject  $H_0$ ”) since they provide a range of plausible values for the unknown parameter. The confidence level is the probability value  $1-\alpha$  associated with a confidence interval. It is often expressed as a percentage. For example, say  $\alpha = 0.05 = 5\%$ , then the confidence level is equal to  $(1-0.05) = 0.95$ , i.e. a 95% confidence level.

**Example1 :** A dentist wished to estimate with 95% confidence, the mean marginal displacement in the teeth taking place by applying a particular treatment modality. He assumes that the marginal displacement values are normally distributed with a mean of 6.2 units after studying 100 people. The population variance is 9 units. (Population Standard Deviation  $= \sqrt{9} = 3$ )

**Solution:** The mean  $\bar{x} = 6.2$  with  $SD = 3$

The z value corresponding to a confidence limit of 95% is found from normal table which is equal to 1.96.

The standard error  $\sigma_{\bar{x}} = \sigma / \sqrt{n} = SD / \sqrt{n} = 3/\sqrt{100} = 0.3$

Thus 95% confidence interval for  $\mu$  is,

$$\begin{aligned} \bar{x} \pm z_{1-\alpha/2} \sigma_{\bar{x}} \\ 6.2 \pm 1.96(0.3) \\ 5.61, 6.79 \end{aligned}$$

**Interpretation :** We say that in repeated sampling from the study population, we are 95% confident that the mean marginal displacement for population lies between 5.61 and 6.79.

**Example 2 :** Suppose a researcher interested in finding the serum TSH in healthy adult females; studied 100 subjects and found that the mean serum TSH was 2 units with a standard deviation (SD) of 0.2. Calculate 95% confidence interval.

**Solution :** The 95% confidence interval for population mean is given by

$$\bar{x} \pm z_{1-\alpha/2} \sigma_{\bar{x}} = \bar{x} \pm z_{1-\alpha/2} SD / \sqrt{n}$$

where,  $\bar{x}$  = the mean from our sample,

SD = standard deviation

n = sample size.

Thus, 95% Confidence interval  $= 2 \pm (1.96 \times 0.2/\sqrt{100})$

$$= 2 \pm (1.96 \times 0.02)$$

$$= 2 \pm (0.0392)$$

$$= 1.9608 \text{ to } 2.0392$$

Thus, while from our sample under study, the mean serum TSH among healthy females is 2 units, we are 95% confident that the reality or truth that exists in the ‘total population’ (of millions of adult healthy females) would be that mean serum TSH would be between 1.9608 to 2.0392.

*Note : In constructing confidence interval knowledge of population variance from which the sample is taken is required. But when sample size is large i.e. greater than 30, we use sample standard deviation as a replacement for the unknown population standard deviation even if it is from non normal distribution by virtue of central limit theorem.*

When sample size is small, less than 30, we have alternate procedure of calculating confidence interval. The procedure remains same except that we use t distribution with n degrees of freedom instead of standard normal distribution ‘z’. The confidence interval for population mean in such cases is given by

$$\bar{x} \pm t_{1-\alpha/2} \frac{SD}{\sqrt{n}}$$

### Confidence Interval for the Difference between Two Population Means

We have already come across situations when the researcher is interested in estimating difference between two population means. When population variances are known the standard error value is given by

$$\sqrt{\frac{\sigma_1^2}{n_1} + \frac{\sigma_2^2}{n_2}}$$

In this case the confidence interval is given by

$$(\bar{x}_1 - \bar{x}_2) \pm z_{1-\alpha/2} \sqrt{\frac{\sigma_1^2}{n_1} + \frac{\sigma_2^2}{n_2}}$$

**Example :** The researcher is interested to find whether waist/hip ratio is different in cases of IHD as compared to healthy adults. For answering the issue the researcher took 100 cases of IHD. Their waist/hip ratio showed a mean of 1.1 with a standard deviation (SD) of 0.05. Another 400 healthy adults of similar age were also examined. Their waist/hip ratio showed an



average of 0.8 with a SD of 0.04. Calculate the 95% confidence interval for difference in means of waist/hip ratio among IHD patients and healthy subjects.

**Solution :** 95% confidence interval for difference between two population means is given by

$$(\bar{x}_1 - \bar{x}_2) \pm z_{1-\alpha/2} \sqrt{\frac{\sigma_1^2}{n_1} + \frac{\sigma_2^2}{n_2}}$$

From the sample we have

$$\bar{x}_1 = 1.1, SD_1 = 0.05, \bar{x}_2 = 0.8, SD_2 = 0.04, n_1 = 100, n_2 = 400$$

Thus the 95% confidence interval is

$$(1.1 - 0.8) \pm 1.96 \sqrt{\frac{0.05^2}{100} + \frac{0.04^2}{400}} \\ = (0.289, 0.311)$$

**Interpretation :** We are 95% confident that the difference between the waist/hip ratio in IHD cases and healthy adults lies in the range of 0.289 and 0.311. Since the 2 limits of the 95% CI are having the same sign (plus), we can also say that our findings are significant at 5% level ( $p < 0.05$ ).

**Note :** When the sampling is from non-normal population but the sample sizes  $n_1$  and  $n_2$  are large, more than 30, the population variances get replaced by the sample variances by virtue of central limit theorem.

**Case 1 :** When the population variances are unknown but we assume it to be equal we obtain the pooled estimate of the common variance which is given by

$$s_p^2 = \frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2}$$

The standard error in this case is given by

$$s = \sqrt{\frac{s_p^2}{n_1} + \frac{s_p^2}{n_2}}$$

The procedure for calculating the confidence interval remains same except that we use t distribution with  $n_1 + n_2 - 2$  degrees of freedom instead of standard normal distribution 'z'. Thus the confidence interval for difference between two population means is given as follows

$$(\bar{x}_1 - \bar{x}_2) \pm t_{1-\alpha/2} \sqrt{\frac{s_p^2}{n_1} + \frac{s_p^2}{n_2}}$$

**Case 2 :** When the population variances are unknown but we assume it to be unequal the standard error is given by

$$\sqrt{\frac{SD_1^2}{n_1} + \frac{SD_2^2}{n_2}}$$

Again we make use of t distribution. Thus the confidence interval in this case is given by

$$(\bar{x}_1 - \bar{x}_2) \pm t_{1-\alpha/2} \sqrt{\frac{SD_1^2}{n_1} + \frac{SD_2^2}{n_2}}$$

**Case 3 :** When the observations are paired. In other words when we are dealing with student's paired 't' test situation.

The confidence interval in this case is given by

$$\text{Mean of the differences} \pm t_{1-\alpha/2} \text{SD}(\text{difference})/\sqrt{n}$$

where  $t_{1-\alpha/2}$  is the t table value at  $(n-1)$  degrees of freedom.

### Confidence Interval for Population Proportion

Many times the researcher is interested not in the mean value but a proportion value [I]. What is the proportion of patients who survive/recover after administering a particular drug or what is the proportion of side effects and so on. In such cases the researcher proceeds in the same way as when estimating mean value. He selects a sample from the population and compute sample proportion  $p$ . The sampling distribution of proportion is normal distribution with standard error as  $\sqrt{p(1-p)/n}$ . Thus the confidence interval for population proportion is given as

$$p \pm z_{1-\alpha/2} \sqrt{p(1-p)/n}$$

**Example :** A researcher is interested in knowing the proportion of young men who are seropositive for HIV infection. He took a sample of, say, 1000 young men and did a sero study. He found that out of 1000 young men, 5 were positive. Calculate the 95% confidence interval for population proportion.

**Solution :** The sample proportion value =  $p = 5/1000 = 0.005$ ; thus,  $q = 1 - p = (1 - 0.005) = 0.995$ , and  $n = \text{total sample} = 1000$ . The 95% Confidence interval for population proportion is given by

$$p \pm z_{1-\alpha/2} \sqrt{p(1-p)/n}$$

$$\text{Thus, 95\% CI} = 0.005 \pm (1.96 \times \sqrt{0.005(1-0.005)/1000})$$

$$= 0.005 \pm 0.0044$$

$$= 0.0006 \text{ to } 0.0094 \text{ (or 6 per 10,000 to 94 per 10,000)}$$

Our interpretation would be that though we are not aware of what exactly the real seropositivity in the entire province would be, we are 95% sure that whatever this reality is, it will be somewhere between 6 per 10,000 to 94 per 10,000 in the total population.

### Confidence Interval for Difference between Population Proportions

When the researcher is interested in the difference between two population proportions, the reliability of his results are given by the 95% confidence interval for difference between the two proportions. The standard error is estimated by

$$\sigma_{p_1 - p_2} = \sqrt{\frac{p_1(1-p_1)}{n_1} + \frac{p_2(1-p_2)}{n_2}}$$

The confidence interval for difference between population proportions is given by

$$(p_1 - p_2) \pm z_{1-\alpha/2} \sqrt{\frac{p_1(1-p_1)}{n_1} + \frac{p_2(1-p_2)}{n_2}}$$

**Example :** In a research study, the researcher took a sample of 500 young, married, healthy ladies attending a Family Welfare Clinic. He found that 100 were using oral contraceptives (OC) while remaining 400 were using other temporary methods of

contraceptives. On following up these 2 groups for 1 year we observed that 10 out of the OC group and 20 out of the non OC group developed Thromboembolism (TE). The researcher is interested in estimating 95% confidence interval for difference between the two proportions of occurrence of TE.

**Solution :** proportion in one group,  $p_1 = 10/100 = 0.1$ ;  $q_1 = (1 - p_1)$

proportion in second group,  $p_2 = 20/100 = 0.05$ ;  $q_2 = (1 - p_2)$

sample size of first group,  $n_1 = 100$

sample size of second group,  $n_2 = 400$

Confidence interval for difference between proportions is given by

$$(p_1 - p_2) \pm z_{1-\alpha/2} \sqrt{\frac{p_1(1-p_1)}{n_1} + \frac{p_2(1-p_2)}{n_2}}$$

$$(0.1-0.05) \pm 1.96 \sqrt{\frac{0.1(1-0.1)}{100} + \frac{0.05(1-0.05)}{400}}$$

$$= (-0.012, 0.11)$$

### Confidence Interval when we are Working Out the Relative Risk

One important aspect when we are calculating the Relative Risk (RR) or Odds Ratio (OR) is that, while we are testing for the difference between two means or two proportions, the value of “no difference” is zero (For example, if the mean waist/hip ratio in both IHD as well as normal subjects is 1.1, the difference between means is zero and we would say that there is ‘no difference’ between IHD and normal subjects as far as waist/hip ratio is concerned). The value of ‘no difference’ is called the ‘null value’ in research.

The slight difference regarding null value when we are calculating the RR or OR is that the null value in these instances is *one and not zero*. When RR is one, it means that the incidence of the disease among both the groups (having the exposure and not having the exposure) is the same and so the factor does not carry any risk.

**95% CI of RR :** Let us consider an example of a “prospective” study in which the “outcome” is IHD occurred and not occurred and the “exposure” is smoking present and absent. The 2 X 2 table in this study would look like :

Smoking	IHD		Total
	+	-	
+	150 (10%)	1350	1500
-	175 (5%)	3325	3500
<b>Total</b>	<b>325</b>	<b>4675</b>	<b>5000</b>

We calculate the RR of developing IHD due to smoking as usual which is equal to 2. However, this is a finding from our ‘sample’ of two large “total populations” of millions of smokers and another millions of non smokers. Is it necessary that the “truth” that we are trying to estimate in the total populations, there will be a two fold risk? Can't it be 3 or 5? Or, it can also be 0.5 in reality. We will therefore, once again, have to work

out the 95% CI around this value of RR, which will give us a range, and we can say that we are 95% confident that the RR in reality, whatever it may be, will be some where in this interval. A rough but simple and reasonably accurate method of calculating the 95% CI of RR or OR is given by

$$95\% \text{ CI of RR} = \text{RR}^{(1 \pm 1.96 / \sqrt{X})}$$

$$95\% \text{ CI of OR} = \text{OR}^{(1 \pm 1.96 / \sqrt{X})}$$

Now in the present example, the  $\chi^2$  (chi square) value comes out to 100, thus

$$95\% \text{ CI of RR} = 2^{(1 \pm 1.96 / \sqrt{100})}$$

$$= 2^{(1 \pm 0.196)}$$

$$= 2^{(0.804, 1.196)}$$

$$= (1.79, 3.96)$$

Thus, we would interpret that the estimated RR for IHD due to smoking from our study sample is 2; however we are 95% confident that the truth, whatever it is, lies in the range of 1.79 to 3.96; smoking increases the risk of developing IHD by at least 1.79 times to as much as almost 4 times and we are 95% confident of this statement.

**The 95% CI of odds Ratio :** Let us say, stimulated by the question of the association between Thromboembolism and Oral Contraceptive use, we conducted a case control study by taking 50 ladies suffering from TE and 200 ladies of similar age and parity who never suffered from TE. We interrogated all these subjects regarding history of OC use during past 2 years. Out of 50 TE cases, 5 (10%) gave history of OC use while out of the 200 healthy ladies, 10 (5%) gave similar history. The data would be presented in the following 2 X 2 table :

History of OC use	TE		Total
	Cases	Controls	
Yes	5 (10%)	10 (5%)	15
No	45	190	235
<b>Total</b>	<b>50 (100%)</b>	<b>200 (100%)</b>	<b>250</b>

In this example, the Odds Ratio (OR) works out to  $(5 \times 190)$  divided by  $(10 \times 45) = 2.11$ . We would conclude that, since OR is a reasonable approximate of the RR, the risk of TE is 2.1 times more if OC have been used during past 2 years. We calculate the 95% CI.

$$\text{Now, } 95\% \text{ CI of OR} = \text{OR}^{(1 \pm 1.96 / \sqrt{X})}$$

Now,  $X^2$  for the given example = 1.77

$$\text{Thus, } 95\% \text{ CI} = 2.11^{(1 \pm 1.96 / \sqrt{1.77})}$$

$$= 2.11^{(1 \pm 1.47)}$$

$$= 2.11^{(-0.47, 2.47)}$$

$$= 0.70 \text{ to } 6.32$$

At this point, note one more surprising thing - the lower limit is less than 1, while the upper limit is more than one. In other words, the null value of 1 is enclosed in this 95% confidence interval. Whenever this happens, i.e. the 95% CI of RR or OR includes 1, we can also conclude that the results are statistically not significant at 5% level ( $p > 0.05$ ). Remember, in the case of 95% CI of the difference between means or proportion this

interpretation is made when zero is included in the interval (i.e. one end is minus and other is having plus sign). The remaining interpretation regarding clinical versus statistical significance has in any case to be made by looking at 95% CI of RR or OR.

## Summary

If an investigator is interested in estimating population mean ( $\mu$ ) or population proportion ( $\pi$ ) he draws a sample from population and computes the sample mean ( $\bar{X}$ ) or sample proportion ( $p$ ) as an estimate for population mean or population proportion. Since the investigator is studying a sample instead of population, error is always present. Most of the research results rely on the premise that what is true for the randomly selected sample from the population will be true for the population from which the sample is selected. But by all logic we know that  $\bar{X}$  cannot be expected to be exactly equal to  $\mu$ . It would hence be required to estimate  $\mu$  by an interval that somehow communicates information regarding the true value of  $\mu$ . This reliability of the results obtained is addressed by Confidence Intervals (CIs). A CI is the range of values that encompass the actual or true population value. They provide information about how precise the estimate is. Wider CIs indicate lesser precision and narrower CIs indicate greater precision. Also  $p$  value and CIs are related to each other. When  $p$  value is less than 5%, the 95% confidence interval will exclude the hypothesized null value. Hence confidence intervals can also tell you whether null hypothesis is rejected or not. While undertaking statistical analysis of any study the estimate values should always be accompanied by the confidence interval.

## Study Exercises

**Short Notes:** Confidence interval

### MCQs

- 95% of confidence limits exist between (a) +1SD (b) + 2SD (c) + 3SD (d) + 4SD
- Wider the range of confidence interval (a) more is the precision of estimate (b) precision does not get affected by it (c) less is the precision of estimate (d) none of the above
- Hypothesised null value for confidence interval of relative risk (a) zero (b) one (c) two (d) five

- If confidence interval includes null value then the results are (a) statistically not significant (b) statistically significant (c) clinically significant (d) none of the above.
- 95 % confidence interval means that we are (a) 5% error in our estimation of population parameter (b) 95% close to the estimation of population parameter (c) 95% confident that parameter will lie in this range (d) none of the above.

**Answers :** (1) b; (2) c; (3) b; (4) a; (5) a.

### Statistical Exercises

- A researcher wants to estimate the mean Hb level of adult male population in Pune. He studied 100 adult males. Previous studies shows that mean Hb level of Pune population is 12gm%. Average Hb level in 100 adult males is 11.5gm% with SD 1gm%. Calculate 95% CI of average Hb level of adult male population in Pune and interpret the results.  
(Answer : 95% CI = 11.30-11.69, we are 95% confident that average Hb level of adult male population lie in the range of 11.30-11.69 gm%. Also since this range does not contain 12gm% therefore mean Hb level of Pune is different from 12gm%).
- A random sample of 100 subjects with family history of diabetes was selected and their mean fasting blood sugar is 100mg/dl with S.D. of 0.06mg/dl. It is known from previous study that mean fasting blood sugar level in persons without history of diabetes is 95 mg/l. Calculate 95% CI for mean fasting blood sugar with history of diabetes and interpret the results.  
(Answer : 95% CI = 98.824-101.176)
- In a prospective study of smoking and IHD following data was collected. Calculate 95% CI of relative risk and interpret the result.

Smoking	IHD	
	Present	Absent
Present	20	80
Absent	12	88

(Answer : 95% CI = 0.87 - 3.20)

*Seema R. Patrikar*

In the initial chapters, we have highlighted that the major reason for utilizing statistics is because we study a sample instead of complete population. Research studies (surveys, experiments,

observational studies, etc.) are always better when they are carefully planned. Determining sample size is a very important issue and hence must be planned carefully because samples that are too large may waste research time, resources, patient effort and money invested in clinical trial, while samples that are too small may lead to inaccurate results. Also, it may be considered unethical to recruit patients into a study that does not have a large enough sample size for the trial to deliver meaningful information. Thus to ensure that a statistical

test will have adequate power, one usually must perform the exercise of calculating how large an 'n' (sample size) is required. It is not possible to compute a sample size for certain types of experiments because prior information is lacking or because the success of the experiment is highly variable. These studies are called as pilot studies. Pilot experiments are designed to explore a new research area to determine whether variables are measurable with sufficient precision as well as to check the logistics of a proposed experiment. Usually a pilot study is conducted by taking an approximate sample size of 30 or less. In most of the other research designs (for hypothesis testing) the sample size calculation depends upon the four major components viz the power, the level of significance, the effect size or the expected parameter value in the population and the expected size of the treatment effect sought. We have already discussed that power of a study is its ability to detect a true difference in outcome. This is usually chosen to be 80%. If study power is set at 80%, it accepts a likelihood of one in five (that is, 20%) of missing such a real difference i.e. the study will have 20% possibility of a "false-negative" result. Level of significance is predefined before we start the experiment. The chosen level of significance or Type I error is the probability of detecting a treatment effect when no effect exists (leading to a "false-positive" result) and defines the threshold "p value". Results with a p value above the threshold lead to the conclusion that an observed difference may be due to chance alone, while those with a p value below the threshold lead to rejecting chance and concluding that the intervention has a real effect. The type I error is most commonly set at 5% (or, sometimes at 1%). This means the investigator is prepared to accept a 5% (or 1%) chance of erroneously reporting a significant effect. The effect size is the biologically significant difference which is specified from a detailed review of literature, from experts or by conducting a pilot study. This is defined as "minimum detectable RR or OR or Treatment Effect (TE)". The four quantities  $\alpha$ ,  $\beta$ , sample size, and clinical difference are related to each other. If the three quantities  $\alpha$ ,  $\beta$  and clinical difference are specified, sample size can be determined. Sample size determination is done for two situations when the researcher is dealing with simple estimation problem or with hypothesis testing problem. We consider below sample size determination in both the situations of estimation and hypothesis testing. In hypothesis testing along with  $\alpha$ , power is also considered.

### Sample Size Determination for Estimating a Mean

Sample size 'n' is given by

$$n \geq \frac{z_{1-\alpha/2}^2 \sigma^2}{d^2}$$

where,

$d$  ---- is the precision or margin of error. In other words, it is the acceptable deviation between the hypothesized value and the true value of population parameter assuming 95% confidence interval.

$\sigma$  ---- is the population standard deviation which is estimated from pilot study or from previous similar study.

$z_{1-\alpha/2}$  - is the table values for alpha error corresponding to the standard normal distribution. This is 1.96 at 5% (i.e. 0.05) and

2.57 at 1% alpha error (two tailed).

### Sample Size Determination for Hypothesis Testing for Single Population Mean

Sample size 'n' is given by

$$n \geq \frac{(z_{1-\alpha/2} - z_{\beta})^2 \sigma^2}{d^2}$$

where,

$d$  ---- is the precision or margin of error. In other words it is the acceptable deviation between the hypothesized value and the true value of population parameter assuming 95% confidence interval.

$\sigma$  ---- is the population standard deviation which is estimated from pilot study or from previous similar study.

$z_{1-\alpha/2}$  - is the table values for alpha error corresponding to the standard normal distribution. This is 1.96 at 5% (i.e. 0.05) and 2.57 at 1% alpha error (two tailed).

### Sample Size Determination for Estimating Proportion

The procedure in estimating sample size for proportion remains same as in case of means. Assuming that population is large we determine the sample size by following equation.

$$n \geq \frac{z_{1-\alpha/2}^2 pq}{d^2}$$

where,

$p$  --- is the proportion in population possessing the characteristic of interest and  $q=1-p$ . This expected proportion in population is estimated from literature or pilot study. If nothing is known of  $p$  then it can be assumed to be 0.5.

$d$  ---- is the acceptable deviation and

$z_{1-\alpha/2}$  --- is the value of two tailed alpha error; this is 1.96 at 5% (i.e. 0.05) and 2.57 at 1% alpha error (two tailed). For one tailed alpha error, this will be 1.64 at 0.05 and 2.33 at 0.01 levels of alpha error.

### Sample Size Determination for Hypothesis Testing for Single Population Proportion

Sample size 'n' is given by

$$n \geq \frac{(z_{1-\alpha/2} \sqrt{\pi_0(1-\pi_0)} - z_{\beta} \sqrt{\pi_1(1-\pi_1)})^2}{(\pi_0 - \pi_1)^2}$$

### Sample Size Determination for Estimating Difference between Means

For estimating the means in two independent samples the sample size calculation remains similar to single population mean. Here  $n_1 = n_2 = n$

$$n \geq \frac{z_{1-\alpha/2}^2 \sigma^2}{d^2}$$

where it is assumed that  $\sigma_1$  and  $\sigma_2$  are same and equal to  $\sigma$ . If they are not equal their average can be taken as an estimate of the standard deviation.



### Sample Size Determination for Hypothesis Testing for Difference between Two Means

The sample size is given as

$$n \geq \frac{(z_{1-\alpha/2} - z_\beta)^2 \sigma^2}{(\mu_1 - \mu_2)^2} * 2$$

where it is assumed that  $\sigma_1$  and  $\sigma_2$  are same and equal to  $\sigma$ . If they are not equal their average can be taken as an estimate of the standard deviation.

### Sample Size Determination for Estimating Difference between Proportions

The method of sample size determination for estimating difference between proportions is slightly tedious than for single population proportion. No estimate of standard deviation from previous work or literature is required but the actual proportions in the two populations must be specified as well as their difference (d).

$$n \geq \frac{z_{1-\alpha/2}^2 (p_1 q_1 + p_2 q_2)}{d^2}$$

where  $p_1$  and  $p_2$  are proportion in population possessing the characteristic of interest and  $q_1 = 1 - p_1$  and  $q_2 = 1 - p_2$ .

### Sample Size Determination for Hypothesis Testing for Difference between Two Proportions

For comparing the proportions in two independent samples the sample size is given as

$$n \geq \frac{[z_{1-\alpha/2} \sqrt{2\pi(1-\pi)} - z_\beta \sqrt{\pi_1(1-\pi_1) + \pi_2(1-\pi_2)}]^2}{(\pi_1 - \pi_2)^2}$$

where  $\pi = \frac{\pi_1 + \pi_2}{2}$

### Sample Size Application for Hypothesis Testing in a Case Control and Prospective Studies

In a case control study, besides giving specifications for acceptable alpha error and acceptable beta error, the proportion of the persons without the outcome who are likely to give a history of the exposure (i.e. proportion of controls who are exposed) and the minimum risk (i.e. the minimum Odds Ratio that our study wants to detect), needs to be specified.

In case of a prospective study, besides giving specifications for acceptable alpha error and acceptable beta error, the proportion of subjects those who are not exposed to the exposure but are likely to develop the outcome and the minimum risk (i.e. the minimum Relative Risk that our study wants to detect) needs to be specified.

Once the above specifications have been made, the calculation becomes simple by the following formula :-

$$n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 * p * q}{(p_1 - p_0)^2}$$

where,  $n$  = minimum sample size for each group;  $z_{1-\alpha/2}$  = value of alpha error;  $z_{1-\beta}$  = value of beta error; For the usual situation when alpha error = 0.05 two tailed, the value is 1.96 and for beta error = 0.20, it is 0.84;  $P_0$  = Proportion of those

“without the exposure” who are likely to develop the “outcome” (in a prospective study) or Proportion of those without the outcome who are likely to have the exposure (in a case control study).

The value of  $P_0$  would have to be specified by us. The methods of obtaining the same are extensive reading into the subject, discussions with experts, or finally, by conducting a pilot study if required. Once  $P_0$  is specified,  $P_1$  is then obtained as follows

In a prospective study,

$$P_1 = \frac{P_0 \times RR}{[1 + P_0 (RR - 1)]}$$

In case-control study,

$$P_1 = \frac{P_0 \times OR}{[1 + P_0 (OR - 1)]}$$

And,

$$P = \frac{P_0 + P_1}{2}$$

$$q = 1 - P$$

(Please note: Sample size determination is discussed in detail with examples in the section on EPI – 2002. Hence it is suggested that the readers also review the details given in that section)

### Summary

Determining sample size is a very important issue and hence must be planned carefully because samples that are too large may waste research time, resources, patient effort and money invested in clinical trial, while samples that are too small may lead to inaccurate results. Also, it may be considered unethical to recruit patients into a study that does not have a large enough sample size for the trial to deliver meaningful information. Thus to ensure that a statistical test will have adequate power, one usually must perform the exercise of calculating how large an ‘n’ (sample size) is required. In most of the research designs the sample size calculation depends upon four major components viz the power, the level of significance, the effect size or the expected parameter value in the population and the expected size of the treatment effect sought. Most of the times, the power is chosen to be 80%. Level of significance is predefined before we start the experiment. The chosen level of significance or Type I error is the probability of detecting a treatment effect when no effect exists (leading to a “false-positive” result) and defines the threshold “p value”. Results with a p value above the threshold lead to the conclusion that an observed difference may be due to chance alone, while those with a p value below the threshold lead to rejecting chance and concluding that the intervention has a real effect. The type I error is most commonly set at 5% (or, sometimes at 1%). This means the investigator is prepared to accept a 5% (or 1%) chance of erroneously reporting a significant effect. The effect size is the biologically or clinically significant difference which is specified from a detailed review of literature, from experts or by conducting a pilot study. This is defined as “minimum detectable RR or OR or Treatment Effect (TE)”. The four quantities  $\alpha$ ,  $\beta$ , sample size and clinical difference are related to each other. If the three quantities  $\alpha$ ,  $\beta$  and clinical difference are specified sample size can be determined.

## Study Exercises

**Short Note :** Determinants of sample size

### MCQs

1. Sample size determinations depends upon all except (a) Type I error (b) Test statistic value (c) Power (d) Expected parameter value
2. In case control study  $P_0$  is proportion of those (a) Without the outcome who are likely to have the exposure (b) With the outcome who are likely to have the exposure (c) Without the outcome who are likely not to have the exposure (d) None of the above
3. Sample size determination for estimating a mean depends upon all except (a) Margin of error (b) Type I error (c) Population standard deviation (d) Population mean
4. In prospective study  $P_0$  is proportion of those (a) Without the exposure who are likely to develop the outcome (b) Without the exposure who are not likely to develop the outcome (c) With the exposure who are likely to develop the outcome (d) None of the above
5. All are true of sample size except (a) It should be representative of population (b) It should be of adequate size (c) It gives exactly the same results as exists in population (d) Sample size should be determined during the planning stage itself

**Answers :** (1) b; (2) a; (3) d; (4) a; (5) c.

### Statistical Exercises

1. An investigator wants to conduct a study to find out whether there is an difference in prevalence of diabetes among adults in town 'A' and 'B'. From previous study it is known that prevalence of diabetes among adults in town 'A' and 'B' are 11% and 8% respectively. How many adults from each of town should be included in a study for testing the null hypothesis that there is no difference in prevalence against the alternative hypothesis that there is difference in prevalence? The investigator wishes to be 90% confident of detecting a difference in prevalence between the towns at 5% level of significance. (Answer : 2004 adults from each town)
2. A researcher wanted to detect relative risk of 2 among smokers developing IHD as compared to nonsmokers. How many smokers and healthy subjects he should take if chances of developing IHD among healthy subjects are 0.03? Let level of significance is 0.05 and power of study to be 80%. (Answer : 335 each of healthy subjects and smokers)

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## Sampling Methods

*Seema R. Patrikar*

As already stated, most researchers come to a conclusion of their study by studying a small sample from the huge population or universe. To draw conclusions about population from sample, there are two major requirements for a sample. Firstly, the sample size should be adequately large, an issue which has been discussed in the previous chapter. Secondly, the sample has to be selected appropriately so that it is representative of the population. Sample should have all the characteristics of the population. In other words, a sample is expected to be mirror of the population from which it comes. Sampling techniques is concerned with the selection of representative sample, especially for the purposes of statistical inference. The idea of sampling is very old and from time immemorial, people have used it in day-to-day life. For example, a housewife examines one or two grains of cooked rice to ascertain whether rice is ready to eat or not. When a person goes to market to buy grains, he does not investigate each and every grain from the bag full of grains but just selects a fistfull to ascertain the quality of the grains. Thus, on the basis of a sample study, we

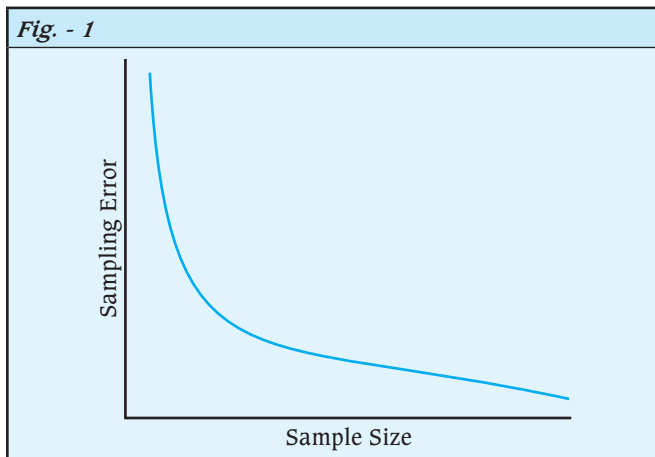
can predict and generalise the behaviour of the population. For sampling purpose, the population has to be divided into smaller units called as sampling unit. Evidently the population must be capable of division such that every element of the population belongs to one and only one sampling unit.

In order to cover the population, there should be a list consisting of all the subjects/units of the population. This list of each and every individual in the population is called as '*Sampling frame*'.

**Sampling errors :** The errors involved in the collection, processing and analysis of a data, may be classified as sampling errors. In other words, errors arising due to drawing inferences about the population on the basis of few observations is termed as 'Sampling error'. Sampling errors may arise due to bias in selection of sample. It may also occur due to faulty work during the collection and analysis. The sampling error can be reduced by ascertaining that the sample drawn is truly random and by increasing the sample size (See Fig. - 1).

**Non Sampling errors :** These errors arise at the stages of observations, compilation and analysis of data. They are present in both sample surveys as well as complete population enumeration survey. Thus the sample survey would be subject to both the sampling errors as well as non-sampling errors whereas the population surveys would be having non

sampling errors only. Non sampling errors occur at every stage of planning and execution because of faulty planning, errors in response by the respondents, compilation errors etc.



**Methods of sampling :** The various methods can be classified into two categories, namely, probability sampling and non-probability sampling. Probability sampling are those where each unit in the population has an equal chance or probability of being chose for the sample. Non probability sampling are those which do not have equal chance to every unit in the population. These methods are also called as Subjective or Purposive sampling. We will discuss few of the important sampling techniques adopted in medical research.

### Simple Random Sampling (SRS)

In this method, the individual units constituting the sample are selected at random. Each unit in the population has equal chance or probability to be selected in the sample. For this reason, it is sometimes referred to as a 'Probability Sample'. There are two types of random sampling, simple random sampling with replacement and simple random sampling without replacement. In SRS with replacement, the selected unit is replaced back to the population and again has the chance of getting selected. In SRS without replacement, which is the usual method in medical research, the selected unit is not put back in the population and hence the population size reduces by one at each selection. Random samples can be drawn by lottery method or by using random number tables. In Lottery method, we make small chits of paper for each unit in the population which are folded and then mixed together. From this the required number are picked blindly. For example, if you want to select 10 subjects randomly from a population of 100, you can write their names, fold them up, mix them thoroughly then pick ten. In this case, every name had an equal chance of being picked. The other method of drawing a random sample is by using random number tables. This method is possible only with finite population i.e. when the population size  $N$  is known. The technique of selecting random sample with the help of these numbers is very simple. Suppose we have to select a sample ( $n$ ) of 100 subjects from a population of 500 ( $N$ ). We first make a serial list of each and every subject of the 500 subjects in the population. This is called the "Sampling frame".

Then from the random number table, random numbers are selected row wise or column wise. Since ' $N$ ' (500) is of 3 digits, the random numbers selected are also 3 digits. If the selected random number is less than  $N$ , then the unit corresponding to that random number from population is selected in the sample. However if the random number is greater than  $N$ , then the remainder after dividing the random number by  $N$  is selected in the sample. For example, if selected random number is 167, then the unit corresponding to this number in the sampling frame is selected in the sample. But if the random number is 641, then the remainder after dividing 641 by 500 is 141. Thus, the unit corresponding to 141 in the sampling frame is taken in the study. The advantage of SRS over other methods is that subjectivity is completely eliminated as each subject has an equal chance of getting selected. Simple random sampling is very scientific but the practical problem is that it may be quite difficult, often impossible to make a complete list of all subjects in the population from which the sample is to be selected.

### Stratified Random Sampling

This method is preferred when the population is heterogeneous with respect to characteristic under study. In this method, the complete population is divided into homogenous sub groups called 'Strata' and then a stratified sample is obtained by independently selecting a separate simple random sample from each population stratum. This gives equal chance to the units in each stratum to be selected as sample. The total sample is the addition of samples of each stratum. Population can be divided into different groups based on some characteristic or variable like income or education. The advantage of this sampling procedure is that each subgroup, however small, has representation in the total sample. For example, if we draw a simple random sample from a population, a sample of 100 may contain only 10 to 15 high income groups, 20 to 30 middle income groups and 80 to 90 low income groups. To get adequately large representation for all the three socio economic structures, we can stratify on socioeconomic class and select simple random samples from each of the three strata. The advantage is that minority group is not left out but we require a sampling frame for each stratum separately.

### Systematic Random Sampling

Systematic sampling is a commonly employed technique, when complete and up to date list of sampling units is available. A systematic random sample is obtained by selecting one unit on a random basis and then choosing additional units at evenly spaced intervals until the desired number of sample size is obtained. For example, if there are 100 students ( $N$ ) in a class and we wish to select a sample of 20 students ( $n$ ) from them by systematic random sampling procedure, than the first step is to write the names of 100 students in alphabetical order or their roll numbers one below the other. In the systematic sampling procedure we divide  $N$  by  $n$  to get the sampling fraction ( $k$ ). Thus in the example  $k = 100/20 = 5$ . Next we randomly select any number between 1 to  $k$  i.e. between 1 to 5. Suppose the number we select is 4. Then the student number 4 is selected in the sample. Thereafter every  $k^{\text{th}}$  student is selected in the sample until we reach the last one. Thus the student's corresponding to numbers 4, 9, 14, 19, .....99 are to be selected in the sample. The advantage of systematic sampling is that it is easier to

draw, but the demerit is that the sample may exhibit a pattern or periodicity.

### Cluster Sampling

Cluster sampling is used when the population is heterogeneous. Clusters are formed by grouping units on the basis of their geographical locations. A cluster sample is obtained by selecting clusters from the population on the basis of simple random sampling. From the selected clusters each and every unit is included for study. Cluster sampling is a very useful method for the field epidemiological research and for health administrators. A special form of cluster sampling called the “30 cluster sampling”, has been recommended by the WHO for field studies in assessing vaccination coverage. In this a list of all villages (clusters) for a given geographical area is made. 30 clusters are selected using Probability Proportional to Size (PPS). From each of the selected clusters, 7 subjects are randomly chosen. Thus a total sample of  $30 \times 7 = 210$  subjects is chosen. The advantage of cluster sampling is that sampling frame is not required and in practice when complete lists are rarely available, cluster sampling is suitable.

### Multistage Sampling

In this method, the whole population is divided in first stage sampling units from which a random sample is selected. The selected first stage is then subdivided into second stage units from which another sample is selected. Third and fourth stage sampling is done in the same manner if necessary. For example, in an urban survey in a state, a sample of towns may be taken first and then in each of the selected towns, a second stage sample of households may be taken. If needed, further from each of the selected household, a third stage sample of individuals may be selected. Since the samples are selected at each stage the method is called ‘Multi stage sampling’.

**Randomization (Random allocation) :** ‘Randomization’ is different from random sampling. Randomization (or, random allocation) is a method used for allocating selected subjects (already selected by random sampling method) into 2 or more than 2 groups, with a view to ensure that these groups are similar in all respects excepting for the drug or vaccine etc. that we are interested in administering to them. Randomization ensures that the treatment groups are comparable with respect to other factors (such as age, sex, severity of illness) which might be associated with the outcome. Hence if a difference in response between groups is seen, we can be confident that this is due to the treatment, rather than due to other factors.

Random allocation can be done in many ways from tossing a coin to using random number tables. For example, keep tossing a coin and all patients who get ‘heads’ get drug ‘X’ and all patients who get ‘tails’ get ‘Y’. If there are 3 groups (drugs X,Y,Z), toss a dice and all patients who get 1 and 4 go to X, 2 and 5 go to Y and 3 and 6 go to Z; or, more scientifically, we should use a random table and all subjects getting even numbers go to ‘X’ and all getting odd numbers get Y.

Let us say, we are having an experimental study in which we are studying a new drug ‘X’ against an existing drug ‘Y’. Our sample size calculations indicated that we will need 10 subjects in each of the groups ‘X’ and ‘Y’ (total 20 subjects).

Now, the first step is to decide by any “random” (fair play) process, as to which all random members so selected will get treatment ‘X’ and which will get ‘Y’. This we can do by keeping two chits, having written ‘X’ on one and ‘Y’ on the other. Similarly, place another 2 chits (with “even” written on one and “odd” written on the other) in another box. Now, ask any impartial observer to pick up one chit from each box. Let us say that chits drawn were ‘X’ from one box and “even” from the other. Thus, we will give treatment “X” to all even random numbers so selected and “Y” to all odd random numbers. Next, make a table, listing all the 20 patients as shown in Table -1.

Now, select any random starting point from the random numbers table by dropping a pencil. Let us say, out of the 35 rows and 36 columns in our random number table, we picked up the intersection of 29<sup>th</sup> row and 4<sup>th</sup> column, i.e. number 9. Now note down this number against patient No. 1. From here we proceed down the 4<sup>th</sup> column, noting the numbers against the patient’s serial numbers *and ignoring* any zero. Once we come to the end of column 4, we continue with column no. 5.

Patient No.	Random No.	Even or odd	Treatment (X or Y)
1.			
2.			
3.			
...			
...			
20.			

Thus, the next number after 9 is zero, hence we ignore it; we take the next number i.e. 7, and write it against patient No.2. The next random member is 8 and we write it against patient No. 3. We continue this process till a random number has been allocated to each of the 20 patients. Now, in the next column of our above table we write down whether the random number selected for the particular patient is odd (O) or even (E). Thus, the random number given to the first patient is 9, i.e. odd and we write ‘O’ opposite it, similarly we write ‘O’ and ‘E’ respectively for 2<sup>nd</sup> and 3<sup>rd</sup> patient and so on. Now, in the fourth column with the heading “treatment X and Y”, write X for all patients getting ‘E’ and ‘Y’ for all patients getting ‘O’. The final layout is given in Table - 2.

Thus, first and second patients will get treatment ‘Y’, third and fourth get ‘X’, next 3 get ‘Y’ and so on, as the patients keep coming to our wards or OPD. We have, thus, “randomized” 20 patients into 2 treatment groups, well in advance.



Table - 2			
Patient No.	Random No.	Even or odd	Treatment (X or Y)
1	9	O	Y
2	7	O	Y
3	8	E	X
4	4	E	X
5	1	O	Y
6	1	O	Y
7	7	O	Y
8	8	E	X
9	9	O	Y
10	2	E	X
11	8	E	X
12	7	O	Y
13	1	O	Y
14	8	E	X
15	6	E	X
16	8	E	X
17	8	E	X
18	5	O	Y
19	9	O	Y
20	6	E	X

## Summary

Most researchers come to conclusion of their study by studying a small sample from the huge population or universe. To draw conclusions about population from sample, there are two major requirements for a sample. Firstly, the sample size should be adequately large and secondly, the sample has to be selected appropriately so that it is representative of the population. Sample should have all the characteristics of the population. In other words, a sample is expected to be mirror of the population from which it comes. Sampling techniques is concerned with the selection of representative sample, especially for the purposes of statistical inference. For sampling purpose the population has to be divided into smaller units called as 'Sampling unit'. In order to cover the population there should be a list consisting of all the subjects/units of the population.

This list of each and every individual in the population is called as 'Sampling frame'. Errors arising due to drawing inferences about the population on the basis of few observations are termed as 'Sampling error'. Whereas non sampling errors arise at the stages of observations, compilation and analysis of data. They are present in both sample surveys as well as complete population enumeration survey. Various methods of sampling are namely probability sampling and non probability sampling. Probability sampling are those where each unit in the population has an equal chance or probability of being chosen for the sample. Non probability sampling are those which do not have equal chance of selection for every unit in the population. These methods are also called as 'Subjective or Purposive Sampling'. Most commonly used sampling methods are simple random sampling, stratified sampling, systematic random sampling and cluster sampling methods.

## Study Exercises

**Long Question :** (1) What are advantages of sampling over complete enumeration? Describe briefly the SRS technique (2) Discuss various type of sampling method.

**Short Notes :** (1) Multistage sampling (2) Cluster sampling (3) Define cluster sampling. How will you evaluate the immunization status of children below five years of age from your district by the cluster sampling method.

## MCQs

- The list of each and every individual in the population is called as (a) Sampling frame (b) Sampling error (c) Sampling ratio (d) Sampling procedure
- All is true about simple random sample sampling except (a) Impractical if N is very large (b) Minority subgroups are adequately represented (c) Every member has an equal chance of being included (d) Population estimate is easy to calculate
- Probability samplings are all except (a) Simple random sampling (b) Systematic random sampling (c) Cluster sampling (d) Quota sampling.
- In simple random sampling if the subject is replaced back in the population it is termed as (a) Simple Random Sampling with replacement (b) Simple Random Sampling without replacement (c) Systematic sampling (d) None of the above
- Requirements of a sample is that it should be (a) Representative (b) Adequate (c) None of the above (d) Both 'a' and 'b'

**Answers :** (1) a; (2) b; (3) d; (4) a; (5) d.

Seema R. Patrikar

### Regression Techniques

Often in medical research it is desirable to analyse the relationship or association between two quantitative (i.e. continuous, discrete or numerical ordinal) variables. The term 'Correlation' indicates the relationship between two variables in which, with changes in the values of one variable, the values in the other variable also changes. The nature and strength of relationship that exists is examined by regression and correlation analysis. When the objective is to determine association or the strength of relationship between two such variables, we use correlation coefficient ( $r$ ). If the objective is to quantify and describe the existing relationship with a view of prediction, we use regression analysis. Correlation can either be positive or negative. When the values of the two variables move in the same direction, implying that if one variable increases the other variable also increases may not be in same magnitude or decrease in variable is associated with the decrease in the value of the other variable, the correlation is called 'Positive'. If on the other hand, the values of the two variables move in opposite directions so that with an increase in the value of one variable, the other variable decreases and with a decrease in the value of one variable the value of the other increases, the correlation in such case is called 'Negative'.

**Scatter Diagram** : Before we develop a mathematical model describing relationship we should first plot the scatter diagram of the variables. A scatter plot is a visual description of the relationship between two continuous variables. It consists of a graph with horizontal axis (x-axis) and vertical axis (y-axis) representing the two variables. Each observation of  $x$  and  $y$  are represented by dot on the graph at the point  $(x, y)$ .

Fig. - 1 shows the scatter diagram where the relationship indicates positive correlation, as the values of the two variables move in the same direction. Fig. - 2 shows the scatter diagram where the relationship indicates negative correlation, as the values of the two variables move in the opposite direction. Fig. - 3 and Fig. - 4 shows the scatter diagram where the relationship indicates perfect correlation, as the values of the two variables move in the same direction but in exact magnitude i.e. if one value increase in 5 units the other variable also increase in the same units whereas Fig. - 4 depicts perfect negative correlation where if one value increases in 5 units, the other variable decreases in the same units. Fig. - 5 shows that there is no correlation between the two variables.

### Correlation Coefficient ( $r$ )

Correlation coefficient is calculated to study the extent or degree of correlation between the two variables. The correlation coefficient ranges between -1 to +1 and is denoted by ' $r$ '. A correlation of zero indicates no association whereas a correlation of 1 indicates perfect association. The sign of correlation coefficient provides information on the type of association between the variables. If it is positive, then the high values of one variable will be associated with high values of

the other variable and if the correlation coefficient is negative, then low values of one variable are associated with high values of other variable. Thus Fig. - 3 & 4 have correlation coefficient value as +1 and -1, whereas the correlation coefficient in Fig. - 5 is zero. Fig. - 1 has  $r$  lying in the range of 0 to 1 and Fig. - 2 has  $r$  lying between -1 to 0. We have two types of correlation depending on whether the variables are continuous variables and joint distribution is following normal distribution or not.

Fig. - 1

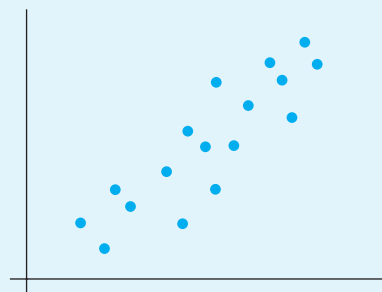


Fig. - 2

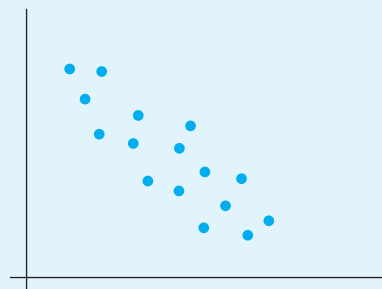


Fig. - 3

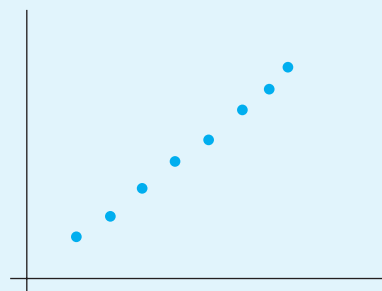


Fig. - 4

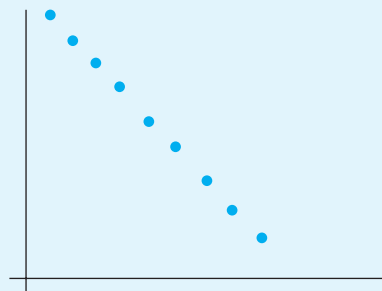
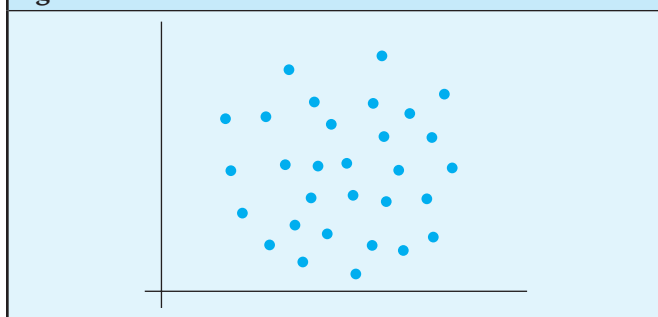


Fig. - 5



**Karl Pearson Correlation Coefficient** : This correlation coefficient works when variables are continuous variables and joint distribution is following normal distribution. The Karl Pearson's correlation coefficient (r) also called as 'Product moment correlation' is given by the following formula.

$$r = \frac{\sum (x - \bar{x})(y - \bar{y})}{\sqrt{\sum (x - \bar{x})^2 \sum (y - \bar{y})^2}}$$

The numerator is the sum of cross products about the mean whereas the denominator is the square root of the product of the sum of squares of deviation about the mean for each of the two variables. As an example, consider two variables x and y as given below. We find out whether the two variables are correlated to each other or not.

x	6	8	12	15	18	25	24	28	31	20
y	10	12	15	15	18	25	22	26	28	18

Mean of x ( $\bar{x}$ ) = 18.7 Mean of y ( $\bar{y}$ ) = 18.9

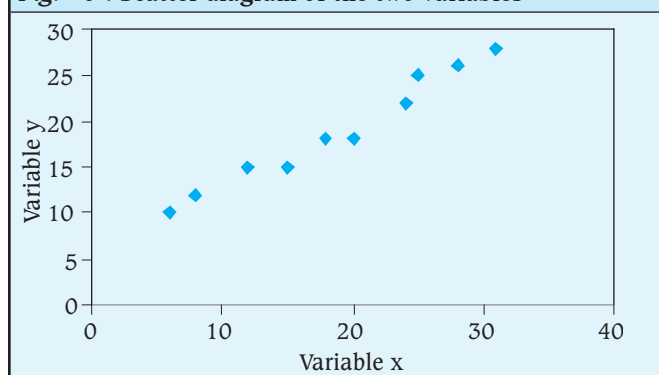
$$r = \frac{\sum (x - \bar{x})(y - \bar{y})}{\sqrt{\sum (x - \bar{x})^2 \sum (y - \bar{y})^2}}$$

Numerator =  $\sum (x - \bar{x})(y - \bar{y}) = 459.7$

Denominator =  $\sqrt{\sum (x - \bar{x})^2 \sum (y - \bar{y})^2} = 466.48$

Thus correlation coefficient  $r = 459.7/466.48 = 0.98$ . There is very good positive correlation between x and y (Fig. - 6).

Fig. - 6 : Scatter diagram of the two variables



**Spearman correlation coefficient** : Sometimes the variables are not normally distributed but are ranked in order, then the appropriate correlation measure is Spearman rank correlation coefficient. The Spearman correlation coefficient also ranges from -1 to +1 and is interpreted in the same way as the 'Pearson correlation coefficient'. The spearman correlation coefficient (r) is given as follows.

$$r = 1 - \frac{6(\sum d^2)}{n(n^2 - 1)}$$

Where  $\sum d^2$  is the total of the squares of the difference of corresponding ranks and n is the number of pairs of observations.

**Example** : Suppose a nurse doing a preliminary assessment of the condition of the patients in the ward, ranks the patients as per two variables of socio economic status and IQ. The data is given in Table - 1.

$$\sum d^2 = 68$$

The correlation coefficient is given as

$$r = 1 - \frac{6(\sum d^2)}{n(n^2 - 1)}$$

Thus,

$$r = 1 - \frac{6(68)}{9(81 - 1)} = 1 - 0.567 = +0.433$$

Table - 1

Patient No.	Ranks as per socio-economic class	Rank as per IQ level	Difference in the ranks d	d <sup>2</sup>
1	1	4	-3	9
2	2	2	0	0
3	3	3	0	0
4	4	9	-5	25
5	5	5	0	0
6	6	1	5	25
7	7	7	0	0
8	8	8	0	0
9	9	6	3	9

The interpretation of r is shown in Table - 2.

Table - 2 : Interpretation of r

Value of r	Relationship
If $0 < r < \pm 0.25$ Between 0 and $\pm 0.25$	Little or no linear relationship.
If $\pm 0.25 \leq r < \pm 0.50$ Between $\pm 0.25$ and $\pm 0.5$	Fair degree of linear relationship
If $\pm 0.50 \leq r < \pm 0.75$ Between $\pm 0.5$ and $\pm 0.75$	Moderate to good linear relationship.
If $r \geq \pm 0.75$ More than $\pm 0.75$	Very good linear relationship.

**Coefficient of determination** : Coefficient of determination is defined as square of correlation coefficient. It is the amount of variation in the dependent variable accounted for by the independent variable. In other words, if coefficient of correlation ( $r$ ) between age and blood pressure is 0.8 then coefficient of determination  $r^2 = 0.64$ . This is interpreted as 64% of variability in blood pressure is accounted by age whereas the remaining 36% is not by age. Other factors such as weight, diet and exercise may account for the 36% variability in blood pressure.

### Hypothesis Testing about Population Correlation Coefficient

The general steps in testing of hypothesis dealing with population correlation coefficient denoted by  $\rho$  are same as discussed in hypothesis testing dealing with mean, proportion or difference between means or proportions. The first step is to formulate the null and the alternative hypothesis. In this situation the hypothesis is stated as follows.

$H_0: \rho = 0$  (No relationship between the two variables)

$H_1: \rho \neq 0$  (There exist relationship between the two variables)

In this case the test statistic is given as follows.

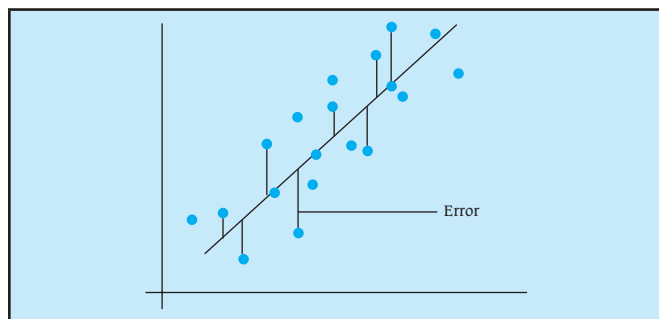
$$\text{Test Statistic} = \frac{r\sqrt{(n-2)}}{\sqrt{(1-r^2)}}$$

Where  $r$  is sample correlation coefficient and  $n$  is sample size.

Under null hypothesis, the test statistic follows student's  $t$  distribution with  $(n-2)$  degrees of freedom. We compare the calculated test statistic value with the table value at specified  $\alpha$  significance level for two tailed hypothesis. If calculated value is smaller than the table value, we accept the null hypothesis otherwise reject it.

### Regression Analysis

As stated earlier, if the objective is to quantify and describe the existing relationship with a view of prediction, we use regression analysis. In regression we assume one variable generally  $y$  as dependent variable and  $x$  as independent variable. Regression analysis determine the form of the relationship by a line which best fits the data. This line is called as 'Regression Equation'. This regression line which is unique is determined by the 'Least Square Method'. The principle of least square method is that the sum of squares of deviations of the observed points about the line is minimum. The deviation is obtained by measuring the distance from observed point to the line.



The equation of the straight line is given by  $Y = a + bx$

Where 'a' is the intercept and 'b' is the slope of the line which measures the amount of increase or change in  $y$  for unit change in  $x$ , whose estimates are found using the normal equations given as follows.

$$\Sigma y = an + b\Sigma x \text{ and } \Sigma xy = a\Sigma x + b\Sigma x^2$$

Solving these two equations we get the estimate of  $a$  and  $b$  as follows.

$$a = \bar{y} - b\bar{x} \text{ and } b = \frac{\Sigma (x - \bar{x})(y - \bar{y})}{\Sigma (x - \bar{x})^2}$$

Using the values of  $a$  and  $b$ , the dependent variable  $y$  for given  $x$  value can be predicted by substituting these values in the regression equation.

### Summary

Often in medical research, it is desirable to analyse the relationship or association between two quantitative (i.e. continuous, discrete or numerical ordinal) variables. The nature and strength of relationship that exists is examined by regression and correlation analysis. When the objective is to determine association or the strength of relationship between two such variables, we use correlation coefficient ( $r$ ). If the objective is to quantify and describe the existing relationship with a view of prediction, we use regression analysis. Before we develop a mathematical model describing relationship we should first plot the scatter diagram of the variables. A scatter plot is a visual description of the relationship between two continuous variables.

**Correlation Coefficient ( $r$ )** : We have two types of correlation depending on whether the variables are continuous variables and joint distribution is following normal distribution or not.

**Pearson Correlation Coefficient**: This correlation coefficient works when variables are continuous variables and joint distribution is following normal distribution. The correlation coefficient ranges between  $-1$  to  $+1$ . A correlation of zero indicates no association whereas a correlation of  $1$  indicates perfect association. The sign of correlation coefficient provides information on the type of association between the variables. If it is positive then high values of one variable will be associated with high values of the other variable and if the correlation coefficient is negative then low values of one variable are associated with high values of other variable.

**Spearman correlation coefficient** : Sometimes the variables are not normally distributed but are ranked in order then the appropriate correlation measure is Spearman rank correlation coefficient. The Spearman correlation coefficient also ranges from  $-1$  to  $+1$  and is interpreted in the same way as the Pearson correlation coefficient.

**Coefficient of determination** : Coefficient of determination is defined as square of correlation coefficient. It is the amount of variation in the dependent variable accounted for by the independent variable. In other words, if coefficient of correlation ( $r$ ) between age and blood pressure is 0.8, then coefficient of determination  $r^2 = 0.64$ . This is interpreted as 64% of variability in blood pressure is accounted by age whereas the remaining 36% is not by age. Other factors such as weight, diet and exercise may account for the 36% variability in blood pressure.

**Regression Analysis** : If the objective is to quantify and



describe the existing relationship with a view of prediction, we use regression analysis. In regression we assume one variable generally  $y$  as dependent variable and  $x$  as independent variable. Regression analysis determine the form of the relationship by a line which best fits the data. This line is called as 'Regression Equation'. This regression line which is unique is determined by the least square method.

## Study Exercises

**Long Question :** (1) What is correlation? Distinguish between positive correlation, negative correlation and zero correlation by means of scatter diagrams with suitable examples (2) Describe how relationship between two variables can be found out? Discuss correlation coefficient.

**Short Note :** Regression and correlation.

### MCQs

1. The scatter plot is used to display (a) Causality (b) Correlation (c) Power (d) Type II error
2. The correct statistical procedure for studying the association between an exposure and an outcome variable when both of them are measured on a continuous scale is (a) Chi square test (b) Pearson's correlation coefficient (c) ANOVA (d) t-test
3. In regression equation  $Y = a + bx$ ,  $b$  represents (a) Intercept on  $Y$  axis (b) Slope of the line (c) Intercept on  $X$  axis (d) None of the above

4. If correlation coefficient  $r=0$  it implies (a) Perfect positive linear relationship (b) Perfect negative linear relationship (c) No linear relationship (d) None of the above
5. When the variables are not normally distributed but are ranked in order then the appropriate correlation measure is (a) Spearman rank correlation coefficients (b) Karl Pearson product moment correlation (c) Wilcoxon sign test (d) None of the above.

**Answers :** (1) b; (2) b; (3) b; (4) c; (5) a.

### Statistical Exercises

1. A researcher collected weights (kgs) and heights (cms) of the 15 children of second standard as 10, 20, 11, 12, 12, 13, 11, 14, 13, 13, 15, 11, 16, 17, 18. If the heights of the same students are 95, 110, 98, 100, 102, 102, 99, 103, 104, 103, 106, 99, 108, 108, 109. Can you conclude from the data that there is a significant linear relationship between age and height of children? Let level of significance be 0.05. Estimate the height of the children for weight of 12kg. (Answer :  $r=0.955$ , T.S.=11.6 highly significant ,height=103cm)
2. Suppose the heights and weights of a group of people are approximately normally distributed with mean weight of 140lb, SD =12lb, mean ht =68 inches, SD=4 inches and correlation coefficient  $2/3$ . If an individual is found to be 66 inches tall. What is his expected weight? ( Answer : 136)

Seema R. Patrikar

In the simple regression discussed in the previous chapter, we had considered only two variables one being a dependent variable and the other being the independent variable. From the simple regression equation, we predict the value of the dependent variable on the basis of independent variable. Many times the researcher may come across situations where he/she is dealing with more than one independent variable. For example, the researcher may be interested in finding out as to how much change is likely to occur in serum cholesterol level (outcome or dependent variable) following changes in age, body weight, alcohol intake, calories consumed per day, and calories spent per day in physical exercise. Thus, we have a set of 5 independent variables, all of which are likely to affect the outcome variable by themselves. Such situations where more than one independent variable and one dependent variable are available and the aim is to predict dependent variable on the basis of many independent variables, the technique used for analysis is called as '*Multivariate Regression Analysis*'.

We will consider three types of situation under multiple regression situations. Multiple linear situation, logistic regression and cox regression.

**Multiple Linear Regression Model :** Multiple regression is the extension of simple linear regression, except that in this regression model, we have more than one independent or explanatory variables, and the outcome (dependent) variable is continuous or discrete numerical scale. When there is one outcome (dependent) variable which is measured on a "Numerical continuous" or else "Numerical discrete" Scale; and there are more than one predictor (independent) variables, this model is used.

In our example on serum cholesterol, there was one outcome variable which was measured on a continuous numerical scale (mg/dl). There were 5 independent variables, with  $X_1$  denoting body weight in Kg,  $X_2$  denoting age in years and so on till the  $n^{\text{th}}$  ( $5^{\text{th}}$  variable) viz, exercise energy, denoted by  $X_5$ . Such a situation when there is a single outcome variable which is measured on a numerical continuous or numerical discrete scale, and there are more than one independent variables, is known as "*Multiple Linear Regression Analysis*".

The advantage of multiple linear regression is that the result gives the  $\beta$  coefficient which indicates the change in the

dependent variable for the change in independent variable. For example, if after carrying out multiple linear regression if the beta coefficient for weight is 2.1, it indicates that for every kilogram increase in weight, the serum cholesterol is likely to increase, on an average, by 2.1 mg/dl. Along with the coefficients, the analysis also gives the 95% confidence interval, the significance value for each variable and the regression equation.

**Multiple Logistic Regression Model** : Another very common situation in epidemiology and medical research is when the outcome variable is measured on a “dichotomous scale”, of “either/or”; for example, the outcome variable could be “either having a disease (cases) or not having that disease (controls)”; or “either developed the disease or did not develop”; or “either survived or died” and so on. In such situations when the outcome variable is measured on a dichotomous scale and the independent (predictor or exposure) variables, which are at least two or more, are measured either on numerical continuous or numerical discrete or categorical dichotomous scale, the regression analysis procedure is “Multiple logistic regression”. Logistic regression is widely used in medical science since the medical researcher many a times is interested in presence or absence of a condition or disease and also the coefficients derived from logistic regression can be interpreted as odds ratio.

The analysis under logistic regression gives the  $\beta$  coefficient along with the odds ratio and 95% confidence interval for odds ratio. The beta coefficients ( $\beta$ ) in multiple logistic regression are interpreted differently as compared to beta coefficients in multiple linear regression. In multiple logistic regression, the beta-coefficients represent the “natural logarithm of the risk of the outcome due to that particular independent variable, following one unit change in the independent variable, or else as compared to the baseline category, and this estimate is, of course, adjusted for the confounding effect of all other independent variables that have put into the analysis.

Since the beta coefficients are the natural logarithm of the “risk”, we will have to exponentiate them to get the estimate of risk. This can be very easily done with a “Scientific calculator”. In any case, it is calculated directly in the results under the heading of “Odds Ratio (OR)”. Thus, if the beta coefficient for age is 0.037; then the odds ratio is 1.04, which is written under the column Odds Ratio (OR). The interpretation of OR is that it represents the independent, adjusted estimate of risk of the outcome, due to “particular level” of the independent variable, as compared to its baseline category (and not the immediately lower category).

**Cox Regression Model** : In the multiple regression and logistic regression models, we have the outcome or the dependent variable as continuous and dichotomous respectively. Apart from this, when the researcher is dealing with situations where the dependent or outcome variable is survival data i.e. time-to-event data or censored data, the regression method applied is called as ‘Cox Regression Model’. It is also called as ‘Proportional Hazard Regression’ as it makes use of the hazard function. The hazard function is defined as a conditional probability that an event will occur at time  $t$ , with the condition that the event has not occurred until time  $t$  (event free survival). Hazard function

is denoted by  $h(t)$ , which is the risk to death at time  $t$ , given survival up to time  $t$ . In other words, it is the probability that an individual dies at time  $t$ , conditional on having survived to that time. As in multiple and logistic regression when the analysis is carried out, it gives the regression coefficients, the hazard ratio estimates and the confidence interval.

## Summary

Situations where more than one independent variable and one dependent variable are available and the aim is to predict dependent variable on the basis of many independent variables the technique used for analysis is called as Multivariate regression analysis. Various regression models are simple, multiple, logistic and cox proportional models.

**Simple Linear Regression** : In simple model we have one outcome or dependent variable associated with only one independent variable. The line describes the linear relationship between the variables. We predict the dependent variable by a straight line equation.

**Multiple Linear Regression** : Multiple regression is the extension of simple linear regression except that in this regression model we have more than one independent or explanatory variables, and the outcome (dependent) variable is continuous or discrete numerical scale.

**Multiple Logistic Regression**: In logistic regression, the outcome variable or dependent variable is dichotomous (Died/Alive, Yes/No, Present/Absent). Logistic regression is widely used in medical science since the medical researcher many a times is interested in presence or absence of a condition or disease and also the coefficients derived from logistic regression can be interpreted as odds ratio.

**Cox Regression Model** : When the researcher is dealing with situations where the dependent or outcome variable is survival data i.e. time-to-event data or censored data, the regression method applied is called as Cox Regression model. It is also called as Proportional Hazard regression as it makes use of the hazard function. The hazard function is defined as a conditional probability that an event will occur at time  $t$ , with the condition that the event has not occurred until time  $t$  (event free survival).

## Study Exercises

### MCQs

1. Multivariate analysis is appropriate when (a) Bivariate analysis fails to reveal statistical significance (b) More than one independent variable is predicting the dependent variable (c) Multiple hypothesis are being tested (d) None of the above
2. When there is a single outcome variable which is measured on a numerical continuous or numerical discrete scale, and there are more than one independent variables statistical test used is (a) Multiple linear regression analysis (b) Multiple logistic regression analysis (c) Cox regression analysis (d) None of the above
3.  $\beta$  coefficient in multiple linear regression indicates (a) The change in the dependent variable for the change in independent variable (b) The change in independent

- variable (c) Variability amongst independent variability (d) All of the above.
4. In situations when the outcome variable is measured on a dichotomous scale and the independent (predictor or exposure) variables are measured on numerical continuous or numerical discrete, the regression analysis procedure is (a) Multiple linear regression analysis (b) Multiple logistic regression analysis (c) Cox regression analysis (d) None of the above
5. When the dependent or outcome variable is survival data, the regression method applied is (a) Multiple linear regression analysis (b) Multiple logistic regression analysis (c) Cox regression analysis (d) None of the above
- Answers :** (1) b; (2) a; (3) a; (4) b; (5) c.

## 53 Life Tables and Survival Analysis

Seema R. Patrikar

A life table is a life history of a hypothetical group or cohort of people as it diminishes gradually by deaths. The concept of life table was first given by John Graunt when he published a elementary life table on his collected data '*Bills of Mortality*'. Edmund Halley in 17<sup>th</sup> century developed a life table for the city of Breslau.

Life tables find numerous applications like finding the longevity of life, expectancy of life, for calculating the insurance premiums by the insurance companies and actuaries. It is also widely used by demographers and public health workers for studying the mortality patterns because of certain disease and comparing survival patterns of different communities. It is useful in projecting future population growth.

**Types of life tables :** There are various types of life tables. It is mainly categorized into different types depending on the reference year of the life table. According to the reference year, life tables are of two types *current life table* and *cohort or generation life table*. A current life table is based on the mortality experience of the community for a short period of time such as one year i.e. a hypothetical population is considered and this population is exposed throughout their entire lifetime to the average mortality rate. The cohort life table is based on the mortality experience of a birth cohort. Thus it is constructed

from the mortality records of individuals followed from the birth of the first to the death of the last member of a group. Life tables are also segregated into two different types on the basis of presentation into complete life tables and abridged life tables. In complete life table information is given for every year of age from birth to the last age whereas in abridged life tables information is given for age intervals such as  $x$  to  $x+5$  years.

**Description of life table:** Before we discuss the various columns of the life table we will consider certain basic assumptions required for the preparation of a life table. The first basic assumption is that the cohort is closed for migration in or out. Hence the change in the cohort is only due to death. People die at each age according to a fixed schedule. The cohort originates from a standard number of births (such as 1,000, 10,000, 100,000) called 'radix' of the life table. The cohort normally contains members of only one sex. (It is possible to construct life tables for both sexes combined). The various columns of the life table are shown in Table - 1.

The first column gives the age interval  $x$  to  $x+1$ . Column 2 gives the probability of dying between  $x$  to  $x+1$ . It is denoted by  $q_x$ . It represents the probability that a person at his  $x^{\text{th}}$  birthday will die before reaching his  $(x+1)^{\text{th}}$  birthday. These  $q_x$  values are the basic values from which the other columns of life tables are computed. The complementary event i.e. the probability of survival is  $p_x = 1 - q_x$ .

Column 3 gives the number alive at the beginning of the age interval which is normally taken as 1000 or 10,000 or 100,000. This starting number is called as the radix of life table.

Table - 1 : Life Table

Age interval ( $x$ to $x+1$ )	Probability of dying in age interval for those alive at the beginning of the interval ( $q_x$ )	Number alive at the beginning of the interval ( $l_x$ )	Number dying in the interval ( $d_x$ )	Number of persons living in interval ( $L_x$ )	Number of persons lived beyond age $X$ ( $T_x$ )	Average number of years of life remaining ( $e^0_x$ )
(1)	(2)	(3)	(4)	(5)	(6)	(7)

Thus  $l_x = l_{x-1} - d_{x-1}$

Column 4 gives the number of deaths  $d_x$  in the interval  $x$  to  $x+1$  which is calculated as the product of number of survivors at age  $x$  multiplied by  $q_x$ .

i.e.  $d_x = l_x * q_x$

Column 5 which gives the number of person years lived between age  $x$  to  $x+1$  is assumed to be the average of  $l_x$  and  $l_{x+1}$ . But it is not logical to use average as deaths are not evenly distributed in the complete life. (More deaths in childhood and old age) Thus at young ages  $L_0$  is estimated as follows

$$L_0 = \alpha.l_0 + (1 - \alpha)l_1$$

where  $\alpha$  is average age at deaths of those dying below age 1 or half of the proportional post neonatal deaths.

For  $L_2$  and ages greater than 2,

$$L_x = \frac{1}{2}(l_x + l_{x+1})$$

Column 6 depicts the total number of years lived beyond age  $x$ . In other words it is the total number of person-years lived from age  $x$  onwards. Thus  $T_x$  is obtained by summing  $L_x$  column from the bottom upwards.

$$T_x = L_x + T_{x+1}$$

Column 7 is the last column of the life table which gives the expectation of life at age. It represents the average number of years lived after the age  $x$ . It is calculated by taking the ratio of  $T_x$  and  $l_x$

Thus,

$$e_x^0 = T_x / l_x$$

## Survival Analysis

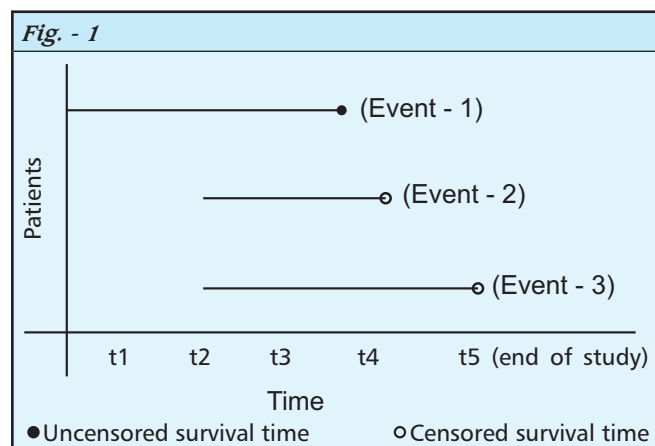
The various statistical situations that we have considered till now relate to “risk” or to “prognosis” or treatment related outcomes. However, sometimes the research question may be more interesting and somewhat different from the above mentioned situations. For example the question could be “what are the chances that a case of HIV infection acquired due to blood transfusion would be surviving at the end of 6 years?”; or, “what are the chances that a lady who has been diagnosed as cervical cancer by early screening and is treated would be alive at the end of 5 years?” or in general how long people with a life threatening disease survive following treatment. The analytical methods used to draw inferences regarding the chances of surviving/dying/getting cured/getting diseased (in short, the chances of developing the “outcome of interest”), over the various points of time are answered by “survival analysis”. Thus survival analysis deals with situations where the outcome is dichotomous and is a function of time.

Suppose patients suffering from a life threatening disease ‘A’ are treated with two treatment modalities and followed over specific time period say 5 years. The study continues during which any of the following three situations may occur.

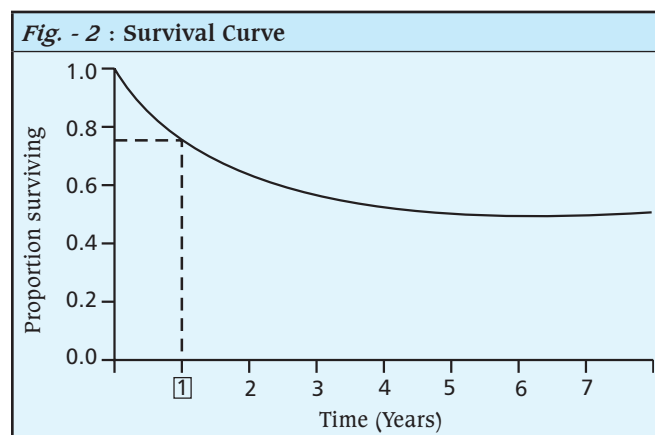
1. The event of interest (death of patient due to disease ‘A’) has occurred.
2. The patient is lost to follow up, from death due to cause other than disease ‘A’ or has left the study by moving out of area etc.

3. The event of interest (death of patient) does not occur till the end of study. i.e. the patient is alive when the study is terminated.

The time from enrollment to experiencing one of the above situations is called survival time. In situations 2 and 3 the survival time of patients is called as ‘Censored Survival Time’. Thus all those who achieve the outcome of interest are “uncensored” data while those who do not achieve the outcome are “censored” data ( Fig. - 1).



Visual representation of the survival experience of patients against time is represented by ‘Survival Curves’. Thus survival curves show the percentage surviving versus time. The following is a graph depicting survival curve (Fig. - 2).

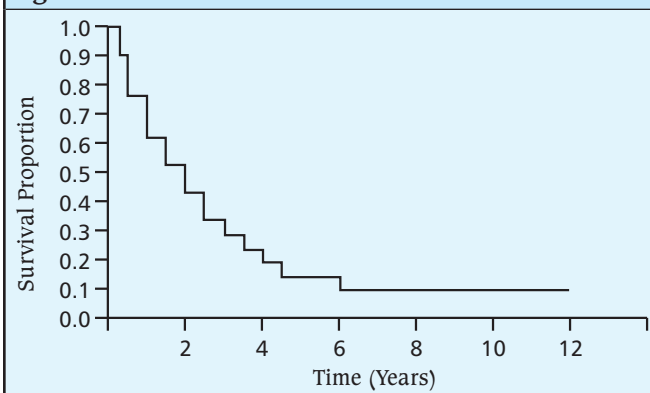


Most real life survival curves (Fig. - 3) usually are shown as staircase curves with a step down each time there is a death. This is because the survival curve represents the actual experience of a particular group of people. At the moment of each death, the proportion of survivors decreases.

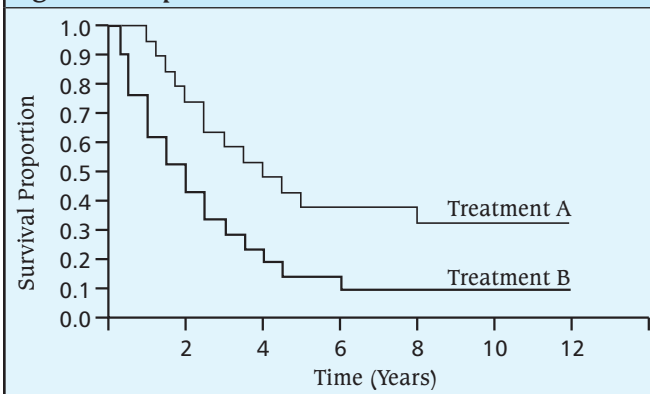
**Comparison between two survival curves :** The curves may compare results from different treatments as in the graph shown in Fig. - 4. If one curve is continuously “above” the other, as with these curves, the conclusion is that the Treatment A associated with the higher curve was more effective for these patients than Treatment B. The two lines represent the two “survival curves”.



**Fig. - 3 : Real Life Survival Curve**



**Fig. - 4 : Comparison between Two Survival Curves**



The vertical (or Y) axis of the graph is the percentage of patients in the group surviving. The horizontal (or X) axis represents time, starting from the time of diagnosis, or the time that treatment starts. As time goes on, some of the patients die and the curve steps down each time this happens. Most of the times these curves flatten out at the ends suggesting that some patients in each of the two groups are cured or at least are long term survivors, though the odds of that are obviously much greater for the upper curve.

There are number of methods of analyzing a survival data. Life table method accounts for differences in follow-up time and also account for changes in survival rate over time. It breaks the follow-up period of the study into intervals and then calculates the proportion of people at risk at the start of each interval who survive until the start of the next interval. There are two methods to calculate life tables viz. *the Actuarial method and the Kaplan-Meier method*. The basic difference between the two methods is the interval classification. The actuarial method adopts fixed class intervals which are most often year following the end of treatment given. The Kaplan-Meier method uses the next death, whenever it occurs, to define the end of the last class interval and the start of the new class interval. In both the methods the statistical test applied to test the null hypothesis that there is no difference in survival rates of the patients treated with two different treatment modalities (comparing two survival curves) is the *Log-Rank Test*. Log-Rank test does not control for confounding. To control for confounding we use

another test called as '*Cox Proportional Hazards Regression*' (which is discussed in chapter on advanced multivariate analysis). The mathematical calculation of the two tests is not discussed in detail but we only need to know that in medical research articles when we see Log-Rank test applied, a crude test for difference in survival curves was conducted whereas when we come across Cox proportional hazard model then the comparison in survival curves was conducted after controlling for confounding. Methods of working out survival curves and statistical testing by statistical software are explained in the EPI INFO section.

## Summary

A life table is a life history of a hypothetical group or cohort of people as it diminishes gradually by deaths. The concept of life table was first given by John Graunt when he published a elementary life table on his collected data 'Bills of Mortality'. Edmund Halley in 17th century developed a life table for the city of Breslau. Life tables find numerous applications like finding the longevity of life, expectancy of life, for calculating the insurance premiums by the insurance companies and actuaries. It is also widely used by demographers and public health workers for studying the mortality patterns because of certain disease and comparing survival patterns of different communities. It is useful in projecting future population growth. There are various types of life tables. It is mainly categorized into different types depending on the reference year of the life table. According to the reference year, life tables are of two types current life table and cohort or generation life table. A current life table is based on the mortality experience of the community for a short period of time such as one year i.e. a hypothetical population is considered and this population is exposed throughout their entire lifetime to the average mortality rate. The cohort life table is based on the mortality experience of a birth cohort. The various columns of the life table are age interval, probability of dying in age interval, number of people alive at the beginning of the interval, number of people dying in the interval, number of persons living in the interval, number of persons who lived beyond particular age and average number of years of life remaining.

The analytical methods used to draw inferences regarding the chances of surviving/dying/getting cured/getting diseased (in short, the chances of developing the "outcome of interest"), over the various points of time are answered by "survival analysis". Thus survival analysis deals with situations where the outcome is dichotomous and is a function of time. Survival analysis makes use of the life tables. In survival analysis data is transformed into censored and uncensored data. A patient who is lost to follow up, from death due to cause other than disease 'A' or has left the study by moving out of area etc. and the event of interest (death of patient) does not occur till the end of study. i.e. the patient is alive when the study is terminated are situations of censored data. Patients in whom the event of interest (death of patient due to disease 'A') has occurred are called uncensored data. There are number of methods of analyzing a survival data. Life table method accounts for differences in follow-up time and also account for changes in survival rate over time. It breaks the follow-up period of the study into intervals and then calculates the proportion of people

at risk at the start of each interval who survive until the start of the next interval. There are two methods to calculate life tables like Actuarial method and the Kaplan-Meier method.

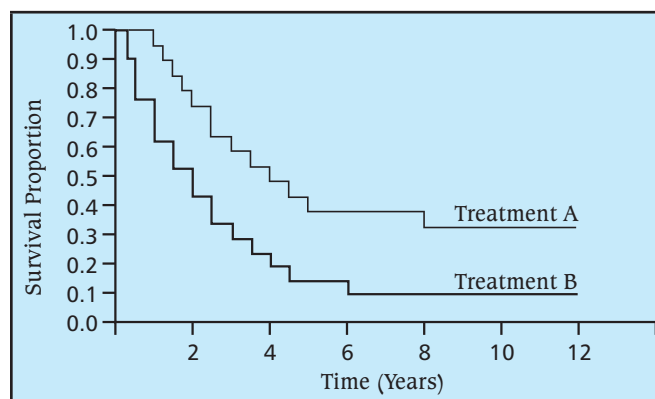
## Study Exercises

**Short Notes :** Survival analysis, life table

### MCQs

1. The starting numbers in life table is known as (a) Radix (b) Radius (c) Origin (d) Cohort
2. The analytical methods used to draw inferences regarding the chance of developing the "outcome of interest" over the various points of time is (a) Multiple logistic regression (b) Multiple linear regression (c) Survival analysis (d) None of the above
3. In survival analysis all those who achieve the outcome of interest are called as (a) Censored data (b) Uncensored data (c) Survival data (d) None of the above
4. The statistical test applied to test the null hypothesis that there is no difference in survival rates of the patients treated with two different treatment modalities (comparing two survival curves) is (a) Log-Rank Test (b) Cox regression analysis method (c) Kruskal wallis test (d) Multiple logistic regression test.

5. Figure given below shows the survival curves of treatment A and treatment B. From these curves it may be inferred that (a) Treatment A is more effective in prolonging life (b) Treatment A is less effective in prolonging life (c) Both treatment are equally effective in prolonging life (d) None of the above .



**Answers :** (1) a; (2) c; (3) b; (4) a; (5) a.

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## Standardisation of Rates

*RajVir Bhalwar & Seema R. Patrikar*

We had mentioned during our discussion on confounding, that one of the methods of making "adjustments" for the potential confounding effect of a variable, during the stage of analysis, is by "standardisation". "Standardisation of rates is sometimes used for controlling the effect of potential confounders during the analysis stage of large scale field research work, though for the usual epidemiological and medical research, such methods as Mantel-Haenszel stratified analysis or multiple regression analysis are definitely preferable.

Let us say, if you were to examine two coloured cards, one having a colour just a marginal shade lighter than "perfect yellow" and the other just a marginal shade darker than perfect yellow, you may find it very difficult to give your opinion as to which is lighter and which is darker of the two. However, your decision would be much better if we interposed, between the two cards, a "standard" card of "perfect yellow colour". This is an every day experience in life that comparison between two characteristics is always better if it is made against a preset, common standard.

On the similar lines, if you were to compare the overall (crude) death rate of a developing country with that of an affluent country, the overall death rate of the developing country would appear to be higher; and, it may be actually higher, or maybe it appears higher because a developing country has a higher proportion of infants and young children as compared to a developed country, and it is a known fact that mortality is much more among infants and young children. Thus, the observed difference as regards the "outcome" (crude death rate) due to the suspected "exposure" (being from developing or from developed country) has been thrown into a "confusion" by a third variable (the "age-structure") which is related to both, the "exposure" (higher proportion of younger persons in developing countries) as well as the "outcome" (higher death rate among younger persons). Thus, for giving a correct verdict in this comparison, we will have to compare the death rates in the two countries against a common standard. This process is called as Standardisation, and, depending on the choice of standard used, the method could be "direct Standardisation" or "indirect Standardisation".

### Direct Standardisation

Let us start with a hypothetical example. While comparing the death rate among children up to 15 years age group in a well developed influential province with the death rate among

children up to 15 years in a developing, poor provincial area, we found that the crude (overall) death rates among this age group were 31.3 per 1000 in the developing province and 27.5 in the well developed province. We would thus conclude that the death rate in the developing province is (31.3 / 27.5), i.e. 1.14 times higher. However, to a certain extent, this may be because of the confounding effect of age structure, with the developing province having a higher proportion of infants and toddlers, among whom the death rate, in any case, would be higher.

For removing the confounding effect of age structure, by direct Standardisation, we will, first of all, make suitable “subgroups” according to the confounding variable. Thus, in our example, we will make three groups, i.e. age 0 to 4 years, 5 to 9 years, and 10 to 14 years. These subgroups should be decided after careful medical and epidemiologic consideration of confounding variable. Next, for undertaking direct Standardisation, we must have the information as regards *at least* the following two aspects:-

a) The category - specific mortality rates (or, morbidity, if the outcome is morbidity and not mortality) of the two populations being compared. Thus, in our example, we should have the information as regards the “age group specific mortality rates per 1000 persons” for the age groups 0 to 4, 5 to 9 and 10 to 14 years, preferably for both the populations but *at least* for one of the populations.

b) The “age structure” of a “standard population” (usually the national population, or else, any other populations whose age structure is known)

Let us say, we had information regarding age group specific mortality rates of the provinces and we also knew the national population structure based on the census figure, which we decided to take as a “standard population”. The information which we had, is presented as in Table - 1.

Now, in the direct method of Standardisation, we will calculate the deaths that would be expected to occur in each age group of the “standard population” if the death rate of the two different populations were to apply separately on such standard population. We would add up the deaths so calculated for each subgroup and calculate the overall, standardised death rates, separately for the two populations.

Let us first of all calculate the deaths that would have been expected to occur in the various age groups of the standard population, if the age specific death rates of the developing province were to apply as follows :

Expected death rate

$$0-4 \text{ years} = (60 \div 1000) \times 27000000 = 1620000$$

$$5-9 \text{ years} = (20 \div 1000) \times 25000000 = 500000$$

$$10-14 \text{ years} = (5 \div 1000) \times 24000000 = 120000$$

Thus, total deaths = 1620000 + 500000 + 120000 = 2240000 and, age standardised mortality rate for developing province, (as standardised for the standard population).

$$= \frac{\text{Expected total deaths in standard population}}{\text{Total standard population}} \times 1000$$

$$= \frac{2240000}{76000000} \times 1000 = 29.47 \text{ per } 1000$$

Next, we shall calculate the expected deaths in the various age groups of standard population if the death rate of the developed province were to apply as follows :

$$0-4 \text{ years} = (55.6 \div 1000) \times 27000000 = 1501200$$

$$5-9 \text{ years} = (18 \div 1000) \times 25000000 = 450000$$

$$10-14 \text{ years} = (4 \div 1000) \times 24000000 = 96000$$

$$\text{Total deaths} = 2047200$$

Thus age standardised mortality rate for developed province

$$2047200 \div 76000000 \times 1000 = 26.94 \text{ per } 1000$$

Thus, after Standardisation, the mortality in developing province is 29.47 / 26.94 = 1.07 times and not 1.14 times higher as was apparent when crude death rates were being compared.

### The Choice of Standard Population

Please note one point - the direct age standardised mortality rates of the two provinces have come out as 29.47 and 26.94 per 1000 respectively. Now, this *does not mean* that mortality rates in the two provinces are actually 29.47 and 26.94 (and not 31.3 and 27.48 as calculated without Standardisation). The age standardised mortality rates so calculated are only for the purpose of comparison, to get an idea of the “comparative mortality” between the two provinces after “adjusting” for the confounding effect of age structure. Thus, these standardised

Table - 1

Age group (Years)	Developing Province			Developed Province			National Population In 1000 (*)
	Total population	Total deaths	Age specific death rate per 1000 [(c/b) X 1000]	Total population	Total deaths	Age specific death rate per 1000 [(f/e) X 1000]	
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
0-4	12000	720	60.0	9000	500	55.6	27000
5-9	10000	200	20.0	8500	153	18.0	25000
10-14	8000	40	5.0	8500	34	4.0	24000
Total	30000	940	31.3	25000	687	27.48	76000
* Multiply by 1000 to get actual value							

rates are basically imaginary or hypothetical figures, calculated only to make comparisons between two (or more) populations which may differ according to their age structure. This concept is important in interpreting the results of large scale health statistics. For example, if you find a table showing “age standardised mortality rates in our country for 1990”, it does not mean that these standardised rates represent the ultimate truth; it simply indicates the overall mortality rate that was expected to occur in our national population with a age structure that was there in 1990, if it was subjected to the subgroup mortality rates that are occurring now, at the time of this study. In the words of Sir A B Hill, the eminent biostatistician, standardised rates are more of a “fiction” meant only for making comparisons between two populations and not a reality. With this background, one can use any population as the “standard population”. One more thing that the field epidemiologist must remember is that “standardised” mortality or morbidity rates, whether directly or indirectly, standardised, cannot replace the “specific death/disease rates” (e.g. age - specific or sex specific death/disease rates). Comparisons of these age or sex specific death/disease rates will provide more meaningful information about the distribution and putative risk factors of the diseases.

## Indirect Standardisation

From what we discussed in the preceding paragraphs regarding direct Standardisation, a different situation may often arise, in that we may not be knowing the age group specific death rates about any one of the population composition in each age group of both the provinces and the total number of deaths in the 2 provinces as in Table - 2.

Table - 2		
Age Group	Total population	
	Developing Province	Developed Province
0-4	14000	8000
5-9	13000	9000
10-14	13000	11000
Total	40000	28000
Total deaths	371	110
Crude death Rate	$(371/40000) \times 1000$ = 9.28 per 1000	$(110/28000) \times 1000$ = 3.95 per 1000

Now, in this case, we will have to find out the “age group specific death rates” of a third, standard population. We can use the “national age group specific death rates” to calculate the overall “expected” deaths in each population. Let us say, hypothetically, the national age specific death rates per 1000 population available to us from census information are 15, 3.5 and 1.5 per 1000 for the age groups 0-4, 5-9 and 10-14 years respectively. The overall expected number of deaths in each population is calculated as

$\sum$  (age specific mortality rate x population in that age group)  
Thus, for the developing province, the “expected deaths”

$$[(15 \div 1000) \times 14000] + [(3.5 \div 1000) \times 13000] + [(1.5 \div 1000) \times 13000] = 210 + 45.5 + 19.5 = 275$$

Similarly, for the developed province, the “expected” deaths.

$$[(15 \div 1000) \times 8000] + [(3.5 \div 1000) \times 9000] + [(1.5 \div 900) \times 11000] = 120 + 31.5 + 16.5 = 168$$

Now, the next step is to calculate the “Standardised Mortality Ratio” (SMR) for each population as

$$SMR = \frac{\text{Observed No. of deaths in the population}}{\text{Expected No. of deaths in that population}}$$

Where observed deaths means the total number of deaths that have actually been recorded in that population. Thus, SMR for developing province  $371 \div 275 = 1.35$  and SMR for developed province  $110 \div 168 = 0.65$ .

A SMR of more than one, as has been calculated for the developing province, indicates that the mortality rate is higher than the standard population and vice versa. Thus, in our example, the developing province has a higher, and the developed province has a lower mortality rate, as compared to the “standard population”. Thus, in indirect Standardisation, we make “relative comparisons” (as the example of inserting perfect yellow cards of different shades given earlier in this chapter). On the other hand, direct Standardisation helps us in making “absolute comparisons”. For this reason, some epidemiologists use the term “changing base method” for indirect Standardisation and “fixed base method” for direct Standardisation.

## Summary

The crude death rate (CDR) could be different among 2 communities simply because their age structures are different. Hence to scientifically compare the 2 CDRs after removing the confounding effect of age structure on mortality, we use the process called as Standardisation. Standardisation can be done by two methods (i) Direct method and (ii) Indirect method.

This is simple and preferred method to calculate the age adjusted mortality rates. To perform a direct Standardisation, one has to first select a standard population. This population is arbitrary, although conventionally one uses either the World Standard Population produced by the World Health Organization, or a census population for the country in which the work is being conducted. Next, one computes the age-specific rates within the study group. Then, one multiplies these age specific mortality rates by the number of people in that age group in the standard population to get the “expected” number of deaths in each age group in the standard population. These expected counts are summed and divided by the total population size of the standard population to yield the direct standardised rate. In other words the standardised crude death rate in direct method is the crude death rate experienced by standard population if it was exposed to the age specific death rate of the study population.

Indirect Standardisation uses the standard population to provide age-specific rates i.e. the age specific mortality rates of the standard population are applied to the age structure of the study population. Within each age stratum, one multiplies the age specific mortality rates of the standard population by



the number of people in that age group in the study population to determine the “expected” number of deaths that would have been expected in each age group of the study population, had the age specific mortality rates of the standard population been applicable to them. These expected numbers are added up across all age groups. We now divide the observed number of deaths by the expected number of deaths. This ratio is multiplied with the crude death rate of the standard population to yield the Standardised Mortality Rates. In other words in indirect Standardisation, one computes the number of cases of deaths (or disease) that would have been expected if the death (or disease) rates from the standard population had applied in the study population. This is also known as standardised mortality or morbidity rate (SMR) and is quite commonly used in Occupation Health Studies.

## Study Exercises

### MCQs

- All are true regarding direct Standardisation except  
(a) Age specific death rate is required for comparison  
(b) Age composition of the standard population is required  
(c) Vital statistics are required (d) Without knowledge of the age composition, the two populations can be compared.
- Which method is used for controlling the effect of potential confounders during the analysis stage of large scale field research work (a) Standardisation (b) Matching (c) Restriction (d) All of the above
- Which statement is true (a) Standardised mortality rate are actual rate (b) For indirect Standardisation age specific mortality rate are required (c) Standardised mortality rate are imaginary (d) Standardisation is done in planning stage.
- Standardised mortality ratio is calculated in (a) Indirect standardisation (b) Direct standardisation (c) Both (d) None
- Direct standardisation is also known as (a) Changing base method (b) Fixed base method (c) Hanging base method (d) None of the above

**Answers :** (1) d; (2) a; (3) c; (4) a; (5) b.

### Statistical Exercise

Two populations of cities A and B are shown below. Crude death rate of population A & B is 38.28 and 36.39 per 1000 respectively. Compare the crude death rate using direct Standardisation.

<i>City A</i>			
Age group	Population	Age specific death rate per 1000	Deaths
0-10	20000	58	1160
11-19	18000	50	900
20-29	17000	35	595
30-39	15000	32	480
>40	55000	30	1650
Total	125000		4785

<i>City B</i>			
Age group	Population	Age specific death rate per 1000	Deaths
0-10	18000	62	1116
11-19	20000	43	860
20-29	22000	42	924
30-39	17000	34	578
>40	65000	26	1690
Total	142000		5168

<i>Standard population</i>	
Age group	Population
0-10	50000
11-19	48000
20-29	54000
30-39	45000
>40	125000
Total	322000

**Answer :** standardised mortality rate in population A and B are 38.44 and 37.925 respectively.

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There are certain issues wherein the public health and community medicine specialist may face situations when the commonly used simple tests may not serve the purpose of analysing the data. A brief overview of these tests is being given in this chapter to orient the readers to the basic terminologies and the situations in which these tests are used. The actual calculations are beyond the scope of this book and interested readers may refer to standard texts referred to at the end of this chapter. In addition, the calculations of these procedures have also been illustrated in the chapter on EPI – 2002.

### Non Parametric Tests

The hypothesis testing procedure discussed earlier, whether z test, unpaired t test or paired t test required the population distribution to be normal or approximately normal. In medical research many times we are not sure about the underlying distribution of the population. In such cases we apply non parametric tests which are not based on the assumption of normality of population especially when the sample size is small ( $n < 30$ ). Since they do not assume any distribution they are also called as distribution free tests. Non parametric tests are weaker than parametric tests as they do not have any information on the parameters of the distribution of data. Non parametric test are mainly used when the researcher is dealing with numerical ordinal scale i.e. when the data is scored. For example history of fever in patients may be recorded in terms of categories like no fever, mild fever, moderate fever and high fever. We can further give numerical values to these categories as No Fever=0, Mild Fever =1, Moderate Fever=2 and High Fever=3. These scores of 0, 1, 2 and 3 are not real mathematical numbers. Thus non parametric test are used when the underlying distribution is not known. It is also useful when the sample size is small. Non parametric tests allow us to test the hypothesis which does not deal with parameter values like mean and variance. Few of the commonly encountered non parametric tests are :-

**Mann Whitney U Test** : This test is the non parametric counterpart of the parametric 't' test. It is used to test whether two independent groups have been drawn from the same population or the two populations have equal median.

**Sign Test** : This test is a frequently used non parametric test for single population as well as paired samples. The test uses plus and minus signs and hence is named as sign test. For the single population the null hypothesis assumes the median value against an alternative hypothesis of not equal to median value. When data are paired (X, Y), the sign test is used to test the null hypothesis that the median difference is zero.

**Wilcoxon Signed Rank Test** : As we may have already explained under paired 't' test, there could be paired sample situations, in the form of "before and after readings", or "paired matched" data. The non - parametric counterpart of the paired 't' test is called "Wilcoxon signed rank test". The sign test takes into

consideration the direction of the differences (either negative or positive) whereas a stronger test, the Wilcoxon test considers the direction as well as the magnitude of the differences. This test gives more weight to a large difference between the two pair than to a pair which shows small difference.

### Inferences with More than 2 Means : Introduction to ANOVA

In the previous chapters on inferential statistics we have dealt in detail with hypothesis testing in difference between two populations with respect to mean. Many times the researcher is dealing with situations where there are more than 2 groups of interest. In such cases the usual z test and t test fails. The correct technique to compare means in three or more groups is analysis of variance or ANOVA. When one qualitative variable defines the groups, a one way ANOVA is used whereas when the groups are defined by two qualitative variables a two way ANOVA is used. It should be noted that the analysis of variance is not intended for testing the significance of sample variances but its purpose is to test for significance of difference among sample means. This chapter provides detail procedure for one way ANOVA.

When dealing with three or more groups the variability creeps in from two sources. One source is because of the groups itself, i.e. between group variability and the second source is within group variability. One of the basic assumptions of ANOVA is that the variances in the groups being compared are all equal i.e. homogenous. Also the variable of interest in the three groups is measured on either continuous or discrete scale. In case if the variable is measured in ordinal scale we use a non parametric test, the Kruskal-Wallis test where we compare the medians in the groups rather than mean. The assumption regarding homogeneity of variances is tested using Bartlett's test. Consider an example where three groups of Vegetarian, Non vegetarian and egg-etarian are considered. The researcher is interested to find out whether there is difference in the mean BMI value in the three groups. The data is as in Table - 1.

**Table - 1**

Sr. No.	Group 1 (Egg-etarian)	Group 2 (Vegetarian)	Group 3 (Non vegetarian)
1	15.40	16.28	21.13
2	16.75	17.02	20.47
3	17.97	17.83	23.32
4	19.29	18.24	18.28
5	18.24	20.00	21.05
Mean ( $\bar{X}_i$ )	17.53	17.87	20.85
SD ( $S_i$ )	1.49	1.41	1.80
n	5	5	5
N= 15 and the grand mean $\bar{X} = 18.75$			

As is already specified the total variability is due to the two sources between groups and within group. If the variation between groups is more than the variation within the groups, it would imply that the groups differ otherwise there would not

have been a difference in the variations between the groups and within the groups. Hence in the analysis of variance we find the relationship of the variation between the groups and the variation within the group. As from the example we find that the individual group means and the grand mean is different as also the group means are different from each other. The between group variance is obtained in the usual way, where the three means  $\bar{X}_i$  replace the individual observations ( $x_i$ ) and the grand mean is subtracted from each value. This between group variance is called as *between group mean square*, or error mean square.

The between group variance is greater than the within group variance which implies that the groups differ significantly. The significance is tested using F test which is based on the ratio of the two variances.

Like the tables of z, t, chi-square distributions, tables of F distribution is also available. F table is based on the degrees of freedom for the two variances i.e. the numerator degree of freedom is (k-1) whereas the denominator degree of freedom is (N-k). The results from analysis of variance are always tabulated in a table called as ANOVA Table. For the example considered above the ANOVA Table is presented as in Table - 2.

**Multiple Comparisons** : When an F test is significant i.e. when we reject the null hypothesis of equal means in all groups, we only come to know that the means are not equal however it is not clear where the difference lies. To know which mean is differing significantly there is a need for multiple comparisons. There are a number of methods for this purpose, viz, Bonferroni's procedure, Schaffe's method, linear contrasts, 'q' statistic, Newman - Keul's procedure and least significant difference (L.S.D.) method. The L.S.D. procedure is easy and uses less assumptions. The value so calculated for each pair is checked against the 't' table value at  $p=0.05$  and d.f. = (N-K). If our calculated 't' value is higher than the t-table value, we conclude that the 2 groups being compared are significantly different. On the other hand if the calculated value is less than the table value, we would conclude that the two groups being compared are not significantly different.

## Inferences with More than 2 Medians : Introduction to Kruskal-Wallis Test

As we have already mentioned if the data in the groups are not quantitative but qualitative ordinal then instead of parametric ANOVA we should use non parametric test called Kruskal Wallis test. Is called as 'H' and follows chi-square with k-1 degree of freedom for specified  $\alpha$ . If the calculated value of H (or,  $H^*$  if there are ties) is more than the table value of chi square then

we conclude that the results are significant and that atleast two or more groups are different amongst each other. If this is so, then we proceed further to do the inter group comparisons, using the Dun's procedure (a counterpart of L.S.D. procedure used for intergroup comparisons after ANOVA).

## Stratified Analysis using Mantel Haenszel Procedure for Control of Confounding

We have discussed in the chapter on confounding in the section on epidemiology and research methodology that there are two methods of controlling confounding in research. First method is during the planning and designing phase of the study. The researcher should plan and set up the study in such a way as to eliminate the effect of confounding variable right at the beginning. This can be done by restriction, matching or randomization. The second method is statistical analytical method called stratified analysis carried out during the analysis phase after completing data collection. Stratification means making a separate table of disease by exposure for each possible combination of confounders and analyzing the tables at each level. In the simplest case, this could mean separate tables for males and females, if SEX is the potential confounder. If AGE, SEX, and CITY are confounders, separate tables would be made for each possible combination of age, sex and city. In a case control study or cohort studies the data are in the form of a 2 x 2 table. The first step in stratification is to split the data into strata, a stratum having the confounder and other not having the confounder. The significance test for each along with the adjusted odds ratio or relative risk is estimated. The significance test performed in stratification is called Mantel-Haenszel chi square test. For example if we have a cross sectional analytical study conducted to see whether there is any association between obesity (exposure variable, defined as Body Mass Index (BMI) > 25) and Hypertension (outcome variable defined as BP > 140/90), among middle aged males. A total of 1099 subjects were studied. Results shown in Table-3:

Table - 3 :			
Obesity	Hypertension		Total
	Present	Absent	
Present	198 (a)	284 (b)	482 (a+b)
Absent	98 (c)	519 (d)	617 (c+d)
Total	296 (a+c)	803(b+d)	1099 (n)

The crude (unadjusted) OR

$$= [(198 \times 519) \div (284 \times 98)] = 3.69$$

Table - 2 : ANOVA Table

Source of Variation	Sum of Squares	Degrees of freedom	Mean Squares	F ratio
Between groups	$n\sum(x_i - \bar{x})^2 = 33.32$	k-1=2	$S_B^2 = \frac{n\sum(x_i - \bar{x})^2}{k-1} = 16.68$	$\frac{S_B^2}{S_W^2} = 6.70$
Within groups	$\sum S_i^2 = 29.83$	N-k=12	$S_W^2 = \frac{\sum S_i^2}{k} = 2.48$	
Total	$\sum(x_{ij} - \bar{x})^2 = 63.16$	N - 1 = 14		

Thus, the risk of hypertension is 3.7 times higher among obese. Now, it was felt that the above observed association between obesity and hypertension may be confounded by “lack of physical exercise”, since it is known fact that lack of regular physical exercise is associated with obesity (i.e. the exposure), and, irrespective of its relation with obesity, is also associated with hypertension (outcome). Thus, “lack of regular physical exercise” qualifies as a potential confounding factor and stratified analysis was required for control of confounding. Thus, the data was broken up into two strata, as follows:-

<b>STRATUM – I : Not exercising regularly</b>			
<b>Obesity</b>	<b>Hypertension</b>		<b>Total</b>
	<i>Present</i>	<i>Absent</i>	
Present	89 ( $a_1$ )	131 ( $b_1$ )	220 ( $a_1 + b_1$ )
Absent	56 ( $c_1$ )	326 ( $d_1$ )	382 ( $c_1 + d_1$ )
Total	145 ( $a_1 + c_1$ )	457 ( $b_1 + d_1$ )	602 ( $n_1$ )

<b>STRATUM – II : Undertaking regular exercise</b>			
<b>Obesity</b>	<b>Hypertension</b>		<b>Total</b>
	<i>Present</i>	<i>Absent</i>	
Present	109 ( $a_2$ )	153 ( $b_2$ )	262 ( $a_2 + b_2$ )
Absent	42 ( $c_2$ )	193 ( $d_2$ )	235 ( $c_2 + d_2$ )
Total	151 ( $a_2 + c_2$ )	346 ( $b_2 + d_2$ )	497 ( $n_2$ )

Now, we calculate the stratum specific OR using the usual formula :

$$\text{Stratum – I OR} = [(89 \times 326) \div (131 \times 56)] = 3.96$$

$$\text{Stratum – II OR} = [(109 \times 193) \div (153 \times 42)] = 3.27$$

The next step is to compare the stratum specific OR to identify whether the variable can be considered as confounder or whether there is a possibility of interaction. If the stratum ORs are not different we say confounding is present and if the stratum ORs are different from each other, we say interaction is present. In the above considered example since the stratum ORs (3.96 and 3.27) are almost same we say that confounding is present. We compare these ORs with the crude OR (3.69) which is calculated for table without stratifying the tables with respect to potential confounding variable. If these are different we say there is definite confounding effect. In the example it is slightly different from stratum ORs. We conclude that there is definitely slight confounding due to lack of regular physical exercise. Since confounding is present there is requirement of calculating adjusted odds ratio which is calculated by Mantel-Haenszel method denoted by (OR(MH)).

In our example, after calculations the OR (MH) comes to 3.60. Now, this OR (MH) of 3.6 tells us that the risk of hypertension due to obesity, after adjusting for physical exercise, i.e. irrespective of whether a middle aged male exercises regularly or not, is 3.6 times. Since the crude OR (3.69) and adjusted OR (3.60) are not very dissimilar, we can also conclude that there was only slight confounding due to lack of physical exercise. Our next step is to estimate the significance using Mantel-Haenszel chi square test.

The degrees of freedom for MH chi-square are always 1 irrespective of the number of strata. The calculated MH-chi square is compared with the table value of chi-square at specified degrees of freedom. The calculated value is much more than the table value and hence we reject the null hypothesis that there is no relationship between the tables at alpha of 5%.

## Tests for Linear Trends in Proportions

When the researcher is dealing with qualitative ordinal variables, the analysis is not simple analyzing proportion in various categories but more powerful test called chi-square for linear trend. The Chi Square for trend tests whether the odds (risk) increase or decrease in each group with respect to the first group, which is taken as the baseline for comparison. Normally the various groups are given an arbitrary numerical value to each category as ‘exposure Score’ ( $x_i$ ). In general, it is best to give the numbers 1, 2, 3, 4, 5, ----- where 1 is the baseline group with which each of the other groups are compared. The procedure calculates odds ratio for each of the group, and the overall chi square for liner trend in proportions. This calculated chi-square has 1 degree of freedom irrespective of the number of categories or groups.

Let us consider an example of a hypothetical cohort study which was undertaken to assess whether smoking by mothers during pregnancy is a possible determinant of congenital malformations in the foetus. A total of 2462 pregnant ladies were taken up and their average daily cigarette consumption was assessed. 2076 ladies were non smokers. While 172, 143 and 71 were smoking up to 10 cigarettes, 11 to 20 and more than 20 cigarettes per day respectively. It was observed that 81 (i.e. 3.09%) of the non-smoker mothers delivered congenitally malformed children. The proportion of such malformed children increased progressively as the smoking category increased.

<b>Smoking habit</b>	<b>Exposure score (<math>x_i</math>)</b>	<b>Status of delivered child</b>		<b>Total (<math>n_i</math>)</b>
		<i>Had congenital malformations (<math>d_i</math>)</i>	<i>Normal</i>	
Non-smokers	1	81	1995	2076
1-10 cig/day	2	10	162	172
11-20 cig/day	3	28	115	143
>20 cig/day	4	21	50	71

In this example, based on the statistical procedures we calculated that the  $\chi^2$  linear trend = 125.50. The calculated chi-square is compared with the table value at 1 d.f. Since the calculated value is more than the table value for specified alpha at 5% we reject the null hypothesis that there is no trend. We thus conclude that the “trend of increasing risk of the outcome (congenital malformations) with increasing dose of exposure (cigarettes smoking) is statistically very highly significant.

## Paired Data Analysis

A paired sample is so termed if every individual in one of the groups has a unique match or pair in other group, for



example when the variable value is measured before and after a particular intervention. At times the patient himself acts as self control i.e. the same patient is in both the groups. We have already seen the paired analysis, paired 't' test when the variable measured is quantitative and observations are paired as before and after or pre and post intervention. An alternative to this parametric paired 't' test is the non parametric sign test taking into account only the direction of the differences between pre and post scores and Wilcoxon signed rank test which takes into account the direction as well as the magnitude of the differences between the paired observations. Both these test are discussed in details in the non parametric chapter. Besides these situations the researcher at times deals with data which is dichotomous and are matched paired. Then the proportions in these matched data are analysed using McNemar's chi-square test. The general layout of the McNemar test is as given below.

Group2	Group1	
	+	-
+	a	b
-	c	d

The McNemar's  $\chi^2 = \frac{(c - b)^2}{b + c}$  which follows a chi-square distribution with 1 degree of freedom. It is important to note that only the paired or united observations contribute to the test statistic value.

## Summary

Most hypothesis testing procedure requires the population distribution to be normal or approximately normal. In medical research many times we are not sure about the underlying distribution of the population. In such cases we apply non parametric tests which are not based on the assumption of normality of population especially when the sample size is small ( $n < 30$ ). Since they do not assume any distribution they are also called as distribution free tests. Non parametric tests are weaker than parametric tests as they do not have any information on the parameters of the distribution of data. Non parametric test are mainly used when the researcher is dealing with numerical ordinal scale i.e. when the data is scored. Non parametric tests allow us to test the hypothesis which does not deal with parameter values like mean and variance.

Many times the researcher is dealing with situations where there are more than 2 groups of interest. In such cases the usual z test and t test fails. The correct technique to compare means in three or more groups is analysis of variance or ANOVA. When one qualitative variable defines the groups, a one way ANOVA is used whereas when the groups are defined by two qualitative variables a two way ANOVA is used. When dealing with three or more groups the variability creeps in from two sources. One source is because of the groups itself, i.e. between group variability and the second source is within group variability. One of the basic assumptions of ANOVA is that the variances in the groups being compared are all equal i.e. homogenous. The assumption regarding homogeneity of variances is tested using Bartlett's test. Also the variable of interest in the three

groups is measured on either continuous or discrete scale. In case if the variable is measured in ordinal scale we use a non parametric test, the Kruskal-Wallis test where we compare the medians in the groups rather than mean.

Confounder is a variable that can distort the true research findings. There are two methods of controlling confounding in research. First method is during the planning and designing phase of the study and the second method is statistical analytical method called stratified analysis carried out during the analysis phase after completing data collection. Stratification means making a separate table of disease by exposure for each possible combination of confounders and analyzing the tables at each level. The first step in stratification is to split the data into strata, a stratum having the confounder and other not having the confounder. The significance test for each along with the adjusted odds ratio or relative risk is estimated. Then stratum odds ratio are compared amongst themselves and with crude ratio. If stratum ORs are not different we say confounding is present and if the stratum ORs are different from each other we say interaction is present. The significance test performed in stratification is called Mantel-Haenszel chi square test. While dealing with qualitative ordinal variables the analysis is not simply analyzing proportion in various categories but more powerful test called chi-square for linear trend. The Chi Square for trend tests whether the odds (risk) increase or decrease in each group with respect to the first group, which is taken as the baseline for comparison. Also when data is dichotomous and are matched paired then the proportions in these matched data are analysed using McNemar's chi-square test.

## Study Exercises

### Non Parametric Test

**Short Note :** What are non-parametric tests?

#### MCQs

1. An obstetrician takes two groups of expectant ladies from her ANC - one group having anemia while the other did not have anemia. She follows them till delivery and notes the APGAR score of baby, to see if anemia in pregnancy was associated with a lower APGAR score in new born. The correct statistical procedure in this study would be: (a) 't' test (b) Mann-Whitney test (c) Odds ratio (d) Correlation coefficient
2. All of the following are non-parametric test except (a) Mann-Whitney test (b) Wilcoxon sign test (c) Chi-square test (d) 't' test
3. All of the following are correct except (a) Non-parametric test are stronger than parametric test (b) Non-parametric test are also known as distribution free test (c) Chi-square is a non-parametric test (d) None of the above
4. For comparing the median of two population statistical test used is (a) z-test (b) 't' test (c) Mann-Whitney test (d) all of the above
5. Wilcoxon signed rank test takes into account (a) Direction of differences (b) Magnitude of differences (c) Both (d) None of the above

**Answers :** (1) b; (2) d; (3) a; (4) c; (5) c.

## ANOVA

**Long Question:** Discuss the theory and application of ANOVA.

### MCQs

1. When more than two treatment groups are present and you wish to test whether the groups differ significantly with respect to a parameter which statistical method would be applied? (a) ANCOVA (b) ANOVA (c) Logistic regression method (d) Multivariate regression
2. The correct technique to compare difference in three or more groups when homogeneity condition fails is (a) z-test (b) 't' test (c) ANOVA (d) Kruskal Wallis test.
3. Assumption that variance in all the group is same is tested by (a) Wilcoxon sign test (b) Bartlett's test (c) Bonferroni's procedure (d) Schaffe's method.
4. All of the following are multiple comparison test except (a) Bonferroni's procedure (b) Schaffe's method (c) Newman - Keul's procedure (d) Wilcoxon sign test.
5. Pair wise comparison between the groups or treatments when F ratio is significant is carried using (a) Paired 't' test (b) Unpaired 't' test (c) Bonferroni's test (d) Duncan's test

**Answers :** (1) b; (2) d; (3) b; (4) d; (5) c.

## Statistical Exercises

A study was conducted among pregnant ladies of age group 20-30 yrs in a community to assess the effect of socioeconomic state on hemoglobin level. The data collected is given below

Lower	Middle	Higher
11, 10, 09, 10.5, 09.5, 10	11, 11.5, 12, 11, 12.5, 13	12, 12.5, 13, 14, 13.5, 14

Can you conclude from the following data that there is no difference in Hemoglobin level in different socioeconomic groups (Answer :  $F=24.72$ , reject null hypothesis there is a significant difference in blood Haemoglobin level in different socioeconomic status)

## Control of Confounding, Linear Trend and Paired Data Analysis

**Short Notes:** McNemars test, paired 't' test.

### MCQs

1. When data is dichotomous and are matched paired what is the correct statistical test (a) Paired 't' test (b) Mantel-Haenszel chi square test (c) McNemar's chi square test (d) Chi square test for linear trend.
2. All are true of confounder variable except (a) It is related to exposure (b) It is related to outcome (c) It is in direct chain of causation from exposure to outcome (d) It is differentially distributed.
3. If stratum odds ratios are different from each other it means (a) Confounding is present (b) Effect modification is there (c) No effect (d) All of the above
4. If stratum odds ratios are different from crude ratio then (a) Confounding is present (b) Effect modification is there (c) No effect (d) All of the above
5. When the researcher is dealing with qualitative ordinal variables the analysis is done by (a) Analyzing proportion in various categories (b) Chi-square for linear trend (c) McNemar's chi-square test (d) sign test

**Answers :** (1) c; (2) c; (3) b; (4) a; (5) b.

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## Which Statistical Procedures to Use Depending upon Exposure and Outcome Variable

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The most commonly used statistical procedures in medical research are the "z" test for comparing two means or two proportions, the unpaired and paired 't' tests and the chi-square test, the details of which have been explained in this section. There are certain situations when different statistical techniques are required. The medical researcher should have an orientation to these procedures so that he/she can decide as to which procedure is most appropriate. As regards actual calculations, the same can be easily undertaken with statistical software EPI-2002, details of which are being described in the

next section.

**Which test to use :** As we said earlier, in the previous section on Research Methodology, the prototype scenario is to study an association between a given exposure variable and an "outcome" variable. (Please refer to detailed discussion on 2 x 2 table in that chapter). Now, we must first decide as to which "scale" have we recorded the exposure and the outcome variable. (i.e. Quantitative - Continuous, Discrete or Ordinal; or, Qualitative- Dichotomous, polychotomous nominal or polychotomous ordinal) Next, depending on the scale on which the exposure and outcome variables have been recorded, the appropriate test can be used as per Table - 1.

1. *For testing One to One (Univariate) relationship between exposure and outcome variable*
2. *One - to - One (Univariate) Situation of Paired (dependent) samples or 'Before and After' situations*  
For Means : Paired 't' test

**Table - 1**

		Outcome					
		<i>Continuous</i>	<i>Discrete</i>	<i>Numerical Ordinal</i>	<i>Dichotomous</i>	<i>Polycho-tomous Nominal</i>	<i>Polychotomous Ordinal</i>
Exposure	Continuous	Pearson Correlation & Regression	Pearson Correlation & Regression	Spearman Rank correlation	't' test	ANOVA	ANOVA
	Discrete	- do -	- do -	- do -	- do -	- do -	- do -
	Numerical Ordinal	Spearman Rank correlation	Spearman Rank correlation	Spearman Rank correlation	Mann Whitney U test	Kruskal Wallis test	Kruskal Wallis test
	Dichotomous	't' test	't' test	Mann Whitney U test	Chi square for 2x2 table	Chi square for r x c table	Chi square for linear trend in proportions
	Polychotomous Nominal	ANOVA	ANOVA	Kruskal Wallis	Chi square for r x c table	Chi square for r x c table	Chi square for r x c table
	Polychotomous Ordinal	ANOVA	ANOVA	Kruskal Wallis	Chi square for linear trend in proportions	- do -	- do -

For proportion : McNemar Chi square

For Medians : Wilcoxon Signed Rank test.

3. *If the outcome variable is dependent on time (as survival)*  
- Use Survival analysis method as Kaplan Meier method
4. *For control of confounding (Bivariate or multivariate analysis)*
  - (a) *For one or two confounding variables and when both the exposure & outcome are recorded on qualitative (usually dichotomous) scale:* Mantel-Haenszel's stratified analysis
  - (b) *For one or two confounding variables and when either exposure or outcome are recorded on quantitative (Continuous, discrete or ordinal) scale :* Two way or Multiple way ANOVA.
  - (c) *When a large number of confounding variables are to be controlled.*
  - (i) *If outcome variable is recorded on quantitative (Continuous or discrete numerical) scale:* Multiple Linear Regression Model.
  - (ii) *If the outcome variable is recorded on dichotomous scale:* Use Multiple Logistic Regression
  - (iii) *If the outcome variable is a dichotomous variable but dependent on some type of time duration, as survival time:* Use Cox Proportional Hazards Regression model.

**Fisher Exact Test for 2 x 2 table :** Many times we face the situation where the variables of classification are qualitative but the sample size is too small. *Chi-square test fails when the sample size is less than 30.* In such situations instead of using chi-square test we should use Fisher Exact Test.

**McNemar Test for related data :** In the situation of a chi square test, as described earlier, if "paired matching" has been done then McNemar test should be done instead of ordinary Chi square test.

**Median based Non Parametric test :** At times when the scale of measurement has been ordinal numerical (as rank achieved, grade of dyspnoea, economic status and so on) we should compare the medians rather than the means, using certain non parametric tests. The following tests are commonly used:-

**Mann-Whitney 'U' test :** When medians of the two independent samples are to be compared. It is the counterpart of unpaired 't' test.

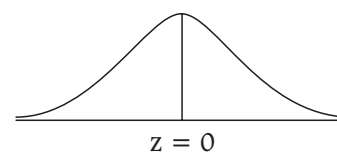
**Wilcoxon Signed Rank test :** When the medians of the paired samples are to be compared. It is the counterpart of "paired t test".

**Kruskal Wallis test :** When medians of three or more samples are to be compared. It is the counterpart of ANOVA.

**Table - 1 : Standard Normal Distribution Table**

(It gives area included between  $Z = 0$  and given positive value of  $Z$ )

For example :  $P(0 \leq Z \leq 1.96) = 0.4750$ ,  $P(0 \leq Z \leq 2.57) = 0.4949$



Z	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
0.00	0.0000	0.0040	0.0080	0.0120	0.0160	0.0199	0.0239	0.0279	0.0319	0.0359
0.10	0.0398	0.0438	0.0478	0.0517	0.0557	0.0596	0.0636	0.0675	0.0714	0.0753
0.20	0.0793	0.0832	0.0871	0.0910	0.0948	0.0987	0.1026	0.1064	0.1103	0.1141
0.30	0.1179	0.1217	0.1255	0.1293	0.1331	0.1368	0.1406	0.1443	0.1480	0.1517
0.40	0.1554	0.1591	0.1628	0.1664	0.1700	0.1736	0.1772	0.1808	0.1844	0.1879
0.50	0.1915	0.1950	0.1985	0.2019	0.2054	0.2088	0.2123	0.2157	0.2190	0.2224
0.60	0.2257	0.2291	0.2324	0.2357	0.2389	0.2422	0.2454	0.2486	0.2517	0.2549
0.70	0.2580	0.2611	0.2642	0.2673	0.2704	0.2734	0.2764	0.2794	0.2823	0.2852
0.80	0.2881	0.2910	0.2939	0.2967	0.2995	0.3023	0.3051	0.3078	0.3106	0.3133
0.90	0.3159	0.3186	0.3212	0.3238	0.3264	0.3289	0.3315	0.3340	0.3365	0.3389
1.00	0.3413	0.3438	0.3461	0.3485	0.3508	0.3531	0.3554	0.3577	0.3599	0.3621
1.10	0.3643	0.3665	0.3686	0.3708	0.3729	0.3749	0.3770	0.3790	0.3810	0.3830
1.20	0.3849	0.3869	0.3888	0.3907	0.3925	0.3944	0.3962	0.3980	0.3997	0.4015
1.30	0.4032	0.4049	0.4066	0.4082	0.4099	0.4115	0.4131	0.4147	0.4162	0.4177
1.40	0.4192	0.4207	0.4222	0.4236	0.4251	0.4265	0.4279	0.4292	0.4306	0.4319
1.50	0.4332	0.4345	0.4357	0.4370	0.4382	0.4394	0.4406	0.4418	0.4429	0.4441
1.60	0.4452	0.4463	0.4474	0.4484	0.4495	0.4505	0.4515	0.4525	0.4535	0.4545
1.70	0.4554	0.4564	0.4573	0.4582	0.4591	0.4599	0.4608	0.4616	0.4625	0.4633
1.80	0.4641	0.4649	0.4656	0.4664	0.4671	0.4678	0.4686	0.4693	0.4699	0.4706
1.90	0.4713	0.4719	0.4726	0.4732	0.4738	0.4744	0.4750	0.4756	0.4761	0.4767
2.00	0.4772	0.4778	0.4783	0.4788	0.4793	0.4798	0.4803	0.4808	0.4812	0.4817
2.10	0.4821	0.4826	0.4830	0.4834	0.4838	0.4842	0.4846	0.4850	0.4854	0.4857
2.20	0.4861	0.4864	0.4868	0.4871	0.4875	0.4878	0.4881	0.4884	0.4887	0.4890
2.30	0.4893	0.4896	0.4898	0.4901	0.4904	0.4906	0.4909	0.4911	0.4913	0.4916
2.40	0.4918	0.4920	0.4922	0.4925	0.4927	0.4929	0.4931	0.4932	0.4934	0.4936
2.50	0.4938	0.4940	0.4941	0.4943	0.4945	0.4946	0.4948	0.4949	0.4951	0.4952
2.60	0.4953	0.4955	0.4956	0.4957	0.4959	0.4960	0.4961	0.4962	0.4963	0.4964
2.70	0.4965	0.4966	0.4967	0.4968	0.4969	0.4970	0.4971	0.4972	0.4973	0.4974
2.80	0.4974	0.4975	0.4976	0.4977	0.4977	0.4978	0.4979	0.4979	0.4980	0.4981
2.90	0.4981	0.4982	0.4982	0.4983	0.4984	0.4984	0.4985	0.4985	0.4986	0.4986
3.00	0.4987	0.4987	0.4987	0.4988	0.4988	0.4989	0.4989	0.4989	0.4990	0.4990
3.10	0.4990	0.4991	0.4991	0.4991	0.4992	0.4992	0.4992	0.4992	0.4993	0.4993
3.20	0.4993	0.4993	0.4994	0.4994	0.4994	0.4994	0.4994	0.4995	0.4995	0.4995
3.30	0.4995	0.4995	0.4995	0.4996	0.4996	0.4996	0.4996	0.4996	0.4996	0.4997
3.40	0.4997	0.4997	0.4997	0.4997	0.4997	0.4997	0.4997	0.4997	0.4997	0.4998
3.50	0.4998	0.4998	0.4998	0.4998	0.4998	0.4998	0.4998	0.4998	0.4998	0.4998
3.60	0.4998	0.4998	0.4999	0.4999	0.4999	0.4999	0.4999	0.4999	0.4999	0.4999
3.70	0.4999	0.4999	0.4999	0.4999	0.4999	0.4999	0.4999	0.4999	0.4999	0.4999
3.80	0.4999	0.4999	0.4999	0.4999	0.4999	0.4999	0.4999	0.4999	0.4999	0.4999



**Table - 2 : Student's t Distribution Table** (It gives  $t$  value for given d.f. and corresponding to two tail areas )

For Example :  $P(-2.571 \leq t_s \leq 2.571) = 0.100$  ,  $P(-2.131 \leq t_{15} \leq 2.131) = 0.05$

D.F.	Probability of greater value, p			
	0.100	0.050	0.010	0.001
1	6.314	12.706	63.656	636.578
2	2.920	4.303	9.925	31.600
3	2.353	3.182	5.841	12.924
4	2.132	2.776	4.604	8.610
5	2.015	2.571	4.032	6.869
6	1.943	2.447	3.707	5.959
7	1.895	2.365	3.499	5.408
8	1.860	2.306	3.355	5.041
9	1.833	2.262	3.250	4.781
10	1.812	2.228	3.169	4.587
11	1.796	2.201	3.106	4.437
12	1.782	2.179	3.055	4.318
13	1.771	2.160	3.012	4.221
14	1.761	2.145	2.977	4.140
15	1.753	2.131	2.947	4.073
16	1.746	2.120	2.921	4.015
17	1.740	2.110	2.898	3.965
18	1.734	2.101	2.878	3.922
19	1.729	2.093	2.861	3.883
20	1.725	2.086	2.845	3.850
21	1.721	2.080	2.831	3.819
22	1.717	2.074	2.819	3.792
23	1.714	2.069	2.807	3.768
24	1.711	2.064	2.797	3.745
25	1.708	2.060	2.787	3.725
26	1.706	2.056	2.779	3.707
27	1.703	2.052	2.771	3.689
28	1.701	2.048	2.763	3.674
29	1.699	2.045	2.756	3.660
30	1.697	2.042	2.750	3.646
40	1.684	2.021	2.704	3.551
50	1.676	2.009	2.678	3.496
60	1.671	2.000	2.660	3.460
80	1.664	1.990	2.639	3.416
100	1.660	1.984	2.626	3.390
120	1.658	1.980	2.617	3.373

For  $\alpha = 0.05$   $t_{k, 0.05} = 1.96 + 2.5/k$  and  $\alpha=0.01$   
 $t_{k, 0.01} = 2.58 + 5.3/k$  where d.f. = k

e.g. k = 45,  $\alpha = 0.05$   $t_{k, 0.05} = 1.96 + 2.5/45 = 2.015556$

**Table - 3 : Chi-square Distribution Table.** (It gives  $\chi^2_{k, \alpha}$  value for given k d.f. and corresponding to right one tail area  $\alpha$  )

For Example :  $\chi^2_{k, \alpha} = 3.841$  is Chi-square Distribution Table for  $\alpha = 0.05$  k = 1

D.F.	Probability of greater value, p			
	0.100	0.050	0.010	0.001
1	2.706	3.841	6.635	10.827
2	4.605	5.991	9.210	13.815
3	6.251	7.815	11.345	16.266
4	7.779	9.488	13.277	18.466
5	9.236	11.070	15.086	20.515
6	10.645	12.592	16.812	22.457
7	12.017	14.067	18.475	24.321
8	13.362	15.507	20.090	26.124
9	14.684	16.919	21.666	27.877
10	15.987	18.307	23.209	29.588
11	17.275	19.675	24.725	31.264
12	18.549	21.026	26.217	32.909
13	19.812	22.362	27.688	34.527
14	21.064	23.685	29.141	36.124
15	22.307	24.996	30.578	37.698
16	23.542	26.296	32.000	39.252
17	24.769	27.587	33.409	40.791
18	25.989	28.869	34.805	42.312
19	27.204	30.144	36.191	43.819
20	28.412	31.410	37.566	45.314
21	29.615	32.671	38.932	46.796
22	30.813	33.924	40.289	48.268
23	32.007	35.172	41.638	49.728
24	33.196	36.415	42.980	51.179
25	34.382	37.652	44.314	52.619
26	35.563	38.885	45.642	54.051
27	36.741	40.113	46.963	55.475
28	37.916	41.337	48.278	56.892
29	39.087	42.557	49.588	58.301
30	40.256	43.773	50.892	59.702
40	51.805	55.758	63.691	73.403
50	63.167	67.505	76.154	86.660
60	74.397	79.082	88.379	99.608
80	96.578	101.879	112.329	124.839
100	118.498	124.342	135.807	149.449
120	140.233	146.567	158.950	173.618

**Table – 4 : F- Table for  $\alpha=0.1$  ,  $N_1$  and  $N_2$  are Numerator and Denominator D.F. e.g.  $P(F_{5,10} \leq 2.52) = 1-\alpha=.90$**

$\alpha = 0.1$	$N_1$																			
$N_2$	1	2	3	4	5	6	7	8	9	10	15	20	25	30	35	40	60	80	100	120
1	39.9	49.5	53.6	55.8	57.2	58.2	58.9	59.4	59.9	60.2	61.2	61.7	62.1	62.3	62.4	62.5	62.8	62.9	63.0	63.1
2	8.53	9.00	9.16	9.24	9.29	9.33	9.35	9.37	9.38	9.39	9.42	9.44	9.45	9.46	9.46	9.47	9.47	9.48	9.48	9.48
3	5.54	5.46	5.39	5.34	5.31	5.28	5.27	5.25	5.24	5.23	5.20	5.18	5.17	5.17	5.16	5.16	5.15	5.15	5.14	5.14
4	4.54	4.32	4.19	4.11	4.05	4.01	3.98	3.95	3.94	3.92	3.87	3.84	3.83	3.82	3.81	3.80	3.79	3.78	3.78	3.78
5	4.06	3.78	3.62	3.52	3.45	3.40	3.37	3.34	3.32	3.30	3.24	3.21	3.19	3.17	3.16	3.16	3.14	3.13	3.13	3.12
6	3.78	3.46	3.29	3.18	3.11	3.05	3.01	2.98	2.96	2.94	2.87	2.84	2.81	2.80	2.79	2.78	2.76	2.75	2.75	2.74
7	3.59	3.26	3.07	2.96	2.88	2.83	2.78	2.75	2.72	2.70	2.63	2.59	2.57	2.56	2.54	2.54	2.51	2.50	2.50	2.49
8	3.46	3.11	2.92	2.81	2.73	2.67	2.62	2.59	2.56	2.54	2.46	2.42	2.40	2.38	2.37	2.36	2.34	2.33	2.32	2.32
9	3.36	3.01	2.81	2.69	2.61	2.55	2.51	2.47	2.44	2.42	2.34	2.30	2.27	2.25	2.24	2.23	2.21	2.20	2.19	2.18
10	3.29	2.92	2.73	2.61	2.52	2.46	2.41	2.38	2.35	2.32	2.24	2.20	2.17	2.16	2.14	2.13	2.11	2.09	2.09	2.08
11	3.23	2.86	2.66	2.54	2.45	2.39	2.34	2.30	2.27	2.25	2.17	2.12	2.10	2.08	2.06	2.05	2.03	2.01	2.01	2.00
12	3.18	2.81	2.61	2.48	2.39	2.33	2.28	2.24	2.21	2.19	2.10	2.06	2.03	2.01	2.00	1.99	1.96	1.95	1.94	1.93
13	3.14	2.76	2.56	2.43	2.35	2.28	2.23	2.20	2.16	2.14	2.05	2.01	1.98	1.96	1.94	1.93	1.90	1.89	1.88	1.88
14	3.10	2.73	2.52	2.39	2.31	2.24	2.19	2.15	2.12	2.10	2.01	1.96	1.93	1.91	1.90	1.89	1.86	1.84	1.83	1.83
15	3.07	2.70	2.49	2.36	2.27	2.21	2.16	2.12	2.09	2.06	1.97	1.92	1.89	1.87	1.86	1.85	1.82	1.80	1.79	1.79
16	3.05	2.67	2.46	2.33	2.24	2.18	2.13	2.09	2.06	2.03	1.94	1.89	1.86	1.84	1.82	1.81	1.78	1.77	1.76	1.75
17	3.03	2.64	2.44	2.31	2.22	2.15	2.10	2.06	2.03	2.00	1.91	1.86	1.83	1.81	1.79	1.78	1.75	1.74	1.73	1.72
18	3.01	2.62	2.42	2.29	2.20	2.13	2.08	2.04	2.00	1.98	1.89	1.84	1.80	1.78	1.77	1.75	1.72	1.71	1.70	1.69
19	2.99	2.61	2.40	2.27	2.18	2.11	2.06	2.02	1.98	1.96	1.86	1.81	1.78	1.76	1.74	1.73	1.70	1.68	1.67	1.67
20	2.97	2.59	2.38	2.25	2.16	2.09	2.04	2.00	1.96	1.94	1.84	1.79	1.76	1.74	1.72	1.71	1.68	1.66	1.65	1.64
21	2.96	2.57	2.36	2.23	2.14	2.08	2.02	1.98	1.95	1.92	1.83	1.78	1.74	1.72	1.70	1.69	1.66	1.64	1.63	1.62
22	2.95	2.56	2.35	2.22	2.13	2.06	2.01	1.97	1.93	1.90	1.81	1.76	1.73	1.70	1.68	1.67	1.64	1.62	1.61	1.60
23	2.94	2.55	2.34	2.21	2.11	2.05	1.99	1.95	1.92	1.89	1.80	1.74	1.71	1.69	1.67	1.66	1.62	1.61	1.59	1.59
24	2.93	2.54	2.33	2.19	2.10	2.04	1.98	1.94	1.91	1.88	1.78	1.73	1.70	1.67	1.65	1.64	1.61	1.59	1.58	1.57
25	2.92	2.53	2.32	2.18	2.09	2.02	1.97	1.93	1.89	1.87	1.77	1.72	1.68	1.66	1.64	1.63	1.59	1.58	1.56	1.56
26	2.91	2.52	2.31	2.17	2.08	2.01	1.96	1.92	1.88	1.86	1.76	1.71	1.67	1.65	1.63	1.61	1.58	1.56	1.55	1.54
27	2.90	2.51	2.30	2.17	2.07	2.00	1.95	1.91	1.87	1.85	1.75	1.70	1.66	1.64	1.62	1.60	1.57	1.55	1.54	1.53
28	2.89	2.50	2.29	2.16	2.06	2.00	1.94	1.90	1.87	1.84	1.74	1.69	1.65	1.63	1.61	1.59	1.56	1.54	1.53	1.52
29	2.89	2.50	2.28	2.15	2.06	1.99	1.93	1.89	1.86	1.83	1.73	1.68	1.64	1.62	1.60	1.58	1.55	1.53	1.52	1.51
30	2.88	2.49	2.28	2.14	2.05	1.98	1.93	1.88	1.85	1.82	1.72	1.67	1.63	1.61	1.59	1.57	1.54	1.52	1.51	1.50
40	2.84	2.44	2.23	2.09	2.00	1.93	1.87	1.83	1.79	1.76	1.66	1.61	1.57	1.54	1.52	1.51	1.47	1.45	1.43	1.42
50	2.81	2.41	2.20	2.06	1.97	1.90	1.84	1.80	1.76	1.73	1.63	1.57	1.53	1.50	1.48	1.46	1.42	1.40	1.39	1.38
60	2.79	2.39	2.18	2.04	1.95	1.87	1.82	1.77	1.74	1.71	1.60	1.54	1.50	1.48	1.45	1.44	1.40	1.37	1.36	1.35
120	2.75	2.35	2.13	1.99	1.90	1.82	1.77	1.72	1.68	1.65	1.55	1.48	1.44	1.41	1.39	1.37	1.32	1.29	1.28	1.26

*F- Table for  $\alpha=0.05$ ,  $N_1$  and  $N_2$  are Numerator and Denominator D.F. e.g.  $P(F_{15,10} \leq 2.8) = 1-\alpha=.95$*

0.05	$N_1$ (Numerator DF)																			
$N_2$	1	2	3	4	5	6	7	8	9	10	15	20	25	30	35	40	60	80	100	120
1	161	199	54	225	230	234	237	239	241	242	246	248	249	250	251	251	252	253	253	253
2	18.5	19.0	9.2	19.2	19.3	19.3	19.4	19.4	19.4	19.4	19.4	19.4	19.5	19.5	19.5	19.5	19.5	19.5	19.5	19.5
3	10.1	9.6	5.4	9.1	9.0	8.9	8.9	8.8	8.8	8.8	8.7	8.7	8.6	8.6	8.6	8.6	8.6	8.6	8.6	8.5
4	7.7	6.9	4.2	6.4	6.3	6.2	6.1	6.0	6.0	6.0	5.9	5.8	5.8	5.7	5.7	5.7	5.7	5.7	5.7	5.7
5	6.6	5.8	3.6	5.2	5.1	5.0	4.9	4.8	4.8	4.7	4.6	4.6	4.5	4.5	4.5	4.5	4.4	4.4	4.4	4.4
6	6.0	5.1	3.3	4.5	4.4	4.3	4.2	4.1	4.1	4.1	3.9	3.9	3.8	3.8	3.8	3.8	3.7	3.7	3.7	3.7
7	5.6	4.7	3.1	4.1	4.0	3.9	3.8	3.7	3.7	3.6	3.5	3.4	3.4	3.4	3.4	3.3	3.3	3.3	3.3	3.3
8	5.3	4.5	2.9	3.8	3.7	3.6	3.5	3.4	3.4	3.3	3.2	3.2	3.1	3.1	3.1	3.0	3.0	3.0	3.0	3.0
9	5.1	4.3	2.8	3.6	3.5	3.4	3.3	3.2	3.2	3.1	3.0	2.9	2.9	2.9	2.8	2.8	2.8	2.8	2.8	2.7
10	5.0	4.1	2.7	3.5	3.3	3.2	3.1	3.1	3.0	3.0	2.8	2.8	2.7	2.7	2.7	2.7	2.6	2.6	2.6	2.6
11	4.8	4.0	2.7	3.4	3.2	3.1	3.0	2.9	2.9	2.9	2.7	2.6	2.6	2.6	2.5	2.5	2.5	2.5	2.5	2.4
12	4.7	3.9	2.6	3.3	3.1	3.0	2.9	2.8	2.8	2.8	2.6	2.5	2.5	2.5	2.4	2.4	2.4	2.4	2.3	2.3
13	4.7	3.8	2.6	3.2	3.0	2.9	2.8	2.8	2.7	2.7	2.5	2.5	2.4	2.4	2.4	2.3	2.3	2.3	2.3	2.3
14	4.6	3.7	2.5	3.1	3.0	2.8	2.8	2.7	2.6	2.6	2.5	2.4	2.3	2.3	2.3	2.3	2.2	2.2	2.2	2.2
15	4.5	3.7	2.5	3.1	2.9	2.8	2.7	2.6	2.6	2.5	2.4	2.3	2.3	2.2	2.2	2.2	2.2	2.1	2.1	2.1
16	4.5	3.6	2.5	3.0	2.9	2.7	2.7	2.6	2.5	2.5	2.4	2.3	2.2	2.2	2.2	2.2	2.1	2.1	2.1	2.1
17	4.5	3.6	2.4	3.0	2.8	2.7	2.6	2.5	2.5	2.4	2.3	2.2	2.2	2.1	2.1	2.1	2.1	2.0	2.0	2.0
18	4.4	3.6	2.4	2.9	2.8	2.7	2.6	2.5	2.5	2.4	2.3	2.2	2.1	2.1	2.1	2.1	2.0	2.0	2.0	2.0
19	4.4	3.5	2.4	2.9	2.7	2.6	2.5	2.5	2.4	2.4	2.2	2.2	2.1	2.1	2.0	2.0	2.0	2.0	1.9	1.9
20	4.4	3.5	2.4	2.9	2.7	2.6	2.5	2.4	2.4	2.3	2.2	2.1	2.1	2.0	2.0	2.0	1.9	1.9	1.9	1.9
21	4.3	3.5	2.4	2.8	2.7	2.6	2.5	2.4	2.4	2.3	2.2	2.1	2.0	2.0	2.0	2.0	1.9	1.9	1.9	1.9
22	4.3	3.4	2.4	2.8	2.7	2.5	2.5	2.4	2.3	2.3	2.2	2.1	2.0	2.0	2.0	1.9	1.9	1.9	1.8	1.8
23	4.3	3.4	2.3	2.8	2.6	2.5	2.4	2.4	2.3	2.3	2.1	2.0	2.0	2.0	1.9	1.9	1.9	1.8	1.8	1.8
24	4.3	3.4	2.3	2.8	2.6	2.5	2.4	2.4	2.3	2.3	2.1	2.0	2.0	1.9	1.9	1.9	1.8	1.8	1.8	1.8
25	4.2	3.4	2.3	2.8	2.6	2.5	2.4	2.3	2.3	2.2	2.1	2.0	2.0	1.9	1.9	1.9	1.8	1.8	1.8	1.8
26	4.2	3.4	2.3	2.7	2.6	2.5	2.4	2.3	2.3	2.2	2.1	2.0	1.9	1.9	1.9	1.9	1.8	1.8	1.8	1.7
27	4.2	3.4	2.3	2.7	2.6	2.5	2.4	2.3	2.3	2.2	2.1	2.0	1.9	1.9	1.9	1.8	1.8	1.8	1.7	1.7
28	4.2	3.3	2.3	2.7	2.6	2.4	2.4	2.3	2.2	2.2	2.0	2.0	1.9	1.9	1.8	1.8	1.8	1.7	1.7	1.7
29	4.2	3.3	2.3	2.7	2.5	2.4	2.3	2.3	2.2	2.2	2.0	1.9	1.9	1.9	1.8	1.8	1.8	1.7	1.7	1.7
30	4.2	3.3	2.3	2.7	2.5	2.4	2.3	2.3	2.2	2.2	2.0	1.9	1.9	1.8	1.8	1.8	1.7	1.7	1.7	1.7
40	4.1	3.2	2.2	2.6	2.4	2.3	2.2	2.2	2.1	2.1	1.9	1.8	1.8	1.7	1.7	1.7	1.6	1.6	1.6	1.6
60	4.0	3.2	2.2	2.5	2.4	2.3	2.2	2.1	2.0	2.0	1.8	1.7	1.7	1.6	1.6	1.6	1.5	1.5	1.5	1.5
80	4.0	3.1	2.2	2.5	2.3	2.2	2.1	2.1	2.0	2.0	1.8	1.7	1.6	1.6	1.6	1.5	1.5	1.4	1.4	1.4
100	3.9	3.1	2.1	2.5	2.3	2.2	2.1	2.0	2.0	1.9	1.8	1.7	1.6	1.6	1.5	1.5	1.5	1.4	1.4	1.4
120	3.9	3.1	2.1	2.4	2.3	2.2	2.1	2.0	2.0	1.9	1.8	1.7	1.6	1.6	1.5	1.5	1.4	1.4	1.4	1.4

*F- Table for  $\alpha=0.01$  ,  $N_1$  and  $N_2$  are Numerator and Denominator D.F. e.g.  $P(F_{5,10} \leq 2.5) = 1-\alpha=.99$*

0.01	$N_1$ (Numerator DF)																			
$N_2$	1	2	3	4	5	6	7	8	9	10	15	20	25	30	35	40	60	80	100	120
1	4052	4999	5404	5624	5764	5859	5928	5981	6022	6056	6157	6209	6240	6260	6275	6286	6313	6326	6334	6340
2	8.5	9.0	9.2	9.2	9.3	9.3	9.3	9.4	9.4	9.4	9.4	9.4	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5
3	5.5	5.5	5.4	5.3	5.3	5.3	5.3	5.3	5.2	5.2	5.2	5.2	5.2	5.2	5.2	5.2	5.2	5.1	5.1	5.1
4	4.5	4.3	4.2	4.1	4.1	4.0	4.0	4.0	3.9	3.9	3.9	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8
5	4.1	3.8	3.6	3.5	3.5	3.4	3.4	3.3	3.3	3.3	3.2	3.2	3.2	3.2	3.2	3.2	3.1	3.1	3.1	3.1
6	3.8	3.5	3.3	3.2	3.1	3.1	3.0	3.0	3.0	2.9	2.9	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.7	2.7
7	3.6	3.3	3.1	3.0	2.9	2.8	2.8	2.8	2.7	2.7	2.6	2.6	2.6	2.6	2.5	2.5	2.5	2.5	2.5	2.5
8	3.5	3.1	2.9	2.8	2.7	2.7	2.6	2.6	2.6	2.5	2.5	2.4	2.4	2.4	2.4	2.4	2.3	2.3	2.3	2.3
9	3.4	3.0	2.8	2.7	2.6	2.6	2.5	2.5	2.4	2.4	2.3	2.3	2.3	2.3	2.2	2.2	2.2	2.2	2.2	2.2
10	3.3	2.9	2.7	2.6	2.5	2.5	2.4	2.4	2.3	2.3	2.2	2.2	2.2	2.2	2.1	2.1	2.1	2.1	2.1	2.1
11	3.2	2.9	2.7	2.5	2.5	2.4	2.3	2.3	2.3	2.2	2.2	2.1	2.1	2.1	2.1	2.1	2.0	2.0	2.0	2.0
12	3.2	2.8	2.6	2.5	2.4	2.3	2.3	2.2	2.2	2.2	2.1	2.1	2.0	2.0	2.0	2.0	2.0	1.9	1.9	1.9
13	3.1	2.8	2.6	2.4	2.3	2.3	2.2	2.2	2.2	2.1	2.1	2.0	2.0	2.0	1.9	1.9	1.9	1.9	1.9	1.9
14	3.1	2.7	2.5	2.4	2.3	2.2	2.2	2.2	2.1	2.1	2.0	2.0	1.9	1.9	1.9	1.9	1.9	1.8	1.8	1.8
15	3.1	2.7	2.5	2.4	2.3	2.2	2.2	2.1	2.1	2.1	2.0	1.9	1.9	1.9	1.9	1.8	1.8	1.8	1.8	1.8
16	3.0	2.7	2.5	2.3	2.2	2.2	2.1	2.1	2.1	2.0	1.9	1.9	1.9	1.8	1.8	1.8	1.8	1.8	1.8	1.8
17	3.0	2.6	2.4	2.3	2.2	2.2	2.1	2.1	2.0	2.0	1.9	1.9	1.8	1.8	1.8	1.8	1.8	1.7	1.7	1.7
18	3.0	2.6	2.4	2.3	2.2	2.1	2.1	2.0	2.0	2.0	1.9	1.8	1.8	1.8	1.8	1.8	1.7	1.7	1.7	1.7
19	3.0	2.6	2.4	2.3	2.2	2.1	2.1	2.0	2.0	2.0	1.9	1.8	1.8	1.8	1.7	1.7	1.7	1.7	1.7	1.7
20	3.0	2.6	2.4	2.2	2.2	2.1	2.0	2.0	2.0	1.9	1.8	1.8	1.8	1.7	1.7	1.7	1.7	1.7	1.7	1.6
21	3.0	2.6	2.4	2.2	2.1	2.1	2.0	2.0	1.9	1.9	1.8	1.8	1.7	1.7	1.7	1.7	1.7	1.6	1.6	1.6
22	2.9	2.6	2.4	2.2	2.1	2.1	2.0	2.0	1.9	1.9	1.8	1.8	1.7	1.7	1.7	1.7	1.6	1.6	1.6	1.6
23	2.9	2.5	2.3	2.2	2.1	2.0	2.0	2.0	1.9	1.9	1.8	1.7	1.7	1.7	1.7	1.7	1.6	1.6	1.6	1.6
24	2.9	2.5	2.3	2.2	2.1	2.0	2.0	1.9	1.9	1.9	1.8	1.7	1.7	1.7	1.7	1.6	1.6	1.6	1.6	1.6
25	2.9	2.5	2.3	2.2	2.1	2.0	2.0	1.9	1.9	1.9	1.8	1.7	1.7	1.7	1.6	1.6	1.6	1.6	1.6	1.6
26	2.9	2.5	2.3	2.2	2.1	2.0	2.0	1.9	1.9	1.9	1.8	1.7	1.7	1.6	1.6	1.6	1.6	1.6	1.6	1.5
27	2.9	2.5	2.3	2.2	2.1	2.0	2.0	1.9	1.9	1.8	1.7	1.7	1.7	1.6	1.6	1.6	1.6	1.6	1.5	1.5
28	2.9	2.5	2.3	2.2	2.1	2.0	1.9	1.9	1.9	1.8	1.7	1.7	1.6	1.6	1.6	1.6	1.6	1.5	1.5	1.5
29	2.9	2.5	2.3	2.1	2.1	2.0	1.9	1.9	1.9	1.8	1.7	1.7	1.6	1.6	1.6	1.6	1.5	1.5	1.5	1.5
30	2.9	2.5	2.3	2.1	2.0	2.0	1.9	1.9	1.8	1.8	1.7	1.7	1.6	1.6	1.6	1.6	1.5	1.5	1.5	1.5
40	2.8	2.4	2.2	2.1	2.0	1.9	1.9	1.8	1.8	1.8	1.7	1.6	1.6	1.5	1.5	1.5	1.5	1.4	1.4	1.4
50	2.8	2.4	2.2	2.1	2.0	1.9	1.8	1.8	1.8	1.7	1.6	1.6	1.5	1.5	1.5	1.5	1.4	1.4	1.4	1.4
60	2.8	2.4	2.2	2.0	1.9	1.9	1.8	1.8	1.7	1.7	1.6	1.5	1.5	1.5	1.5	1.4	1.4	1.4	1.4	1.3
80	2.8	2.4	2.2	2.0	1.9	1.8	1.8	1.7	1.7	1.7	1.6	1.5	1.5	1.4	1.4	1.4	1.4	1.3	1.3	1.3
100	2.8	2.4	2.1	2.0	1.9	1.8	1.8	1.7	1.7	1.7	1.6	1.5	1.5	1.4	1.4	1.4	1.3	1.3	1.3	1.3
120	2.7	2.3	2.1	2.0	1.9	1.8	1.8	1.7	1.7	1.7	1.5	1.5	1.4	1.4	1.4	1.4	1.3	1.3	1.3	1.3



**Table – 5 : Random Number Table**

10838	39674	89911	16909	83608	63979	66741	42709	46563	76944
64601	07625	01465	64301	71790	26366	62953	79705	33810	87546
54643	18925	93054	95890	38892	62488	70789	25861	03719	03970
77348	16408	55270	06117	61493	61510	89303	51985	34871	76215
40104	83291	32504	42842	30286	43155	95258	67060	69903	65423
85216	98509	78323	77764	69896	95662	27286	10722	36265	39615
28588	29907	20466	26485	14847	33531	64206	93115	86752	82449
33751	55762	25276	54916	62443	66464	92239	43236	02699	16769
67723	34495	98411	43515	97707	42557	13714	16347	50418	83529
79005	11664	04796	11857	40223	02676	19535	59259	22257	20256
56119	43690	42472	64297	54310	40488	35266	70226	83504	32941
73588	60392	18412	84417	98384	35002	12488	99278	91876	82296
67554	64737	55638	12651	23054	90869	79381	46283	13366	90955
11414	09278	66628	69337	66686	17579	43505	08991	33382	53675
39323	75978	63972	65640	98032	83002	61684	43222	11423	79214
98319	50678	02023	58482	24355	21029	13134	03311	57265	41429
54432	06585	59008	84337	76569	38336	38606	64179	73219	49716
40763	24174	33999	31368	06454	83040	96709	68371	16423	96239
72332	58963	53537	11469	41213	89216	44909	23066	43871	80858
69761	55042	14891	54426	43936	27407	33293	74938	17011	85482
87873	72273	42944	96894	80898	53445	10201	45928	18629	48959
42278	79931	62099	60437	04587	87458	36577	01702	78616	12841
23165	50501	89317	36867	80958	53072	96652	78267	73213	48715
87237	95685	95952	06582	27022	94823	32451	91855	60943	70454
82041	03514	70485	37985	36667	50861	25091	34252	03632	61015
88355	92247	97975	34543	64945	19461	52918	91425	99176	34515
21806	74545	61188	41797	70002	02872	81656	48758	80149	91556
20975	55582	19259	81095	83846	71903	41044	42770	15231	40263
21954	52543	38566	70988	54325	50596	22218	18191	45111	28703
85089	51557	93609	12622	77329	03640	46631	31689	97070	97309
54546	92819	29149	83084	76654	01076	16724	41000	09300	94014
01754	26721	35183	81988	95253	66582	17299	11590	63272	31238
85944	94433	39537	42614	92225	68449	00686	93847	26511	83890
65048	86902	25259	31229	00884	17551	14667	53141	55042	62400
64566	07756	37967	47665	51022	75362	25983	04358	51045	25764
66807	39597	17885	88457	99223	78718	10317	92847	22848	57867
74376	70644	78935	71771	00968	37679	28158	06380	07794	97288
36289	11045	19039	32468	03741	89949	41237	78992	99881	17457
58775	96668	88083	07075	97464	80930	52419	88715	29610	81945
61967	73958	19022	23434	33644	13965	29412	38380	79516	79784
44599	63827	49516	19684	73974	61937	05509	73239	41654	59515
87642	46835	82761	23171	58925	80287	95276	12317	38956	59263

20894	77185	62758	53191	53308	94052	25645	83344	97397	54852
00063	50788	27707	53380	35336	78882	19694	35263	76266	50012
52164	03882	61518	41259	04339	99445	87718	88667	95976	93395
50227	34832	44018	65324	96496	39452	34156	54608	52973	57582
30791	03929	11465	15231	73803	36884	85922	37016	35578	36857
75571	05560	36721	19356	95323	57307	43905	14986	59411	44459
98282	05260	29189	17703	47898	78429	61024	09437	82549	97519
15226	22165	94521	97756	11952	51760	13639	55584	45015	00274
90071	96443	89545	57984	23338	33513	64438	59374	60922	54590
35516	42718	14975	99311	70361	67973	70508	93881	80740	72654
83534	35519	13563	70391	92580	43793	76317	21841	92024	21042
07913	32658	40684	89058	30871	58201	04093	94240	45802	19662
53911	98376	54105	61312	72897	97267	19826	03550	38889	34372
06611	71427	86220	01651	50706	03371	68021	44810	55915	69745
67835	15129	21479	55981	33983	35052	38793	89938	35127	69740
17920	18189	60459	21770	29817	60924	12956	91157	75225	00152
69140	67908	16162	80889	03778	49272	30940	30028	02963	98890
78664	22562	14009	90031	84138	49871	05602	00085	79120	69736
36642	48525	60857	42785	57213	95511	53848	85046	90118	43322
85767	91313	66425	07807	13484	08988	13442	52051	60111	67097
18583	99430	49043	90191	17544	68245	45880	51766	80235	95131
44224	46949	92903	39420	56241	89091	59884	85652	93960	59985
73416	86414	52221	68380	24971	12698	29227	96480	56508	03972
45631	39129	75122	35139	48095	65345	79502	42583	08254	56918
71640	76478	53036	03742	52239	71564	87264	60563	23244	53558
94477	94860	45942	23401	26917	80508	28066	86525	20607	16941
38335	19327	96470	78482	71887	90036	33425	23548	15009	76164
24372	18391	82636	45725	51053	55091	27039	94408	38679	68467
41130	55906	76286	81601	04852	27562	13751	34669	48060	78543
71399	76753	28345	32725	23165	25332	47243	43457	39200	23138
53251	02427	98909	47061	05108	49782	10332	48789	93754	77714
96802	31883	46438	44685	36835	94952	61364	42487	68177	95645
46368	83321	91945	15113	60021	99083	37811	27663	78619	70045
76150	05265	37478	25117	88104	11617	19997	80875	29495	65438
92903	11559	49511	77702	11130	67198	50135	92470	40759	82081
97216	86031	73465	40738	19146	04031	30911	93635	54068	41273
82507	39762	31568	93891	25001	18294	99758	38560	97312	76539
33724	18455	29061	06330	86247	40631	46228	66060	66760	14524
82379	30560	59450	86235	68891	35988	16465	48327	02623	11926
87159	29774	14462	17876	69309	95791	87196	26332	93232	12205
96123	19625	74764	54065	70868	92728	98014	63186	01819	79197
13847	84292	39633	42453	65021	34478	61246	99575	73929	85637
00827	69811	53869	64589	69100	64971	29791	00553	09500	63914
79452	74677	64563	38293	30925	51311	51028	21767	77377	95695

67049	39851	95093	07772	79985	42601	75637	26791	68194	07318
08129	86407	15258	03460	72543	24954	80100	36945	29992	80576
91410	16040	20907	25917	39826	06019	07077	22046	66305	64772
18466	96302	70129	76571	90760	73767	84969	26157	04567	17020
96460	80346	62215	53897	99712	69355	63093	97916	20204	85004
63456	91072	46491	38019	31645	23676	48169	41587	34652	10934
77527	13381	16971	30962	78333	13225	57673	53897	50178	58588
16642	16824	41835	85104	05903	24179	72050	44291	46990	78339
01217	55671	00289	70068	02366	55473	77280	83516	04912	09098
71646	95454	09585	79545	70144	73440	97995	68988	29217	02593
85266	75674	28257	95670	89167	33346	35469	66135	14191	25374
47269	68893	74003	90778	87155	38400	00723	64338	74988	78815
14438	17962	02619	85896	51430	95527	76802	05317	74514	58351
15340	57098	13954	83505	07367	80844	12373	82140	73752	81464
72119	30024	88527	80065	28494	27473	47288	99717	97309	30861
93505	40763	70191	22905	38688	25365	56078	13903	37325	15984
92350	91116	02555	37469	74019	58485	73491	57440	74426	33866
70154	04675	55881	95972	96924	30155	93681	98211	80478	40484
61939	91601	53133	58359	54679	23963	17540	89773	40607	07561
53652	02648	75026	72397	53933	46574	17307	47330	97712	68366
27366	36218	00641	03090	39587	81265	00182	45271	37618	30767
63080	29974	78487	53434	25735	78419	39471	66485	03418	87851
86156	69702	29287	70322	85128	02623	09114	70094	09723	67070
02675	14342	12294	82200	67737	76841	61406	64257	27586	59338
67421	48222	48013	20274	44889	93541	34734	05569	85200	41132

*Mrs Seema R. Patrikar & Col RajVir Bhalwar*

## Overview of Epi Info

Epi Info is a package which is most suitable for doctors and researchers. It is a package which suffices for nearly all the usual clinical research and epidemiological settings. Epi Info is a public domain database and statistics program for performing statistical applications in clinical research. Statistics, graphs, tables, and maps can be produced with simple commands. *Epi Info is free, downloadable software provided by the CDC (www.cdc.gov/epiinfo/) and has been developed as a joint collaboration between WHO and CDC, Atlanta.* In our experience Epi-Info 2002 is the best for all the statistical requirements of most clinical researchers and epidemiologists and it would be worthwhile that we master the use of this programme.

A word of caution, however, is required. Statistical software are actually “enlarged calculators”, which make easy your problems of calculation. However, they can never substitute for the essential knowledge of epidemiology, research methodology and bio-statistics. In fact, inadvertent use of statistical software without adequate background of research methodology and biostatistics may create more problems than do good. Secondly, please do remember that no statistical software can substitute for accurate, valid and reliable data. In the field of Information Technology, there is an old saying “Garbage In, garbage Out” (GIGO) !

## Installing Epi Info 2002

You will need to uninstall any earlier versions of EPI that may already be on your system.

- On your desktop, click Start, then Programs, then Epi Info 2000, then Uninstall Epi Info 2000.
- Continue to follow the instructions on your screen.
- When this is complete, install the new Epi Info.

### A. Installation from the Internet

**Step 1:** Log on to CDC's website at [www.cdc.gov/epiinfo/epiinfo.htm](http://www.cdc.gov/epiinfo/epiinfo.htm)

**Step 2:** Click the *Download* button to perform a Web Install of the latest Epi Info.

**Step 3:** Save the file to a temporary folder on your hard drive (anywhere except where Epi Info will be stored).

**Step 4:** Go to this temporary folder and double click the *Setupweb.exe* icon for a complete installation by following the directions on your screen. You *must be* connected to the Internet while this installation occurs. Web Install will NOT result in a copy of setup files after the installation is complete. This means that you will not be able to install the program onto another system with these files. To do so, you must download the Complete Installation Package, then save onto a CD-ROM.

**Step 5:** Begin using Epi Info

### B. Installation from a CD-ROM

**Step 1:** Insert disc in CD-ROM drive.

**Step 2:** Open *My Computer*, click on (E:) (CD Drive)

**Step 3:** Click on *Epi Info* folder and select *Full Version* folder

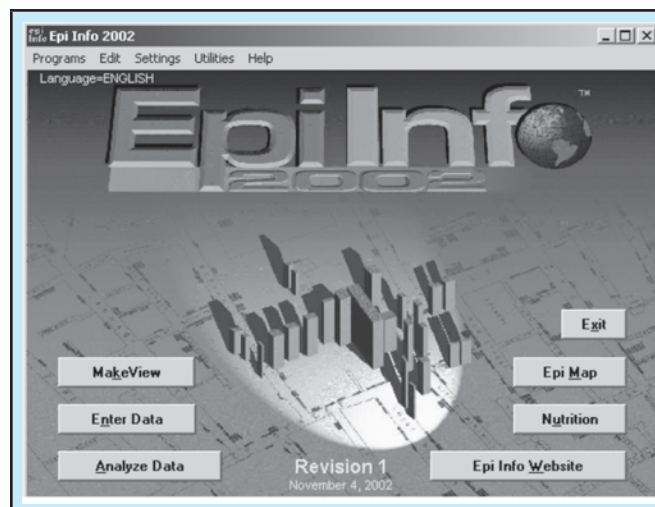
**Step 4:** Click on *Setup* icon. The Installation Wizard should begin. Follow the instructions as they appear. Most of your selections should be *OK* and *Next*.

**Step 5:** Click OK to put Epi Info icon on your desktop. Make sure icon is on your desktop; double click to make sure it works.

**Step 6:** Begin using Epi Info.

## How to Run Epi Info

Once Epi Info is installed on your computer, the easiest way to “run” the software is clicking the Epi Info icon on your desktop. The Epi Info main menu should then appear:



### Main Menu

The main programs of Epi Info can be accessed either through the PROGRAMS menu or by clicking on the buttons. The components of the Main Menu of Epi Info 2002 are -

*MakeView, Enter Data, Analyze Data, Epi Map, Nutrition, Epi Info Website and Exit*

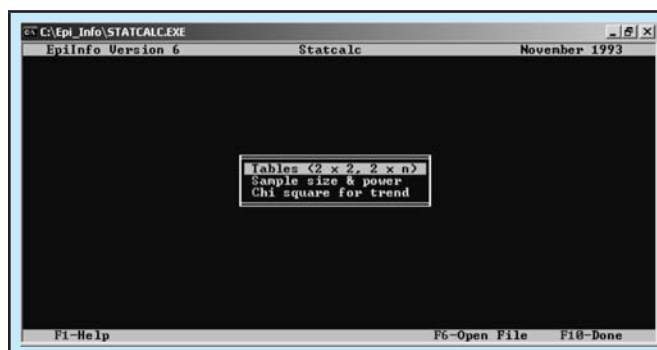
Though all these programs are being mentioned we would concentrate on two major programs- Statcalc (assessed through Utilities) and Analyze Data because these are the major requirements for epidemiologists and clinical researchers.

### Statcalc

Statcalc is assessed through the dropdown menu in Utilities on the top of the main menu. Statcalc is an epidemiologic calculator that gives various statistical analysis of the data entered in the table form which appears on the screen. Three types of analysis are offered. Each option can be assessed by pressing <Enter>.

- Tables (2 x 2, 2 x n)
- Sample size and power
- Chi square for trend





## Tables

It provides statistical analysis of tables (from 2 x 2 to 2 x 9 tables) along with the exact confidence limits for odds ratios. Stratified analysis of 2 X 2 tables can be carried out to produce odds ratios and risk ratios (relative risks) with confidence limits. Several types of chi-square tests, Fisher exact tests, Mantel Haenszel summary odds ratios and associated p values are provided.

### Single 2 X 2 Tables

2 X 2 tables are frequently used in medical research to explore associations between EXPOSURE (to risk factors or the intervention in a clinical trial) and DISEASE (or other outcomes, if the outcome is not a disease but rather improvement from disease as may occur in a clinical trial). The table in STATCALC is set up with EXPOSURE on the left and DISEASE across the top. STATCALC produces results that test for relationships between EXPOSURE and DISEASE. The 2x2 layout is given in Table - 1.

Table 1			
	Disease present (D+)	Disease Absent (D-)	Total
Exposure present(E+)	a	b	a+b
Exposure Absent(E-)	c	d	c+d
Total	a+c	b+d	

When a 2 x 2 table appears on the screen we need to enter four numbers in the table. To do this enter the number in the first cell and press <Enter>, the cursor goes in the next cell. Again enter the next cell entry and press <Enter> to go to the next cell. (If any entry is wrongly entered this option does not allow you to edit hence you have to keep on pressing <Enter> till we are back to the empty 2 x 2 table). After the entry in the 4<sup>th</sup> cell press <Enter> or <F4> to calculate the single table statistics showing associations between EXPOSURE to the risk factor and DISEASE or other outcomes. Generally an association is suggested by an odds ratio or relative risk. The statistical significance is interpreted by 'p' values for chi square tests.

Pressing <Enter> or <F4> displays the statistical result which gives all the summary statistics i.e. Odds ratio along with the 95% confidence interval, Relative Risk along with 95% confidence interval. Remember that only one of these will be appropriate so don't quote both. You will also get some test statistics, such as  $\chi^2$  values. If the computer says that Cornfield not accurate, you can generally ignore this, but take advice from Epidemiologist or Statistician. Depending on the study design (a case-control or a cohort or a cross sectional design) we should select summary statistics (as either OR or RR). Generally, an association is suggested by an odds ratio or relative risk larger or smaller than 1.0. The further the odds ratio or relative risk is from 1.0, the stronger the apparent association. The significance is assessed by the p value. Whenever  $p < 0.05$  it is considered to be statistically significant; also when the confidence limits for the odds ratio do not include 1.0 it is significant. Whenever the frequencies entered in the table are very small (<5) the program recommends Fisher Exact Test Results and the Exact confidence limits to be used.

Consider an example where we picked up 100 diagnosed patients of IHD from our Cardiology centre and another 100 subjects from the same centre in whom IHD had been excluded (Total = 200). We took the history from each and every one regarding smoking. Suppose we observed from our data that out of the 100 IHD cases, 80 were smokers and 20 non-smokers; while out of 100 healthy (non-IHD) subjects, there were 20 smokers and 80 non smokers. We would then consolidate our data into a '2 X 2' table. The data is given in Table - 2.

Table - 2			
	Disease present (D+)	Disease Absent (D-)	Total
Exposure present(E+)	80	20	100
Exposure Absent(E-)	20	80	100
Total	100	100	200

Once we enter this data, press <Enter> or <F4> to get the table statistics.

On pressing <Enter> or <F4> analysis is provided as given in Table - 3.

The output given by the software includes the odds ratio as well as the RR along with the 95% confidence interval (which is shown in parentheses after the value of OR or RR. Depending on our study design we select between the two estimates. If the study design is a case control study (as was in this example) then select odds ratio (OR) along with 95% confidence limits. If the study design is a cohort study then select RR and if cross sectional then also select the odds ratio which is approximately equal to the prevalence odds ratio. Whether you select the RR or OR, also select the chi square along with the p value for mentioning in your results. To be on the safer side, select Mantel-Haenszel Chi-square along with the p value.

Table - 3 : Analysis of Single Table		
Odds ratio = 16.00 (7.60<OR<34.18)		
Cornfield 95% confidence limits for OR		
Relative Risk = 4.00 (2.67<RR<5.99)		
Taylor Series 95% confidence limits for RR		
Ignore relative risk if case control study.		
	Chi-Squares	P-values
Uncorrected	72.00	0.0000000
Mantel-Haenszel	71.64	0.0000000
Yates corrected	69.62	0.0000000
F2 More Strata; <Enter> No more Strata; F10 Quit		

### Stratified Analysis of 2 X 2 tables

Associations between DISEASE and EXPOSURE can be missed or falsely detected if CONFOUNDING is present. A confounding factor is one that is associated with both the DISEASE and the EXPOSURE. Age is a frequent confounder. Any factor other than the main EXPOSURE being considered can be treated as a confounder.

Stratification means making a separate table of DISEASE by EXPOSURE for each possible combination of confounders. In the simplest case, this could mean separate tables for males and females, if SEX is the potential confounder. If AGE, SEX, and CITY are confounders, separate tables would be made for each possible combination of age, sex and city. The Mantel-Haenszel weighted odds ratio, relative risk, summary chi square and p value combines results from different strata to remove confounding caused by the variables. Thus, if tables are entered for males and females, confounding by SEX will be removed. The degree of confounding can be judged by comparing the crude and weighted odds ratios; if they are identical, there was no confounding by SEX. The approximate and exact confidence limits provide additional measures. If the weighted odds ratio or relative risk has confidence limits that do not include 1.0, then there is a significant statistical association between the DISEASE and the EXPOSURE, after controlling for confounding by the stratifying factor.

Table - 4			
History of Alcohol	Oral cancer		
	<i>Present</i>	<i>Absent</i>	<i>Total</i>
Present	80	20	100
Absent	20	80	100
Total	100	100	200

Consider following example. A study was done to see whether consumption of alcohol is a risk factor for oral cancer. 100

cases of oral CA and 100 healthy subjects were asked regarding history of alcohol consumption during past 15 years. The results are shown in Table - 4. Enter the four numbers in the 2 X 2 table on the screen and press <Enter> or <F4>. On pressing <Enter> or <F4> the following output is given (Table - 5).

Table - 5 : Analysis of Single Table		
Odds ratio = 16.00 (7.60<OR<34.18)		
Cornfield 95% confidence limits for OR		
Relative Risk = 4.00 (2.67<RR<5.99)		
Taylor Series 95% confidence limits for RR		
Ignore relative risk if case control study.		
	<i>Chi-Squares</i>	<i>P-values</i>
Uncorrected	72.00	0.0000000
Mantel-Haenszel	71.64	0.0000000
Yates corrected	69.62	0.0000000
F2 More Strata; <Enter> No more Strata; F10 Quit		

Since above is a case control study we select *odds ratio* = 16 which concludes that the risk of getting oral cancer is 16 times higher if a person drinks alcohol.

Now we also know that tobacco use is related to oral cancer. Hence stratifying the data by Tobacco status, we have two tables, one for tobacco users and the other for non-users. This becomes stratified 2 X 2 tables with 2 stratum. In this case enter the four numbers for the first stratum and press <F4> or <Enter> to calculate the related statistics. Press <F2> to enter another stratum. Enter the four numbers for this second stratum and press <F4> or <Enter>. Repeat the process for all the stratum available. Pressing <Enter> when there are no more stratum will present the stratified analysis summary for all strata entered. Pressing <Enter> again will then offer an opportunity to do exact confidence limits. Stratified analysis are not done for tables larger than 2 X 2

In the example considered the stratum for Tobacco users and non-Tobacco users are as follows. Substituting the values for first stratum and pressing <Enter> or <F4> yields the following output

Stratum I : Tobacco users			
History of Alcohol	Oral cancer		
	<i>Present</i>	<i>Absent</i>	<i>Total</i>
Present	60	15	75
Absent	20	5	25
Total	80	20	100

<b>Analysis of Single Table (Stratum I)</b>		
Odds ratio = 1.00 (0.28 < OR < 3.46*)		
Cornfield 95% confidence limits for OR		
*Cornfield not accurate. Exact limits preferred.		
Relative Risk = 1.00 (0.80<RR<1.25)		
Taylor Series 95% confidence limits for RR		
Ignore relative risk if case control study.		
	<i>Chi-Squares</i>	<i>p-values</i>
Uncorrected	0.00	1.0000000
Mantel-Haenszel	0.00	1.0000000
Yates corrected	0.08	0.7728300
F2 More Strata; <Enter> No more Strata; F10 Quit		
Since we have one more stratum of non-Tobacco users we press <F2>.		

On pressing <F2> another 2 X 2 table appears on the screen. Enter all the four cell values for non-Tobacco users and press <Enter>. The following output appears on the screen.

<b>Stratum II : Non users of Tobacco</b>			
History of Alcohol	Oral cancer		
	Present	Absent	Total
Present	5	20	25
Absent	15	60	75
Total	20	80	100

<b>Analysis of Single Table (Stratum II)</b>		
Odds ratio = 1.00 (0.28<OR<3.46*)		
Cornfield 95% confidence limits for OR		
*Cornfield not accurate. Exact limits preferred.		
Relative Risk = 1.00 (0.40<RR<2.47)		
Taylor Series 95% confidence limits for RR		
Ignore relative risk if case control study.		
	<i>Chi-Squares</i>	<i>p-values</i>
Uncorrected	0.00	1.0000000
Mantel-Haenszel	0.00	1.0000000
Yates corrected	0.08	0.7728300
F2 More Strata; <Enter> No more Strata; F10 Quit		

Since no more stratum are available press <Enter>. On pressing <Enter> the stratified analysis or the summary of 2 tables appears on the screen as follows:

<b>Stratified Analysis</b>	
Summary of 2 Tables	
Crude odds ratio for all strata = 3.45	
Mantel-Haenszel Weighted Odds Ratio = 1.00	
Cornfield 95% Confidence Limits	
0.41 < 1.00 < 2.37	
Mantel-Haenszel Summary Chi Square = 0.04	
P Value = 0.83907676	
Crude RR for all strata = 1.86	
Mantel-Haenszel Weighted Relative Risk	
Of Disease, given Exposure = 1.00	
Greenland / Robins Confidence Limits =	
0.77 < MHRR < 1.29	
<Enter> for more; F10 to quit	

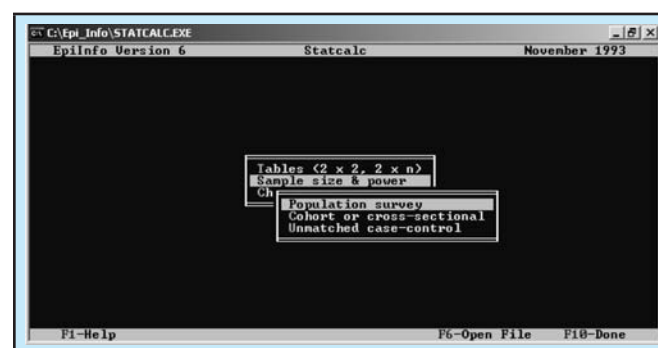
The odds ratio for each table is 1.0 and the Mantel-Haenszel summary odds ratio is 1.0. The crude odds ratio and the Mantel – Haenszel summary odds ratio are quite different, leading to the conclusion that use of tobacco was a confounding factor and that there appears to be no risk of cancer due to alcohol after considering the effect of tobacco.

### Sample Size & Power

Determining sample size is a very important issue, as already emphasized in the section of biostatistics. In the sample size calculations, an initial screen explains the data items and allows input of a single set of values. Pressing <F4> then shows the results on the second screen. On pressing *Sample size & power* three options are made available

- Population Survey
- Cohort or cross-sectional
- Unmatched case-control

The screen is as follows



Sample size calculations are possible by both *Statcalc* as well as *EpiTable*. *EpiTable* is separately discussed after the Epi2002 module. For cohort, cross sectional and unmatched case-control design you can calculate by either *EpiTable* or *Statcalc*. For matched pair case-control design calculate sample size using *EpiTable*.

**Population Survey :** Let us understand this with an example. Suppose a study on gestational diabetes is undertaken. The expected proportion is  $p=10\%$  with the desired precision or acceptable deviation as 7% to 13% i.e. 3% on either side. ( $d=0.03$ ). Alpha error is considered to be 5%. The information required to in this module is the population size from which the sample is selected. If the population size is known the researcher should substitute it, but in case if the total population size is not known then a default value of 999,999 is taken by the software. The prevalence or proportion of the disease or parameter under study should be substituted in percentage. The third requirement is regarding the worst acceptable result by the researcher.

Population Survey or Descriptive Study Using Random (Not Cluster) Sampling

Size of population from which the sample will be selected : 999,999

Expected frequency of the factor under study (err toward 50%) : 10.00 %

If 10.00 % is the true rate in the population, what is the result farthest from the rate that you would accept in your sample (higher or lower)?

Worst acceptable result : 7.00 %

In the above considered example since the population size is unknown we take the default value of 999,999. The proportion of gestational diabetes is 10%. And worst acceptable result as per the researcher varies from 7% to 13%, so we can either put the lower value of 7% or upper value of 13% as worst acceptable result. On pressing <F4> we get 384 as the minimum sample size against 95% confidence interval.

Population Survey or Descriptive Study Using Random (Not Cluster) Sampling

Population Size : 999,999

Expected Frequency : 10.00 %

Worst Acceptable : 7.00 %

Confidence Level	Sample Size
80 %	164
90 %	270
95 %	384
99 %	663
99.9 %	1,082
99.99 %	1,511

Change value of Population, Frequency, or Worst Acceptable to recalculate.

**Cohort or Cross-Sectional Studies :** For this type of study the proportion of disease in the unexposed group and the relative risk that the study anticipates to detect needs to be specified. Also the confidence interval along with desired power of the study requires to be specified. Once all the specifications are filled up, pressing <F4> calculates the minimum required sample size for our study.

Consider following study. We want to try acetazolamide as a prophylactic therapy against the development of High Altitude Pulmonary Oedema (HAPO). Our background information based on available data tells us that till now people have not been taking Diamox (i.e. are 'not exposed' to Diamox) and 10 out of

every thousand such persons develop HAPO; thus proportion of 'outcome' (HAPO) among those who are 'not exposed' (i.e. not taking Diamox) is  $10/1000 = 0.01$  or 1%.

Considering the cost and problems of logistics, we would say that putting this prophylactic therapy into routine preventive use will be worthwhile only if Diamox reduces the load of HAPO by at least 50%; thus the minimum detectable RR = 0.5. We specify an alpha error of 0.05 (two tailed) (i.e. confidence level of 95%) and beta error of 0.20 i.e. power of 80%.

Unmatched Cohort and Cross-Sectional Studies (Exposed and Nonexposed)

Probability that if the two SAMPLES differ this reflects a true difference in the two POPULATIONS (Confidence level or 1-α) : 95.00 %

Probability that if the two POPULATIONS differ, the two SAMPLES will show a "significant" difference (Power or 1-β) : 80.00 %

Ratio (Number of Unexposed : Number of Exposed) : 1 : 1

Expected frequency of disease in unexposed group : 1.00 %

Please fill in the closest value to be detected for ONE of the following:

Risk ratio (RR) or relative risk—closest to 1.00 : 0.50

Odds ratio (OR)—closest to 1.00 : 0.50

Percent disease among exposed—closest to % for unexposed : 0.50 %

Substituting the values as above, the required minimum sample size is obtained by pressing <F4>. The result screen is as follows.

Unmatched Cohort and Cross-Sectional Studies (Exposed and Nonexposed)

Sample Sizes for 1.00 % Disease in Unexposed Group

Conf.	Power	Unex:Exp	Disease in Exposed	Risk Ratio	Odds Ratio	Sample Size Unexposed	Sample Size Exposed	Total
95.00 %	80.00 %	1:1	0.50 %	0.50	0.50	5,065	5,065	10,130
90.00 %	80.00 %	1:1	0.50 %	0.50	0.50	4,071	4,071	8,142
95.00 %	90.00 %	1:1	0.50 %	0.50	0.50	5,065	5,065	10,130
99.00 %	80.00 %	1:1	0.50 %	0.50	0.50	7,348	7,348	14,696
99.90 %	80.00 %	1:1	0.50 %	0.50	0.50	10,562	10,562	21,124
95.00 %	80.00 %	1:1	0.50 %	0.50	0.50	5,065	5,065	10,130
95.00 %	90.00 %	1:1	0.50 %	0.50	0.50	6,649	6,649	13,298
95.00 %	95.00 %	1:1	0.50 %	0.50	0.50	8,130	8,130	16,260
95.00 %	99.00 %	1:1	0.50 %	0.50	0.50	11,332	11,332	22,664
95.00 %	80.00 %	4:1	0.50 %	0.50	0.50	13,488	3,372	16,860
95.00 %	80.00 %	2:1	0.50 %	0.50	0.50	10,492	3,564	14,056
95.00 %	80.00 %	2:1	0.50 %	0.50	0.50	7,888	3,944	11,832
95.00 %	80.00 %	1:2	0.50 %	0.50	0.50	3,635	7,270	10,905
95.00 %	80.00 %	1:3	0.50 %	0.50	0.50	3,152	9,456	12,608
95.00 %	80.00 %	1:4	0.50 %	0.50	0.50	2,987	11,635	14,622

Thus we would require a total of 10130 subjects to be studied, 5065 subjects who would get Diamox and another 5065 subjects who would not get any drug.

**Case-control Study :** This option deals with the sample size determination when the study design is case control study. For this type of study the proportion of exposure in the not ill group (control) and the odds ratio that the study anticipates to detect needs to be specified. Also the confidence interval along with desired power of the study requires to be specified. Once all the specification is filled up pressing <F4> calculates the minimum required sample size for our study.

Continuing the same situation of HAPO, a research study wanted to find out whether even a slight physical exertion during first 24 hours of entry into high altitude may be associated with the development of HAPO. To proceed with this question as a case-control study, we want to take up cases of HAPO admitted to the hospital and healthy subjects who did not develop HAPO as a control group. Our background information from pilot study gives an indication that out of the healthy persons who did



Once all the required information is substituted in the Case-control study screen and press <F4> the required minimum sample size is displayed on the screen as under.

Conf. %		Power	NOT ILL	Exposure	Odds	Sample Size	Total
95.00 %		80.00 %	1:1	in ILL	Ratio	NOT ILL	ILL
				25.00 %	3.00	112	112
90.00 %	"	"	"			91	91
95.00 %	"	"	"			112	112
99.00 %	"	"	"			161	161
99.90 %	"	"	"			231	231
95.00 %	80.00 %	"	"			112	112
	90.00 %	"	"			146	146
	95.00 %	"	"			177	177
	99.00 %	"	"			244	244
	80.00 %	4:1	"			256	64
	"	3:1	"			210	70
	"	2:1	"			162	81
	"	1:2	"			88	175
	"	1:3	"			79	236
	"	1:4	"			74	297

### Chi Square for Trend

Many times the variables of interest are measured on qualitative polychotomous ordinal scale, i.e. there are more than two exposure categories and these multiple categories have a definite common-sense ordering. In such situations, it is advisable to do the chi-square test for linear trend in proportions and not a simple chi-square test for  $R \times C$  contingency table. The Chi Square for trend tests whether the odds (risk) increase or decrease in each group with respect to the first group, which is taken as the baseline for comparison. Epi calculates the chi-square for trend if there are at least three or more exposure levels and which have a sensible ordering of categories. For this we have to choose Chi square for trend and press return (`<enter>`). The screen looks as under

C:\Tpi\_Info\STATCALC.EXE

Epiinfo Version 6      Statcalc      November 1993

Analysis For Linear Trend In Proportions

Stratum : 1

Exposure Score      Cases      Controls

\_\_\_\_\_

You have to choose an exposure score. The first category should be your unexposed (or least exposed) group. Choose 1 as their exposure score, then go on to fill in the cases and controls columns, which refer to the outcome. Fill in your next group as

Consider an example to understand this concept in detail. Suppose we have a hypothetical cohort study, which was undertaken to assess whether smoking by mothers during pregnancy is a possible determinant of congenital malformations in the foetus. Let us assume that a total of 2462 pregnant ladies were taken up and their average daily cigarette consumption was assessed. 2076 ladies were non smokers, while 172, 143 and 71 were smoking upto 10 cigarettes, 11 to 20 and more than 20 cigarettes per day respectively. It was observed that 81 (i.e. 3.09%) of the non-smoker mothers delivered congenitally malformed children. The proportion of such malformed children increased progressively. It was 10, 28 and 21 as the smoking category increased respectively. Putting the following information in a table form we have the following, which is clearly an qualitative, ordinal, polychotomous data :-

Exposure Category (Exposure Score)	Smoking habits during pregnancy (Exposure score)	Status of delivered child	
		<i>Congenital Malformation (cases)</i>	<i>Normal (controls)</i>
1	Non-smokers	81	1995
2	1 to 10 cig/day	10	162
3	11 – 20 cig/day	28	115
4	> 20 cig/day	21	50
	Total	140	2322

After entering all the numbers in the table, pressing <F4> gives the following output

Analysis for Linear Trend in Proportions			
Chi Square for linear trend : 128.167			
		<i>Exposure Score</i>	<i>Odds Ratio</i>
p value	0.00000	1.00	1.00
		2.00	1.52
		3.00	6.00
		4.00	10.34

**Interpretation :** There exist highly significant linear trend in the odds of successive levels of the smoking and congenital malformation. The odds of congenital malformation in ladies who are smoking 11-20 cig/day increases by 6 times and in ladies who smoke > 20 cig/day the odds increases by more than 10 times as compared to non smokers. In addition with a p value of < 0.0001, this overall 'trend' (of increasing risk of congenital malformation with increasing smoking) is statistically very highly significant.

## Analyze Data

Let us once again revert back to the main menu of Epi 2002.

One of the most important component of Epi 2002 is Analyze Data. This program allows access to data entered in 20 data formats (e.g. Epi Info data files, Foxpro data base files, Excel files, Access data base files etc.) to perform statistical analysis. Though you can directly enter data in the EPI INFO we strongly recommend that the data be first entered in Excel, Foxpro or Access and then imported to EPI. To understand this option in detail a practice data file named "SAMPLE.dbf" consisting of 200 records is provided. It is suggested that the readers use this file and try out all the options available in the Analyze Data menu of Epi 2002. The description of the data set in "SAMPLE.dbf" is given below.

#### Description of data set SAMPLE.dbf

Description of the data : SAMPLE.dbf file is a HYPOTHETICAL data given in Table - 5, meant for practicing only. It was a cross sectional study in which 614 healthy army subjects aged more than equal to 35 years were randomly selected from various army units in a very

large cantonment. General particulars included age, rank, native state. History was recorded of details of physical exercise, alcohol consumption and tobacco use. Clinical measurements included measurement of height, weight, waist circumference, hip circumference and systolic & diastolic blood pressure. Biochemical measurements included fasting and 2 hour PP blood sugar, lipid profile and fasting insulin levels. Resting ECG was recorded and assessed for evidence of coronary insufficiency (CI) as per the standard Minnesota code criteria. Syndrome X was defined as per standard international code criteria. A total of 52 persons out of 614 studied were found to have syndrome X as per defined criteria.

In Analyze Data menu following statistical analysis can be carried out.

- It produces tables, epidemiologic statistics and graphs.
- It can also produce lists, frequencies, cross tabulations, and other epidemiologic statistics, such as odds ratios,

**Table 5 : SAMPLE data file.**

AGE	WK_EX_CAL	WKEXCAT01	EXCAT	BMICAT_01	WHR_CAT	S_CHOL	HYPERINSUL	HR_CAT_0_1	SYNDX	FINAL_IHD
36	2240	1	MODERATE	0	0	151.0	1	0	0	FALSE
35	2140	1	MODERATE	0	0	123.0	0	1	0	FALSE
40	5600	1	HEAVY	0	0	132.0	0	0	0	FALSE
37	0	0	NIL	0	0	163.0	0	0	0	FALSE
36	0	0	NIL	0	0	242.0	0	0	0	FALSE
36	1010	1	MILD	0	0	164.0	0	0	0	FALSE
35	0	0	NIL	0	0	159.0	0	0	0	FALSE
35	2240	1	MODERATE	0	0	146.0	0	0	0	FALSE
36	2650	1	HEAVY	0	0	121.0	0	0	0	FALSE
43	5450	1	HEAVY	0	0	139.0	0	0	0	FALSE
35	5600	1	HEAVY	0	0	116.0	0	0	0	FALSE
55	1620	1	MODERATE	0	0	125.0	0	0	0	FALSE
35	2700	1	HEAVY	0	0	117.0	0	0	0	FALSE
37	2240	1	MODERATE	0	0	173.0	0	0	0	FALSE
35	5750	1	HEAVY	0	0	128.0	0	0	0	FALSE
36	5200	1	HEAVY	0	0	141.0	0	1	0	FALSE
38	920	1	MILD	0	0	170.0	0	1	0	FALSE
35	5200	1	HEAVY	0	0	152.0	0	1	0	FALSE
37	2300	1	MODERATE	0	0	155.0	0	0	0	FALSE
41	5700	1	HEAVY	0	0	138.5	0	0	0	FALSE
43	5550	1	HEAVY	0	0	123.0	0	0	0	FALSE
36	2320	1	MODERATE	0	0	163.0	0	1	0	FALSE
35	2080	1	MODERATE	0	0	146.0	0	0	0	FALSE
38	2300	1	MODERATE	0	0	136.0	0	0	0	FALSE

AGE	WK_EX_CAL	WKEXCAT01	EXCAT	BMICAT_01	WHR_CAT	S_CHOL	HYPERINSUL	HR_CAT_0_1	SYNDX	FINAL_IHD
37	2520	1	HEAVY	1	0	145.0	1	0	0	FALSE
44	0	0	NIL	0	0	159.0	0	0	0	FALSE
35	0	0	NIL	0	0	170.0	0	1	0	FALSE
35	2440	1	MODERATE	0	0	176.0	0	0	0	FALSE
35	6350	1	HEAVY	1	0	119.0	0	0	0	FALSE
49	0	0	NIL	0	0	121.0	0	1	0	FALSE
35	2260	1	MODERATE	0	0	115.0	0	0	0	FALSE
35	2360	1	MODERATE	0	0	185.0	0	0	0	FALSE
45	0	0	NIL	0	0	199.0	0	0	0	FALSE
41	5400	1	HEAVY	0	0	176.0	0	1	0	FALSE
37	0	0	NIL	0	0	135.0	0	0	0	FALSE
40	5700	1	HEAVY	0	0	97.0	0	0	0	FALSE
47	1176	1	MILD	0	0	146.0	0	0	0	FALSE
36	2240	1	MODERATE	0	0	148.0	0	1	0	FALSE
36	464	1	MILD	1	0	140.0	0	0	0	FALSE
42	1856	1	MODERATE	0	0	218.0	0	0	0	FALSE
37	912	1	MILD	0	0	153.0	0	0	0	FALSE
37	1728	1	MODERATE	0	0	197.0	0	0	0	FALSE
35	2260	1	MODERATE	0	0	111.0	0	1	0	FALSE
39	1416	1	MODERATE	0	0	146.0	0	1	0	FALSE
35	1695	1	MODERATE	0	0	128.0	0	0	0	TRUE
41	5700	1	HEAVY	0	0	127.0	0	0	0	FALSE
37	5650	1	HEAVY	0	0	123.0	0	0	0	FALSE
35	5500	1	HEAVY	0	0	103.0	0	1	0	FALSE
35	2280	1	MODERATE	0	0	119.0	0	0	0	FALSE
39	5900	1	HEAVY	0	0	131.0	0	0	0	FALSE
35	1160	1	MILD	0	0	162.0	0	0	0	FALSE
48	2430	1	MODERATE	0	0	152.0	1	1	0	FALSE
43	1830	1	MODERATE	1	0	209.0	0	1	0	FALSE
36	0	0	NIL	0	0	175.0	0	0	0	FALSE
37	0	0	NIL	0	0	154.0	1	0	0	FALSE
35	2440	1	MODERATE	1	0	115.0	0	0	0	FALSE
36	1875	1	MODERATE	1	0	151.0	1	1	1	FALSE
39	5550	1	HEAVY	0	0	156.0	0	0	0	FALSE
37	5700	1	HEAVY	0	0	124.0	0	1	0	FALSE
42	5700	1	HEAVY	0	0	130.0	0	1	0	FALSE
37	6200	1	HEAVY	1	0	126.0	0	0	0	FALSE
37	5450	1	HEAVY	0	0	150.0	0	0	0	FALSE
36	1452	1	MODERATE	1	0	149.0	0	0	0	FALSE

AGE	WK_EX_CAL	WKEXCAT01	EXCAT	BMICAT_01	WHR_CAT	S_CHOL	HYPERINSUL	HR_CAT_0_1	SYNDX	FINAL_IHD
37	2300	1	MODERATE	0	0	176.0	0	0	0	FALSE
36	2420	1	MODERATE	0	0	181.0	0	1	0	FALSE
35	0	0	NIL	0	0	157.0	0	0	0	FALSE
37	0	0	NIL	0	0	162.0	0	0	0	FALSE
36	2588	1	HEAVY	0	0	143.0	0	1	0	FALSE
36	1770	1	MODERATE	0	0	140.0	1	0	0	FALSE
35	2430	1	MODERATE	0	0	178.0	0	1	0	FALSE
43	2240	1	MODERATE	0	0	160.0	0	0	0	TRUE
42	5950	1	HEAVY	0	1	189.0	1	0	0	FALSE
43	893	1	MILD	1	1	186.0	0	0	0	FALSE
35	0	0	NIL	0	1	143.0	0	0	0	FALSE
36	2360	1	MODERATE	0	1	158.0	0	0	0	FALSE
35	2380	1	MODERATE	0	1	148.0	1	0	0	FALSE
35	0	0	NIL	0	1	132.0	0	0	0	FALSE
37	2440	1	MODERATE	1	1	186.0	0	0	0	FALSE
35	972	1	MILD	0	1	181.0	0	1	0	FALSE
35	5700	1	HEAVY	0	1	151.0	1	1	0	FALSE
35	476	1	MILD	0	1	138.0	1	0	1	FALSE
38	5500	1	HEAVY	0	1	154.0	0	0	0	TRUE
41	5550	1	HEAVY	0	1	146.0	0	1	0	TRUE
54	580	1	MILD	0	1	167.0	0	1	0	TRUE
35	2975	1	HEAVY	1	1	107.0	0	0	0	FALSE
38	5400	1	HEAVY	0	1	171.0	0	0	0	FALSE
39	1815	1	MODERATE	0	1	138.0	0	1	0	FALSE
36	5950	1	HEAVY	0	1	128.0	0	0	0	FALSE
36	5900	1	HEAVY	0	1	138.0	0	1	0	FALSE
36	1230	1	MILD	1	1	138.0	1	1	0	FALSE
35	6400	1	HEAVY	1	1	126.0	0	1	0	FALSE
42	5750	1	HEAVY	0	1	150.0	0	0	0	FALSE
37	2440	1	MODERATE	1	1	157.0	1	1	0	FALSE
36	0	0	NIL	0	1	172.0	0	0	0	FALSE
37	0	0	NIL	0	1	120.0	0	0	0	FALSE
37	3360	1	HEAVY	0	1	110.0	0	0	0	FALSE
37	2678	1	HEAVY	0	1	138.0	0	0	0	FALSE
36	5750	1	HEAVY	0	1	144.0	0	0	0	FALSE
40	0	0	NIL	0	1	122.0	1	1	0	FALSE
46	1150	1	MILD	0	1	158.0	1	0	1	FALSE
45	6000	1	HEAVY	1	1	135.4	0	0	0	FALSE
38	1710	1	MODERATE	0	1	193.5	0	0	0	FALSE



AGE	WK_EX_CAL	WKEXCAT01	EXCAT	BMICAT_01	WHR_CAT	S_CHOL	HYPERINSUL	HR_CAT_0_1	SYNDX	FINAL_IHD
39	5650	1	HEAVY	0	1	104.0	0	0	0	FALSE
36	2200	1	MODERATE	0	1	146.0	0	0	0	FALSE
35	2620	1	HEAVY	1	1	161.0	0	0	0	FALSE
35	0	0	NIL	0	1	168.0	0	0	0	FALSE
40	0	0	NIL	0	1	119.0	0	0	0	FALSE
37	2460	1	MODERATE	0	1	152.0	0	0	0	FALSE
36	6250	1	HEAVY	1	1	173.0	0	0	0	FALSE
36	1722	1	MODERATE	0	1	150.0	0	0	0	FALSE
48	803	1	MILD	0	1	155.0	0	0	0	TRUE
44	5500	1	HEAVY	0	1	142.0	0	1	0	FALSE
45	1620	1	MODERATE	0	1	137.0	0	0	0	FALSE
36	1100	1	MILD	0	1	185.0	0	1	0	FALSE
36	1725	1	MODERATE	0	1	176.0	0	0	0	FALSE
35	1524	1	MODERATE	1	1	112.0	0	0	0	FALSE
35	2360	1	MODERATE	0	1	219.0	0	0	0	FALSE
38	5550	1	HEAVY	0	1	143.0	0	1	0	FALSE
37	5950	1	HEAVY	0	1	149.0	0	1	0	FALSE
47	0	0	NIL	0	1	154.0	0	1	0	FALSE
45	1418	1	MODERATE	1	1	179.0	0	0	0	TRUE
35	5700	1	HEAVY	0	1	136.0	0	0	0	FALSE
36	2480	1	MODERATE	0	1	158.0	0	0	0	FALSE
35	2360	1	MODERATE	0	1	147.0	0	0	0	FALSE
38	2500	1	MODERATE	1	1	210.0	0	0	0	FALSE
35	1024	1	MILD	1	1	184.0	0	0	0	FALSE
39	1815	1	MODERATE	0	1	162.0	0	1	0	FALSE
36	0	0	NIL	1	1	140.0	1	0	1	FALSE
35	2400	1	MODERATE	0	1	158.0	1	0	1	FALSE
44	1190	1	MILD	0	1	172.5	0	0	0	FALSE
38	1785	1	MODERATE	0	1	140.0	1	0	0	FALSE
37	0	0	NIL	0	1	181.0	0	1	0	FALSE
35	2600	1	HEAVY	1	1	164.0	1	0	0	FALSE
36	0	0	NIL	1	1	118.0	0	1	0	FALSE
36	1764	1	MODERATE	0	1	221.0	0	1	0	FALSE
36	1392	1	MILD	0	1	176.0	0	1	0	FALSE
44	0	0	NIL	1	1	180.0	0	0	0	FALSE
41	0	0	NIL	0	1	160.0	0	0	0	FALSE
35	2380	1	MODERATE	0	1	157.0	0	1	0	FALSE
36	0	0	NIL	0	1	212.0	0	1	0	FALSE
37	0	0	NIL	1	1	233.0	0	0	0	FALSE

AGE	WK_EX_CAL	WKEXCAT01	EXCAT	BMICAT_01	WHR_CAT	S_CHOL	HYPERINSUL	HR_CAT_0_1	SYNDX	FINAL_IHD
47	3906	1	HEAVY	0	1	203.0	1	1	0	FALSE
38	2420	1	MODERATE	1	1	178.0	0	0	0	FALSE
52	536	1	MILD	0	1	147.0	0	1	0	FALSE
38	0	0	NIL	1	1	137.0	1	1	0	FALSE
35	2620	1	HEAVY	1	1	147.0	1	1	1	FALSE
45	0	0	NIL	0	1	120.0	1	0	1	FALSE
37	2420	1	MODERATE	1	1	173.0	0	0	0	TRUE
40	6318	1	HEAVY	1	1	221.5	0	0	0	FALSE
38	5650	1	HEAVY	0	1	112.0	0	0	0	FALSE
37	5950	1	HEAVY	1	1	151.0	0	0	0	FALSE
41	2220	1	MODERATE	0	1	154.0	1	1	0	FALSE
42	3075	1	HEAVY	1	1	151.0	0	1	0	FALSE
36	6150	1	HEAVY	0	1	151.0	0	0	0	FALSE
52	1890	1	MODERATE	1	1	162.0	1	1	0	FALSE
49	1200	1	MILD	0	1	147.0	0	0	0	FALSE
48	1187	1	MILD	0	1	161.0	0	0	0	FALSE
38	0	0	NIL	1	1	164.0	0	0	0	FALSE
36	0	0	NIL	1	1	150.0	0	0	0	FALSE
37	2580	1	HEAVY	1	1	236.0	1	0	0	FALSE
41	0	0	NIL	1	1	145.0	0	0	0	FALSE
37	432	1	MILD	0	1	124.0	0	1	0	FALSE
36	660	1	MILD	0	1	181.0	1	0	0	FALSE
43	2220	1	MODERATE	0	1	167.0	0	0	0	FALSE
35	968	1	MILD	1	1	188.0	1	0	1	FALSE
39	2380	1	MODERATE	0	1	114.0	1	1	1	FALSE
46	5650	1	HEAVY	0	1	103.8	1	1	1	TRUE
48	0	0	NIL	0	1	174.0	1	1	1	TRUE
41	0	0	NIL	0	1	179.0	0	0	0	FALSE
37	0	0	NIL	0	1	149.0	0	0	0	FALSE
45	1110	1	MILD	0	1	124.0	0	0	0	FALSE
37	0	0	NIL	1	1	166.0	1	0	0	FALSE
50	2583	1	HEAVY	1	1	151.0	1	1	0	FALSE
36	726	1	MILD	0	1	118.0	0	0	0	FALSE
37	1098	1	MILD	1	1	149.0	1	0	1	FALSE
46	6150	1	HEAVY	1	1	206.0	0	0	0	FALSE
47	6100	1	HEAVY	0	1	167.0	0	0	0	FALSE
49	1190	1	MILD	1	1	173.0	0	0	0	FALSE
36	1856	1	MODERATE	0	1	187.0	0	1	0	FALSE
35	2420	1	MODERATE	1	1	144.0	1	1	0	FALSE

AGE	WK_EX_CAL	WKEXCAT01	EXCAT	BMICAT_01	WHR_CAT	S_CHOL	HYPERINSUL	HR_CAT_0_1	SYNDX	FINAL_IHD
39	6300	1	HEAVY	1	1	216.0	1	1	1	FALSE
44	0	0	NIL	1	1	187.0	1	1	1	FALSE
35	6050	1	HEAVY	0	1	148.0	0	0	0	FALSE
35	3100	1	HEAVY	1	1	126.0	0	0	0	FALSE
47	0	0	NIL	1	1	188.0	0	0	0	FALSE
36	2560	1	HEAVY	1	1	170.0	0	1	0	FALSE
36	2480	1	MODERATE	1	1	223.0	0	0	0	FALSE
47	1355	1	MILD	1	1	120.0	1	1	1	FALSE
48	1845	1	MODERATE	1	1	182.0	0	1	0	FALSE
37	0	0	NIL	1	1	160.0	0	0	0	TRUE
48	5700	1	HEAVY	1	1	122.0	0	1	0	FALSE
39	0	0	NIL	0	1	152.0	0	1	0	FALSE
46	1013	1	MILD	1	1	187.0	1	0	0	FALSE
48	975	1	MILD	1	1	170.0	1	1	0	FALSE
35	6750	1	HEAVY	1	1	149.0	0	0	0	FALSE
36	2320	1	MODERATE	0	1	179.0	0	0	0	FALSE
45	0	0	NIL	1	1	127.0	1	1	1	TRUE
40	5750	1	HEAVY	0	1	181.6	0	0	0	FALSE
40	2440	1	MODERATE	1	1	150.0	1	0	1	FALSE
37	2120	1	MODERATE	0	1	152.0	0	0	0	FALSE

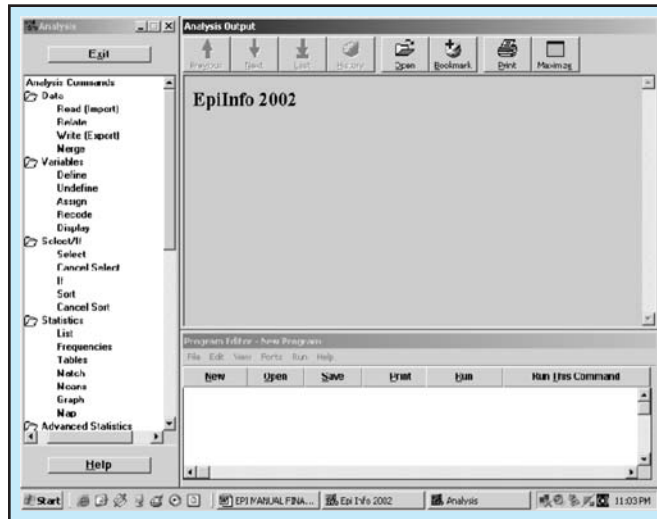
*The description of various variables coded in the data sheet is as follows*

AGE	Actual age in completed years.
WK_EX_CAL	The number of K-calories spent on an average in one week in structured physical exercise (as Games, Walking, running, etc)
EXCAT	NIL-undertaking no exercise; Similarly MILD, MODERATE & HEAVY INTENSITY EXERCISE.
BMICAT_01	0 means < 25 and 1 ≥ 25
WAIST_HIP	Waist-Hip ratio (WHR)
WHR_CAT	0 = Having normal waist, normal WHR ≤ 0.90; 1 = Having central obesity i.e. WHR>0.90
S_CHOL	Serum total cholesterol mg/dl.
HYPERINSUL	1 = Having hyperinsulinimea as per defined criteria of fasting insulin in uppermost quintile; 0 for Normoinsulinimea
HR_CAT_01	0 Heart Rate ≤72 beats/min, 1 for Heart Rate> 72 beats/min
SYNDX	1= SyndX present as per defined criteria; 0= SyndX absent
FINAL_IHD	TRUE=evidence of IHD present; FALSE=No evidence (Normal)

relative risks, and p-values.

- Graphing and mapping are also available using this component.

First, to activate the analysis screen, click on the “Analyze Data” button on the main screen of EPI - 2002. The following menu appears on the screen.



**Read :** By using READ command, located in the left hand column we can tell EPIINFO which file or table to analyze. The Data Formats requires the format in which the data is entered. If the researcher has the data in the form of excel or FoxPro, he should specify the data format accordingly. The Data Source requires the source destination of this file from where it can be extracted to read.

**List :** List does a line listing of the current dataset. If variable names are given, *List* option will list only these variables whereas *List \** will list all variables of all active records, using several pages across to accommodate all the variables, if necessary. The simplest and sometimes the best way to analyze data are to produce a line listing, using the List command.

**Frequencies :** The *Freq* command is used to determine the frequency of values for numeric character. The output shows a table of the values for a variable, the number and percent of records having each value, and the confidence intervals for each value as a proportion of the total. For numeric data only, descriptive statistics such as mean and standard deviation are also shown. On selecting the variables and clicking OK the results appear in the browser window. The yellow bars accompany each table to the right indicates the frequencies. Statistics will be displayed below the table if the value of the variable is numeric.

**Example:** Suppose in the example “SAMPLE” data file we want to find the frequencies of the person with hyperinsulinemia and without hyperinsulinemia. The variable we have used for hyperinsulinemia is HYPERINSUL. Click frequencies and specify HYPERINSUL in the drop down menu of Frequency. Pressing OK yields the Frequencies, Percent, cumulative percent along with 95% confidence intervals for the frequencies in the following manner. The yellow bars also

indicate the frequencies for each category.

FREQ HYPERINSUL				
HYPER-INSUL	Freq- uency	Percent	Cum Percent	
0	159	79.5%	79.5%	Yellow Bar (YB)
1	41	20.5%	100.0%	(YB)
Total	200	100.0%	100.0%	Yellow Bar (YB)

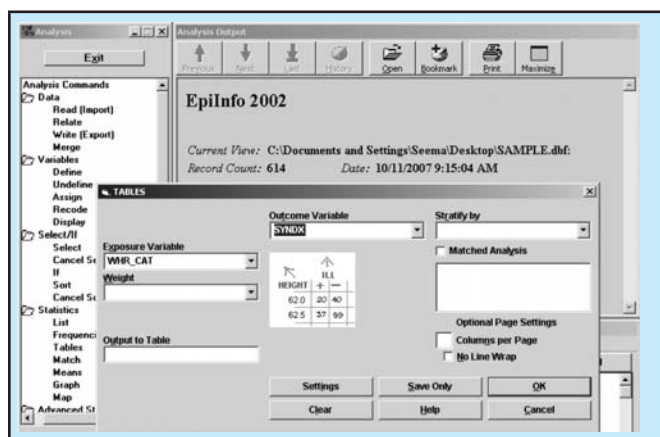
95% Confidence Limits		
0	73.2%	84.9%
1	15.1%	26.8%

Tables : The *Tables* command is used to create a table of categorical data, often called as cross-tabulation. Two variables can be compared using Tables. This is similar to the ‘Tables (2 x 2, 2 x n)’ option of “Statcalc”. In Statcalc when ‘Tables’ option is used either for analyzing a single table or carrying out stratification analysis for confounding effect, we make use of the readymade 2 x 2 tables. The disease status as well as the exposure status cross classification cell values is directly entered by counting them separately from raw data. In the “Tables” option of “Analyze Data” the difference is that we do not count the frequencies manually but the raw data file is accessed through the ‘Read’ (Import) command in “Analyze Data”. The computer counts the cell frequencies.

On clicking the command *Tables*, we select the Exposure (Independent variable) and the Outcome (Dependent variable) variables. Exposure variable is that variable in the database which is to be considered as the risk factor. Outcome variable is the variable in the database considered as the Disease of consequence. Click on OK when done. A single table of 2 or more rows and 2 or more columns can be provided, which is called as an R x C table (Row by Column). In addition to the row and column variables, the user can stratify on additional variables, which is then called as an R x C x S table (Row by Column by Strata). This is used for control of confounding and is equivalent to stratification in Statcalc. The output gives frequency tables accompanied by confidence limits on the proportions and 2x2 tables by odds ratios, risk ratios, and several types of confidence limits on these ratios, as well as chi square and Fisher exact tests. Stratified analyses result in Mantel-Haenszel summary odds ratios and confidence limits.

We will understand the usage of this command by considering our hypothetical data set of “SAMPLE”. Let us say that we are interested in exploring association between SyndromeX and central obesity. Central Obesity (WHR\_CAT) is considered to be a risk factor for development of SyndromeX and hence is selected as exposure factor and SyndromeX as our variable of interest as Outcome. We select these variables and then press <OK>.





On pressing OK following single 2 x 2 analysis is provided. The disease measures in terms of Odds ratio and relative risk along with 95% confidence interval and their significance is given in tabular form. This output is almost same as what we get in *Tables* (2 x 2, 2 x n) option of *Statcalc*.

TABLES WHR\_CAT SYNDX.

SYNDX			
WHR_CAT	0	1	TOTAL
0	70	1	71
Row %	98.6	1.4	100.0
Col %	38.3	5.9	35.5
1	113	16	129
Row %	87.6	12.4	100.0
Col %	61.7	94.1	64.5
TOTAL	183	17	200
Row %	91.5	8.5	100.0
Col %	100.0	100.0	100.0

Single Table Analysis			
	Point	95% Confidence Interval	
	Estimate	Lower	Upper
PARAMETERS: Odds-based			
Odds Ratio (cross product)	9.9115	1.2859	76.3933 (T)
Odds Ratio (MLE)	9.8393	1.7117	212.7045 (M)
		1.4653	421.4652 (F)
PARAMETERS: Risk-based			
Risk Ratio (RR)	1.1255	1.0488	1.2079 (T)
Risk Difference (RD%)	10.9947	4.6805	17.3088 (T)
(T=Taylor series; C=Cornfield; M=Mid-P; F=Fisher Exact)			
STATISTICAL TESTS	Chi-square	1-tailed p	2-tailed p
Chi square - uncorrected	7.1177		0.0076337339
Chi square - Mantel-Haenszel	7.0821		0.0077867976
Chi square - corrected (Yates)	5.7743		0.0162636962
Mid-p exact		0.0024530858	
Fisher exact		0.0045192928	

Let us now consider another variable BMI. We now wish to explore whether BMI is a confounding variable in the observed association between central obesity and syndromeX. Hence along with exposure and outcome variable we also give the variable BMI in the Stratify By on the screen.

The procedure is to click on Tables in Analyze Data after the data file is imported through 'Read' command. In the exposure dropdown we select the exposure variable as WHR\_CAT and the outcome variable as SYNDX. Along with these we also select the confounding variable (BMICAT\_01) from the dropdown list of "Stratify By". This is equivalent to stratification in Statcalc. On pressing <OK> the output is rendered as a single 2 x 2 analysis of WHRCAT and SYNDX but taking into consideration BMICAT\_01 as 0 and 1. In other words the cross tabulated frequencies are only for the group having BMICAT as 0 (<25) and another single 2 x 2 analysis for the group having BMICAT\_01 as 1 (≥25). A SUMMARY TABLE provides the summary statistics after removing the effect of confounder. The output is given as under.

WHR\_CAT : SYNDX, BMICAT\_01=0

SYNDX			
WHR_CAT	0	1	TOTAL
0	63	0	63
Row %	100.0	0.0	100.0
Col %	47.4	0.0	45.0
1	70	7	77
Row %	90.9	9.1	100.0
Col %	52.6	100.0	55.0
TOTAL	133	7	140
Row %	95.0	5.0	100.0
Col %	100.0	100.0	100.0

Single Table Analysis			
	Point	95% Confidence Interval	
	Estimate	Lower	Upper
PARAMETERS: Odds-based			
Odds Ratio (cross product)	Undefined	Undefined	Undefined (T)
Odds Ratio (MLE)	Undefined	1.6108	Undefined (M)
		1.2333	Undefined (F)
PARAMETERS: Risk-based			
Risk Ratio (RR)	1.1000	1.0250	1.1805 (T)
Risk Difference (RD%)	9.0909	2.6697	15.5121 (T)
(T=Taylor series; C=Cornfield; M=Mid-P; F=Fisher Exact)			
STATISTICAL TESTS	Chi-square	1-tailed p	2-tailed p
Chi square - uncorrected	6.0287		0.0140761836
Chi square - Mantel-Haenszel	5.9856		0.0144239123
Chi square - corrected (Yates)	4.2667		0.0388668378
Mid-p exact		0.0066951613	
Fisher exact		0.0133903226	

Warning : The expected value of a cell is <5. Fisher Exact Test should be used.

SYNDX			
WHR_CAT	0	1	TOTAL
0	7	1	8
Row %	87.5	12.5	100.0
Col %	14.0	10.0	13.3
1	43	9	52
Row %	82.7	17.3	100.0
Col %	86.0	90.0	86.7
TOTAL	50	10	60
Row %	83.3	16.7	100.0
Col %	100.0	100.0	100.0

Single Table Analysis			
	Point	95% Confidence Interval	
	Estimate	Lower	Upper
PARAMETERS: Odds-based			
Odds Ratio (cross product)	1.4651	0.1599	13.4236(T)
Odds Ratio (MLE)	1.4567	0.1896	36.7751(M)
		0.1523	73.2705(F)
PARAMETERS: Risk-based			
Risk Ratio (RR)	1.0581	0.7918	1.4140(T)
Risk Difference (RD%)	4.8077	-20.3111	29.9265(T)
(T= Taylor series; C= Cornfield; M= Mid-P; F= Fisher Exact)			
STATISTICAL TESTS	Chi-square	1-tailed p	2-tailed p
Chi square - uncorrected	0.1154		0.7340954932
Chi square - Mantel-Haenszel	0.1135		0.7362374312
Chi square - corrected (Yates)	0.0288		0.8651349031
Mid-p exact		0.4050231405	
Fisher exact		0.6002150154	

Warning : The expected value of a cell is <5. Fisher Exact Test should be used.

### Summary

#### Summary Information

	Point	95% Confidence Interval	
Parameters	Estimate	Lower	Upper
Odds Ratio Estimates			
Crude OR (cross product)	9.9115	1.2859	76.3933 (T)
Crude OR (MLE)	9.8393	1.7117	212.7045 (M)
		1.4653	421.4652 (F)
Adjusted OR (MH)	5.8605	0.8374	41.0157 (R)
Adjusted OR (MLE)	7.1924	1.1775	160.4871 (M)
		0.9946	318.3655 (F)
Risk Ratios (RR)			
Crude Risk Ratio (RR)	1.1255	1.0488	1.2079
Adjusted RR (MH)	1.0936	1.0152	1.1779
(T= Taylor series; R= RGB; M= Exact mid-P; F= Fisher exact)			

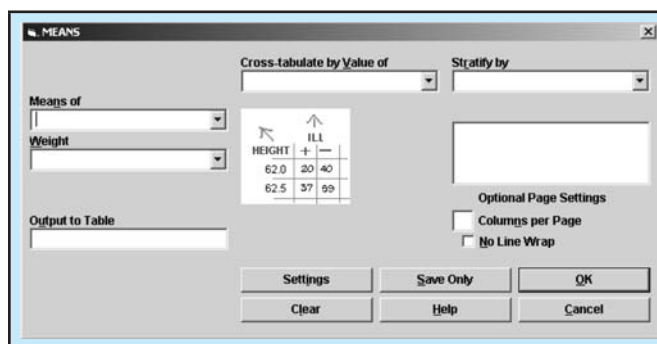
STATISTICAL TESTS (overall assoc)	Chi-square	1-tailed p	2-tailed p
MH Chi square - uncorrected	4.6013		0.0319
MH Chi square - corrected	3.3752		0.0662
Mid-p exact		0.0141	
Fisher exact		0.0255	

We conclude that BMI\_CAT\_01 is a confounder variable as the crude odds ratio and adjusted odds ratio differ. Based on Adjusted OR(MH) of 5.86, we conclude that the risk of syndromeX due to high WHR, after controlling (adjusting) for the confounding effect of raised BMI, increase the risk by almost 6 times.

Means : The Means command can compare mean values of a variable between the groups. The Means command can also compare mean group values before and after the event. This method, however, ignores the matching that occurs from using the same student or subject for both tests. A better method is to subtract the before score from the after score to find the difference for each student, and then to see if the average difference is significantly different from zero, using Students t-test. Epi Info performs the t-test every time the Means command is given with a single variable, just in case the variable represents a difference and you would like to know if it differs, on the average, from zero. If there are only two groups, the equivalent of an independent t-test is performed. If there are more than two groups, then a one-way analysis of variance (ANOVA) is computed. Thus Means provides the equivalent of ANOVA for two or more samples. "One way" means that there is only one grouping variable. If there were two grouping variables, then that would be a two-way ANOVA, which Epi Info *does not perform*. The one-way ANOVA can be thought of as an extension of the independent t-test to more than two groups. Because the ANOVA test requires certain assumptions about the data and the underlying population, another test (Kruskal-Wallis, also known as the Mann Whitney/Wilcoxon test if there are only two groups) is also provided. This is a non-parametric test, meaning that it does not require assumptions about the underlying population. We will discuss in detail each of the output section separately.

Consider again the example of "SAMPLE.dbf". One of the numeric variables considered is age of the person. If we wish to test whether there is any significant difference between the three ranks of the personnel as regards to the age parameter, we use one way ANOVA. For carrying out this analysis we first click on Means. The following screen will appear.

In the *Means of* we substitute the continuous numeric age variable and in the *Cross Tabulate by values of* substitute groups which is given in the column of Rank i.e. press Rank and then Press OK. The output is provided in 5 different sections:



1. A table of the two variables with the continuous variable forming the rows and the grouping variable forming the columns.
2. Descriptive information of the continuous variable by each group such as number of observations, mean, variance, and standard deviation; minimum and maximum values; the 25th, 50th (median), and 75th percentiles; and the mode values are described.
3. An Analysis of Variance (ANOVA) table and a p-value for whether or not the means are equal.
4. A test to determine whether the variances in each group are similar (Bartlett's test for homogeneity of variance).
5. A non-parametric equivalent, Kruskal-Wallis test instead of the independent t-test and one-way ANOVA is also provided.

For the example considered from SAMPLE.dbf following output is given on the screen.

Descriptive Statistics for Each Value of Crosstab Variable					
	Obs	Total	Mean	Variance	Std Dev
Heavy	65	2513.0000	38.6615	14.8524	3.8539
Mild	30	1242.0000	41.4000	38.7310	6.2234
Moderate	64	2430.0000	37.9688	17.8720	4.2275
Nil	41	1608.0000	39.2195	17.6256	4.1983

	Minimum	25%	Median	75%	Maximum	Mode
Heavy	35.0000	36.0000	37.0000	41.0000	50.0000	35.0000
Mild	35.0000	36.0000	37.5000	47.0000	54.0000	36.0000
Moderate	35.0000	35.0000	36.0000	38.5000	55.0000	35.0000
Nil	35.0000	36.0000	37.0000	41.0000	49.0000	37.0000

ANOVA, a Parametric Test for Inequality of Population Means (For normally distributed data only)

Variation	SS	df	MS	F statistic
Between	250.0393	3	83.3464	4.1836
Within	3904.7157	196	19.9220	
Total	4154.7550	199		
p-value = 0.0067				

#### Bartlett's Test for Inequality of Population Variances

Bartlett's chi square= 11.1485	df=3	p-value=0.0110
--------------------------------	------	----------------

A small p-value (e.g. less than 0.05 suggests that the variances are not homogeneous and that the ANOVA may not be appropriate.

Mann-Whitney/Wilcoxon Two-Sample Test (Kruskal-Wallis test for two groups)

Kruskal-Wallis H (equivalent to Chi square) = 7.6873
Degrees of freedom = 3
P value = 0.0429

The overall one-way ANOVA results are said to be significant ( $p = 0.0000$ ) so we conclude that the mean age in the exercise groups are not same.

Note : All statistical methods require assumptions.

ANOVA requires *distributional assumptions* of

- Independence
- Normality
- Equal variance

*Bartlett's Test for Inequality of Population Variances* test for the assumption of equal variances. It also advises you as to whether ANOVA results are appropriate or Non-parametric test are more appropriate.

#### Kruskal-Wallis Test

The Kruskal-Wallis test is the nonparametric analogue to one-way ANOVA. It can be viewed as ANOVA based on *rank-transformed data*. The initial data are transformed to their ranks before submitted to ANOVA. The p-value suggests the significance. The null and alternative hypotheses for the K-W test may be stated in several different ways. We choose to state:

$H_0$ : the population medians are equal

$H_1$ : the population medians differ

In case when the ANOVA results are significant ( $p < 0.05$ ), multiple comparisons between two groups at a time should be carried out. Since in our case results are significant ( $p < 0.05$ ) we now compare two means at a time. This is a *post hoc (after-the-fact) comparison*. In other words it means that after rejecting  $H_0$  we conduct the following six tests:

Test 1:  $H_0$ : Group 1 = Group 2 vs.  $H_1$  Group 1  $\neq$  Group 2

Test 2:  $H_0$ : Group 1 = Group 3 vs.  $H_1$  Group 1  $\neq$  Group 3

Test 3:  $H_0$ : Group 1 = Group 4 vs.  $H_1$  Group 1  $\neq$  Group 4

Test 4:  $H_0$ : Group 2 = Group 3 vs.  $H_1$  Group 2  $\neq$  Group 3

Test 5:  $H_0$ : Group 2 = Group 4 vs.  $H_1$  Group 2  $\neq$  Group 4

Test 6:  $H_0$ : Group 3 = Group 4 vs.  $H_1$  Group 3  $\neq$  Group 4

This is carried out by the procedure explained in EPITABLE section of COMPARE.

#### Match

MATCH performs a matched analysis of the specified exposure and outcome variables, which are assumed to be yes/no variables. One table is produced for each number of cases in a match group. The first variable will appear on the left margin

and will contain values from zero to the number of cases in the match group. The second variable will appear on the top margin and will contain values from zero to the number of cases in the match group. The cells contain the number of match groups showing the combination of positive exposures and positive outcomes shown in the margins. The output table produced by the command is similar to that produced by TABLES.

## Graph

The GRAPH command in Analysis offers many types of charts for displaying the values of one or more fields in a data table. A toolbar within the graphing module can be activated to allow customization of the resulting graphs. Settings can be saved as templates and used again from Analysis.

## Advanced Statistics

**Linear regression** : Regression analysis deals with developing a mathematical relationship between two variables of interest. Regression is used when the primary interest is to predict one dependent variable (y) from one or more independent variables (x1, ... xk). When only one independent variable is used to predict the dependent variable then it is termed as simple linear regression. When multiple independent variables are used to predict the dependent variable it is defined as multiple linear regression and for quantifying the relationship between two variables we calculate correlation. To analyse the relationship between the independent and dependent variables we click on Linear Regression. From the dropdown menu in Outcome Variable select the outcome or dependent variable. In the Other Variables select the multiple independent variables and press OK. On pressing OK the output is visible on the screen.

Consider the SAMPLE data file. Suppose the outcome variable is diastolic blood pressure (DIA\_BP). Let the independent variables or predictors be BMI (BMICAT\_01), Waist-hip ratio (WAIST\_HIP), serum cholesterol level (S\_CHOL) and heart rate (HR\_CAT\_0\_1). Follow the instructions given above and arrive at the solution.

Linear Regression				
Variable	Coefficient	Std Error	F-test	P-Value
BMICAT_01	6.340	1.624	15.2339	0.000131
HR_CAT_0_1	2.891	1.461	3.9177	0.049196
S_CHOL	0.029	0.025	1.3625	0.244546
WAIST_HIP	18.3	13.839	0.1339	0.714821
CONSTANT	82.277	12.640	42.3677	0.000000
Correlation Coefficient : $r^2 = 0.11$				

Source	df	Sum of Squares	Mean Square	F-statistic
Regression	4	2200.351	550.088	5.969
Residuals	195	17970.844	92.158	
Total	199	20171.195		

Thus in the above example, the regression line is:

$$DIA\_BP = a + b_1x_1 + b_2x_2 + b_3x_3 + b_4x_4$$

$$DIA\_BP = 82.277 + 6.340(BMICAT\_01) + 2.891(HR\_CAT\_0\_1) + 0.029(S\_CHOL) + 18.3(WAIST\_HIP)$$

For any given value of independent variables, diastolic blood pressure (DIA\_BP) value can be predicted.

**Logistic Regression** : Logistic regression shows the relationship between an outcome variable with two values (i.e. dichotomous) and explanatory variables that can be categorical or continuous. In Epi Info 2002, either the TABLES command or logistic regression (LOGISTIC command) can be used when the outcome variable is dichotomous (for example, disease/no disease). Analysis with the TABLES command in Epi Info is possible if there is only one "risk factor." Logistic regression is needed when the number of explanatory variables ("risk factors") is more than one. The method is often called "multivariate logistic regression." A model might predict the probability of occurrence of a myocardial infarction (MI) over a 5-year period, given a patient's age, sex, race, blood pressure, cholesterol level, and smoking status. Please note that the outcome variable has to be of YES/NO type or logical (TRUE/FALSE). The latest version of EPI2002 can take the outcome variable in logical form as 0 and 1. Epi Info 2002 uses a process called "maximum likelihood estimation" to arrive at the best estimate of the relationships based (usually) on a follow-up study. The results include values for the beta coefficients 'β' but more important for epidemiologists, can produce an odds ratio (OR) for each value of a risk factor compared with its baseline ("absent" or "normal") state.

Consider in SAMPLE data file the dependent outcome variable as having IHD (which is coded separately as FINAL\_IHD and is logical type) given the different risk factors as BMICAT\_01(categorized 0 for BMI<25 and 1 for BMI ≥ 25), weekly exercise (WK\_EX\_CAT categorized 0 for no exercise and 1 for exercise), waist-hip ratio, (WHR\_CAT categorized 0 for having normal waist i.e. ≤ 0.90 and 1 for having central obesity i.e. >0.90), heart rate (HR\_CAT\_01 categorized 0 for heart rate ≤72 beats/min and 1 for >72 beats/min) and SyndromeX (categorized 0 for all those who did not qualify as having syndrome X and 1 for all those who qualified as having or presence of syndrome X). Follow the instructions given above and arrive at the solution.

## Survival Analysis

Survival Analysis deals with situations where the outcome variable is dichotomous and is a *function of time*. The analytical methods used to draw inferences regarding the chances of surviving/dying/getting cured/getting diseased (in short, the chances of developing the "outcome of interest"), over the various points of time are answered by "survival analysis". Consider a HYPOTHETICAL data of a new drug which was being tried out for treatment of Leukemia. 100 patients of confirmed leukemia were randomized into two groups. One group of 50 subjects which continued with the existing standard therapy (Group1) and another 50 subjects (Group 2) were given the trial modality. All subjects were followed up for maximum period of 7 years (84 months) from the point of starting treatment or else till they died due to leukemia or lost to follow up or died due to some other disease. Subject who died because of leukemia are called as uncensored data (0) whereas subjects who died of



some other cause and not leukemia or were lost to follow up or were still alive by the end of 7 years are called as censored data (1). The defined outcome of interest was the subject who was living at the end of followup. (This includes those who were lost to followup assuming that they would have lived).

There are three columns. The first column named “Time\_since” represents the time in months of the event (death) taking place. The second column, named “Outcome” represents the status of the patient, whether the patient is alive or has died, and the third column, named “Group” represents the group to which the patient belongs, with 1 = existing treatment given and 2 = new trial treatment given.

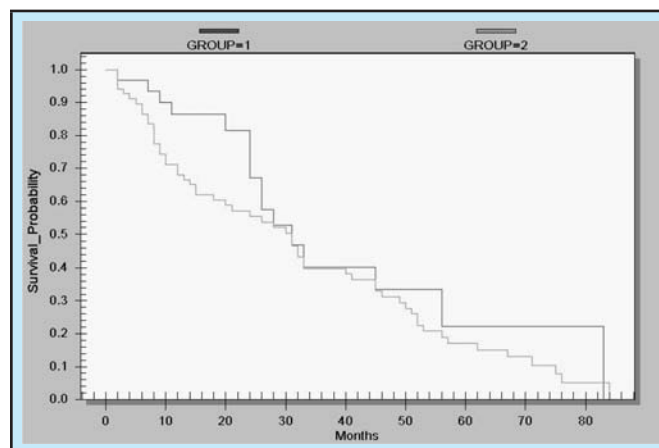
Subjects	TIME_SINCE	OUTCOME	GROUP
1	2	0	1
2	2	1	1
3	2	0	2
4	2	0	2
5	2	0	2
6	2	0	2
7	2	1	2
8	3	1	1
9	3	0	2
10	3	1	2
11	4	0	2
12	5	0	2
13	6	1	1
14	6	0	2
15	6	0	2
16	7	0	1
17	7	0	2
18	7	0	2
19	8	0	2
20	8	0	2
21	8	0	2
22	8	0	2
23	8	1	2
24	9	0	1
25	9	1	1
26	9	0	2
27	9	0	2
28	10	0	2
29	10	0	2
30	11	0	1
31	12	1	1
32	12	0	2
33	12	0	2
34	13	0	2
35	14	1	1
36	14	1	1
37	14	0	2
38	15	1	1
39	15	0	2

Subjects	TIME_SINCE	OUTCOME	GROUP
40	15	0	2
41	17	1	1
42	18	0	2
43	19	1	1
44	19	1	2
45	19	1	2
46	20	0	1
47	20	0	2
48	21	0	2
49	21	1	2
50	24	0	1
51	24	0	1
52	24	0	1
53	24	0	2
54	25	1	2
55	26	0	1
56	26	0	1
57	26	0	2
58	28	0	1
59	28	1	1
60	28	0	2
61	30	1	1
62	30	0	2
63	31	0	1
64	31	1	1
65	31	0	2
66	31	0	2
67	32	0	2
68	32	0	2
69	33	0	1
70	33	0	2
71	33	0	2
72	40	0	2
73	41	0	2
74	45	0	1
75	45	0	2
76	45	0	2
77	46	0	2
78	49	0	2
79	50	1	1
80	50	0	2
81	51	1	1
82	51	0	2
83	52	0	2
84	52	0	2
85	53	0	2
86	54	1	2
87	56	0	1
88	56	0	2
89	57	0	2

Subjects	TIME_SINCE	OUTCOME	GROUP
90	62	0	2
91	62	1	2
92	67	1	1
93	67	0	2
94	68	1	2
95	71	0	2
96	75	0	2
97	76	0	2
98	83	0	1
99	84	0	2
100	84	1	2

Firstly read the file through Analyze Data and Import Data option. Once the data is imported press Kaplan-Meier Survival from Advanced Statistics and give input of all the required variables. The Censored Variable is the Outcome variable, Time Variable is Time\_Since and Group Variable is Group respectively in our example. Value of uncensored is 0 whereas Time Unit is taken as months. Once you press OK the survival curve along with statistical difference between the two survival curves are provided. (The details on Survival Analysis are given in the section of Biostatistics). Following the instructions given above we arrive at the solution.

KMSURVIVAL TIME\_SINCE = GROUP \* OUTCOME ( 0 )  
TIMEUNIT="Months"



Test	Statistic	D.F.	P-Value
Log-Rank	1.2764	1	0.2586
Wilcoxon	2.3399	1	0.1261

## Study Exercise

Using SAMPLE data file answer the following questions:

- Write the scales of measurement for all the variables considered in the SAMPLE file.
- If the investigator is interested in assessing whether there exist any association between the occurrence of IHD and systolic blood pressure as risk factor. How will the investigator proceed to test this association?
- In the above situation how will the investigator check whether age is a confounder variable or not?
- Describe the following variables along with the 95% confidence interval. (a) Heart Rate (b) Serum Cholesterol Level (c) Tobacco consumption (d) Age.
- Test whether there is any difference in the proportion of subjects consuming tobacco in the two groups with presence of IHD and absence of IHD.
- To test whether there is any correlation between Waist Hip Ratio and BMI (taking both as dichotomous variables) what type of statistical analysis will be carried out?
- Taking Fasting Insulin as a continuous variable and age as dichotomous variable (0 for  $\leq 35$  years of age and 1 as  $> 35$  years of age) test whether there is any difference between the insulin levels in the two age groups.
- Carry out analysis to find out whether there is any association between the exposure variables WK\_EX\_CAL and the outcome variable FINAL\_IHD with and without considering the confounder variable BMI.
- If we wish to test whether there is any significant difference in the proportion of people of different ranks (RANK) with outcome of "SyndromeX" using EPITABLE and ANALYZE DATA, what would be the difference?
- Which statistics will be used to predict the outcome of SyndromeX in subjects, considering the risk factors as Age, Exercise (WKEXCAT01), TOBACCO consumption (categorized as 0 and 1)?
- Correlate Fasting Insulin and Fasting Sugar using 'Graph' from "Analyze Data".

EPITABLE is statistical calculator with many statistical functions and graphs which you should become acquainted with to carry out various research analysis. EPITABLE is a module which is available in the previous version *EPI6* which is again a freely downloadable software from internet. This programme can be accessed by first pressing on the EPI6 icon and then subsequently pressing EPITABLE calculator through Programs. The EPITABLE appears as below.



The components of Epitable are: (a) Describe (b) Compare (c) Study (d) Sample (e) Probability (f) Setup

### Describe

This option calculates confidence intervals around an estimate of a proportion, a mean or a median.

**Proportion** : Confidence interval is calculated for proportions estimated from simple random samples or cluster samples. Three methods for calculating confidence intervals of a proportion are presented. These are Fleiss quadratic, exact binomial and mid-p.

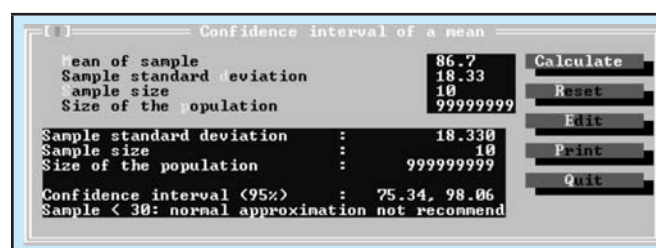
**Ex** : Suppose in a survey we wish to detect the seropositivity for HIV in blood donors. Total of 997 cases are considered. Out of these 12 are found to be positive. In the describe dropdown menu select the proportion option and then select Simple random sampling. Substitute 12 in the numerator and 997 in the denominator. On pressing calculate, the following output is given.

Simple Random Sampling	
Numerator	12
Total observations	997
Proportion	1.2036%
Fleiss quadratic 95% CI	[0.6534 – 2.1552]
Exact binomial 95% CI	[0.6234 – 2.0930]
Mid-p 95% CI	[0.6538 – 2.0372]
Select the Exact binomial 95% CI	

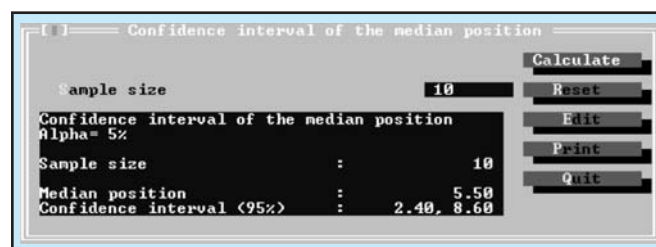
**Mean** : This command provides the confidence interval of a mean using the alpha risk specified in the setup option. The

inputs required are the mean and the standard deviation values for the given data. If the size of the population from which the sample is taken is not known, we should use the default maximum value of 999999999.

Let us consider a hypothetical example where 10 volunteers are weighed in a consistent manner before they start consuming an experimental diet. Weights in kg for these 10 volunteers are as follows, 81, 79, 92, 112, 76, 126, 80, 75, 68, 78. We calculate the mean in the usual manner by adding all the observations (weights) and then dividing by 10 to give us the mean weight as 86.7. Similarly we calculate the standard deviation which is equal to 18.33. Now if we wish to calculate the 95% confidence interval for mean we select 'Mean' and substitute the requisite information, i.e. value of mean as 86.7, Sample standard deviation as 18.33 along with the sample size as 10. On pressing calculate following output renders the 95% confidence interval.



**Median** : This option gives the confidence interval of a median using the alpha risk specified in the setup option. The inputs required are the median and the sample size for the given data. For example we ask the 10 patients attending OPD to evaluate his pain on a scale of 0 (no pain) to 10 (the worst pain). The scores given by the patients are 3,4,2,6,1,8,1,9,3,6.



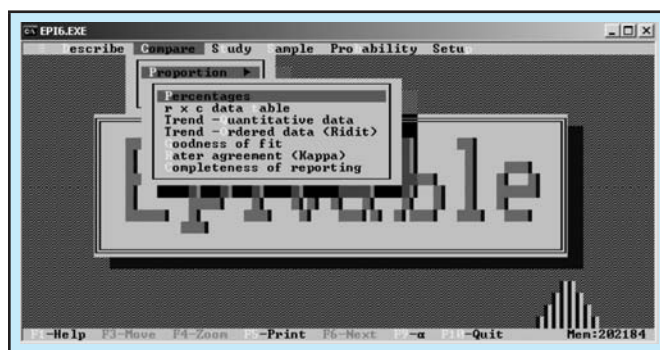
Note that the package gives the median position along with 95% confidence interval for median position and not the median value.

The median score of pain after arranging the patients in ascending order is 3.5 which is the middle most position i.e. 5.5.

### Compare

This menu compares the *proportions, means* and *variances* using various statistical methods. Under proportion menu following components are available:

**Proportion** : This option compares several proportion expressed either as percentages, rows or columns, quantitative or qualitative manner using the chi square test. The various options available are as follows.



**Percentages :** When we have the percentages in the two groups which we are interested to compare we use this option. The program requires the percentage values along with the sample sizes for each group. On analyzing it gives the chi-square statistics along with the significance value i.e. p-value. Consider a hypothetical example where we sampled 55 males in their adolescent ages. 44% of them were obese. Another sample of 149 females had 24% obese ladies. To test whether from the sampled populations the proportion of obese males was comparatively higher than that of females, we use the Percentage option of Proportion in EpiTable.

Chi <sup>2</sup>	7.34
Degrees of freedom	1
p value	0.006748

Since  $p < 0.05$  we reject the hypothesis i.e. we can conclude that there is significant difference in proportion of obese. In other words we say that the percentage of obese males is greater than percentage of obese females in the sampled population.

**Chi square for r x c data table :** This is applicable when we have qualitative data in terms of counts which can be compiled in terms of rows and columns. The procedure is as follows. First indicate the number of rows and the number of columns. Then enter the data for each cell. Chi square calculation will be performed when the calculate button is selected. The percentage of cells with an expected value  $< 5$  is returned if any such cells are found. When more than 10% of the cells have expected values  $< 5$ , chi square calculation is no longer recommended. The chi square calculation is not valid if there are expected cells with values  $< 1$ . In this case, an error message is displayed.

Let us illustrate the procedure of Chi-square for r x c table using the hypothetical example on the association between maternal age and congenital malformations. Let us say, we started with the research issue by taking two groups of mothers, one group upto 35 years of age and other above 35 years of age. We took a sample each, 500 pregnant ladies aged  $> 35$  years and another 1000 pregnant ladies aged upto 35 years and followed them till delivery. We found that out of the 500 children born to ladies  $> 35$  years, 50 had congenital malformations, while out of 1000 ladies upto 35 years, there were again 50 children born with congenital malformations. Converting it into a 2 x 2 table.

Mothers	Status of delivered child	
	<i>Congenital Malformation</i>	<i>Normal</i>
Upto 35 years of age	50	950
$> 35$ years	50	450

Substitute all the observed frequencies and press calculate. The following output is displayed.

Chi square calculation	
Chi <sup>2</sup>	13.39
Degrees of freedom	1
p value	0.000253

Since  $p < 0.05$  we can conclude that there is statistically significant association or that there is a definite relationship between advanced maternal age ( $> 35$  years) and congenital malformations in the offspring.

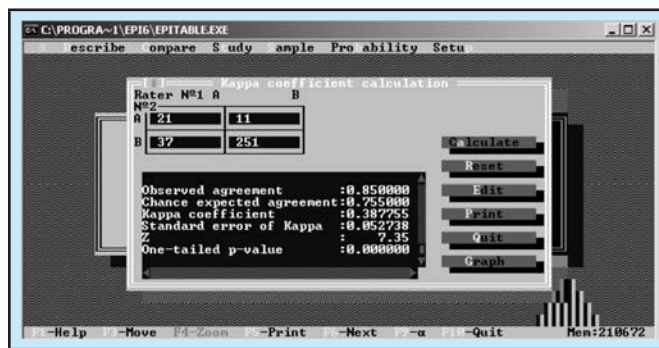
**Trend - Quantitative data :** This is same as discussed under chi square for trend in 'Statcalc' and hence is not repeated here.

**Two Rater Agreement (Kappa) :** This allows us to measure the inter observer reliability. The consistency of measurement by different observers is assessed by kappa coefficient. This measure is carried out only for categorical data upto 6 categories. Each cell of the table corresponds to the count of observation classified by rater 1 and rater 2. For example we may be desirous of undertaking a study on Pulmonary TB, with AFB on sputum smear as the method of measurement. Let us say we are using Laboratory technicians to examine the sputum slides after training given to them by microbiologist. For doing an inter observer reliability assessment (between the microbiologist and Lab technician) we took 320 stained slides and each slide was examined by both of them. The results are as follows:

Lab Technician's Diagnosis	Microbiologist's Diagnosis		
	<i>Positive</i>	<i>Negative</i>	<i>Total</i>
Positive	21	11	32
Negative	37	251	288
Total	58	262	320

On pressing Rater Agreement (Kappa) and substituting the values as given above the following output is rendered.





The Kappa coefficient of 0.38 is interpreted as moderate agreement.

**Means :** This option performs a test (F test), which is equivalent to a student's t test for 2 samples. This test is not valid if all samples come from normally distributed populations with variances not statistically different.

Consider a hypothetical data of a research study to answer the question whether the serum cholesterol of healthy adult males, living in hot desert areas is, on an average, different (i.e. significantly higher or lower) from the average serum cholesterol of healthy young males living in temperate climates. The serum cholesterol values of 12 subjects from the deserts yielded a mean value of 216.25 mg/dl with variance of 795.24 mg/dl. Similarly 14 subjects from temperate climate yielded a mean value of 198.07 mg/dl with variance of 992.25 mg/dl.

The details of the two population means along with variance ( $SD^2$ ) and sample size are substituted to give us following output.

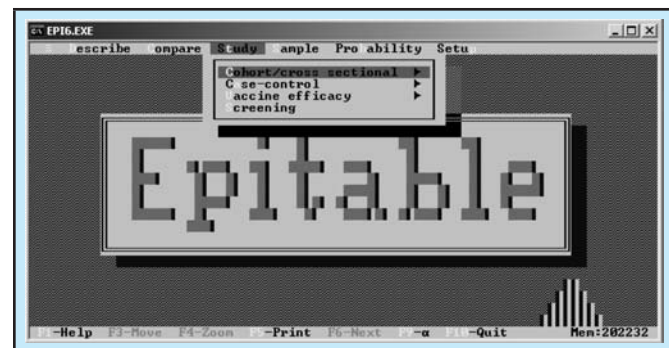
Variance between samples	2135.62
Residual variance	901.95
F Statistic	2.37
p value	0.135090

Since  $p > 0.05$  we accept the null hypothesis i.e. we can conclude that Serum Cholesterol levels of healthy adult males, living in hot desert areas is, on an average, *not different* from the average serum cholesterol of healthy young males living in temperate climates.

### Study

This option gives methods of measuring association for cohort and case control studies. Different methods for measuring vaccine efficacy are also presented. There are various methods available. The control method uses the *proportion of population* vaccinated and the *proportion of cases* vaccinated. Methods based on the estimation of attack rates in cohort study, estimation of odds ratio in case control and matched case-control study is given. Also measures of parameters in screening studies are performed using this module. Examples are not carried out for each sub option. It is expected that students solve few modules on their own with real life data set.

The screen appears as given below.



**Cohort / cross sectional :** Cohort/cross sectional (In cohort study, associations are measured for data tables with cumulative incidence and incidence density). In stratified cohort studies, after specifying the number of strata, associations are measured on cumulative incidence and incidence density

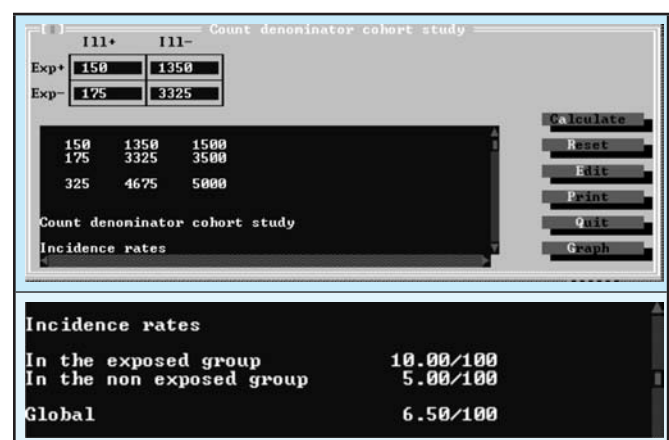
- Cumulative incidence
- Incidence density
- Stratified, cumulative
- Stratified, density

For example, if we take 5000 healthy adult males in whom IHD was excluded based on history of smoking and resting/exercise ECG. Then, on asking them about history of smoking we found that 1500 were smokers and 3500 non-smokers. We followed up these 2 groups (1500 smokers and 3500 non-smokers) for 20 years and observed that during this period there were 150 cases of IHD among smokers and 175 cases of IHD among non-smokers.

Thus substituting the values of this 2x2 table on the screen as

	III+	III-
Exp+	150	1350
Exp-	175	3325

On pressing Calculate following output is given. Again depending on the type of study carried out the correct statistics is selected



Test of significance			
One-tailed p-value(Fisher):	p:	0.000000	
Two-tailed p-value(Fisher):	p:	0.000000	
Pearson's chi square	$\chi^2$ :	43.19	p:0.000000
Yates' chi square	$\chi^2$ :	42.37	p:0.000000

Measure of association and 95% confidence interval			
Relative risk	2.00	1.62, 2.47	
Risk difference	5.00/100	3.32, 6.68	
Attributable fraction	50.0%	38.3, 59.5	
Population risk dif.	1.5/100	1.0, 2.0	
Population attr. fraction	23.1%	17.7, 27.4	
Odds ratio	2.11	1.68, 2.65	

Please compare the results as they are shown in the above screen with the calculations of RR, AR and PAR% which were calculated for the same example in the chapter on "Measurement of Risk" in the section of epidemiology.

### Case-control

(1) Unmatched (2) Matched 1:1 (3) Matched 1: 2 (4) Stratified

Depending whether the cases and controls are unmatched or matched in the ratio of 1:1 or 1:2 (1:2 means number of controls will be twice the number of cases) we select that particular option

Please refer to our example on odds ratio in the chapter on "Measurement of Risk". We observed from our data that out of the 100 IHD cases, 80 were smokers and 20 non-smokers; while out of 100 healthy (non-IHD) subjects; there were 20 smokers and 80 non smokers. Substituting the values in a 2 x 2 table and pressing calculate gives the following output on the screen

Output : Measures of association and 95% confidence interval		
Odds ratio	16.00	8.00, 31.99
Attributable fraction	93.8%	87.5, 96.9
Exact confidence limits of the odds ratio		
Fisher	7.6013	34.0195
Mid-p	7.9638	32.1333

### Vaccine efficacy

(1) Control method (2) Cohort study (3) Case-control study (4) Matched case control study 1:1 (5) Matched case control study 1:2

Vaccine efficacy is measured by comparing Attack Rates among Vaccinated and Attack Rate among Non vaccinated people. There are four different methods presented which corresponds to different approaches for measuring or estimating Attack Rates among Vaccinated and Attack Rate among Non vaccinated people. The first method i.e. control method is not very precise method. Also confidence interval cannot be calculated unless denominators are known for calculation of various proportions. Other methods are used depending on the study design.

Let us take a hypothetical example where isoniazid chemoprophylaxis and development of tuberculosis is studied.

The information gathered is set in the form of a 2 x 2 table.

Exposure	Outcome		
	Developed TB	Did not develop TB	Total
Given isoniazid (intervention group)	3	42	45
Not given isoniazid (Control group)	9	36	45
Total	12	78	90

Vaccine efficacy Cohort study			
Vac+	3	42	
Vac-	9	36	
Pearson's chi square	$\chi^2$ :	3.46	p:0.062812
Yates' chi square	$\chi^2$ :	2.40	p:0.121037
Measure of association and 95% confidence interval			
Relative risk	0.33	0.10, 1.15	
Vaccine efficacy	66.7%	-15.1, 98.4	
Population vaccine effica	16.7%	22.6, -3.8	
Odds ratio	0.29	0.07, 1.14	

Substituting all the four cell values of the cohort study with the aim to find beneficial effect of the drug or vaccine we press Calculate. This yields us the efficacy of 66.7% and hence we conclude that isoniazid chemoprophylaxis reduces the occurrence of TB in close contacts by 66.7%.

**Screening** : This option is used to evaluate the performance of a diagnostic test. On substituting the true+ and true- values (Gold standard + and - values) and the test+ and test- values the option gives the sensitivity, specificity along with the Predictive value positive and predictive value negative.

Consider an example on evaluating the performance of ELISA as a diagnostic test for HIV infection as compared to the gold standard as PCR. We took 1,00,000 subjects and subjected each and every one of them to both, the ELISA as well as the PCR tests. After substituting the values of a=990, b=9900, c=10 and d=89100 in the table the following output is given.

Screening		
Measures of association and 95% confidence interval		
Sensitivity	99.0%	98.1, 99.5
Specificity	90.0%	89.8, 90.2
Predictive Value Positive	9.1%	8.6, 9.7
Predictive Value Negative	00%	100.0, 100.0

The interpretation of each of the parameters listed in the table is explained in detail in the section on Research Methodology.

### Sample

On pressing sample following options are made available.

- Sample size
- Power Calculation
- Random number table
- Random number list

**Sample size:** The first option gives the desired number of *minimum* sample size required for the various studies. The parameter under consideration can be single proportion or two proportions. Also sample size can be calculated for cohort and case-control studies.

**Single proportion :** Let us understand this with an example. Suppose a study on gestational diabetes is undertaken. The expected proportion is  $p=10\%$  with the desired precision or acceptable deviation as 7% to 13% i.e. 3% on either side. ( $d=0.03$ ). We specify the alpha error as 5%. To estimate the minimum sample size for the above proposed study we first have to press *sample* and then select the first option *single proportion* which displays the screen requesting the information on the size of the population, desired precision (%), expected prevalence (%) and design effect.

Sample size, Single proportion	
Size of the population	999999
Desired precision (%)	3
Expected prevalence (%)	10
Design effect	1.00
Desired precision (%)	3.0
Expected prevalence (%)	10.0
Design effect	1.0
Confidence level	95%
Sample size	385

Design effect is a bias introduced in the sampling design and is taken as 1 which means that there is no design effect. (Note: In case of cluster sampling the design effect is taken as 2). After substituting the required information press *calculate*. The required minimum sample size is calculated as 385. It is noted that the sample size is same as was calculated by the Population Survey from Statcalc option of EPI2002.

**Two proportions :** This option is used when we are interested in comparing two groups with respect to variable of interest. The specifications required are the anticipated or expected proportions in both the groups along with the alpha error and power of the test. Let us calculate the sample size for the following situation. Suppose the proportions of patients who develop complications after a particular type of surgery is 5% while the proportion of patients who develop complications after another type of surgery is 15%. We wish to test whether the second surgery has more complication rate than the first type of surgery with a power of 90%. The level of significance or type I error is assumed to be 5%. In this given situation to arrive at the number of patients that would be required in each group we first press *sample size* from the menu sample. From the sample size select *Two Proportions*. After specifying the requirements as given above and then pressing Calculate the

results on the screen appear are as follows:

Sample size, Two proportions	
Ratio group 1/group 2	1.000
Percentage group 1	5
Percentage group 2	15
Alpha risk	5%
Power	90%
Confidence level	95%
Sample required in group 1	207
Sample required in group 2	207
Total #	414

Thus a total of 414 i.e. 207 patients in each group are required to study.

**Cohort study :** Refer back to the example on HAPO which was considered for sample size determination using Statcalc. Substitute the required values of attack rate among non exposed as 1% and the detectable RR as 0.5. Also substitute the alpha error and power as 5% and 80% respectively. After pressing Calculate the minimum required sample size is 10134. In other words we would require to study 5067 subjects who would get Diamox and another 5067 subjects who would not get any drug.

**Case control study :** Refer back to the example on HAPO which was considered for sample size determination using Statcalc. Substitute the required values of percentage of exposure among controls as 10% the OR worth detectable as 3. Also substitute the alpha error and power as 5% and 80% respectively. After pressing Calculate the minimum required sample size rendered is 226. In other words we will need 113 cases of HAPO and another 113 healthy controls to do this study. (Note that the sample size determined are almost same when calculated by sample size option of Statcalc)

Sample size, Case-control study	
Ratio of controls per cases	1.000
Odds ratio worth detecting	3
% of exposure among controls (%)	10
Alpha risk	5%
Power	80%
Confidence level	95%
Number of Cases	113
Number of Controls	113
Total #	226

**Power calculation :** The power calculation option calculates the power of the study. It is the complement of the beta error. In other words it is the probability of making the correct decision. It can be calculated in both the cohort studies and case-control studies. The specifications required in both the situations are as seen in subsequent figure.

Substitute the sample size along with alpha error and other information of the study. Pressing *Calculate* reveals the power of the study.



Consider the two examples that we have discussed above in the sample size determination option for cohort and case-control study. If we substitute retrospectively all the specification (except power) taken into consideration including sample size which was calculated. On pressing *Calculate* the power of the study is detected as 80% for cohort study and 84% for case-control study.

Please note that the calculations for sample size and power by the package differ from the manual way of calculations by slight margin. Hence it is recommended that for calculation of sample size and power the reader preferably uses the ready tables from WHO manual.

**Random Number Table** : This option generates a table of random numbers with a specified number of digits. Available options include the number of digits of generated numbers, as well as the total number of random numbers generated.

**Ex :** Let us consider a hypothetical study where we require selecting 25 subjects by simple random sampling technique using random number method. Thus we want to generate 25 random numbers. On the screen we specify the number of random numbers as 25 and the digits per number as 2 (Since we have population which consists of subjects numbered in two digits). Pressing calculate gives a list of 25 two digit random numbers as follows.

Thus, from the population we will choose the subjects with numbers 12, 58, 73 and so on, to form our study sample.

**Random number list** : This option generates a list of random numbers ranging from a minimum to a maximum value. These random numbers can be drawn with or without replacement. In without replacement duplicate are not allowed whereas in with replacement duplicates are allowed. The random numbers generated are presented in sorted order.

The difference between random number table and random number list is that the random number table generates the specified number of random numbers from all the available digit number that we have specified. For example in the above example the 25 random numbers are generated from 01 to 99. Whereas the random number list gives us a list of numbers where the range can be specified by us. For example if we want a list of 25 random numbers from 10 to 50 without replacement then the output is as follows

Note that none of the random number repeats itself in the list. Let us draw the same number of random numbers (25) but now if we specify with replacement then the output is as given below.

Note that the random number 12, 26 38 and 47 are repeated in the study.

## References

1. Alperin, M. and Miner, K, Using Epi Info 2002: A Step-by-Step Guide, 2003
2. CDC Epidemiology Program Office Epi Info website: [www.cdc.gov/epiinfo/about.htm](http://www.cdc.gov/epiinfo/about.htm) accessed on 29 Sept 2007
3. CDC, Epi Info 2000 Manual
4. CDC, Epi Info 2002 Training Manual, March 2003.



LS Vaz

Medical informatics is the application of computers, communications and information technology and systems to all fields of medicine - medical care, medical education and medical research. Medical informatics is the rapidly developing scientific field that deals with resources, devices and formalized methods for optimizing the storage, retrieval and management of biomedical information for problem solving and decision making. It is the branch of science concerned with the use of computers and communication technology to acquire, store, analyze, communicate and display medical information and knowledge to facilitate understanding and improve the accuracy, timeliness and reliability of decision-making. Medical Informatics (MI) provides a comprehensive survey of current work performed to develop information technology for the clinical workplace. It deals with the acquisition of data from patients, processing and storage of data in computers and the transformation from data into information data. Some topics pertain to methodological aspects of medical informatics and others are intended to be used for more advanced or specialised education. They contain the methodology for information systems and their processing. The future of MI as a profession is very promising. The international standards on Health informatics are covered by ICS 35.240.80 in which ISO 27799:2008 is one of the core components.

The earliest use of computation for medicine was for dental projects in the 1950s at the United States National Bureau of Standards by Robert Ledley. The next step in the mid 1950s were the development of expert systems such as MYCIN and INTERNIST-I. In 1965, the National Library of Medicine started to use MEDLINE and MEDLARS. MUMPS (Massachusetts General Hospital Utility Multi-Programming System) was developed at Massachusetts General Hospital in Boston. The largest enterprise-wide health information system that includes an electronic medical record is known as the Veterans Health Information Systems and Technology Architecture or VistA. A graphical user interface known as the Computerized Patient Record System (CPRS) allows health care providers to review and update a patient's electronic medical record at any of the VA's over 1,000 health care facilities. Since then, Internet-based communications are evolving at a tremendous speed. Searching medical literature: The information technology has made searching the medical literature easier and more readily accessible. The United States National Library of Medicine (NLM) maintains several comprehensive, cross-referenced medical literature databases.

In the 1970's a growing number of commercial vendors began to market practice management and electronic medical records systems. Although many products exist only a small number of health practitioners use fully featured electronic health care records systems. The NHS in England has also contracted out to several vendors for a National Medical Informatics system 'NPFIT' that divides the country into five regions and is to be

united by a central electronic medical record system nicknamed "the spine". 60% of residents in England and Wales have more or less extensive clinical records and their prescriptions generated on 4000 installations of one system (EMIS) written in 'M' similar to MUMPS. The other 40% predominantly have records stored on assorted SQL or file-based systems. Scotland has the GPASS system whose source code is owned by the State and controlled and developed by NHS Scotland. It has been provided free to all GPs in Scotland. The European Commission's preference is for Free/Libre and Open Source Software (FLOSS) for healthcare. In Hong Kong a computerized patient record system called the Clinical Management System (CMS) has been developed by the Hospital Authority since 1994. This system has been deployed at all the sites of the Authority (40 hospitals and 120 clinics) and is used by all 30,000 clinical staff on a daily basis, with a daily transaction of up to 2 millions. The comprehensive records of 7 million patients are available on-line in the Electronic Patient Record (ePR), with data integrated from all sites. Radiology image viewing has been added to the ePR, with radiography images

The hospital management and information system consists of not only information of the hospital and clinical information of a patient but also includes telemedicine, computer-assisted instructions to patient as well as doctors and may even cover computer-assisted imaging and surgery. Surgical simulations and virtual environment are educational tools not only for doctors but also for patients. It is the era of convergence with the computer screen.

**Uses of Medical Informatics :** Informatics Use in Health Care can be in the following fields:

- 1) Communication : This includes Telemedicine, Tele-radiology, Patient e-mail and Presentations
- 2) Knowledge management : Including Journals, Consumer Health information and Evidence-based medical information
- 3) Decision Support : Including Reminder systems, Diagnostic Expert Systems and Drug Interaction
- 4) Information Management : Examples are Electronic Medical Records, Billing transactions and Ordering Systems

**Hospital management and information system :** Hospitals are the main providers of medical and health care. Significant progress has been made in improving their efficiency and operations. Effective computerised systems and procedures need to be implemented to ensure proper utilisation of limited resources toward cost-effective quality health care and the patient satisfaction. Before deciding to go for such system one should have some insight to the implementation of the different modules and evolving user-friendly computerised systems, which are loved and cared by all. The various parts of the Hospital information systems are

- a) Electronic medical records & medical vocabularies
- b) Laboratory information systems
- c) Pharmaceutical information systems
- d) Radiological (imaging) information systems
- e) Patient monitoring systems

**Computer-based patient record:** Physicians and health administrators can efficiently retrieve data for consequent research from the computerised medical records. Good clinical

research needs accurate and detailed clinical information and they significantly improve the medical care. This detailed information can even be used for other processes in the business of medical and health care. The knowledge of advantages and disadvantages of different systems available for recording and codifying are important.

**Knowledge-based and expert systems:** The rapid evolution of technology and clinical research makes it difficult even for the specialist to keep up. In the light of this 'information explosion', it has been demonstrated that physicians do not always make optimal decisions. A computer-assisted diagnostic support system generates diagnostic hypothesis from a set of patient data. It can be used simultaneously with the doctor-patient consultation.

The knowledge-based system (KBS) is designed to meet the knowledge gaps of the individual physician with specific patient problems. KBS and such other expert systems (ES) can be a boon to the rural health centres because even the general medical practitioners can operate the systems. Computer-assisted medical decision making and knowledge-based systems are ideal examples of artificial intelligence.

Clinical decision-support systems help the physician in Diagnosis/Interpretation and then further in Therapy/Management. The software for such Diagnosis/Interpretation could have a broad scope as in Internist-I/QMR which deals with internal medicine. Others include softwares like Dx; DxPlain; Iliad; EON for guideline-based therapy. Softwares with Narrow scope include de Dombal's system for diagnosis of acute abdominal pain; MYCIN for infectious diseases; ECG interpretation systems; ONCOCIN support application of oncology protocols. Specific softwares like MYCIN, QMR are useful for human-initiated consultation; while data-driven reminders are provided by MLMs. Some closed loop systems help which help in certain specific activities e.g. ICU ventilator control

**Telemedicine:** With the advancement in information technology, telemedicine has become an important part of medical practice. This method of distance management in medical and health care not only benefits patients but also medical practitioners. How to use the electronic transmission of medical data to enhance patient care and empower the physician is the hotly discussed topic among the health providers. Telemedicine is set to revolutionise health care system. The advances and convergence of IT and telecommunication can bring the entire health care services to the patient's doorstep. Telemedicine is delivery of health care information across distances using telecom technology. This includes transfer of images like X-rays, CT, MRI, ECG etc. from patient to expert doctors seamlessly, apart from the live video conferencing between the patient at remote hospital with the specialists at the super speciality hospital for tele-consultation and treatment.

Telemedicine has been successful in reaching masses and telemedicine is set to revolutionise the health care system because it is one of the innovative methods of connecting two distant hospitals through Satcom-based communication link. It may be noted that generally 90 per cent of the patients do not require surgery and if so the doctor generally need not touch

the patient and in that case both need not be at the same place. They can be at different locations and still the patient can be treated. Telemedicine makes an ordinary doctor in rural area do extraordinary work since the doctor is advised by the specialist in handling the medical problems including emergencies. Further, the needy patient need not undertake long and difficult journey to towns and cities, especially when the condition of the patient is serious like in case of heart attack or trauma. There will be cost-saving in terms of reduced necessity to travel for the patient and the family when telemedicine facility is used.

ISRO has initiated a number of telemedicine pilot projects which are very specific to the needs of development of our society. The projects consist of linking hospitals in remote and inaccessible areas with superspeciality hospital located in the city through Indian National Satellite (INSAT). Remote areas covered are J&K and Ladakh in North, offshore islands of Andaman and Lakshadweep, interior parts of Orissa, north-eastern states of country and some tribal districts in the mainland states. Telemedicine is most effective for India which is vast and has different regions like the mountain region of J&K and Ladakh, far-flung areas of North East and offshore islands of Andaman and Lakshadweep. With a majority of our population living in rural area and majority of doctors living in urban areas, telemedicine can be a solution for providing improved health care for benefits like improved access, reduced cost, reduced isolation of doctors and finally improved quality of health care.

The telemedicine has good potential to grow since it provides speciality health care to the remote hospitals. The growth could be the connectivity between (a) district hospitals/ health centres and super-speciality hospitals in the cities (b) Community Health Centres (CHC) at block level and district hospital (c) Primary Health Centre (PHC) at village level and community health centres for health care and delivery of medical advice. Further, there could be a network of super-speciality hospitals providing telemedicine consultation to any of the regions.

**Physician Education:** Computer-assisted learning is rapidly evolving and provides several advantages over traditional approaches. The biomedical knowledge base can no longer be taught in its entirety; therefore, one must depend on his learning skills. Self-directed learning and lifelong learning skills can enhance and accelerate the application of the application of an expanding knowledge base to patient care. The impact of computers on the continuing medical education (CME) programmes is immense.

**Patient Education:** On the Internet, patients can quickly obtain the latest information on support groups, therapeutic modalities, late-breaking research and individual coping strategies. If clinicians incorporate some sort of Computer-assisted patient education in their practice that can empower their patients to make the right individual decisions. Informatics applications will have their greatest impact on the quality of patient care and patient safety when in the future applications are merged into one seamless system. Evidence that this trend has begun can be seen in the latest clinical information systems that include communications and decision support as well as

knowledge management.

More recently, hospitals are installing or planning to install computerized physician order entry systems. Research has shown that these systems as well as telemedicine, computerized reminder systems and broader based decision support systems can enhance clinician's performance and improve patient care.

Order entry systems reduce medication errors and detect potential drug interactions while clinical decision support systems improve drug dosing, improve preventive care but not diagnosis.

**Barriers to Progress :** Five categories of barriers to technology integration: time, expertise, access, resources and support.

The lack of time is at the top of their list as the obstacle most often mentioned. This includes time to plan, collaborate with peers, prepare lessons and materials, explore, practice and evaluate, as well as develop, maintain and expand skills. Other articles also identify time as an important barrier. Expertise is another potential barrier to technology integration. Technology training for teachers must be available. Effective technology training must be hands-on, systematic and ongoing. Additionally, a variety of models and approaches should be available to accommodate different needs, schedules and learning styles. Teachers must have uninterrupted, on-demand access to the technologies they intend to use, both while inside and outside of the classroom. Hardware and software availability is a potential barrier.

The fourth category is resources. This includes resources to purchase, maintain and upgrade hardware and software; to provide training and support; and for auxiliary costs, such as coordinating technology access and continuing costs, such as purchasing printer ink. They also note a relationship where time, expertise and access are dependent on resources.

Support is their fifth barrier category, both administrative and technical. Administrative leadership and support may be the most critical factor. In addition to providing the needed financial resources, the administration can set expectations, develop a vision and plan for technology integration and provide incentives and encouragement. Technical support not only includes the personnel for maintaining the technology, but it also includes personnel who are knowledgeable about pedagogical issues, such as appropriate instructional methods or media. Growth of Medical Informatics has also been stifled due to lack of:

- Universally agreed-on medical vocabulary
- Principled and standard formats for laboratory data, medical images, medical record...
- Standardization of medical literature formats--structured abstracts
- Health care standards -- treatment guidelines
- Standards for health data exchange

### Some Important Internet Sites for Public Health Professionals

1. Global Burden of Disease : [www.who.int/evidence/bod](http://www.who.int/evidence/bod)
2. World Health Report : Statistical Annex : [www.who.int/shr/2004/annex/en/index.html](http://www.who.int/shr/2004/annex/en/index.html)
3. Millennium Development Goals : [www.undp.org/mdg/](http://www.undp.org/mdg/)

4. Environmental Health, WHO : [www.who.int/topics/environmental\\_health/en/](http://www.who.int/topics/environmental_health/en/)
5. Centre for Science and Environment, India : [www.cseindia.org](http://www.cseindia.org)
6. Ministry of Environment and Forests, India : [envfor.nic.in](http://envfor.nic.in)
7. Health Aspects of Air Pollution : [www.euro.who.int/document/E83080.pdf](http://www.euro.who.int/document/E83080.pdf)
8. Indoor Air Pollution and Health : [www.who.int/mediacentre/factsheets/fs292/en/index.html](http://www.who.int/mediacentre/factsheets/fs292/en/index.html)
9. Climate and Health : Who [www.who.int/mediacentre/factsheets/fs266/en/](http://www.who.int/mediacentre/factsheets/fs266/en/)
10. Global warming: NASA [maui.net/~jstark/nasa.html](http://maui.net/~jstark/nasa.html)
11. WHO: Water, Sanitation and Health: [www.who.int/water\\_sanitation\\_health/en/](http://www.who.int/water_sanitation_health/en/)
12. Global Water Supply and Sanitation Assessment Report 2000: [www.who.int/water\\_sanitation\\_health/monitoring/jmp2000.pdf](http://www.who.int/water_sanitation_health/monitoring/jmp2000.pdf)
13. Water in India: [www.devalt.org/water/waterinindia.htm](http://www.devalt.org/water/waterinindia.htm)3.9
14. Water and Sanitation Program: [www.wsp.org/](http://www.wsp.org/)
15. Waste Management: WHO: [www.who.int/topics/waste\\_management/en/](http://www.who.int/topics/waste_management/en/)
16. Environmental Guidelines: India: [www.ecoindia.com/ecobiz.htm](http://www.ecoindia.com/ecobiz.htm)
17. Guidelines of Biomedical Waste Management: India: [www.epcb.nic.in/](http://www.epcb.nic.in/)
18. Central Pollution Control Board, India: [www.epcb.nic.in](http://www.epcb.nic.in)
19. Global Atlas of Infectious Diseases: [globalatlas.who.int/](http://globalatlas.who.int/)
20. Zoonoses: [www.int/zoonoses/en/](http://www.int/zoonoses/en/)
21. Preventing Emerging Infectious Diseases: [www.cdc.gov/ncidod/emergplan/index.htm](http://www.cdc.gov/ncidod/emergplan/index.htm)
22. Development of New Vaccines: [www.who.int/mediacentre/factsheets/fs289/en/index.html](http://www.who.int/mediacentre/factsheets/fs289/en/index.html)
23. Immunization: [www.who.int/mediacentre/factsheets/fs288/en/index.html](http://www.who.int/mediacentre/factsheets/fs288/en/index.html)
24. Vaccine development and control of communicable diseases: [www.wpro.who.int/rcm/en/archives/rc39/wprrc39r11.htm](http://www.wpro.who.int/rcm/en/archives/rc39/wprrc39r11.htm)
25. National AIDS Control Organization: [www.nacoonline.org](http://www.nacoonline.org)
26. UNAIDS India: [www.unaids.org.in](http://www.unaids.org.in)
27. Tuberculosis Control: India : [www.tbhindia.org / documents.asp](http://www.tbhindia.org/documents.asp)
28. Tuberculosis Research Center, Chennai : [www.trc-chennai.org /](http://www.trc-chennai.org/)
29. WHO's Global TB Program : [www.who.ch / gtb](http://www.who.ch/gtb)
30. The Stop Tuberculosis Initiative Website : [www.stoptb.org /](http://www.stoptb.org/)
31. Global Fund for AIDS, TB and Malaria : [www.globalfundatm.org /](http://www.globalfundatm.org/)
32. Malaria : [www.who.int/mediacentre/factsheets/fs094/en/](http://www.who.int/mediacentre/factsheets/fs094/en/)
33. Roll Back Malaria Partnership : [rbm.who.int/cgi/bin/rbm/rbmportal/custom/rbm/home.do](http://rbm.who.int/cgi/bin/rbm/rbmportal/custom/rbm/home.do)
34. The Global Polio Eradication Initiative : [www.polioeradication.org/](http://www.polioeradication.org/)
35. Managing an Outbreak of Acute Diarrhea : [www.who.int/csr/resources/publications/cholera/WHOCDSCRNCS20037.pdf](http://www.who.int/csr/resources/publications/cholera/WHOCDSCRNCS20037.pdf)
36. Guidelines for Cholera Control. Geneva, WHO, 1993: [www.who.int/csr/disease/cholera/publications/en/](http://www.who.int/csr/disease/cholera/publications/en/)
37. Cholera : [www.who.int/csr/resources/publications/cholera/](http://www.who.int/csr/resources/publications/cholera/)



38. Maternal and Newborn Health : [www.who.int/reproductive-health/MNBH/index.htm](http://www.who.int/reproductive-health/MNBH/index.htm)
39. Reproductive Health Library : [www.who.int/reproductive-health/rhl/index.html](http://www.who.int/reproductive-health/rhl/index.html)
40. Indicators of Child Health : [www.who.int/child-adolescent-health/OVER-VIEW/CHILD\\_HEALTH/child\\_monitoring.htm](http://www.who.int/child-adolescent-health/OVER-VIEW/CHILD_HEALTH/child_monitoring.htm)
41. Census of India : [www.censusindia.net/](http://www.censusindia.net/)
42. Health Information of India,2007: [cbhidghs.nic.in/hii2007/content1.asp](http://cbhidghs.nic.in/hii2007/content1.asp)
43. Key Health Indicators,India2007: [cbhidghs.nic.in/indicate2007.htm](http://cbhidghs.nic.in/indicate2007.htm)
44. IMCI Information Package : [www.who.int/child-adolescent-health/publications/IMCI/WHO\\_CHS\\_CAH\\_98.1HTM](http://www.who.int/child-adolescent-health/publications/IMCI/WHO_CHS_CAH_98.1HTM)
45. WHO Guidelines on Hypertension: [www.who.int/cardiovascular\\_diseases/guidelines/hypertension\\_guidelines](http://www.who.int/cardiovascular_diseases/guidelines/hypertension_guidelines)
46. Cardiovascular Disease: WHO Publications : [www.who.int/cardiovascular\\_diseases/en/](http://www.who.int/cardiovascular_diseases/en/)
47. Overweight and Obesity :CDC : [www.cdc.gov/nccdphp/dnpa/obesity/index.htm](http://www.cdc.gov/nccdphp/dnpa/obesity/index.htm)
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### The Future

So let's see what it is like to be a student of medical informatics or a doctor living in the 21st century. Here is a typical basic sciences classroom. Students who normally have a microscope in front of them now have a wireless laptop computer and PDAs. These would be loaded with Microsoft Office Professional, Stedman's Medical Spellchecker, Endnotes, Adobe Photoshop Elements and Medical References InfoRetriever. The students would be capable of Evidence Based Ref., Disease Reference, Medical Calculator, Drug Reference and Medical Dictionary. The Computer Lab is being used for Student teaching and Faculty development. The faculty would be assisted with programs like Anatomy lab video enabled, digital BacusLabs web-slide program, Gold Standard Multimedia, Cross Sectional Anatomy. The students test themselves with LXR Testing Program which has Question bank, Computer-based testing and Item analysis/grading. The United Streaming Videos in Anatomy and



Histology provide an insight into aspects difficult to visualize earlier. The internet provides the students with guides for Knowledge management through eJournals , Consumer Health information and Evidence-based medical information.

## Summary

Medical informatics is the application of computers, communications and information technology and systems to all fields of medicine - medical care, medical education and medical research. It is the branch of science concerned with the use of computers and communication technology to acquire, store, analyze, communicate and display medical information and knowledge to facilitate understanding and improve the accuracy, timeliness and reliability of decision-making. It deals with the acquisition of data from patients, processing and storage of data in computers and the transformation from data into information data. Informatics Medical informatics is used in Health Care can as Communication (Telemedicine, Tele-radiology, Patient e-mail and Presentations), Knowledge management (Journals, Consumer Health information and Evidence-based medical information), Decision Support (Reminder systems, Diagnostic Expert Systems and Drug Interaction), Information Management (Electronic Medical Records, Billing transactions and Ordering Systems).

Various health information systems like MEDLINE, MEDLARS, MUMPS (Massachusetts General Hospital Utility Multi-Programming System), VISTA (Veterans Health Information Systems and Technology Architecture) CPRS (Computerized Patient Record System) were developed in various nations. The NHS in England has also contracted out to several vendors for a National Medical Informatics system 'NPFIT' and Scotland has the GPASS system. The various parts of the Hospital information systems are Electronic medical records & medical vocabularies, laboratory information systems, pharmaceutical information systems, radiological (imaging) information systems and Patient monitoring systems.

The Knowledge-Based System (KBS) is designed to meet the knowledge gaps of the individual physician with specific patient problems. KBS and such other Expert Systems (ES) can be a boon to the rural health centres because even the general medical practitioners can operate the systems.

Clinical decision-support systems help the physician in Diagnosis/interpretation and then further in Therapy/management. The software for such Diagnosis/interpretation could have a broad scope as in Internist-I/QMR which deals with internal medicine .Others include softwares like Dx; DxPlain; Iliad; EON for guideline-based therapy. Softwares with Narrow scope include de Dombal's system for diagnosis of acute abdominal pain; MYCIN for infectious diseases ;

ECG interpretation systems; ONCOCIN support application of oncology protocols. Specific softwares like MYCIN, QMR are useful for human-initiated consultation ; while data-driven reminders are provided by MLMs. Some closed loop systems help which help in certain specific activities e.g. ICU ventilator control.

Telemedicine is a method of distance management in medical and health care not only benefits patients but also medical practitioners. Telemedicine is delivery of health care information across distances using telecom technology. This includes transfer of images like X-rays, CT, MRI, ECG, etc. from patient to expert doctors seamlessly, apart from the live video conferencing between the patient at remote hospital with the specialists at the super speciality hospital for tele-consultation and treatment.

Five categories of barriers to technology integration are time, expertise, access, resources and support. Time to plan, collaborate with peers, prepare lessons and materials, explore, practice and evaluate, as well as develop, maintain and expand skills. Effective technology training must be hands-on, systematic and ongoing. Teachers must have uninterrupted, on-demand access to the technologies they intend to use, both while inside and outside of the classroom. Resources to purchase, maintain and upgrade hardware and software; to provide training and support; and for auxiliary costs are required. Administrative leadership and support may be the most critical factor.

## Study Exercises

**Long Question :** Describe various parts of the Hospital information systems. How is it used in a Health care system?

**Short Notes :** (1) Uses of Medical Informatics (2) Hospital information system (3) Telemedicine (4) Clinical decision-support systems

### MCQs

1. NPFIT is a Hospital information system in (a) UK (b) Scotland (c) India (d) USA
2. Dx software is a (a) Knowledge-based system (b) Clinical decision-support systems (c) Hospital information system (d) None
3. The transfer of images like X-rays, CT, MRI, ECG etc. from patient or doctor to expert doctors/specialists at speciality hospital for consultation and treatment is known as (a) Hospital information system (b) Telemedicine (c) knowledge-based system (d) Clinical decision-support systems

**Answers :** (1) a; (2) b; (3) b.



# 3

## Health Policy & Health Care Systems

- 3a) Management Process in Health Care
- 3b) Health Systems and Policies
- 3c) Public Health Administration &  
Community Health Care in India



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Anuj Bhatnagar

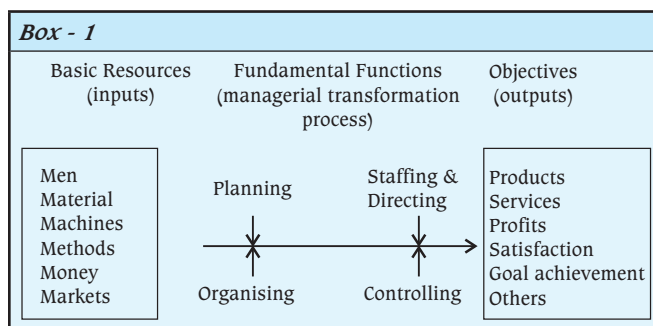
The key issue which forms the basis of any organisation or group of people is a common objective or a goal, which may be winning the match, prevent thefts in the neighborhood, deliver good quality health care to community or earn maximum profits. It is thus natural that without a common goal or objective, there would be no need for people to form groups or organisations. Since achievement of a common goal forms the basis for forming groups, each organisation must then also have some plans to achieve the common goals and every organisation must also procure and dedicate certain resources (in the form of money, material and men) for achieving the common goals.

### Definition of Management

The shortest definition of 'Management' is "*Management is getting things done through and with people*". However, two of the most widely quoted definitions are :

"Management is the art of getting things done through and with people in formally organized groups. It is the art of creating the environment in which people can perform and individuals can cooperate towards attainment of organisational goals. It is the art of removing blocks to such performance and a way of optimizing efficiency in reaching goals." (Harold Koontz)

"Management is a distinct process consisting of planning, organizing, actuating and controlling, performed to determine and accomplish stated objectives, by the use of human beings and other resources." (George R Terry). Box - 1 represents this often quoted definition of management :



### Basic Principles of Management

Henry Fayol (1881-1925), generally considered as the founder of classical management theory, laid down certain basic principles of management. Prior to Fayol, it was believed that good managers were born, not made. Fayol proposed that management, like any other skill, could be taught and mastered once its basic underlying principles, as under, were understood. These principles are :

1. Division of work according to the ability, capacity and aptitude of the workers is essential in any organisation for optimal utilization of scarce human resource and to maximize productivity in any form.

2. Well-defined responsibility leads to accountability and thus enhances performance of individuals. However responsibility can only be effective when it is combined with delegation of authority.
3. Discipline in any organisation is essential and a hallmark of compliance and mutual cooperation between various functionaries. Discipline within any organisation directly depends on good supervision, fair codes of conduct and judiciously implemented rewards & punishments.
4. An employee should ideally receive his/her orders only from one superior since multiple commanding authorities would lead to confusion and chaos. This principle is well entrenched in the armed forces, where the unity of command is practiced.
5. Organisational goals should receive preference and are more important than individual goals.
6. Remuneration in form of pay and allowances should be pre-determined for all personnel, to avoid uncertainty.
7. Centralization of important policy decisions and key matters is essential in any organisation to provide a well defined direction to efforts of individuals.
8. Employees should function in well defined functional chain of senior-subordinate relationships, called scalar chains, ideally depicted by a line organisation (explained subsequently).
9. Unity of direction, which means that directions for the entire organisation should flow downwards from the head of the organisation to all other functionaries.
10. An order in an organisation ensures stability & efficiency.
11. Equity in an organisation removes conflicts and ensures compliance & cooperation.
12. Stability of working period (tenure) ensures certainty in minds of workers and enhances performance by inculcating a sense of belonging & responsibility among individuals.
13. Initiative among employees gives them a chance to utilize their skills and hence results in better employee satisfaction, besides enhancing performance.
14. Team spirit (spirit-de-corps) is essential for any organisational work.

### Why must you study management as a medical doctor?:

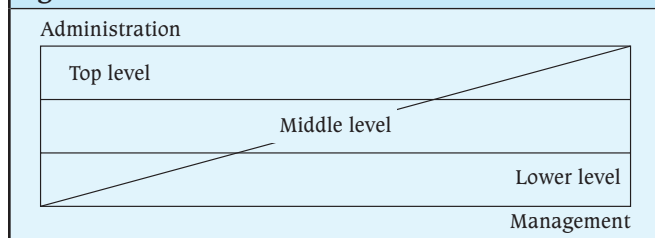
It is sometimes said that doctors are poor managers. The unwillingness to study management sciences has led to a large number of brilliant doctors being failures when it comes to leading. Like any other team, any medical team also consists of various individuals who perform their respective tasks in order to meet the common goal - of providing best health care with optimum utilization of scarce medical resources. All aspects of management are equally, in fact more, applicable to a health team, be it at a PHC or a highly specialized team of a multi-speciality tertiary care centre in a metropolis. As a medical doctor, you are expected to lead a highly professional team of trained health care workers. All your activities, be it a vaccination drive in a village or a highly complicated surgery has to be planned well in advance. You will have to carefully select your team members & motivate them to perform. In short, any health team with you as its leader is just like any other organisation with its unique organisational objectives, which have to be attained through sustained efforts of all the members.

In addition, we must also remember that all medical personnel are highly trained and intellectual, posing a challenge to any leader of such capability. Medical logistics and resources, like in any other field are always in short supply and hence have to be optimally deployed and utilized to ensure maximum benefit. For example, a MRI scan machine worth a few crores must give adequate returns in the form of adequate patient load. Investing heavily in such equipment at a location where only one or two MRI scans are done in a month would be waste of vital resources which could be better utilized elsewhere. Thus, medical profession today is no more isolated and has to extensively draw upon all managerial sciences of human resource development, financial and material management for smooth functioning of the health team. Hospitals today are complex organisations and hospital management, as a sub-specialty of management, has gained grounds rapidly. It is now being increasingly felt that basic management skills are essential for every medical doctor for him/her to function effectively as a team leader.

### Management Vs Administration

Some ambiguity exists regarding '*management*' and '*administration*', with some writers thinking them to be distinct activities whereas others feel they are different aspects of management itself. Having defined management, administration can be defined as 'those functions in an organisation, which are concerned with policy formulation, finance, production, distribution and ultimately control all key activities for meeting the organisational objectives' (Sheldon). It can thus be assumed that policy-making, planning and decision making are the basic components of administration whereas supervision, implementation and operational aspects are considered components of management. Thus the top management such as Director or Dean of a teaching hospital is more concerned with policy and decision making and lesser of day-to-day supervision & control, whereas lower management levels (Heads of Departments and Registrar) are concerned more with effective supervision & control of daily activities being carried out. Fig - 1 depicts the difference between Administration (administrative management) and Management (operative management).

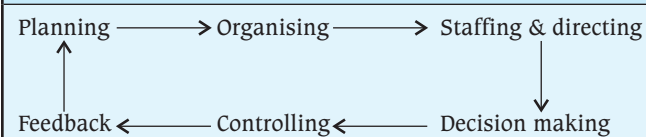
**Fig - 1**



### The Management Processes

A medical officer, in many ways is like any other leader and manager and has to daily meet some objectives, which may range from implementing a health program in a district to undertaking a complicated surgery with his surgical team. To successfully attain the objectives with optimum resources, requires a series of managerial processes, which are as shown in Fig. 2 :

**Fig. - 2**



### Planning

Planning is the fundamental and initial process in any activity and success of any project or activity depends on how well it has been planned. If any team effort has to be successful, all team members must know in advance what they are expected to accomplish (objectives). Thus setting the objectives is a major function of planning. Planning consists of deciding in advance what to do, how to do, when to do and who is to do it, and thus it bridges the gap between where we are presently and where we have to reach. Planning consists of taking conscious and well thought out decisions about which course of action to take out of the many available and most suitable method to achieve these objectives. Planning ensures that pre-determined objectives and goals are identified so that all resources can be allocated and dedicated in achieving these goals in the most optimal manner. In short, it can be said that the process of planning answers the following questions for the manager :

- What will be done – identifying short and long term objectives and goals.
- What resources will be used – identifying the available & potential resources required for achieving the objectives and filling the gaps in resources, if any.
- How will it be done - determining the specific activities required for attaining the goals and formulating strategies, policies, procedures, methods, standards & budgets.
- Who will do what – delegating responsibilities to various individuals for attaining the organisational goals.
- When will it be done – assigning the time frame and sequence for completing each activity.

### The Planning Process in Health Sector

As a leader of medical professionals, a doctor is often faced with a situation where he has to plan various health activities. The basics of planning process in the health sector can be remembered by answering the following key questions :

- Where are we at present (situational analysis)
- Where do we finally want to reach (objectives & goals)
- How do we get there (resources & constraints)
- How effectively we have performed the required activities (evaluation, monitoring & feedback)
- What new problems do we face and how do we overcome them (re-planning)

### Steps Involved in Planning a Health Program

This aspect has been deliberated in detail in an exclusive chapter in the section on epidemiology. You are advised to go through the same.

**General Terms used in Relation to Plans :** As a leader of the health team, it is important for a medical officer to know about the various types of plans and the distinction between them. As discussed earlier, all organizational plans are formulated with the instinct to achieve the pre-determined objectives in the



most efficient manner. Various types of plans can be classified as under :

**(a) Mission :** The mission of an organization is described as the very reason why that organization exists. It is always described in terms of the benefit (direct or indirect) provided to users by the organization and not in terms of the product or services rendered. It is of utmost importance for any organization to clearly define its mission, since that will determine all efforts of that organization. The organization must ask the question “what is our business” and answer it from the users’ viewpoint. The mission of an organization is described in its ‘mission statement’. For example the ‘mission statement’ of Department of Community Medicine of a medical college would be “To provide comprehensive training in community medicine to medical graduates and post graduates, with the aim to make them better public health specialists.” The mission of an organization is dynamic and must adapt to the environmental changes and requirements. The organization has to decide how it would like to define what its business would be. Formulating the mission is of utmost importance and never easy; it must balance between the present & the future. A narrow definition of ‘mission’ will limit the activities of the organization to the immediate present & prevent its growth and utilization of newer opportunities & technologies, whereas too broad a definition of mission will not enable the organization to concentrate on any workable activity and opportunities at present. For example, a doctor at PHC would most likely describe his mission as “providing timely and expert primary care to villagers in his jurisdiction” whereas a cardiothoracic surgeon at a large multispeciality metropolitan hospital would describe his mission as “providing highly specialized cardio-thoracic surgery to all those who are brought to the cardiothoracic department of the hospital”.

**(b) Objectives :** Having first formulated the ‘Mission’ of the organization, which answers the question ‘what is our business’, the next step would be to translate this relatively abstract mission into smaller, tangible, measurable & achievable ‘objectives’ for managers at lower levels. Thus objectives are the ‘action orientation of the mission’ and form the basis for taking action in appropriate direction and for measuring the performance. For example, let us assume that the mission statement of a measles immunization program is ‘to immunize children below 2 yrs with measles vaccine to protect them against measles’. The objective in this case would be ‘immunization of 90% of all children in any given village’, which would form the basis of action to be taken by the health workers and would also act as a measurement of performance. However, it must be remembered that objectives remain statements of expected outcomes and not the actual performance or outcome.

**(c) Goals :** Goals can be described as intermediate time-bound and specific targets which are necessary for achievement of objectives in the organization. Being derived from objectives, goals are very specific (quantitatively or qualitatively). ‘Goals’ would broadly have four characteristics as under:

- (i) Goals are derived from the objective which they seek to fulfill.
- (ii) Goals form the benchmark and standards for measuring performances & progress towards achieving the larger

organizational objectives.

- (iii) Goals often represent a target to be achieved or a hurdle to be overcome.
- (iv) Achievement of goals has to be within a specific time frame.

Thus we have seen that goals are action-oriented, provide a means for converting plans into smaller achievable tasks and are time bound. Goals also play a major role in motivating people towards working in a coordinated fashion towards the larger organizational objectives.

**(d) Strategies :** Strategy is any decision, plan or action which takes into consideration the actions of competitors and other factors in external environment, with the aim of achieving the objectives. For example, when as a doctor, you would plan your IEC campaign for promoting condom usage among community, keeping in mind the reaction and resistance of a particular section of community, it would be called a strategy. The strategist would thus consider the reaction of external environment and plans of his ‘rivals’ (anyone who could delay or derail the achievement of his goals & objectives), while planning his course of action. As a health strategist, one would select strategies (plans) that would help in achieving the objectives and which would create an advantageous position for the entire health team in dealing with the external (socio-economic & socio demographic) environment in which the health team has to operate.

**(e) Policies :** It is important to understand the difference between strategies and policies, since both are often confused and used interchangeably. Whereas strategies focus of the best course of action (among alternatives) after considering external environment and possible actions of competitors / rivals, policies on the other hand, provide guidelines for decisions and actions. For example, it is the policy of a state government to immunize all children against Hepatitis B, which is thus the guideline for the health directorate of that state to procure vaccines and implement Hepatitis B vaccination at all its health centers & hospitals. Policies do not tell a manager what he should or should not do in a given situation. Policies tell a manager what he can do by setting a limit within which a manager must operate. Well formulated policies in any organization help in achieving the pre-determined objectives by channelising all managerial decisions in the right direction, providing tangible and measurable criteria for evaluation of decisions taken and by ensuring uniformity in decisions throughout the entire organization.

**(f) Rules :** As compared to policies (which are guide to decisions), rules are guides to action and prescribe a type of behavior / actions which are permissible. Rules define what should or should not be done. For example, the attendance rule of PHC staff states that if any health worker is late for three days in a month, he shall loose one day’s casual leave. Rules are effective only when they carry a penalty / punishment for non-compliance and thus regulate employee behavior, though at the same time restricting their initiative and innovativeness. Policies by and large, define a broad sphere within which a leader has to act using his discretion. Rules on the other hand, leave no scope for any discretion by clearly defining the acceptable behaviour/actions.

<i>General principles to be followed for formulating organizational policies</i>	
1.	Policies should always assist in achieving the organizational objectives.
2.	Policies should be well defined and should be in writing.
3.	Policies at each level should be derived from and should support the policies of the next higher level.
4.	Policies of a department in the organization should be well coordinated with policies of other departments, and should not pose a hindrance / obstacle to policies of other departments.
5.	Policies should be just, unbiased and equitable towards all sections of employees.
6.	To incorporate the changing needs and changing organizational environment, policies should be periodically reviewed and revised.

**(g) Procedures :** We have seen that policies are guides to decisions and rules are guides to action. Procedures are chronological steps involved in performing any action or taking any decision. For example, the procedure of administering an intra muscular injection to a patient can be broken down into distinct sequence of actions as under :

- (i) Disinfection of site with spirit.
- (ii) Assemble the syringe & needle.
- (iii) Break the injection vial.
- (iv) Fill the syringe with injectable drug (say Inj Voveran).
- (v) Insert the needle into the muscle (deltoid or gluteal region)
- (vi) Partly withdraw the plunger to ensure that needle is not in a blood vessel.
- (vii) Depress the plunger to inject the drug.
- (viii) Withdraw the needle out of the skin without shaking/bending .
- (ix) Swab the injection site with cotton.

Thus, procedures are sequence of activities that have to be performed in order to achieve a certain objective (e.g. giving an intramuscular injection). All medical officers are well conversant with many surgical or nursing procedures which have to be performed sequentially to complete a task, such as 'Hand washing procedure' in operation theatre, procedure for starting an intravenous lifeline in intensive care unit etc.

**(h) Programs :** As a doctor, one is often required to manage and implement various health programs in our respective areas, which makes it important for every doctor to understand the concept of a program as a plan at the national level. A program is a set of those activities which have a specific time schedule and a distinct mission. Thus programs are a series of actions performed for achieving the organizational objectives '*within the scheduled time*'. In our example, when a medical officer of a PHC undertakes specific actions with the objective of attaining the 90% vaccination mark for measles among children below 2 years by the end of the year 2010, it is a health program. All medical students are also well aware of several National Health Programs (described in detail elsewhere in this book),

which aim at achieving certain health related objectives within a stipulated time-frame through a series of actions.

## Organising

As a function of management, organizing deals with identifying and grouping various activities, delegating authority and command to managers and coordination of various activities and hierarchies in the organization. The process of organizing can be described as a series of steps as under :

**(i) Detailed description of various activities to be performed for achieving organizational goals :** For achieving the pre-determined organizational goals, we must know in detail what activities are to be performed. For example, before a hospital team can actually start treating the sick (organizational goal), they must know what equipment to buy, how many doctors, nurses and paramedical workers to hire, where to locate the hospital, how to construct and how many departments to create in the hospital.

**(ii) Grouping of various activities in some meaningful manner :** An organization invariably functions better when activities of a similar nature are grouped together, based on their essential similarity & difference from other activities. This would be best exemplified in creation of various departments in a large hospital. For example, all patients requiring surgical intervention (which may be for hernia, burst abdomen, gun shot wound or a simple abscess requiring incision & drainage) are referred to & attended in the surgery department (which itself may be further divided into cardio-thoracic surgery, gastrointestinal surgery, neurosurgery or vascular surgery depending on the detailed type of surgeries performed).

**(iii) Delegation (comprising of authority, responsibility and accountability) :** Consists of assigning each group of activities (departments) to a manager with authority to supervise its functioning (head of the department). Delegation, thus, is the most important part of organizing since any manager due to limited individual capabilities, can not carry out all organizational activities alone and has to delegate work to his subordinates. Successful delegation of work is accompanied by delegation of authority to take decisions & actions of accountability.

**(iv) Coordination (horizontal and vertical) :** Makes the organizing process complete. In any organization, every individual or group of individuals very often start concentrating on performing only their specific assigned task, often relegating the overall organizational goals to the background and generating conflicts. For example, in a large multispeciality hospital, the medicine department may be unwilling to part with their assigned vacant bed in ICU in anticipation of a case even when the surgery department needs it urgently for a patient of burst abdomen. The medical stores may be refusing to issue costly medicines prescribed by a junior doctor with the aim to curb wasteful expenditure, not realizing that the medicine is urgently required by the patient. Such occurrences are quite common in medical practice and this is where the role of the medical superintendent as a manager is of utmost importance. Coordination between departments and between various hierarchies in organization is thus an essential requirement to channelise energies towards achieving the

overall organizational goals and look beyond individual or departmental goals.

**Principles of organizing** : Some important principles of organizing are enumerated below :

*(i) Unity of direction* : One leader & one plan for a group of activities having the same objectives.

*(ii) Unity of command* : A subordinate reports only one boss to avoid conflict of orders.

*(iii) Authority* : Every individual in an organization has some responsibility commensurate with his authority.

*(iv) Span of control* : Number of subordinates supervised by a leader should not be too many for better control.

*(v) Flexibility* : Organisational staffing pattern & structure should be able to accommodate changes in internal & external environments.

*(vi) Management by exception* : All routine decisions should be taken by subordinates & only policy decisions and unusual matters should be referred to the leader.

*(vii) Scalar principle* : Clear lines of authority in hierarchical structure ensures more effective performance.

**Formal and Informal Organisations** : The organizing process results in a deliberately designed and thought out organizational structure where it is specified who will do what, with whom and under whose supervision. Such an organization is said to have a *formal organization* where hierarchies and levels of authority are formally laid down and observed. For example, a large corporate hospital, with its clearly and formally defined departments and its rigid hierarchy with the CEO at the top is a formal organization. On the other hand, a volunteer group of specialists who undertake charity work every weekend at a nearby charitable hospital for the poor would have emerged spontaneously due to their common likes and dislikes. Such an organization, which was not 'planned' to come into existence and which has no formal departments or hierarchies, is an informal organization. As a doctor, one is faced everyday with informal groups, like the village elders, a village self help group, a youth club etc and we must remember that informal organizations, with expressed shared values and sentiments of a large majority, can be very effectively utilized for achieving the organizational goals. The effort to include religious leaders & volunteer groups such as Rotary Club in the Pulse Polio Immunization in India is an example where such informal groups are often more successful in achieving organizational goals than the highly formal organization of the government.

### Staffing

**The concept of 'span of control'** : Depending on the type of organization and objectives to be achieved, every manager must decide how many subordinates he/she can effectively supervise. Consequently, a wider span of control (generally found in highly technical organization with highly motivated subordinates) will result in lesser 'levels of management' than a narrow span of control (where one subordinate is controlled only by one superior). A 'flat organisation' (with lesser levels of management) has faster flow of information and greater satisfaction levels for individual subordinates. Such type of organization, where subordinates are highly motivated and

responsible is ideal for research and development such as in groups developing new drugs, vaccines or conceptualizing newer & better methods of health care delivery in remote villages.

Factors determining an effective span of control : Though there is no laid down limit of the optimum number of subordinates a manager can supervise effectively, the most important factor is the managers ability to reduce the time he spends with each subordinate in order to gain the maximum output from him. Seven important factors which determine the frequency and duration of superior-subordinate interaction (time spent by a superior with each subordinate, hence the span of control of each manager) are as under :

*(a) Training levels of subordinates* : Well trained subordinates require less frequency and duration of contact with superiors & result in wider span of control for the superiors.

*(b) Clear delegation of authority* : If a subordinate's task is not clearly defined or if he is not given enough authority, he would be spending disproportionate time seeking clarifications, thereby reducing his span of control.

*(c) Clarity of plans* : A superior would need to spend considerable time supervising & guiding the decisions of subordinates wherever subordinates have to do much of their own planning. This usually occurs whenever organizational plans are not clearly laid down.

*(d) Objectivity in standards* : Use of tangible and measurable standards against which actual performance of subordinates is to be measured enables the manager to avoid time-consuming procedures to ascertain if his subordinates are actually following the plans.

*(e) Rate of organizational change* : Narrow span of control becomes necessary wherever the rate of change in the organization is fast; which determines the stability of policies. Organizations with slow rate of changes (or relatively stable organizations in stable environment) would do better to have a broader span of control.

*(f) Communication techniques* : If instructions have to be personally delivered by a superior to his subordinates and repeated clarifications have to be sought, naturally there will be an added burden on the managers time, reducing his span of control.

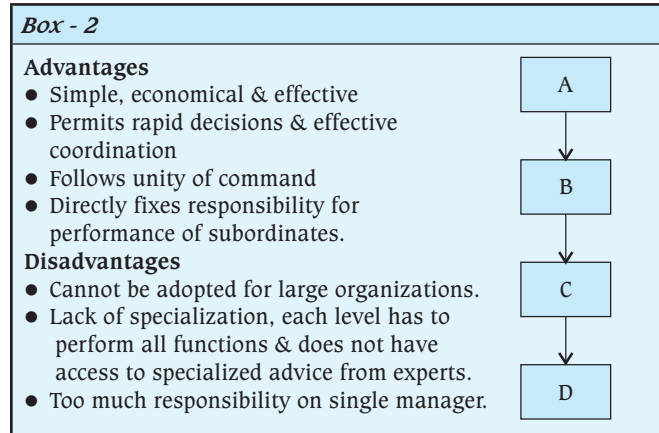
*(g) Amount of personal contact required* : Under many circumstances, face to face meetings or conferences with subordinates are essential, which draw upon the time of a manager resulting in narrower span of control.

**The concept of line and staff relationships** : Traditionally, it has been held that line functions & personnel are those that are directly responsible for achieving an organization's primary objectives, while staff functions and personnel are those that assist line managers to function more effectively. Conceptually, it is important to note that in line relationship, there is a direct relationship of command between superior and subordinate, whereas staff functions are advisory nature to line managers whom they support. It is essential for any medical manager to know in what capacity (for example, an orthopedic consultant to a tertiary care hospital) their job is to advise and not command,

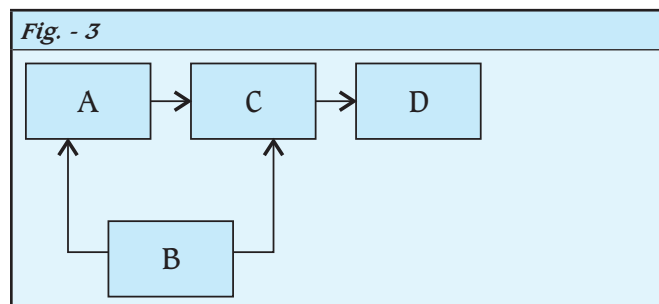


but when in line capacity (such as a medical superintendent of a large government hospital), they must make decisions and issue instructions for others to follow.

**Line organization** : A line organization consists of line personnel, where each position has direct authority over all lower positions. No subordinate is under more than one superior, and the scalar principle and principle of unity of command are strictly adhered to. The flow of authority in line organisation is depicted in Box - 2.



**Line and staff organization** : When in addition to the line authority of managers, there are specialists and experts to advise various levels on specialized issues, it is called the line and staff organization . In the figure below, A, C and D managers are in direct line relationship as discussed earlier; but B is in staff relationship and advises A and C on important issues. B may have lower status than A and higher status than C in the organization, but is not in direct line of command. Generally in any organization, those personnel who develop new ideas, undertake research and advise on technical matters and fall outside the direct chain of command are staff personnel. It is important to remember however that even in a staff department (for example, finance department of a large corporate hospital), the departmental head would still have line control over all subordinate financial experts. The flow of authority in line and staff organization is depicted in Fig. - 3.



The advantages and disadvantages of Line and Staff Organization are as in Box - 3.

Box - 3 : Line and staff organization
<p><b>Advantages</b></p> <ul style="list-style-type: none"> <li>• Managers at various levels get the benefit of specialized technical advise of specialists.</li> <li>• Staff specialists (like financial experts) are able to concentrate fully on their technical jobs and perform them more effectively.</li> <li>• Staff specialists assist line managers in taking better decisions, by providing them the right information at the right time.</li> <li>• Since experts can be appointed to advise line managers on technical issues, the structure is more flexible than the line pattern.</li> </ul>
<p><b>Disadvantages</b></p> <ul style="list-style-type: none"> <li>• Conflict between line and staff personnel is very common in such kind of organizational structure.</li> <li>• Performance of staff personnel may not be optimum since, they in their capacity as technical advisors, are not directly accountable for achieving the objectives.</li> <li>• Inadequate job satisfaction among staff personnel due to slower promotional avenues.</li> </ul>

**Functional organization** : In the large and complex organizations of the present day, the traditional principle of one boss and one subordinate (unity of command) is not possible. In such organizations, different superiors performing different functions (finance, human resource, inventory control etc) exercise control over a subordinate in respect of their respective functions. Thus a functional organization is one wherein a worker is accountable to two or more different executives for a given specific and specialized function. For example a radiographer in a large corporate hospital may be providing specialized services (radiotherapy) in three different wards and thus would be accountable or advising their respective Medical Officers in-charge in addition to being accountable to the Head of Department of Radiology Services. The advantages and disadvantages are as in Box - 4.

Box - 4 : Functional Organization
<p><b>Advantages</b></p> <ul style="list-style-type: none"> <li>• Benefits of specialization at work are available to all levels of managers.</li> <li>• Supervision is easier since each specialized manager is an expert in his / her own field.</li> </ul>
<p><b>Disadvantages</b></p> <ul style="list-style-type: none"> <li>• From the view point of control, the system appears confusing since exact nature of functional authority is often not well defined.</li> <li>• The lines of authority and responsibility, as seen in line organization are totally merged.</li> <li>• Since same worker has to work under different superiors, control is not easy.</li> <li>• It is difficult for the management to fix responsibility for non performance.</li> </ul>



**The Matrix Organisation** : A combination of the product and functional structures, the matrix structures are the choice for large and complicated projects where the skills of a functional man (manager) and specialized (technical) knowledge (e.g. finance consultant) are both required. Under the matrix structure, an employee is accountable & takes orders from two different superiors at the same time. For example, a ward nurse is accountable to the Head Nurse of the Hospital as well as to the ward MO in which she is working. An example of the matrix organization in a large hospital is as represented in Box - 5.

Box - 5			
	Ward MO	ICU i/c	Anesthesiologist
Head Nurse	Ward Nurse	ICU Nurse	OT Nurse
Chief Sanitary Supervisor	Ward sweeper	ICU Sweeper	OT Sweeper
Chief Pharmacist	Ward Pharmacist	ICU Nurse	OT Storekeeper

### Directing (Leading)

Leadership can be described as the activity of influencing people to strive *willingly* to achieve the group objectives. This ability may be *formal* (as in form of formal authority vested with an individual) or *informal* (as in form of power and ability to influence people outside the formal structure of an organization).

**Leadership styles** : This refers to the way in which a leader would influence the followers. Some of the leadership styles are described below :

(a) **Iowa leadership studies** : Lewin, Lippitt and White, in 1939, studied different styles of leadership among 10 year old boys in three groups. Three main types of leadership which emerged from their studies were :

(i) **Authoritarian leader** : Where the leader was directive and did not permit any participation from team members. Concern for completing the task was of prime importance and each member of the team was told what to do and how to do.

(ii) **Democratic leader** : One who encouraged participation and discussions by group members, he involved all group members in planning and completing the task.

(iii) **Laissez-faire leader** : Such a leader give complete freedom to the group members, did not provide any leadership, did not establish policies or procedures to complete the job. Under such scenario, no member of the group influenced another member.

### (b) The Managerial Grid Theory

The Managerial Grid Theory proposed by Black and Mouton in 1978 indicates that leaders can be oriented towards both tasks and persons. The managerial grid, based on the interaction between person-orientation and task orientation of a leader, is depicted in Box - 6 :

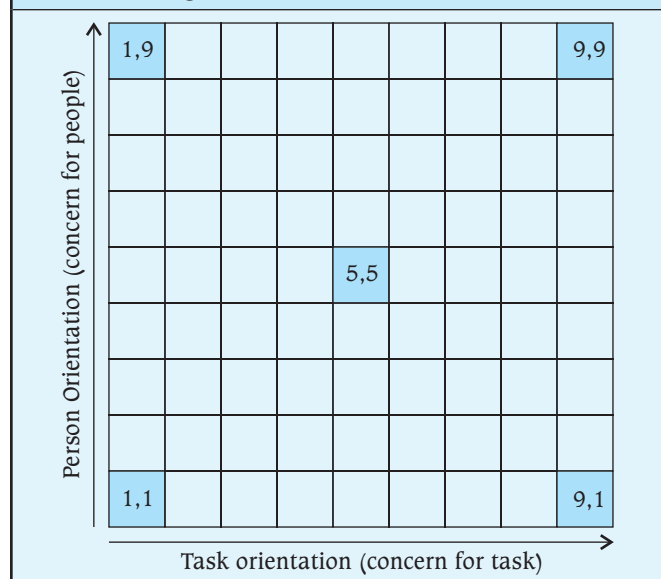
The Managerial Grid shown here is characterized by the following qualities among the leaders :

- The (9, 1) leader is only concerned with task and has least concern for welfare of his subordinates. Such a leader is

called a 'task-management leader'.

- The (1, 9) leader, called the 'Country Club' management leader, is only concerned with people, to establish good relationship with and among his subordinates such leaders has least concern for tasks.
- The (1, 1) leader (impoverished leader) is neither concerned with welfare of his subordinates nor with the task. Such a leader does not take any decision and stays out of the way.
- The (9, 9) leader (Team Management leader) has maximum concern both for people and for task. Though an ideal situation, such a leader wants to achieve the goals through committed people.
- The (5, 5) leader (middle-of-the-road leader) attempts to compromise between high production and satisfaction of the subordinates.

Box - 6 : Managerial Grid



### Summary

Management is the art of getting things done through and with people in formally organized groups. It is the art of creating the environment in which people can perform and individuals can cooperate towards attainment of organisational goals. It is the art of removing blocks to such performance and a way of optimizing efficiency in reaching goals. It is a process consisting of planning, organizing, actuating and controlling, performed to determine and accomplish stated objectives, by the use of resources like men, material, machines, methods, money and markets. The basic principles of management are Division of work according to the ability, capacity and aptitude of the workers; Well-defined responsibility; Discipline; Orders only from one superior; Preference of Organisational goals to individual goals; Pre-determination of remuneration in form of pay and allowances for all personnel; Centralization of important policy decisions and key matters; Functioning in well defined functional chain of senior-subordinate relationships (scalar chains); Unity of direction; Equity; Stability of working

period (tenure); Initiative among employees; and the Team spirit. Administration can be defined as 'those functions in an organisation, which are concerned with policy formulation, finance, production, distribution and ultimately control all key activities for meeting the organisational objectives'. It can thus be assumed that policy-making, planning and decision making are the basic components of administration whereas supervision, implementation and operational aspects are considered components of management.

To successfully attain the objectives with optimum resources, requires a series of Managerial processes which are Planning, Organising, Staffing & directing, Decision making, Controlling and Feedback. Planning is the fundamental and initial process in any activity. Setting the objectives is a major function of planning. The basics of planning process in the health sector consists of deciding Where are we at present (situational analysis), Where do we finally want to reach (objectives & goals), How do we get there (resources & constraints), How effectively we have performed the required activities (evaluation, monitoring & feedback), what new problems do we face and how do we overcome them (re- planning). Various types of plans can be classified as Mission of an organization (described as the very reason why that organization exists), Strategy (any decision, plan or action which takes into consideration the actions of competitors and other factors in external environment, with the aim of achieving the objectives), Policies (guide to decisions), Rules (guides to action), Procedures (chronological steps involved in performing any action or taking any decision), Program (a series of actions performed for achieving the organizational objectives within the scheduled time).

As a function of management, organizing deals with identifying and grouping various activities, delegating authority and command to managers, and coordination of various activities and hierarchies in the organization. The process of organizing can be described as a series of steps which include Detailed description of various activities to be performed for achieving organizational goals, Grouping of various activities in some meaningful manner, Delegation (comprising of authority, responsibility and accountability), and Coordination (horizontal and vertical). Some important principles of organizing are Unity of direction, Unity of command, Authority, Span of control, Flexibility, Management by exception and Scalar principle. Depending on the type of organization and objectives to be achieved, every manager must decide how many subordinates he/she can effectively supervise. Consequently, a wider span of control will result in lesser 'levels of management'. Seven important factors which determine the frequency and duration of superior-subordinate interaction are Training levels of subordinates, Clear delegation of authority, Clarity of plans, Objectivity in standards, Rate of organizational change, Communication techniques and amount of personal contact required.

In line and staff relationship, there is a direct relationship of command between superior and subordinate, whereas staff

functions are advisory nature to line managers whom they support. A line organization consists of line personnel, where each position has direct authority over all lower positions. No subordinate is under more than one superior, and the scalar principle and principle of unity of command are strictly adhered to. A functional organization is one wherein a worker is accountable to two or more different executives for a given specific and specialized function. A combination of the product and functional structures, the matrix structures are the choice for large and complicated projects where the skills of a functional man (manager) and specialized (technical) knowledge (e.g. finance consultant) are both required. Under the matrix structure, an employee is accountable & takes orders from two different superiors at the same time. Leadership can be described as the activity of influencing people to strive willingly to achieve the group objectives. This ability may be formal (as in form of formal authority vested with an individual) or informal (as in form of power and ability to influence people outside the formal structure of an organization).

## Study Exercises

**Long Question :** Enumerate the basic principles of Management and describe the steps involved in Planning process.

**Short Notes :** (1) Management and administration (2) Line and staff relationship (3) Steps in planning process (4) Concepts of strategy, policy and program.

### MCQs :

- Following is a guide to Action (a) Policy (b) Rule (c) Program (d) Objective.
- A series of actions performed for achieving the organizational objectives within the scheduled time is known as (a) Policy (b) Rule (c) Program (d) Procedure.
- The following are basic components of "Administration" *Except* (a) Policy-making (b) Planning (c) Implementation (d) Decision making.
- Unity of direction and Unity of command are some of the important principles of (a) Planning (b) Organising (c) Staffing (d) None.
- A wider span of control will result in (a) Lesser levels of management (b) Wider levels of management (c) Independent of each other (d) None.
- The type of organization in which worker is accountable to two or more different executives for a given specific and specialized function is (a) Line (b) Functional (c) Matrix (d) None of the above.
- The type of organization in which no subordinate is under more than one superior, and the scalar principle and principle of unity of command are strictly adhered to is (a) Line (b) Functional (c) Matrix (d) None of the above.
- The type of organization in which an employee is accountable & takes orders from two different superiors at the same time is (a) Line (b) Functional (c) Matrix (d) None of the above.

**Answers :** (1) b; (2) c; (3) c; (4) b; (5) a; (6) b; (7) a; (8) c.

Anuj Bhatnagar

Any organization is entirely dependent on the people who work there, for its success, i.e. for achieving the organizational goals. Broadly, four competency requirements have been identified for any organisation; Technical, Managerial, Human and Conceptual. Human resources, unlike all others, have to be nurtured and have almost unlimited potential. Since all organisations are made up of 'people', acquiring their services, developing skills, motivating people for high levels of performance and maintaining their commitment towards organizational goals are essential in achieving these goals. Human Resource Development (HRD) system uses various mechanisms, as under, with the view to achieve these objectives.

- (i) Recruitment & training
- (ii) Potential appraisal & development
- (iii) Performance appraisal
- (iv) Career planning
- (v) Organisational Development (OD)
- (vi) Rewards & compensation
- (vii) Employee welfare
- (viii) Human Resources Information

### Personnel Management

Personnel management (also known by several other terms such as personnel administration, labour management, industrial relations, employee relations) is the functional front of HRD in any organisation. Thus, personnel management :

- (a) Is concerned with employees as individuals as well as groups.
- (b) Covers all levels of employees including senior managers, clerks, technical workers as well as the 'blue collar' workers.
- (c) Aims to help employees to develop their potential to the maximum.
- (d) Is an inherent and continuous process in any organisation.
- (e) Attempts to obtain willing cooperation of all employees to achieve the organizational goals.

### Objectives of Personnel Management

- (a) Achieve optimal utilization of human resources with the aim to achieve organizational goals.
- (b) Maintain adequate organizational structure among members of the organisation.
- (c) Develop a feeling of involvement, commitment & loyalty towards the organisation among the members.
- (d) Personal growth & development of individual workers through opportunities for advancement.
- (e) Satisfy the individual needs through optimal remuneration.
- (f) Develop high morale and better human relationships.

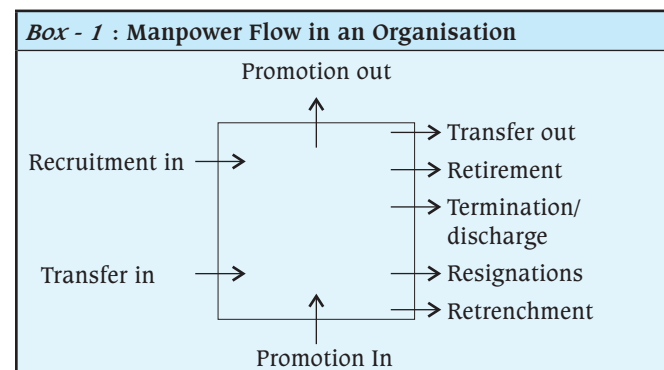
### Functions of Personnel Management

The functions of personnel management include the following : Planning of the manpower requirement; Recruitment; Organising manpower resources; Selection; Classification of employees; Staffing; Transfer & promotion; Manpower development; Training; Motivation; Recreation; Communication; Collective bargaining; Employee discipline; Performance evaluation; Employee counseling.

**Manpower Planning** : Manpower planning is an essential and integral part of any organisation which has to survive in future. It can be defined as the 'Strategy for the acquisition, utilization, improvement and presentation of human resource of an organisation. It is aimed at meeting the future requirements and assessing the availability of different types of human resource available to an organisation and ensures that the organisation always has the right kind of the people for the right job, at the right time. For example, as a Medical Officer in-charge of a hospital, it would be essential for you to keep in mind, if your pharmacist is retiring next year, to start the process of recruiting another pharmacist for your hospital before the present one retires. This is essential to ensure the smooth functioning of your hospital.

Broadly, manpower planning consists of *Forecasting* (estimating future manpower requirement), *Inventorying* (analyzing the present manpower available and the extent to which they are employed optimally), *Anticipating* (projection of the present resources for the future and assessing their adequacy) and *Planning* (drawing up plans for recruitment, selection, training, development etc. to meet the future requirements).

Manpower planning for any organisation is a vital activity to ensure optimal utilization of presently available human resource. At the same time, it also forecasts the future requirements of trained manpower and ensures that right type of manpower is available when needed. Human resource being the most important resource in any organisation, manpower planning directly affects future of the organisation by anticipating and catering for the redundancies and recruitment levels. It indicates the optimum training needs and infrastructure like accommodation, office space, recreational facilities etc based on the manpower projections. Manpower flow in an organisation is as shown in Box - 1.



**Recruitment of Personnel** : The success of any organisation naturally depends entirely on its workforce and the people

who work for the organisation. Recruitment, thus, naturally assumes great importance to ensure that the right person is selected and employed. This section would deal with the issues of recruitment, selection, placement and induction.

**Recruitment** : It is defined as the “process of identifying prospective employees, stimulating and encouraging them to apply for a particular job in an organisation”. The aim of recruitment is to have an inventory of eligible and qualified people from whom most eligible will be selected by the organisation to work for it.

**Selection** : This is the process of “examining a large number of applicants for their suitability for a given job and selecting the best suited & qualified candidate(s) and rejecting the others”.

**Placement** : It is the “determination of the job for which a selected candidate is best suited and assigning that job to him”. Proper employee placement improves productivity, motivation & output by reducing absenteeism, accidents & turnover of employees.

**Induction** : This can be defined as “introducing the new employee to the job and to the organisation with the view to ‘sell’ the organisation to him so that he takes pride in his new job and association with the organisation”. This is also called ‘indoctrination’.

Before we actually start ‘recruiting’ people, we have to clearly know what job is required to be done. For example, before advertising for an anesthesiologist for a hospital, we must know that he would be required to provide anesthesia in OT during surgeries and would also be required to manage seriously ill patients in ICU. Only then can we plan our recruitment effectively. This process is carried out by *job analysis*. It can be defined as “a systemic compiling of detailed description of tasks, determination of relationship of the job to technology and to other jobs and examination of knowledge, qualifications and employment standards, accountability and other requirements”. Simply put, job analysis indicates the activities and accountabilities associated with any job. It is the process of examining a job to identify its various components and the circumstances in which it is performed. The information gathered from job analysis is used to make vital decisions about organizational design & planning, recruitment and selection of personnel and all other managerial functions. Ideally, all jobs in an organisation need to be analyzed, but the complexity of the process will depend on the complexity of the job. For example, the job analysis of a safai worker’s job in a corporate hospital can be simple description of the steps required to be taken to sweep an OPD. However, job analysis of a cardio-thoracic surgeon in the same hospital (including his position in the hospital hierarchy) is very complex.

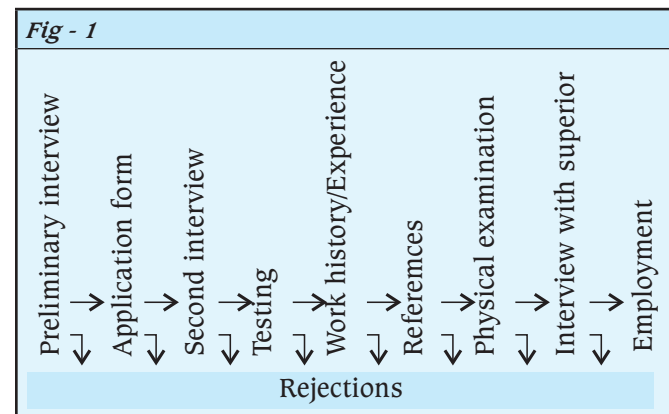
**The step-wise process of recruitment** : These include the following steps

**1. Preparation for recruitment** : Identifying the ‘job specifications’ (based on job description) to decide what type of people, with what characteristics should be invited to apply for the job. These will include specifications of physical, medical, mental, social and behavioural attributes for the job.

**2. Identifying the sources of manpower** : These could be following :

- (i) Internal sources are personnel already employed, (including past employees who quit voluntarily or on production lay off, whom the organisation could retire for the new posts.
- (ii) External sources that are not associated with the organisation, selecting internal candidates for new posts improves morale of the workforce and promotes loyalty for the organisation. External sources on the other hand provide wide choice and bring in new ideas and enthusiasm. However larger investments in training & induction have to be made in case of external candidates.

**Selection of Personnel** : Selection of personnel can be defined as the ‘process of acquiring the relevant information about an applicant, evaluation his qualifications & experience in order to match these to the job requirements’ and is thus the process of picking out the best suited individual for the organisation. The ‘*successive hurdles technique*’ is often used for selection process in organisation, which is depicted in Fig - 1.



**Training & Development of Personnel** : We have seen that after an individual is selected & inducted into an organisation, he/she has to learn how the assigned work can be done most efficiently and effectively. This is done through training programs. Training is defined as a “short term process utilizing a systematic and organized procedure by which non-managerial personnel acquire technical knowledge and skills for definite purpose.” Designed primarily for non-managerial personnel, training is essentially of *short duration* and for a *specific job related* purpose. *Development*, on the other hand is a “long term educational process utilizing a systemic and organized procedure by which managerial personnel get conceptual and theoretical knowledge. Thus, development pertains not only to technical knowledge and skill, but also to theoretical and conceptual concepts; and involves education and long-term development. Training of personnel is undertaken by both “on the job” as well as “off the job” training methods.

## Performance Appraisal as an Element of HRD

Performance Appraisal (PA) is an important managerial tool by which an employee’s performance, accomplishments and



behavior are evaluated for a given period of time. This becomes important for any organisation to achieve the maximum possible utilization of human resources available. Thus performance Appraisal is an important managerial tool for monitoring and measuring the performance of employees, with the overall aim to improve performance and enhance individual efficiency to benefit the organisation. PA is therefore an important method for collecting, reviewing, analyzing and recording information about performance of an employee.

### Methods of Performance Appraisal

As managers and leaders of men, all doctors should be able to objectively and successfully assess the performance of their subordinates, whether in a PHC or in a tertiary health care centre. Ideally, all performance appraisals should be based on pre-determined and objective performance standards; should lead to improvement of the subordinate by means of a joint performance review and should be based on more than one channel/ method of assessment, as explained subsequently.

Performance appraisal becomes more important where work performed can not be directly measured in terms of tangible goods and where individual characteristics affecting productivity and performance must be determined. It is important to specify the job performance criteria to be measured. The following methods are used for PA in most organisations.

- (a) *Global Assays & Rating* where the assessor, in an essay form, provides an overall impression of the performance of the ratee during a specified time period. This method may have serious disadvantages in the absence of specific performance criteria derived from a job analysis procedure undertaken well in advance.
- (b) *Trait Rating Scales* usually include a list of personal traits of an individual, such as loyalty, leadership qualities, sincerity, courage of conviction etc, which are required to be rated on a numerical scale. Trait Rating Scales tend to be unreliable if elements of halo effect, leniency/ strictness or central tendency creep into the evaluation process.
- (c) *Ranking Procedures* involves an overall assessment of performance and classifying the employees into categories (such as Top 10%, Bottom 10%, Exceptional, Unsatisfactory etc). This procedure, even though it prevents rating-errors like central tendency, but is not based on specific and objective rating criteria.
- (d) *Behavioural Anchored Rating Scales (BARS)* are based on objective parameters on which the behaviour of an employee is assessed. Although the performance appraisal in such a case tends to be more job oriented, it still faces the problem of identifying which actual behaviour matches with which (objectively determined) performance scale.
- (e) *Objective and Goal-setting procedures* focus on the outcomes and the output of an employee, as a measure of performance appraisal. Goals and targets are previously set, most often by the manager and the performance appraisal of a subordinate is undertaken based on the extent to which these objective have been achieved.

## Important Issues in Employee Compensation

Employee compensation and wages paid to employees are the foremost issues for any manager. Over a period, these issues have become more complicated with the involvement of legislature, issues of equity and justice and also national economy. The wages for employees, which was initially only an issue decided by the employer, is now an inescapable component of the socio-economic texture of a country.

### Basic Wage and Dearness Allowance

*Basic wage* is the stable wage paid to employee, which is based on the statutory minimum wage and is aimed at providing not only basic sustenance for family of four, but also provide for social amenities like education, health, recreation etc. *Dearness allowance* was first conceptualized after First World War subsequent to the steep and uncontrolled increase in cost of essential household commodities, the basic idea being to offset the rising cost of living by giving some additional monetary relief over and above the basic wage.

*The flat rate system* of DA administration provides a one-time standard payment to the employee to offset the inflation. On the other hand, the *consumer price-linked system*, though complex is more realistic because it attempts to offset the actual increase in cost of living. In one form of DA based on consumer price-linked index, a specified rate of DA is determined for every point increase in consumer price index, irrespective of the income, and thus employees of all pay-scales get the same amount of DA, thereby giving higher proportion of basic wage as DA to the lower paid employees. The other system is based on income groups where the actual DA admissible (as a proportion of basic pay) steadily reduces with each higher income group.

## The Concept of Social Security

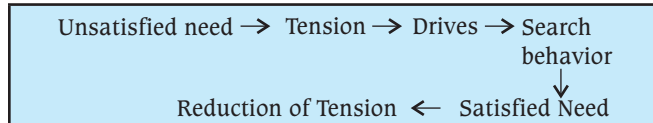
Social security programs are essentially instruments of social and economic justice and forms one of the major pillars of a welfare state such as ours. The International Labour Organisation (ILO) has defined social security as "the protection which society provides for its members through a series of public measures, against the economic and social distress that otherwise would be caused by the stoppage or substantial reduction of earnings resulting from sickness, maternity, employment injury, unemployment, invalidity, old age and death, the provision of medical care, and the provision of subsidies for families with children".

In India, a number of legislative measures such as 'The Workmen's Compensation Act 1923', 'The Employees' State Insurance Act 1948' etc have been passed as social security measures, which are described in the section of occupational health.

## Motivation

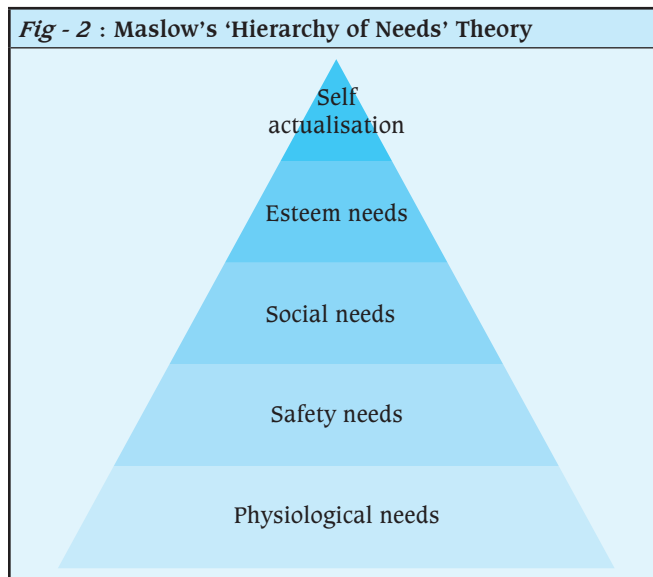
As a doctor and manager of men, you are often faced with a situation where one wonders about "what is motivation"? We may erroneously label people who have no motivation as 'lazy'. Today we know that motivation is the result of interaction between the individual and the situation. We may get easily bored reading a textbook but may finish an interesting novel in

a single sitting. Motivation can be defined as the willingness on the part of an individual to exert extra effort for attaining organizational goals, which is determined by such an effort's ability to satisfy some individual need (tangible or intangible). In short, when an individual is motivated, he 'tries hard'. But this effort has to be also channelised in the direction that would benefit the organization. Therefore, motivation is dependent both on the intensity and quality of the effort. In addition, there is also a component that satisfies some tangible or intangible 'need' in the individual. The motivation process can be summarized as :



## Theories of Motivation

**1. Maslow's 'Hierarchy of Needs' Theory** : Abraham Maslow postulated that a hierarchy of five needs exists inside every human being, which are (Fig - 2) :



- (a) *Physiological needs* such as hunger, thirst, sex, shelter & other bodily needs.
- (b) *Safety needs* like protection from physical & emotional harm.
- (c) *Social needs* like needs for affection, belonging & acceptance etc.
- (d) *Esteem needs* including internal needs (self respect, autonomy & achievement) and external needs (status, recognition and attention).
- (e) *Needs for self actualization* i.e. to become what the individual is capable of becoming, achieving one's full potential & self fulfillment.

According to Abraham Maslow, from motivational viewpoint, if a need is substantially satisfied, it ceases to motivate a person and he moves on to the next plane of hierarchical need. Maslow's theory of hierarchy of need was widely accepted initially but has not been validated by research, which has

shown that need structures are not necessarily organized as proposed by Maslow and that satisfied needs at a particular level may not necessitate movement to the next level.

**2. Theory X and Theory Y** : Proposed by Douglas McGregor, this theory broadly divides human being into inherently negative (Theory X) and inherently positive (Theory Y) individuals. Under 'Theory X' the basic assumptions are that individuals are inherently dislike work, will attempt to avoid it whenever possible and hence must be coerced or threatened with punishment to achieve organizational goals, since they inherently dislike work. 'Theory Y' in contrast, proposes that the individuals would inherently consider work to be as natural as rest or recreation and will naturally exercise self control if they are committed to the organisational goals.

When McGregor's theory is superimposed on Maslow's Hierarchy of Needs theory, it is evident that Theory X assumes that lower-order needs such as physiological needs and safety needs dominates individuals whereas Theory Y assumes that higher order needs dominate individuals.

**3. Herzberg's Motivation-Hygiene Theory** : Fredrick Herzberg, after asking workers for situations when they felt exceptionally good or bad about their jobs, came to the conclusion that certain variables (intrinsic factors like achievement, recognition, responsibility & growth) are always related to job satisfaction and certain variables (extrinsic factors like company policies, administration, interpersonal relations and working conditions) are always related to job dissatisfaction. According to him, factors responsible for job satisfaction are distinctly different from those that are responsible for job dissatisfaction. Hence, when managers remove the factors responsible for job dissatisfaction, workers are merely placated rather than motivated in the true sense. Herzberg emphasized that if we want to truly motivate individuals, focus should be on achievement, recognition, responsibility and growth, which individuals find inherently rewarding and motivating.

## Summary

Since all organisations are made up of 'people', acquiring their services, developing skills, motivating people for high levels of performance and maintaining their commitment towards organizational goals are essential in achieving these goals. Personnel management is the functional front of Human Resource Development HRD in any organisation. Thus, personnel management is concerned with employees as individuals as well as groups, covers all levels of employees, aims to help employees to develop their potential to the maximum, inherent and continuous process in any organization, and attempts to obtain willing cooperation of all employees to achieve the organizational goals. The functions of personnel management include the following : Planning of the manpower requirement; Recruitment; Organising manpower resources; Selection; Classification of employees; Staffing; Transfer & promotion; Manpower development; Training; Motivation; Recreation; Communication; Collective bargaining; Employee discipline; Performance evaluation; Employee counseling. Employee compensation and wages paid to employees are the foremost issues for any manager. Over a period, these issues have become more complicated with the involvement of legislature,

issues of equity and justice and also national economy. The wages for employees, which was initially only an issue decided by the employer, is now an inescapable component of the socio-economic texture of a country.

Social security programs are essentially instruments of social and economic justice. The International Labour Organisation (ILO) has defined social security as “the protection which society provides for its members through a series of public measures, against the economic and social distress that otherwise would be caused by the stoppage or substantial reduction of earnings resulting from sickness, maternity, employment injury, unemployment, invalidity, old age and death, the provision of medical care, and the provision of subsidies for families with children”. In India, a number of legislative measures such as ‘The Workmen’s Compensation Act 1923’, ‘The Employees’ State Insurance Act 1948’ etc have been passed as social security measures.

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organization. Therefore motivation is dependent both on the intensity and quality of the effort. In addition, there is also a component that satisfies some tangible or intangible ‘need’ in the individual. The Theories of Motivation which explain the concept are Maslow’s ‘Hierarchy of Needs’ Theory, Douglas McGregor’s Theory X and Theory Y, Herzberg’s Motivation–Hygiene Theory.

### Study Exercises :

**Short Notes :** (1) Personnel management (2) Human Resource Development (3) Motivation (4) Social security.

### MCQs

1. Strategy for the acquisition, utilization, improvement and presentation of human resource of an organization is (a) Manpower Planning (b) Recruitment (c) Employee counseling (d) Collective bargaining.
2. According to which theory, from motivational viewpoint, if a need is substantially satisfied, it ceases to motivate a person and he moves on to the next plane of hierarchical need (a) Abraham Maslow (b) Mc Gregor (c) Herzberg (d) None.

**Answers :** (1) a; (2) a.

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## Financial Management

*Anuj Bhatnagar*

Accounting is defined as the “art of recording, classifying and summarizing in a significant manner and in terms of money, transactions and events which are financial in nature, and interpreting the result there of”. Accounting can also be described as “the process of identifying, measuring and communicating economic information to permit informed judgments and decisions by the user”.

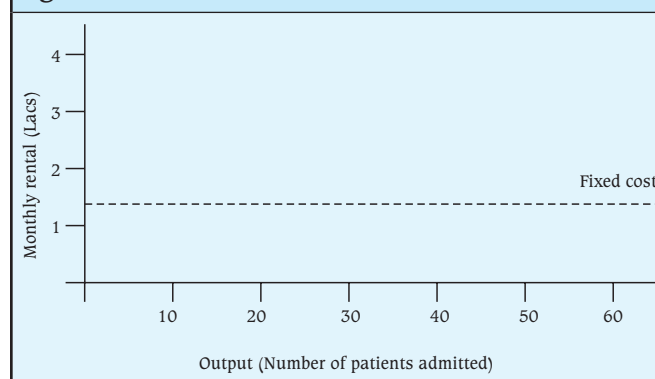
### Concepts of Costs

‘Cost’ can be described as the amount of expenditure (actual or notional) incurred on a thing. For example if a printer prints a book by spending Rs 1000/- on paper, Rs. 500/- on printing ink and Rs. 100/- on its binding, the cost to the printer is said to be Rs. 1600/-. The elements of a cost are :-

#### Fixed Cost

Fixed costs (Fig - 1) are the costs which remain constant and do not depend of the amount of output for example, if a hospital pays Rs.1.5 lac per month as rent for the premises, this amount is constant and has to be paid even if no patient is admitted in the hospital in the entire month.

**Fig - 1**



**Fixed costs can be broadly divided further into :**

- (i) **Committed Fixed Costs** which are fixed costs that result from the possession of infrastructure such as building and equipment or services to be rendered. For example, once a hospital has been set up, the management has committed itself to paying property tax, salaries of health care providers, depreciation of value of equipment etc.
- (ii) **Discretionary Fixed Costs** also called ‘managed’ or ‘programmed’ fixed costs, are costs that are fixed for a specified period by management through their budgeting

process. For example, costs involved in Research & Development, social donations etc have no link with the quantum of output, can be even abolished completely and reflect the policies of the top management.

### Variable Costs

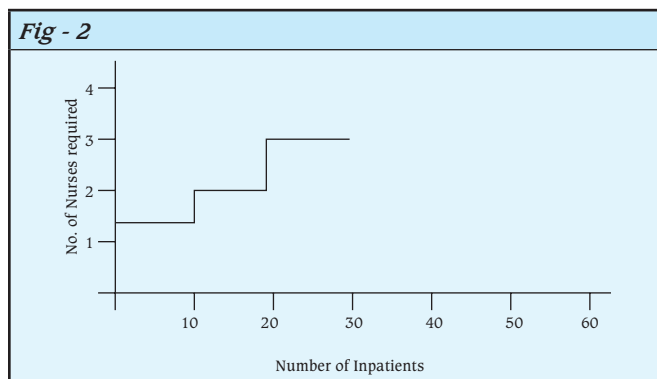
Variable costs are costs which are directly dependent on the quantity of output, such as cost of direct labour, direct material etc. For example, if Rs 200/- are required for a film by a Radiologist to undertake one X ray, Rs 4000/- would be required for 20 films to undertake 20 radiographs by the same radiologist. This type of direct proportionate variation in cost is constant per unit of output

### Semi Variable Costs

Semi variable costs are the cost which vary with the quantum of output but not in direct proportion, such as electricity bill, telephone bill etc.

### Step Costs

Under some circumstances, the cost remains fixed for a range of time period or for certain quantum of output and then steps up to the next level of cost. For example, it may take one nurse to provide nursing care to 10 indoor patients. However, as soon as the number of in-patients rise to beyond 10, a second nurse is required to be employed, as depicted in Fig - 2 :



### Shut Down Costs

Shut down costs are the fixed costs that are incurred by the organisation even when it is shut down and no production / service is produced / rendered. For example, even if a MRI centre is temporarily shut down for a period of one month due to any reason, it would still have to pay the rent for the premises, insurance for the equipment etc.

### Sunk Costs

Sunk costs are the costs incurred in the past due to past decisions, which can not be reversed or recovered by any subsequent decisions. For example let us assume that a hospital invests an amount of Rs. 10 lac in an X Ray machine with the expectation of earning an income of Rs. 9 lac over a period of next 10 years. However, immediately after procurement of the machine, it was realized that the machine should not have been bought in the first place and it can be immediately re-sold for Rs. 9.5 lac. When the hospital administrators have to take a decision whether to sell the machine or not, the original cost of Rs. 10 lac would not be considered since it is 'sunk cost'. Hence

the hospital should sell the machine immediately and recover at least Rs. 9.5 lac.

### Controllable Cost

Controllable cost is the cost which can be influenced (controlled) by the intervention of any member of the organisation. For example, the cost of expired medicines can be controlled in a hospital if the pharmacist is careful in inventory control and issues the medicines well before their expiry date.

### Uncontrollable Costs

Uncontrollable costs are those that can not be controlled by the initiative of an individual. For example, the pharmacist may be able to control cost of expired medicines but he shall have no control over the unwanted medicines prescribed by an overzealous medical officer. Thus controllable costs are controllable at a particular level of management while being uncontrollable at other levels.

### Differential Cost

Differential cost is used for assessing the suitability of an alternative out of many alternatives, since it indicates the difference in total cost involved between two or more alternatives. When an alternative option results in an increase in total cost involved, it is called '*incremental cost*' and when it involves a decrease in total cost, it is called '*decremented cost*' and is used to assess the profitability of an option out of many alternatives available.

### Out-of-Pocket Cost

Out-of-pocket cost are the cash expenditures which would be incurred or saved, based on a decision. Let us assume that a hospital decides to shut down its own MRI centre and decides to out-source it to a nearby existing private MRI centre. The hospital management should ideally take into consideration the cost of electricity, salary of its own operators, rent for premises that the hospital would be saving if it decides to out-source. However, the initial cost of the MRI machine (sunk cost) and depreciation of the machinery would not be considered in this case.

### Opportunity Cost

Opportunity cost can be described as the cost of foregoing an opportunity in favour of another alternative. For example, if a building originally planned and constructed for a PHC is used as a community centre, the planners must consider the 'opportunity cost' of not providing primary health care to an entire village, the disease burden and morbidity/mortality resulting from the lack of primary health centre (PHC) in the area.

## The Concept of Marginal Cost

The "traditional" Costing Technique (also called "Absorption" or "full cost" method) is a method of ascertaining the cost of a product or service (to the manufacture / provider) by identifying and taking into account both the *variable costs* (direct labour & materials etc) (which are directly attributed to each unit of finished product) and the *fixed costs*, (which are allocated proportionately to different products produced during the given time period). A certain amount of 'profit' is added to this total cost (variable cost + fixed cost) to arrive at the '*price*' (fixed



cost + variable cost + profit) of a product/service. However, absorption costing technique has the disadvantages that prices are assumed to be dependent only on costs, only past costs are considered which may not be appropriate for deciding the price currently and demand is not taken into consideration which fixes the price of a commodity/service (in other words the amount that the community members are willing to spend on that item) in a community. In order to overcome these disadvantages, 'marginal costing technique' is adopted.

Marginal cost can be defined as "*the amount at any given volume of output by which aggregate costs are changed if the volume of output is increased or decreased by one unit*". This would entail an increase (or decrease) in the cost when the output increases (or decreases) by a single unit. Ordinarily, marginal cost is considered to be equal to the increase/decrease in total variable cost only because within the existing capacity, increase or decrease of a single unit of output would have a negligible or no impact on the fixed cost and any change in cost would only be due to variable cost such as direct labour & material used to produce that single unit.

### Break Even Analysis

Break Even Analysis is an important financial tool to determine the level of production (output) where the total cost to producer equals the total revenue from sales. This is important for any organisation because it would indicate the probable profit at any given level of output. Thus, break even analysis is used by financial experts to establish the relationship between cost of production incurred by the producer, volume of production and profit and sales volume.

### Break Even Point (BEP)

BEP refers to the level of output where the revenue from the business would exactly equal its expenditure (cost to the producer). Thus, when the output reaches the BEP, it is a point of 'No profit, No loss'. If the production is now increased to beyond this level, profit would be accrued and if the production level is reduced beyond this BEP, loss shall be incurred.

## Budgeting

The word 'budget' derives its origin from a leather 'pouch' or leather bag in which the Chancellor of exchequer of Great Britain carried the government's statement of anticipated financial needs & available resources, to be presented to the Parliament. A 'budget' is thus the anticipated receipts and available resources of an organisation during the given year, and is the basis of all financial decisions during the year.

A budget can be defined as a statement of future plans described in quantitative and monetary terms, for a specific period of time, which is usually one year in case of financial budgets. It can also be defined as a financial statement, prepared and approved by the management in advance for a period of time, which determines all future actions of the organisation.

Like any other organisation, a systematic approach to financial planning is required to manage any health care establishment and budget is an important tool in the hands of a trained health professional. Financing in health care sector is presently in its nascent stage in India and it is imperative that all health care professionals and those associated with health have a sound

knowledge of budgeting and health care financing. It must be realized that a budget for health care establishment has to be also prepared and approved in advance, has to be based on the long term strategy, has to focus on future and is expressed in monetary term. Advantages of budgeting are as in Box - 1.

<b>Box - 1 : Advantages of budgeting</b>	
Every healthcare professional should also be aware of advantages of budgeting, which are as under:-	
(a)	Budgets are effective means of communicating the future organizational plans to all people, in monetary and financial terms.
(b)	A pre-decided and approved budget serves as an effective benchmark for monitoring the ongoing operations.
(c)	Budgeting reduces wastage and losses by identifying wasteful expenditures well in advance and rectifying them.
(d)	Budgets, when drawn up through participation, encourage, and develop team spirit and collective responsibility towards excellence.
(e)	Budgets form the basis for assessing the performance of senior managers in any organisation.

### Types of Budgets

Budgets are broadly classified on the basis of time, function and flexibility, as under :

#### Time-based Budgets

- Long term budgets which are financial estimates and planning for more than five year duration.
- Short term budgets which pertain to financial planning for up to one year duration.
- Current budgets pertain to very short term periods.
- Rolling (Progressive) budgets wherein some duration of advance budget will always remain. In this scheme after a quarter passes, the financial figures for that period are dropped and a new budget is prepared for the next 12 month period.

#### Function-based budgets

- Sales (Revenue) budgets are the basis for developing most other budgets, especially in commercial and profit-based organisations. Sales budgets are developed based on the anticipated sales volume that are to be achieved in a given time period.
- Production (Expenditure) budgets are based on the expected expenditure under various heads such as materials requirement, material procurement, labour, overheads and research.
- Capital based (Planned) budgets have to be drawn up for earmarking financial resources for new proposed projects, such as setting up of a new ICU or a Cobalt Therapy Unit for a hospital.
- Operation budgets (Non-Plan budgets) are the financial outlays for routine and operational running of an organisation, and are generally short term in nature.
- Cash budgets are financial plans which indicate the expected cash inflow and cash outflow over a given period

of time, in an organisation. These are comparisons of income in cash and cash disbursement undertaken by an organisation and are helpful by preventing unwanted accumulation of large amounts of cash, determining future cash requirements and providing better control over liquidity of an organisation during the budget period.

- (vi) Research budgets are financial plans for undertaking research and development activities & allocation of financial resources for innovation, developing new products and services. Unlike budgets allocated for fixed costs, research budgets reflect the mindset of a top management and may be increased or decreased depending on the policies of top management.
- (vii) Master budget is an amalgamation of all organizational budgets and indicates in detail the planned working of all departments in financial terms. The master or the final budget may be presented in the form of a balance sheet, fund flow statement or a profit & loss statement at the end of the budget period.

#### Flexibility-based budgets

- (i) Fixed budgets are prepared in advance based on a standard level of output or activity and do not change mid-way with a change in level of output. Let us assume that a budget for a PHC has been drawn up to provide primary health services to a population of five lakh people in that area. This kind of fixed budget will then be unable to accommodate any changes if it is realized that the population is seven lakh instead of five lakh and hence performance of the health care facilities can not be accurately measured since the actual services rendered will not match the budgeted quantum of services to be rendered.
- (ii) Flexible budgets are the financial outlays which are planned in such a way that they can change with the level of output/activity. In this, the fixed cost and variable costs are taken into account and a flexible budget drawn up. Let us assume that a hospital has to draw out a financial budget for maintaining an ICU, assuming the following :

Fixed cost for maintaining the ICU = Rs 5,00,000 per month

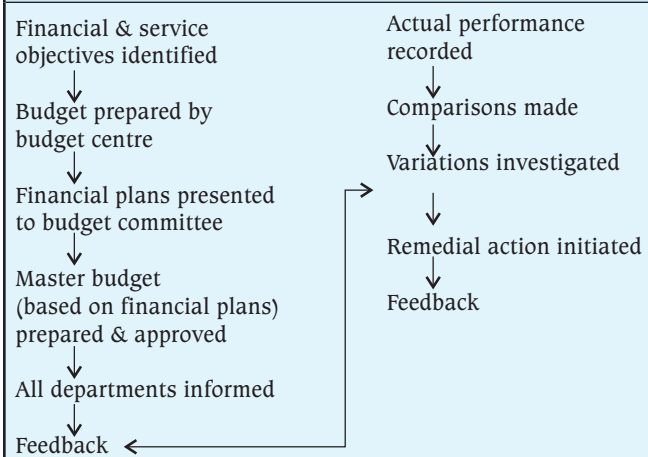
Thus, it is seen that to maintain an ICU of 10 beds, it would need Rs 15, 00,000/- whereas to maintain an ICU with 5 beds, the hospital would need Rs 10,00,000/-.

Flexible budgets are better indicators of actual performance since the actual and proposed levels of activity are matched beforehand while preparing the financial outlay and finances are allocated accordingly. Procedure for budgeting is outlined in Box - 2.

#### Approaches to Budgeting

**Incremental approach :** It is a process of budgeting where the previous year's expenditure is applied to the next year with additional components of increased salaries and cost of materials. Though widely followed for most public health expenditures being simple to understand, incremental budgeting however assumes that all activities carried out in the last year are essential, were most cost-effectively carried out and still remain more important than the new proposed activities. Thus under this scheme, only the increment over the previous year's budget is actually justified for the present duration.

#### Box - 2 : Procedure for Budgeting



Incremental budgets have been often described as “an elephant with muscles of a mouse and brains of an amoeba” since it does not promote operational efficiency due to following major disadvantages :-

- (i) Wasteful expenditures of previous years are again included for drawing up financial outlays of the next year.
- (ii) Alternative better options for achieving the same objectives are not even considered since it is assumed that previous year's actions are still essential and most cost-effective.
- (iii) Main problem areas, wasteful expenditures and priorities are not ascertained before drawing up the budget.
- (iv) Decisions taken regarding the amount of financial outlays for any given year are arbitrary and not based on any justifiable reasoning.
- (v) There is no linkage between inputs and outputs and it is assumed that cost efficiency of all past activities would remain same in future years.
- (vi) Administrators of various departments often tend to inflate their proposed individual budgets, since no detailed justification is sought along with the proposal.

**Performance budgeting (Program budgeting) :** It is defined as “the process of analyzing, identifying, simplifying and crystallizing specific performance objectives of a job to be achieved over a period of time”. Developed and adopted in 1949 in USA, it lays more stress on precise detailment of a job to be done or services to be rendered. A performance budget thus presents the actual operations undertaken by an organisation, department-wise, in terms of functions, activities, projects and programs. In order to undertake performance budgeting, it is essential that objectives should be clearly defined and financially feasible & activity classification should be done logically into distinct department. Such budgeting procedure is better than the traditional system; it involves the evaluation of actual performance of the organisation in terms of departmental and organizational objectives, provides a definite direction to efforts of every employee and is a useful control tool for higher managers. It is upto the departmental head usually to prepare the periodic performance reports (required for performance budgeting) which compare the budgeted actual performance (in terms of output, production or services rendered) with the aim to detect any deviations at the earliest possible.

**Zero Based Budgeting (ZBB)** : With both traditional (incremental) budgeting and performance (program) budgeting, it was increasingly realized that scarce resources were not being optimally utilized, wasteful expenditures were not being identified, decision making was often irrational, budgets tended to be over inflated by managers and there was very little relationship between the expenditure and the results obtained. Thus, need was felt to further improve the budgeting procedure with the view to utilize the scarce financial resources in the best possible manner. Zero Based Budgeting (ZBB) is defined as “the planning and budgeting process which requires each manager to justify the entire budget in detail from ‘scratch’ (‘zero base’) thereby making it the responsibility of each manager to justify why he should spend any money at all during the budget period.” Under zero based budgeting, an organisation should not only decide about financial allocation to new programs & plans but must also review the existing & old programs, especially which involve a high degree of discretionary costs such as research & development programs, newer vaccine initiatives etc. Under ZBB, therefore, the proposer of an activity must justify before each budget that the activity proposed is essential, cost effective and must detail the output levels expected. No activity or action is financed simply because it was done in the past and the entire program must be justified each time a budget is being drawn up. Advantages and limitations of ZBB are given in Box - 3.

**Box - 3 : Advantages and limitations of ZBB**

Advantages
Based on cost benefit analysis. No arbitrary decisions are taken.
Allocation of scarce financial resources is strictly based on priority of programs/ actions.
Links the budgets to organizational objectives & performance by not financing those activities which though carried out in the past, now do not contribute to the overall objectives or are not carried out cost effectively.
Complements the concept of ‘Management By Objectives.’ (MBO)
Ensures that only essential projects and activities are undertaken by the managers.
Identifies areas of wasteful expenditure, problem areas and key result areas for an organisation.
Limitations
Initial planning stage before each budget requires greater effort and time by all departmental heads.
Less applicable for those activities which do not have a direct and tangible cost-benefit relationship such as immunization programs or public health programs for supplying safe water and sanitation to villages.
Identification of decision variables in case of non-tangible benefits such as public health programs invariably require complicated managerial processes.

## Financial Control in Health Settings

Financial control is as important in health care settings as in any other field. In addition, the issue is complicated by the intangibility and often non-measurability of the product (ie health care rendered and the result thereof). Financial control in a health setup would include a proper accounting system for funds, equipment and expendables; laid down standards of performance against which actual performance would be measured and regular audits of performance. Some important tools used for exercising financial control are as under :-

### Budgets

Budgets are an important tool in the hands of a health manager because they lay down the expected standards of performance against which the actual performance is measured to identify the variations. Operational control in any organisation can only be exercised when actual performance is compared and evaluated with some pre-decided standards and remedial actions instituted to correct any deviations from the expected & pre-determined standards.

### Hospital Statistics and Cost Control

The most important hospital statistic from the point of view of financial control is ‘patient day’ which is defined as ‘the number of patients to whom in-patient services have been provided in a healthcare setup between two successive census’. The performance of the hospital as a whole and that of individual departments can be ascertained by calculating the ‘cost per patient-day’ as under :

$$\text{Cost per patient day} = \frac{\text{Total expenditure by hospital}}{\text{Total number of patient-days}}$$

Similarly, department-wise or bed-wise cost per patient-day can also be worked out, which indicates the performance of the department or a ward.

**Other indicators** which may be used as financial control tools in a health care set up are :

- Hospital census** : The total number of in-patients occupying beds in the hospital at a particular time.
- Bed occupancy** : is calculated by patient days divided by bed-days multiplied by 100 and indicates the future expansion needs of a hospital.
- Average length of hospital stay** : indicates the average time spent by a patient in a hospital and when compared with other similar hospitals, is an indicator of performance of that hospital.

### Financial Statement Analysis and Control

They are important tools for financial control in any organisation and are broadly of the following variety :-

**(i) Balance sheet** : indicates the financial state on a given date (which may be the last date of the month) and by showing ‘assets’ and ‘liabilities’ the organisation, it shows what the organisation owns (assets) and what it has to give to others (liabilities). In case of a health care establishment, the assets may be ‘fixed assets’ (such as buildings, land, furniture, ambulances, medical equipment etc) or ‘current assets’ (such as cash in bank, hospital bills receivable from patients, medicines and expendables in current stock etc). On the other hand,



the liabilities in case of a hospital may be 'current liabilities' (like electricity/telephone/property bills payable), 'long term liabilities' (such as loan taken from bank initially to set up the hospital/buy equipment) and 'special funds' such as funds earmarked for training or disaster management.

**(ii) Income and expenditure statement :** In contrast to balance sheet (which is the financial state on a given single day), income and expenditure statement of an organisation is the record of all financial transactions of the organisation over a given period of time. In case of a health care setup, the inflow of finances (income) may be in form of payment by the patients for various medical and support services, grants and charity donations, interest on bank deposits and other investments. On the other hand, expenditures would be in the form of salaries of health care providers and ancillary staff, inventory costs, payment for amenities such as electricity, water, telephones etc.

#### Income statement vs Balance sheet

The income statement is a record of all financial transactions of an organisation over a period of time (which may be taken as a year or a month) whereas the balance sheet depicts the final assets and liabilities of an organisation at the end of a period of time (which may be on the last day of the month or year at a point of time).

**(iii) Cash flow statement :** is also a type of financial statement used for financial control by managers, wherein cash inflow from the three major activities (operations, investments and financing) are summarized.

**(iv) Funds flow analysis :** records the various sources of funds available to an organisation and the usage of these funds over a given period of time. For the survival of any organisation, it is important to be able to finance the various operations and assets through appropriate sources and hence the importance of identifying and recording all possible sources from where funds are obtained.

**(v) Liquidity ratios :** are a form of financial analysis which indicates the utilization of cash and the ready availability of cash for future payments in an organisation. Current ratio is a ratio of current assets to current liabilities and indicates proper management of cash (current ratio of more than one) or possible shortage of cash for payments in the near future (current ratio less than one). The current ratio can be made more accurate by excluding the inventories (which are not considered 'liquid' or easily available in terms of cash) so as to provide the Quick Ratio (Acid test ratio)

$$\text{Quick ratio} = \frac{\text{Current assets} - \text{Inventories}}{\text{Current liabilities}}$$

## The Concept of Audit

Auditing is a financial process undertaken as a *verification process based on past records, assessed against a set of predetermined rules, regulations and standards*. Thus, audit is undertaken to ascertain that all financial transactions during a given past period were undertaken as per the rules and regulations. *Auditing* has been defined as "An examination of

accounts and records undertaken with a view to ascertain if they completely and correctly reflect the transactions to which they relate and to ascertain that the transactions themselves are supported by the competent authority wherever required" (Lawrence R Dicksee). Box - 4 lists out the special issues involved in audit of a healthcare establishment.

#### Box - 4 : Special issues involved in audit of a health care establishment

It must be remembered that the financial audit of a health care establishment differs from a routine audit of any other organisation, primarily since hospital activities are fundamentally different from any other commodity or service based activity. Hospitals do not produce or sell a commodity, but render medical care which is highly personalized and varies from patient to patient. Any auditor therefore should keep in mind the following aspects while auditing services of a hospital :

- Essential documents governing the policies of a hospital like the constitution of the hospital, the rules and regulations regarding employing health care professionals and ancillary staff, the policy regarding admission of patient and their treatment etc should be examined in detail.
- Comparison of figures of corresponding periods of two years can not be relied upon to detect internal discrepancies, since the services rendered by a hospital are highly unique & not standardized.
- It must be ensured through hospital records (like bed occupancy report, daily admissions/ discharge summary etc) that all services rendered have been correctly billed and recorded.
- Transactions must be recorded and completed promptly because after a patient is discharged from the hospital, the charges against services not recorded remain un-recovered.
- Procedures for recording and taking 'on charge' any gifts, grants and donations to the hospital should be in place and should be followed.
- Authority to allow discounts to patients should not be vested with the people concerned with billing and all discounts should be properly recorded.

Audit can thus be said to be financial tool undertaken to check the arithmetic accuracy of account records, check the relevant supporting documents like vouchers, sanction noting, invoices, bills etc.; check the balance sheets prepared by verifying all entries and assets & liabilities recorded with the aim to appraise the management of any discrepancies noted. Even though audit is carried out for ensuring completeness, correctness and honesty in financial transactions, an auditor's ultimate aim remains to detect clerical errors in accounts by checking the past records of accounts. Audits are based entirely on past documents and the actual circumstances under which the financial documents had taken place are not known to the auditors.

## Summary

Accounting is defined as the "art of recording, classifying and summarizing in a significant manner and in terms of money, transactions and events which are financial in nature, and



interpreting the result there of". 'Cost' can be described as the amount of expenditure (actual or notional) incurred on a thing. The elements of a cost are Fixed costs (remain constant and do not depend of the amount of output); Variable costs (directly dependent on the quantity of output); Semi variable costs (vary with the quantum of output but not in direct proportion); Step costs (remains fixed for a range of time period or for certain quantum of output and then steps up to the next level of cost.); Shut down costs (fixed costs that are incurred by the organisation even when it is shut down and no production / service is produced / rendered); Sunk costs (incurred in the past due to past decisions, which can not be reversed or recovered by any subsequent decisions); Controllable cost (influenced by the intervention of any member of the organization); Uncontrollable costs (can not be controlled by the initiative of an individual); Differential cost (indicates the difference in total cost involved between two or more alternatives); Out-of-pocket cost (incurred or saved, based on a decision) Opportunity cost (the cost of foregoing an opportunity in favour of another alternative).

Marginal cost can be defined as "the amount at any given volume of output by which aggregate costs are changed if the volume of output is increased or decreased by one unit". This would entail an increase (or decrease) in the cost when the output increases (or decreases) by a single unit. Ordinarily, marginal cost is considered to be equal to the increase/decrease in total variable cost only.

Break Even Analysis is an important financial tool to determine the level of production (output) where the total cost to producer equals the total revenue from sales. It is used by financial experts to establish the relationship between cost of production incurred by the producer, volume of production and profit and sales volume. Break Even Point (BEP) refers to the level of output where the revenue from the business would exactly equal its expenditure (cost to the producer). Thus, when the output reaches the BEP, it is a point of 'No profit, No loss'.

A budget can be defined as a statement of future plans described in quantitative and monetary terms, for a specific period of time, which is usually one year in case of financial budgets. It can also be defined as a financial statement, prepared and approved by the management in advance for a period of time, which determines all future actions of the organisation. Like any other organisation, a systematic approach to financial planning is required to manage any health care establishment and budget is an important tool in the hands of a trained health professional. Budgets are broadly classified as Time-based Budgets (Long term, Short term, Current, Rolling/Progressive budgets); Function-based budgets (Sales /Revenue, Production /Expenditure, Capital based/Planned, Operation/Non-Plan budgets, Cash, Research, Master Budgets); Flexibility-based budgets (Fixed and Flexible). The approaches to Budgeting are Incremental approach, Performance budgeting (Program budgeting) and Zero Based Budgeting (ZBB).

Financial control is important in health care settings as in any other field. Financial control in a health setup would include a proper accounting system for funds, equipment and expendables; laid down standards of performance against which actual performance would be measured and regular audits of performance. Some important tools used for exercising financial control are Budgets, Hospital statistics and cost control (like Cost per patient day, Hospital census, Bed occupancy, Average length of hospital stay), Financial Statement Analysis and Control (like Balance sheet, Income and expenditure statement, Cash flow statement, Funds flow analysis, Liquidity ratios). Auditing is a financial process undertaken as a verification process based on past records, assessed against a set of predetermined rules, regulations and standards. The financial audit of a health care establishment differs from a routine audit of any other organisation, primarily since hospital activities are fundamentally different from any other commodity or service based activity and render medical care which is highly personalized and varies from patient to patient.

## Study Exercises

**Short Notes :** (1) Types of costs (2) Break Even Analysis (3) Medical Audit (4) Tools for financial control in Health care setting.

### MCQs

1. The cost incurred in the past due to past decisions, which can not be reversed or recovered by any subsequent decisions is (a) Semi variable costs (b) Step costs (c) Sunk costs (d) Uncontrollable cost.
2. The process of analyzing, identifying, simplifying and crystallizing specific performance objectives of a job to be achieved over a period of time is (a) Incremental approach of budgeting (b) Program budgeting (c) Zero based budgeting (d) Flexible budgeting.
3. The planning and budgeting process which requires each manager to justify the entire budget in detail from 'scratch' is (a) Incremental approach of budgeting (b) Program budgeting (c) Zero based budgeting (d) Flexible budgeting.
4. The record of all financial transactions of the organisation over a given period of time is (a) Balance sheet (b) Income and expenditure statement (c) Cash flow statement (d) Funds flow analysis.
5. A financial process undertaken as a verification process based on past records, assessed against a set of predetermined rules, regulations and standards is (a) Budgeting (b) Accounting (c) Auditing (d) Analysis.

**Answers :** (1) c; (2) b; (3) c; (4) b; (5) c.

Anuj Bhatnagar

## Logistics Management

Logistics management is defined as “the systematic and scientific process of planning, implementing and controlling the efficient and effective flow and storage of resources (goods & services) from point of origin to the point of consumption in order to meet the customer's requirements”. Logistics management in a health care set up becomes essential to ensure procurement and provisioning of vital medical supplies at the correct cost, consistency in quality, low storage cost and high turnover of items. In addition, logistics management also ensures proper forecasting & standardization of medical supplies and assists the manager in deciding whether ‘to make’ or ‘to buy’ a facility such as MRI facility to the patients.

One of the important components of logistics management is *materials management* which aims to “coordinate, supervise and execute the tasks of flow of materials to, through and out of an organisation”. It thus ensures a continuous supply of good quality material at the lowest possible price, at the same time keeping the inventory level to minimum so that working capital is not blocked in inventory but without compromising the operations due to shortage of inventory.

### Logistics Management in a Health Care Setup

Any healthcare establishment is heavily dependent on material, equipments and medicines and hence logistics management assumes great importance since availability of the right item, at right time, right place and in the hands of the right person can often make the difference between life and death in a hospital. Broadly, Logistics and materials management involve a large number of activities, which are more sensitive in a hospital because each activity influences & is influenced by other activities. These are listed below and are explained subsequently :

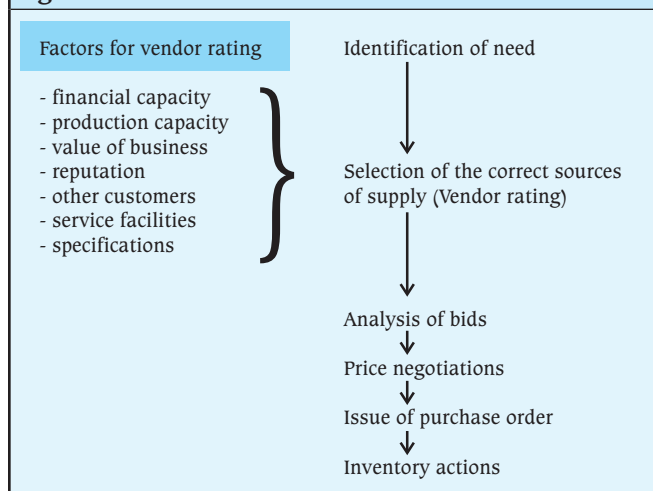
- (a) Tendering, procurement & inspection
- (b) Storage, standardization, codification & classification
- (c) Materials accounting & physical distribution
- (d) Transportation
- (e) Security of materials
- (f) Condemnation and disposal of stores

**(a) Tendering, procurement & inspection :** Any organisation has to resort to purchasing of goods or services (process of actual buying of materials for services) to ensure an uninterrupted flow of materials, a minimum inventory investment and to buy materials / services at a reasonable cost .

Broadly, the steps involved in purchasing are summarized as in Fig-1.

**Concept of Tenders :** Tender buying is resorted to by all govt./ public sector organisations wherein enquiries are floated to various short-listed vendors, for purchases to be done. Tenders may be Open tenders (through advertisement in media) Limited tenders (where bids are called for only from reputed / pre-qualified parties); Simple tenders (where only one firm is asked

Fig. - 1



to submit its rates in writing) and Global tenders (in case of large purchases tenders are often invited from within India and abroad). All govt and public sector undertakings should follow the following steps in the tendering system while undertaking purchases :

1. Specifications of the item to be purchased are established carefully.
2. A vendor list is identified which should have as many vendors as possible.
3. Competitive bids are invited from vendors through an open advertisement, which should also mention the technical specifications of the item, modalities of payment and any other terms & conditions.
4. Bids received are opened in front of representatives of vendors on a pre-notified date and time.
5. Comparative statement is drawn up of the quality, price & support services of those bids which meet the qualifying requirements.
6. Bids are evaluated. Contract is awarded to lowest responsible bidder, who meets the specifications which are pre-determined.
7. Price negotiation with the selected vendor.
8. Issue of purchase order.
9. Supply of items within the stipulated time frame.
10. Inventory action (including inspection and issue to concerned department)

### Types of purchase processes

- (1) Rate contract is the purchase system wherein the rate of an item is determined through a tender system, without specifying the quantity to be purchased. Under running contract system, the minimum quantity to be purchased is specified. Followed by all Govt./ PSU through DG S&D, the system reduces the lead time for the organisation, since purchases are made at pre-determined rates (centrally carried out by the DG S&D).
- (2) Blanket ordering is a contract with a vendor to periodically supply low cost items only on receipt of an authorized release order from the organisation.
- (3) Cash purchases (Imprest purchases) are the purchases made from the open market on strictly need basis and are

usually confined to urgently required but low priced items, required in small quantities.

- (4) System contracting is a form of purchasing which does not involve maintenance of any stocks and inventory by the organisation and where authorized individuals from the organisation can draw low priced materials needed in high quantity directly from a supplier's store.
- (5) Reciprocal purchases involve a policy where two contracting parties purchase their specialized items from each other on a mutual basis.

#### Storage, Standardization, Codification & Classification

(a) **The storage system** : The main function of a storage system is to receive material, check it for quality and quantity, prepare the receipt vouchers, accept the inspected and passed material, undertake documentation for payment of bills, store the accepted material properly and safely, issue required material to various departments on requisition from them, prepare issue vouchers and account for them. Broadly any storage system in an organisation consists of the following sub- systems which work together to cater to the existing demands and also the further growth potential of an organisation :

- (i) Receipt system
- (ii) Maintenance & upkeep system
- (iii) Issue system

(b) **Codification of goods** : One of the basic requirements of an efficient stocking and logistics management system is an effective and scientific system of coding the items, to ensure quick tracing & retrieval and early identification of dead / duplicate stocks. In a health care setting, this task is more complicated since detailed characteristics and nature of large number of drugs available are required to be known for their coding and classification. Ideally, all health care stores should be classified in broad categories (such as pharmacy, X-rays, chemicals, laboratory items, waste disposal, ancillary items etc) and then grouped and sub-grouped logically according to functions and usage. Various systems presently in vogue for codification are described as under :

- (i) *Alphabetical system* (Table - 1)

Table - 1		
Class	Group	Code
Patient bed (PB)	Iron(I), Hydraulic(H)	PB-I-H

- (ii) *Numerical system* (Table - 2)

Table - 2				
Class	System	Generic name with strength	Family of drug	Condition
Drug (01)	Musculo-skeletal (38)	Ibuprofen IP 400mg (08/4)	Tablet (1)	New (1)
In this example, the Code would be : 01-38-08/4-1-1.				

- (iii) *Combined alphabetical and numerical system* (Table - 3)

Table - 3			
Class	Sub group I	Sub group II	Code
Ibuprofen	IP-400	08/4	IP400-08/4

- (iv) *Other Systems* : These include the "*Brisch system*", which is a complex and detailed system wherein a 7-digit unique number is allotted to each item based on its position and value; "*Kodak system*" which is based on numerical system and grouping done based on purchase category of the particular item, with 10-digits. Thus, the code allotted to an item may be depicted as 301-1234-123.

#### Accounting of Stores

**Accounting of materials** : It is essential that in order to demand the optimal material, the stock held with the stores must be accurately known and maintained. This is important to prevent over-ordering of material and is absolutely essential to avoid 'stock- outs', both of which are detrimental to functioning of an organisation. Thus, in order to continuously keep a track of the material available in stock, the following systems are adopted :-

- (i) *Bin Cards* show the daily receipt, issue and balance in hand in the form of cards attached to each bin / shelf containing the particular item. Bin cards can also be suitably and effectively modified to indicate the maximum / minimum permissible stocks and the re-order levels.
- (ii) *Stock identification cards* are identification cards for each item, with details such as material code number, description, ledger folio number etc, kept next to the bin/ rack in order to identify the item completely.
- (iii) *Material requisition slip* is a requisition for the type and quantity of material required by any department from issue counter. When maintained properly it accurately indicates the exact quantity and type of material issued to various departments for various purposes.
- (iv) *Material received note* is a document through which the material received from a supplier is taken on ledger charge. Subsequently the accounts department, based on this document makes the payment to the suppliers.
- (v) *Stores ledger* is a complete record of materials indicating the details such as suppliers' details, price of the item, invoice / bill number and stock levels.
- (vi) *Material return note* : Surplus material lying with various departments are returned to the stores through a 'material return note' which enables the stores to take this surplus material on ledger charge once again and to adjust their stock levels.
- (vii) *Material transfer note* : Surplus material lying with one department may be transferred directly to another department in need of the same material through such a note, by informing the stores.

#### Concept of Flow of Goods and Stores Accounting

Flow of goods (issue of stock) is of utmost importance in any health care setup since the problems of obsolete items, expired medicines and old stocks are faced by every store keeper in a hospital. Such avoidable wastages not only increase the cost of managing a hospital but may also occasionally result in a fatality due to issue of expired and out of date medicine to a

critical patient. The following are some of the methods followed for flow of goods and stores accounting :-

(a) **First In, First Out (FIFO)** : Material from the oldest stock is issued first with the view to turnover the stock.

(b) **Last In, First Out (LIFO)** : Materials which are received last are issued first in this case, but it usually results in poor inventory management and hence is generally not recommended in health care establishments.

(c) **Specific cost method** : Provides the most realistic valuation of inventory stock and physical stock-taking of stores can be done any time of the year. Under this method, values of the material charged off / taken on charge are identical to the material issued / received and hence is the most suitable method of maintaining stocks in commercial organisations.

(d) **Average cost method** : Average cost of each item issued from stores/ received at stores is assessed and this value is taken for maintaining the cost of inventory held by the organisation. Though easy to follow, this method often leads to inaccurate values of inventory in the organisation.

## Inventory Control

Inventory may be defined as “usable but idle resource having an economic value”. It can also be described in financial terms as the sum total value of raw materials; semi processed and finished goods at any given time. When we deal with tangible items such as materials, it is called ‘stock’. The basic issue involved in inventory management is to ensure that adequate amount of raw materials are available to meet the demand of the organisation, while at the same time ensuring that too much inventory is not accumulated and also that there are no ‘stock-outs’ in the organisation. Thus, a well managed organisation would necessarily have a higher inventory turn-over rate and lesser cash would be blocked as inventory/stocks. In order to manage any organisation without affecting its outputs, some amount of ‘inventory’ is necessary so that raw materials are available in correct quantity at correct time. Similarly, in a health care establishment some inventory of essential drugs and supplies has to be maintained to ensure that health care to patients does not suffer.

In any hospital, high quantities of inventory in form of large number of costly drugs and supplies would be detrimental to profitability and smooth running of the hospital due to blocking of cash in form of idle stores, requirement of large storage space for medical stores, substantial handling and transportation charges, pilferage and cost of expired medical stores. The ultimate aim of inventory control in a healthcare setting is to ensure that adequate and optimal essential items are properly stored, controlled, are easily retrievable and distributed to points of uses so that patient care does not suffer due to lack of these essential medical supplies.

### Some Important Economic Terms in Inventory Control

(a) **Purchase cost** is the actual cost paid for the purchase of materials & stores, and the aim should be to reduce this as far as possible without compromising on the quality and quantity of items purchased.

(b) **Inventory carrying cost** are the hidden costs and pertain to maintenance of a large inventory/stock, which lies idle and which blocks the finances of the organisation. Special efforts are required by a manager to identify these carrying costs, since they are often hidden and not easily decipherable. Some such inventory carrying cost are the (i) **Cost of borrowed money** which is the interest paid to a financier or the interest lost which could have been earned, had a large amount of money not been used for purchasing the stock presently held as inventory; (ii) **Cost of space** : which needs to be hired for storage; (iii) **Cost of additional manpower** : by incurring additional expenditure on salaries etc of manpower required to manage the stocks; (iv) **Cost of obsolescence** : All materials, especially hospital supplies, become obsolete, leading to financial loss; (v) **Cost of deterioration** : Supplies when stored for a very long time tend to deteriorate with time, especially crucial hospital supplies like injections, medicines and intravenous medicines etc; and; (vi) **Cost of pilferage** : A large and unmanageable inventory is bound to lead to pilferage and loss to the organisation.

(c) **Ordering Costs** are costs incurred by an organisation in placing an order for some material with a supplier. In case of large orders and government orders, the ordering costs can be substantial if we also include the salaries and time of personnel involved in the purchase procedures, besides the ancillary like paper, stationery etc. At times, a professional expert may also have to be called from abroad or the manager may be required to visit a foreign country to place an order, in which case the ordering cost would also include the travel cost etc.

(d) **Shortage costs** are the ‘direct’ and ‘indirect’ costs paid by an organisation for not having a particular item in ready stock. The impact of this shortage would depend on the criticality of that item and its importance for functioning of the organisation. In a hospital set up, let us assume that there is a sudden shortage of life saving drugs like Digoxin. The **direct cost of this shortage** would be in form of the expenditure incurred by the hospital in procuring these drugs urgently from the open market at a premium. The **‘indirect cost’** would be in the form of adverse publicity, suspended healthcare in form of refusal of admissions and may be a few avoidable deaths due to shortage of those critical drugs.

### Types of Inventory Control

Pareto, a German economist found that in any given city, 20% of the people controlled 80% of the income & 80% of the other people controlled only 20% of the finances of the city. This ‘**Pareto’s law**’ also forms the basis for inventory control, wherein it is theorized that a few items in the inventory will account for a large proportion of total cost whereas bulk of the items will account for only a small percentage of the cost or importance of total inventory. Thus, basic principle of inventory control is based on the effort to closely control costly / critical items in inventory all the time, while other, less important / less costly items could enjoy less stringent controls. Various selective inventory control measures are as under :-



- (a) ABC : Inventory control based on annual total cost of items and not on unit cost of an item. This type of inventory control is described in detail subsequently.
- (b) VED : Based on criticality and importance of consumables, items are classified as Vital (V), Essential (E) and Desirable (D).
- (c) HML : Items are classified based on cost of individual item as High cost (H), Medium cost (M) and Low cost (L). This classification does not depend on consumption of items.
- (d) SDE system is based on the ease of availability of items and items are classified as Scarce (S), Difficult to obtain (D) and Easy to obtain (E).
- (e) GOLF system is based on the source of supply & include Governmental sources (G), Ordinary (O), Local (L) and Foreign (F).
- (f) FSN : Items are classified based on the rate of issue from the stores into Fast- moving (F), Slow moving (S) and Non-moving (N) items.
- (g) SOS is the classification of items based on Seasonal (S) and Off-seasonal (OS) availability.
- (h) XYZ is the classification based on the value of stocks of items held.

An ideal inventory control mechanism would ensure the optimal quantity of resources at all times at all places where they are required for smooth & unhindered operations and would prevent stock- outs and under-stocking. At the same time, a good inventory control system would also prevent over-stocking and blockage of vital finances in form of idle stocked stores. In a health care setup, a good inventory control systems would improve the service delivery and enhance patient satisfaction, reduce the operating (functional) costs of the hospital, increase efficiency and liquidity (cash availability), thereby improving the return on investment (ROI).

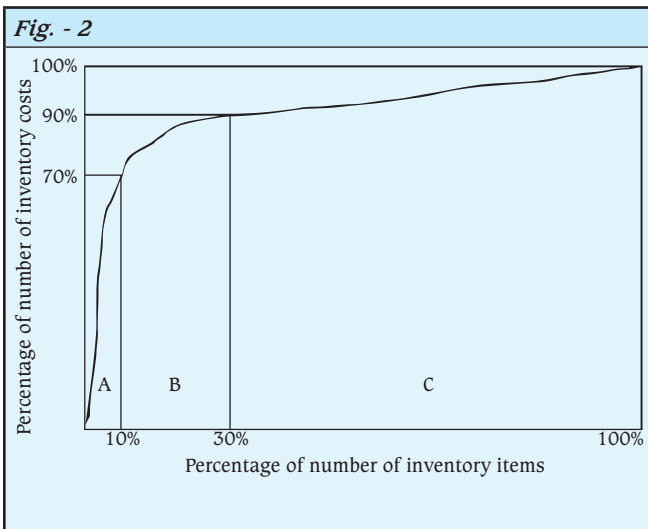
### ABC Analysis

ABC Analysis is based on the principle that generally a small proportion of items account for a large proportion of cost and vice versa (Pareto's Law) and under this system, inventory items are classified based on the total annual cost of the different items. It is usually seen that 10% of the stores would cost 70% of the total resources (Group A items); 20% of the items would cost around 20% of total resources (Group B items) and remaining 70% of items would cost only 10% of the total resources (Group C items).

#### Steps Involved in ABC Analysis in a Hospital

- (a) Consumption cost of each medicine/ item is worked out for the whole year.
- (b) The medical store items are arranged in descending value of their annual cost, the most expensive being at the top and item which is least costly being placed at the bottom.
- (c) The cumulative cost is then calculated and a table is prepared (Table - 4) .
- (d) From Table - 4 above it is seen that about 10 % of items would cost 70 % of total annual cost. These are termed as group 'A' items. The next 20 % items would cost 20 % of total annual cost and these are termed as group 'B' items. The rest of 70 % items account for only 10 % of the total annual cost of all hospital items and these are the group 'C' items. Same is depicted in Fig - 2.

S. No.	Name of drug /Item	Annual consumption cost (Rs)	Cumulative cost (Rs)	% of total cost
01	Inj Ciprofloxacin	9000	9000	9 %
02	Tab Ciprofloxacin	8500	17500	17.5 %
03	Inj Dexamethasone	8300	25800	25.8 %
04	Inj Ampicillin	8000	33800	33.8 %
.....				
10	Inj Streptokinase	5000	70000	70%
.....				
30	Oint Soframycin	1000	90000	90%
.....				
100	Gauze	100	100000	100%



It is thus derived that group A items, which are the costliest should be kept under strict control and should be monitored closely for turnover and expiry. If such costly items accumulate in large quantities in a hospital, they would block scarce finances and lead to high cost of operating the hospital. ABC analysis of inventory leads to certain benefits in form of guidance to the manager about level of control for each type of item, which are summarized in Table - 5.

### VED Analysis

VED analysis is based on the 'criticality' and importance of an item and not merely on the annual cost of consumption of items. Often it is seen, especially in health care settings that a medicine of low cost and low consumption is critical in saving lives and the hospital can not ignore such drugs simply because they fall in group 'C' category (if classified as per their annual cost). For example, Inj Rabipur or Anti snake venom may be used only once or twice in a month and thus have very low annual cost and usage, but these drugs are vital & life saving drugs and have to be available in every hospital at all times.

Table - 5			
Activity	Group A	Group B	Group C
Monitoring	Very strict	Strict	Moderate
Safety stock to be kept	Low	Medium	High
Level of control for issue	Tight	Moderate	Low
Estimates of requirements	Very accurate	Moderately accurate	May be low
Frequency of purchase	Most frequent	Less frequent	Least frequent
Turnover	Maximum	Medium turnover	Least turnover
Management involvement	Top level	Middle level	Lower level

VED analysis of inventory classifies various items into three categories of *Vital (V)*, *Essential (E)* and *Desirable (D)*.

- Vital items (V)* are items like Oxygen which are vital for functioning of a health care establishment and whose shortage will have serious adverse effects on routine functioning of the organisation. Such vital items should be monitored by top management, irrespective of their cost and their availability should be ensured with sufficient stocks available in medical stores.
- Essential items (E)* are the items whose shortage or non-availability can only be afforded for a short time (such as intravenous sets & IV fluids in a hospital) and if their shortage continues for anything more than the shortest time, the functioning would be affected seriously and adversely.
- Desirable items (D)* are those items whose shortage would not affect the routine functioning of an organisation even if the shortage is for a long time (such as Vit E capsules or sun screen lotions in a hospital's medical store).

As highlighted earlier, hospital and medical stores can not be only classified on the basis of their annual cost and annual consumption, since some items may be vital life saving stores even though they are of low cost and low usage. If a hospital inventory is classified only by 'ABC system' based on cost and usage, such vital drugs would invariably fall in group 'C' and would be given least importance. Thus it is felt that in a hospital setting, a combination of ABC analysis (based on annual cost) and VED analysis (based on the criticality of the item) is to be adopted, as under :

- Category I* contains all the vital and costly items, whose shortage may adversely affect the functioning of the hospital or whose over stocking /pilferage may lead to financial loss to the hospital. These items such as Inj Rabipur, Anti snake venom or costly medicines and vaccines should be monitored by a senior manager himself.
- Category II* items are essential but are less costly and can have lesser stringent controls.
- Category III* items are the stores and medicines which are desirable but would not affect the functioning of the hospital

even if they are not available for a long time. In addition this category would also include least costly medical stores which need not be kept under strict control.

## Summary

Logistics management is defined as "the systematic and scientific process of planning, implementing and controlling the efficient and effective flow and storage of resources (goods & services) from point of origin to the point of consumption in order to meet the customer's requirements". Logistics management in a health care set up becomes essential to ensure procurement and provisioning of vital medical supplies at the correct cost, consistency in quality, low storage cost and high turnover of items. Any healthcare establishment is heavily dependent on material, equipment and medicines and hence logistics management assumes great importance since availability of the right item, at right time, right place and in the hands of the right person can often make the difference between life and death in a hospital.

Broadly, Logistics Management in a health care establishment would encompass the activities like Tendering, procurement & inspection; Storage, standardization, codification & classification; Materials accounting & physical distribution; Transportation; Security of materials; Condemnation and disposal of stores. The process of Tendering and Procurement involves Vendor rating, Analysis of bids, Price negotiations, Issue of purchase order and Purchasing. The storage system is to receive material, check it for quality and quantity, prepare the receipt vouchers, accept the inspected and passed material, undertake documentation for payment of bills, store the accepted material properly and safely, issue required material to various departments on requisition from them, prepare issue vouchers and account for them. Codification of goods is to ensure quick tracing & retrieval and early identification of dead / duplicate stocks. It is done by various methods like Alphabetical system, Numerical system, Combined alphabetical and numerical system, Brisch system, Kodak system etc. Accounting of materials is essential that in order to demand the optimal material, the stock held with the stores must be accurately known and maintained. This is important to prevent over-ordering of material and is absolutely essential to avoid 'stock-outs', both of which are detrimental to functioning of an organisation.

Inventory may be defined as "usable but idle resource having an economic value". It can also be described in financial terms as the sum total value of raw materials; semi processed and finished goods at any given time. In any hospital, high quantities of inventory in form of large number of costly drugs and supplies would be detrimental to profitability and smooth running of the hospital due to blocking of cash in form of idle stores, requirement of large storage space for medical stores, substantial handling and transportation charges, pilferage and cost of expired medical stores. The ultimate aim of inventory control in a healthcare setting is to ensure that adequate and optimal essential items are properly stored, controlled, are easily retrievable and distributed to points of uses so that patient care does not suffer due to lack of these essential medical supplies. Various selective inventory control measures

are ABC (Inventory control based on annual total cost of items and not on unit cost of an item); VED (Based on criticality and importance of consumables, items are classified as Vital, Essential and Desirable); HML (Items are classified based on cost of individual item as High cost, Medium cost, and Low cost); SDE system (based on the ease of availability of items and items are classified as Scarce, Difficult to obtain and Easy to obtain); GOLF system (based on the source of supply & include Governmental sources, Ordinary, Local and Foreign); FSN (based on the rate of issue from the stores into Fast-moving, Slow moving, and Non-moving items); SOS (based on Seasonal and Off-seasonal availability); XYZ (based on the value of stocks of items held). ABC Analysis is based on the principle that generally a small proportion of items account for a large proportion of cost and vice versa (Pareto's Law). VED analysis is based on the 'criticality' and importance of an item and not merely on the annual cost of consumption of items.

## Study Exercises

**Short Notes :** (1) Tendering and procurement of medical stores. (2) ABC Analysis (3) VED analysis.

### MCQs

1. The analysis which is based on the principle that generally a small proportion of items account for a large proportion of cost and vice versa is a) ABC analysis b) VED analysis c) HML d) SOS.
2. The analysis which is based on the 'criticality' and importance of an item and not merely on the annual cost of consumption of items is a) ABC analysis b) VED analysis c) HML d) SOS.
3. A contract with a vendor to periodically supply low cost items only on receipt of an authorized release order from the organization is called a) Rate contract b) Blanket ordering c) Cash purchases d) System contracting.

**Answers :** (1) a; (2) b; (3) b.

*Anuj Bhatnagar*

It has been increasingly realized that with increasing complexities of activities and projects being planned and undertaken, the conventional methods of management are no longer adequate to meet the demand of today's projects. With larger and complicated organisations with their own unique organisational and structural issues a need has been felt for better, more effective and innovative managerial methods, some of which are discussed in this chapter.

## Network Analysis

Network analysis is a means of planning and controlling processes. In this, a project is broken up into small operations which are arranged into logical sequence. Thereafter, the order in which these actions are to be performed is decided and a network diagram shows the relationship between the various operations involved. Thus, any network analysis indicates the relationship between various operations involved and also points out which activities are to be completed before the others are begun. For example, the simple process of making tea and snacks may be interlinked with each other by common resource (gas stove). Also the activity of serving tea can not be completed till the time the activity of preparing tea has been completed. This is a highly simplified example of network analysis, which indicates interdependence between two or more activities and the time-schedule between such activities in a large project. Time management of a project, an important managerial control technique, can be done through Critical

Path Method (CPM) and Project Evaluation & Review Technique (PERT), which are discussed subsequently.

**Critical Path Method (CPM) :** Here, it is assumed that durations of individual activities in a project are known with certainty. The method thus helps to determine the earliest possible start time & latest possible start time for each activity. CPM also identifies the critical activities, which are critical because if any of these activities are delayed by even a short period, the entire project will be delayed. CPM requires greater planning but this is justified by concentrating on critical path only and avoiding expense on strict supervision & control on non-critical activities or on whole project. Besides ascertaining the time schedule of a project, CPM is also the standard method of communicating project plans, progress and costs.

**Project Evaluation & Review Technique (PERT) :** PERT involves planning, monitoring and controlling of projects where time taken for each activity in the project is not known. It uses probability to estimate the timings of various activities in the project and linear programming for maximizing the achievement of objectives. PERT is classically used in long-term projects like construction of hospitals, ships, roadways and buildings, in planning & launching of new health programs, products & services, in publication of books etc where exact time for each phase is not known with certainty. PERT uses probabilistic and linear programming methods to assist a manager in planning schedules & costs, determining time & cost status, forecasting skill requirements, predicting schedule slippages & cost overruns, developing alternate time cost plans & committing resources to various tasks. Under PERT, three time-estimates are made, as under :

- (a) *Most Likely Time* is the time taken most frequently in completing a particular activity.





effectiveness. Once KRAs have been correctly identified, it is easy to concentrate on important aspects and give lower priority to less important activities, thereby conserving vital resources. A KRA is an area where results are important, where success would lead to significant gains and where failure would be disastrous. Although the emphasis is on objectives in MBO, it is even more important to identify KRAs. There are several ways to identify KRAs, including data analysis and brain storming, wherein all possible KRAs are listed and a short list is thereafter selected. The process of identifying KRAs by the top management consists of the following broad steps :-

- (i) SWOT Analysis : Analysis of Strengths, Weaknesses, Opportunities and Threats.
- (ii) Brainstorming exercise to identify all possible KRAs.
- (iii) Discussion, analysis & classification to arrive at an agreed list of KRAs.
- (iv) Establishment of specific objectives in each KRA.
- (v) Preparation of Action Plans, including assignment of responsibilities for results to be achieved.

**(b) Setting up Objectives** : Having identified KRAs, the next step is to set up objectives within these KRAs, which have to be measurable and quantifiable. The broad organisational objectives define the purpose & mission of the organisation and generally answer the question “what is our business?” Long-term and short-term objectives emanate from organisational objectives. Strategic objectives are related to choice of product, technology or market. Choice of objectives (statement of expected result) is the starting point for management process in MBO. Hence under MBO, all inputs and processes are modified to meet the requirements of objectives. No doubt that activities are essential to obtain results, but it is well known that all activities do not contribute to achievement of objectives. In addition, objectives should be stated in terms of expected results and not merely in terms of planning activities or activities. It is well established that specific, quantifiable, measurable and concrete objectives result in higher levels of performance as compared to when managers are merely told to perform their best. An objective is a statement of expected results, which provides guidelines for decisions and actions at lower level & provides standards against which performance is assessed.

Any objective thus, should have the following four elements, which are also determinants of improved performance, viz., Quantity, Quality, Cost and Time. Objectives are successful as guidelines only if they are quantifiable & measurable. If you can not count, can not describe, can not measure what you want, you probably do not know what you want, and hence can not use it as an objective in your plan of action.

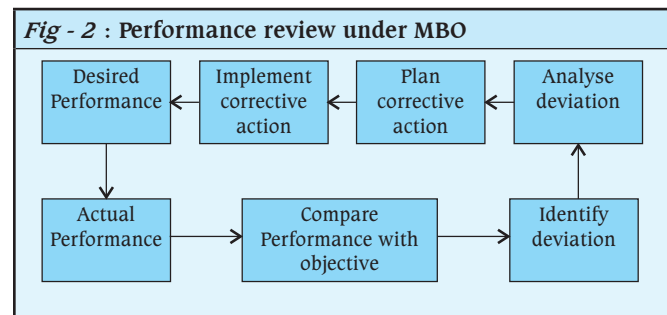
**(c) Action Planning** : Action plans are the means to convert objectives into reality. Objectives describe what is to be achieved, whereas action plans describe how these objectives are to be achieved. Every objective has to be achieved only through converting them into specific action plans, which specify what activities will

be performed and the specific time when each activity will be performed. The four broad steps essential in all action plans are:

- (i) Choice of strategies which are essential for achieving objectives.
- (ii) Fixing the responsibility for achieving each objective.
- (iii) Resource allocation for achieving the objectives.
- (iv) Scheduling specific activities in specific sequence for maximum utilization of resources.

Activities (series of acts) have to be done in a particular sequence for attaining the objectives. Thus, all activities have to be arranged sequentially in most logical manner & each activity has to be completed within a stipulated time frame. This is called scheduling, which converts plans into action plans. An example of Action Plan is given below. Let us assume that as the District Health Officer, you, after SWOT analysis and brain storming session with your peers and colleagues, have identified two of your KRAs as “upgradation of infrastructure” at all hospitals/PHCs and “printing of new health education material on HIV/AIDS prevention” for the district. With these KRAs, an action plan would be drawn out as in Box - 2.

**(d) Performance Review** : Performance review, in the MBO process, focuses on performance appraisal, improvement, future corrective action, frequency of reviews & self appraisal. The main purpose of performance review in MBO process is to provide corrective feedback to the concerned person. A system of Performance Review under MBO is shown in Fig - 2 :



Advantages & Disadvantages of MBO are shown in Box-3

<b>Box - 3 : Advantages &amp; Disadvantages of MBO</b>	
<b>Advantages</b>	
<ul style="list-style-type: none"> <li>• Greater role clarity, job satisfaction and better measurement of performance.</li> <li>• No wastage of scarce resources.</li> <li>• Single-minded dedication to achievement of objectives.</li> <li>• Motivating factor &amp; weeds out non-performers.</li> <li>• Increases productivity through role clarity &amp; increasing job satisfaction.</li> <li>• Provides objective appraisal method.</li> <li>• Strengthens superior-subordinate relationship.</li> <li>• Based on concept of participation</li> </ul>	
<b>Disadvantages</b>	
<ul style="list-style-type: none"> <li>• Problem of joint setting of objectives among unequals in the organisation.</li> <li>• MBO may not always percolate to the lowest level in the organisation</li> <li>• Difficult to implement in situation of change.</li> </ul>	

Box - 2 : Action Plan													
KRA's	Objectives	Action Plans											
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	
Upgradation of infrastructure	Timing of rooms in PHC's												
	Est. of LAN at all PHCs and district hospitals												
	Est. of computer room at all PHCs												
Printing of new health education material on HIV AIDS prevention	Release of funds												
	Designing, printing and distribution of health education material												
Legend : Where Planning Phase is depicted by							& Execution of activities by						

## Total Quality Management (TQM)

Quality can be defined as “the totality of features and characteristics of a product / service which have the ability to satisfy the clients felt / implied needs”. Total Quality Management (TQM) as a management tool, focuses on continuous improvement of procedures and processes involved in any activity or any services. The entire focus in TQM is to continuously improve the way things are done in an organisation, for which each member of the organisation must know what is the right thing to do, how to do these right things and how to measure the current level of quality and improvement in this level. The basic principles of TQM, on which all activities in TQM are carried out are described as under :

(a) **Satisfy the consumer** : TQM involves satisfying the felt or perceived needs of the customer, which tend to change with time and circumstances. Managers need to be sensitive to these changes in expectations of clients since being able to always satisfy the customer in an integral part of TQM.

(b) **Management based on facts** : Every manager needs to have access to correct facts about the product or services being offered by the organisation. Based on these facts, improvements can be initiated in the product / services. TQM also involves apprising the client of the correct facts about the product.

(c) **People-centric management** : It has been seen that people tend to take responsibility for their actions and are willing to improve upon the processes once they understand what to do and how to do. By themselves, mere procedures, standards and technology can not ensure quality without the commitment of people involved in producing the product / rendering the service. By involving the stakeholders, especially the workers, commitment to quality (and customer satisfaction) can be enhanced significantly.

(d) **Ongoing improvement** : TQM is not a short term or one-time activity which would end once the target has been achieved. It is an ongoing process which aims to improve the every day routine procedures & processes involved in product /

service. Under TQM, improvement is viewed as an incremental change over the previously existing level of quality rather than any major breakthrough in the manufacturing process.

### Various TQM Methods and their Role in Management

TQM methods are aimed at bringing about a change in the organisational culture wherein customer satisfaction is the over-riding concern in the mind of each and every member of the organisation, irrespective of the importance or status of his or her job. The introduction of TQM in an organisation invariably begins with setting up of teams to solve problems and by educating and training team members.

#### Some important TQM methods are as under

- Acceptable Quality Level (AQL)* provides a set of pre-determined rules and standards for acceptance or rejection of a product, so that each item inspected for its 'quality' is classified as acceptable or unacceptable. This is used to ensure that the supplier provides at least the minimum quality mutually agreed upon by both the customer and the supplier of the product/services.
- Affinity diagrams* provide some type of relationship to groups within an organisation. Such methods are useful when a team attempts to translate the customer requirements into an organisational structure, which requires to highlight the associations rather than only the logical sequence & connections of client needs.
- Arrow diagram* is used to depict the time required to solve a problem in the organisation. This can be used for planning routine daily projects where depiction of time required for completing each step is essential.
- Benchmarking* provides comparison with pre-determined standard of quality of product/service, thereby focusing on overall mission of the organisation and is a process which compares the performance (quality) with that of others, thereby ensuring better performance through comparison.
- Consensus reaching* is a way of examining alternatives so that an organisation can collectively reach a conclusion which is acceptable to all members of the organisation.

- (vi) *Contingency planning* is the process of planning for unforeseen circumstances to ensure least wastage of resources and to avoid 'fire-fighting' at the last moment.
- (vii) *Cost benefit analysis* involves the analysis of real cost and benefit involved in the project. It is used to assess if the solution is practical and achievable in terms of the cost incurred by the organisation.
- (viii) *Criteria testing* is the process of listing the various criteria and evaluating an alternative course of action against these pre-determined & pre-decided criteria.
- (ix) *Deming Wheel (PDCA)* is a graphical representation of essential requirements to satisfy a customer's requirements, namely, plan (P), do (D), check (C) & action (A). Such a managerial tool is used extensively to develop new products & services based on the felt needs of the clients.
- (x) *Error proofing (pokayoke)* is the managerial process of designing and conducting an operation in such a manner so as to eliminate specific errors which cause major disruption of process / services, thereby causing dissatisfaction to customers.
- (xi) *Force analysis* is used while developing the contingency plan for identifying the various issues (forces) and problems and their effect on the organisation.
- (xii) *Gantt Charts* are graphical representation of the essential steps for completing a project. Thus the entire project is broken down into smaller component steps and a graph is created to depict the time scheduling of each step (as shown under "action plan" earlier under MBO). Gantt charts make it easier to identify the various steps involved and also easily indicate (visually) when the deadline for particular step in the project has been missed.
- (xiii) *Kaizen* (change for the better) is a Japanese concept which implies an on-going and continuous improvement in all activities in an organisation and at all levels. It is a people-centric concept which depends on their commitment and participation for effective implementation, which may be for products or for services. Quality circles & suggestion schemes in organisations are important methods to implement the concept of Kaizen.
- (xiv) *Pareto analysis* (proposed by Wilfredo Pareto) is used extensively and effectively to identify the important causes for poor performance (or quality) which need to be addressed on priority. This is also called the 80/20 rule which states that 80% of the problems are caused by 20% of the activities and hence the organisation should ideally concentrate on these 20% activities which determine the large proportion of problems in manufacturing a product or delivery of a service.
- (xv) *Quality Circles (QC)* are small groups of individuals who regularly meet voluntarily during duty time and attempt to solve problems faced by the workers in the organisation. QCs provide a direction and aim to individuals to identify their own problems and solve them.

Quality assurance in health care is rendered difficult due to the fact that the output (health care) is most often intangible, highly personalized and can not be standardized in most cases. However, it must be remembered that patients perceive quality of health care provided not only by the end result, but also

through small routine procedures and facilities provided by a hospital. Quality can be described as "doing the right thing the first time and doing it better the next time". Quality in health care has to be patient-centric and should meet the expectations of a patient (client) in the most cost-effective manner. The need and importance of quality in health care settings imply that Total Quality Management (TQM) in health care has vast scope.

## Summary

With larger and complicated organisations with their own unique organisational and structural issues a need has been felt for better, more effective and innovative managerial methods, some of which are Network Analysis, Management By Objectives (MBO) and Total Quality Management (TQM). Network analysis is a means of planning and controlling processes. In this, a project is broken up into small operations which are arranged into logical sequence. Thereafter, the order in which these actions are to be performed is decided and a network diagram shows the relationship between the various operations involved. Time management of a project, an important managerial control technique, can be done through Critical Path Method (CPM) and Project Evaluation & Review Technique (PERT). In CPM it is assumed that durations of individual activities in a project are known with certainty. The method thus helps to determine the earliest possible start time & latest possible start time for each activity. CPM also identifies the critical activities, which are critical because if any of these activities are delayed by even a short period, the entire project will be delayed. PERT involves planning, monitoring and controlling of projects where time taken for each activity in the project is not known. It uses probability to estimate the timings of various activities in the project and linear programming for maximizing the achievement of objectives. It is classically used in long-term projects and uses probabilistic and linear programming methods to assist a manager in planning schedules & costs, determining time & cost status, forecasting skill requirements, predicting schedule slippages & cost overruns, developing alternate time cost plans & committing resources to various tasks.

Management By Objectives (MBO) is a modern managerial tool by which managers can improve their performance and their overall effectiveness. It is a system which integrates an organisation's need to achieve its objectives with the managers' need to contribute and develop himself. It can be defined as a managerial approach which uses objectives as a focal point to improve managerial performance & effectiveness at individual and organisational levels. The important feature of MBO which distinguishes it from other planning and control processes is the emphasis on results (objectives) rather than on activities & processes. It also emphasizes the concept of "means-ends" sequence. There are broadly four steps involved in MBO process which are (a) Identifying the Key Result Areas (KRAs), which in turn include SWOT Analysis, Brainstorming exercises, Discussion, analysis & classification, Establishment of specific objectives in each KRA, Preparation of Action Plans, including assignment of responsibilities for results to be achieved; (b) Setting up Objectives within these KRAs, which have to be measurable and quantifiable. Any objective should have the

four elements, which are Quantity, Quality, Cost and Time. (c) Action Planning: Action plans are the means to convert objectives into reality. The four broad steps essential in all action plans are choosing strategies, fixing the responsibility, allocation of resources and scheduling specific activities in specific sequence. (d) Performance Review: It focuses on performance appraisal, improvement, future corrective action, frequency of reviews & self appraisal.

Total Quality Management (TQM) focuses on continuous improvement of procedures and processes involved in any activity or any services. The basic principles of TQM, on which all activities in TQM are carried out, are Satisfy the consumer, Management based on facts, People-centric management and Ongoing improvement. Some important TQM methods are Acceptable quality level (AQL), Affinity diagrams, Arrow diagram, Benchmarking, Consensus reaching, Contingency planning, Cost benefit analysis, Criteria testing, Deming Wheel (PDCA), Quality Circles (QC) etc.

## Study Exercises

**Long Questions :** (1) Enumerate some modern management techniques. Describe Network Analysis. (2) Enumerate some modern management techniques. Describe Management by Objective.

**Short Notes :** (1) Critical Path Method (CPM) (2) Project Evaluation & Review Technique (PERT) (3) Management By Objectives (MBO) (4) Total Quality Management (TQM).

### MCQs

1. Planning, monitoring and controlling of projects where time taken for each activity in the project is not known is (a) CPM (b) PERT (c) MBO (d) TQM.
2. Emphasis is on results rather than on activities & processes in (a) CPM (b) PERT (c) MBO (d) TQM.
3. Identifying the Key Result Areas (KRAs) is first step in (a) CPM (b) PERT (c) MBO (d) TQM.
4. Cost benefit analysis is an example of (a) CPM (b) PERT (c) MBO (d) TQM.

**Answers :** (1) b; (2) c; (3) c; (4) d.

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## Planning and Evaluation of Health Services / Programmes

Rajvir Bhalwar

Today the importance of planning and evaluation needs no further emphasis. What is relevant to note, at this point is that epidemiology is central to the successful execution of these key managerial functions. The reason is simple – the indispensable requirement for any planning or evaluation process is “valid and reliable data” and epidemiology is the science which deals with valid and reliable data collection, collation, analysis and interpretation (1).

### The Planning Process

Planning is a very scientific and systematic process which essentially visualizes as to where we are at present (*present situation or baseline*), where do we want to go (*the future or “outcome”*), why do we want to go there (*logic*) and how do we get there (*process*). It consists of a series of steps and we need accurate data at each of these steps (2).

**Step 1 - Laying down the premises (scope) :** This defines the general perimeters or “boundaries”, in terms of place, time, population and disease condition(s), within which the health program being planned, will be restricted to (3).

**Step 2 - Situational analysis :** Relevant Demographic (age, sex, population distribution etc.), socio-economic (literacy, occupation, economic status etc.) and disease data (mortality and morbidity) is obtained and analysed.

**Step 3 - Resource analysis :** Data on available resources (health manpower, money and material) is obtained and analysed.

Data for steps – 2 and 3 is either obtained as a secondary data, from various sources as already described in detail in the chapter on sources of data in epidemiology or else obtained as primary data by a survey, as per details given in a subsequent chapter.

**Step 4 - SWOT Analysis :** The Strengths (S), Weaknesses (W), Opportunities (O) and Threats (T) are identified in context of the proposed programme. S and W are permanent phenomena that exist within the organization or community; O and T are temporary, often fleeting, phenomena that exist in the external environment. For example, in a proposed programme for prevention and control of HIV in our country, the organizational and constitutional philosophy and political will of the country to prevent HIV / AIDS is a “strength” which should be utilized to the maximum. At the same time, the common social tendency not to encourage talking about sexual health is a weakness pitched against us, and we need to either neutralise it or circumvent it. The fact that recently funds have been made available for developing health educational material and that the new Mayor of the city is strongly in favour of educating the public as well as high risk groups for HIV / AIDS, is an opportunity and we should grab this opportunity. However, if there has been some recent resistance and objection from parents against sex education of children, it is a threat and we need to either negotiate it or else bypass it.

**Step 5 - Ensure Community participation :** Identify the community leaders, peers and voluntary groups and involve



them fully in the planning process.

**Step 6 - Enunciation of the “Community Needs”** : We now carefully evaluate our findings of situational, resource and SWOT analyses and decide as to what are the major issues (within the boundaries defined by our scope) which need to be addressed and which can be feasibly addressed by us. We should also work out an optimum trade-off between ‘normative’ or ‘professionally assessed needs’ (what we, as Doctors or public health care managers, feel that the community requires) and the “felt needs” of the community (what the community members feel is their need). By way of community participation, educate and convince the community if, in your perception, their felt needs are unscientific or cannot be addressed within the resources (4 - 7).

**Step 7 - Setting the Priorities** : On the basis of our adjudged community needs and the resources, work out the “priority” areas within the proposed programme, which are the most important requirements and we, given our available (and expected) resources, can feasibly address them. An epidemiological method for according priorities is to consider the following three headings and give marks (as numerals 1, 2 or 3) to each heading as per following description. Disease which gets the highest score (max possible will be a score of 9) would get the highest priority while the lowest scoring disease (minimum possible score will be 3) gets lowest priority.

- **Importance of disease (based on mortality, morbidity, suffering, cost of treatment and loss of productivity)**: 3 marks if high importance, 2 if moderate, 1 if low importance.
- **Effectiveness of Interventions** : 3 marks if interventions known to be very effective, 2 if moderately effective, 1 if low or non effective.
- **Cost of interventions** : 3 marks if cost is low, 2 if moderate cost and 1 if cost is high (Intervention could be a treatment or preventive modality).

**Step 8 - Identify the “High Risk” Groups** : High Risk groups are those persons, who due to some characteristics, have a much higher chance of being affected by the disease or it’s adverse consequences. It is important, at this stage, to identify who are the high risk persons, based on our situational analysis and identification of community needs, so that extra efforts may be directed towards them. Young children, women of child bearing age, the elderly, people living in slums or inaccessible area are some of the usual examples of high risk groups. However, it depends on the disease or condition being addressed. For example, in an educational programme to obtain favourable change in sexual lifestyle, truck drivers may be identified as high risk group. The importance of identifying these groups lies in the fact that while we shall direct our activities to all members of the community but more focused and elaborate (targeted) actions will be directed towards these special groups. Consequently, large amount of benefit will occur from the programme if these groups are addressed.

**Step 9 - Enunciate the Goal (Aim), Objectives, Indicators and Targets of the Programme** : Once the community needs have been identified within the context of the proposed programme, we enunciate the Aim or the Goal. This is a broad statement of the overall end-point which the programme

intends to achieve. Objectives, on the other hand, are specific statements, through which the overall goal would be achieved. Objectives are thus specific, quantifiable and usually relate to a time-plan. Indicators are parameters and targets are numerical quantities written in conjunction with the indicators, which actually quantify the end points which the objectives are to achieve. For example in a program directed towards healthy lifestyle, the statement “to bring about healthy improvement in various aspects of lifestyle and a reduction of lifestyle diseases so that they are no more a significant health problem” is the broad goal or aim. The statement “To ensure that by 31 Dec 2008, at least 80% of the adults undertake 45 minutes of brisk walk, daily, on at least 5 days a week” is an objective, in which “community members who are undertaking regular aerobic exercise as per defined criteria of 45 min a day on at least 5 days a week” is an indicator and “80% achievement by 31 Dec 2008” is the qualifying target.

One of the most crucial steps in planning process is to intelligently enunciate the goal, objectives, indicators and targets. A lot of thought process and expert evaluation should go in at this stage. They should be realistically set, should be do-able, neither too ambitious nor too under-achieving.

**Step 10 - Choose a Strategy and Draw an Action Plan** : With the background of the enunciated goal, objectives, targets and indicators, and duly considering the resources (step - 3), select out as to what overall strategy you will use in the proposed programme. For instance, in a proposed programme for prevention of HIV, the strategy could be to only have health educational efforts, or else it could be a comprehensive strategy of combination of health education, blood safety, diagnosis and treatment, surveillance and PPTCT. Obviously the choice of strategy will be strongly guided by the programme objectives and your available / expected resources. If you do not have lot of resources, naturally you would select a strategy of limited activities which are likely to give you the best results. Now, having decided the strategy, write down a detailed action plan as to how the programme will be executed, as has been already explained in the previous chapter. Do ensure that a “time-line” has been given for each objective, target and indicator, giving the date of each end point.

**Step 11 - Address the Issues of Accessibility and Coverage** : Get detailed spot maps of your areas and work out the aspects of population distribution, roads, communications and transportation. Do remember that very often, those who would benefit most from your programme, are also the ones who are living far off, do not have access to your services, are often thought to be not really in need of the proposed preventive or curative services. Hence at this point, work out where are your high risk persons located and how will you ensure that they are covered adequately.

**Step 12 - Organise the manpower, material, and finances** : Place the required manpower, equipment, material and other logistics at the required places. If some more resources are expected, make a plan as to where they will be relocated and how. Make out detailed, written “operations manual” including the operative procedures for each activity, i.e. “who will do what to whom and in what manner”. Ensure that your personnel have been centrally trained and tested for undertaking the procedures.

**Step 13 - Undertake a “Pilot Run”** : This is another very important step. Do a small scale trial run of your procedures and rectify any defects that are observed.

**Step 14 - Conduct the Programme** : Launch the programme in a full fledged manner. Ensure that you or your dependable deputies are there always at the sites where the services are being delivered. Make it a point to regularly obtain and analyze data on various aspects as the programme progresses, making changes if required.

**Step 15 - Evaluate the programme** : Evaluation is the process of assessing the extent to which our results are commensurate with our pre-decided objectives. Evaluation should be a continuous process as the programme progresses (concurrent evaluation) and not simply an exercise to be undertaken at the end of the programme (terminal evaluation). For evaluation, we again need valid and reliable data in the same way that we obtained in the planning stage. Broadly, evaluation is undertaken for six different facets, as follows :

- **Evaluation of Relevance** : This evaluates whether we need to continue it as such or in some modified manner (concurrent evaluation) or, at the end when we do terminal evaluation, to find out whether the programme was required at all. This requires obtaining and reviewing the data / intelligence about situational analysis, resources and community needs.
- **Evaluation of Adequacy** : Whether the required amount of manpower, equipment, expendables, logistics, other type of material and finances have been provided? Have they been suitably placed?
- **Evaluation of Process** : How are / were the services/ activities undertaken? What has been the quality of services? Were the services accessible to or provided to all the beneficiaries or only few segments? For example, are the targeted number of children being vaccinated, have some areas been left out, the scheduled number of patients being seen and the planned number of health education sessions being taken, and so on?
- **Evaluation of Efficacy, Effectiveness and Efficiency**: Efficacy answers the question “can the programme or procedure work” (maybe in ideal or controlled situations); Effectiveness addresses the question “Does it work” (i.e., in the real life situations); Efficiency answers the issue “Is it the most economical way (in terms of time or money)”. For example the conventional combination regime of Streptomycin, INH and Thioacetazone may still give good results for curing pulmonary tuberculosis if we were to treat patients admitted into the sanatoria for 18 months (i.e., is efficacious), but in the real domiciliary settings, bring about only about 30% cure (is not effective), while MDT would cure 70 to 80% patients in real life domiciliary settings (is effective). Finally, comparison between the total costs of the two regimen (drugs, duration of treatment, requirement of doctors, paramedics and hospital buildings, commuted cost of reduction in human suffering due to earlier cure, etc) vis-à-vis the overall cure rate may finally indicate that short term MDT may be more “efficient”. We have already had a detailed discussion on these aspects in the chapter on studies on economic evaluation, in this section.

#### Summary Box: Steps in Planning The Health Programme

- Laying down the premises (scope)
- Situational analysis
- Resource analysis
- SWOT analysis
- Enunciation of the “Community Needs”
- Setting the Priorities
- Identify the “High Risk” Groups
- Enunciate the Goal (Aim), Objectives, Indicators and Targets of the Programme
- Choose a Strategy
- Draw an Action Plan
- Work out where are your high risk persons are located and how will you address accessibility and coverage
- Ensure Community participation
- Organise the manpower, material, and finances
- Undertake a “Pilot Run
- Conduct the Programme
- Evaluate the programme
  - Relevance
  - Adequacy
  - Process
  - Efficacy, Effectiveness and Efficiency

### Summary

Planning is a very scientific and systematic process which essentially visualizes the present situation or baseline, the future or “outcome”, the logic of doing so and the process therein. It consists of a series of steps, each of which necessitates accurate data. The first step in planning & evaluation of a health programme involves laying down the premises or scope of the programme i.e., the general perimeters or “boundaries”, within which the health program being planned, will be restricted to. Thereafter, a Situational analysis is undertaken, in which relevant demographic, socio-economic and disease data is obtained and analysed.

The next step would be an analysis of resources available; health manpower, money and material is assessed at this step. After this, we proceed to perform a SWOT analysis, wherein Strengths, Weaknesses, Opportunities & Threats are assessed. S and W are permanent phenomena that exist within the organization or community; O and T are temporary, often flitting, phenomena that exist in the external environment. Ensuring community participation and enunciation of the “Community Needs” (vis-à-vis the “professionally assessed needs”) would be the next step in the process. Setting the Priorities i.e. addressing the most important requirements given the available (and expected) resources, would be the next step. An epidemiological method for according priorities is to consider Importance of disease, Effectiveness of Interventions and Cost of interventions and give marks (as numerals 1, 2 or 3) to each heading.

The next step would be identification of “High Risk” Groups i.e. those persons, who due to some characteristics, have a much higher chance of being affected by the disease or it's adverse consequences- this would differ according to the health issue being addressed. Subsequently, we proceed to enunciate the

Goal (Aim), Objectives, Indicators and Targets of the Programme. They should be realistically set, should be do-able, neither too ambitious nor too under-achieving.

Thereafter, the Strategy to be followed will have to be chosen- the choice of strategy will be strongly guided by the programme objectives and your available / expected resources. After this is done, we proceed to draw an Action plan as to how the programme will be executed, giving a time-frame for each activity. The next action would be to work out where the high risk persons are located and how the issues of accessibility and coverage are to be addressed- this may be achieved by getting detailed spot maps of the relevant areas and working out the aspects of population distribution, roads, communications and transportation. At this point, a vital component would be to ensure community participation, without which the entire programme will be laid to waste.

Organizing the manpower, material, and finances forms the next step, wherein a detailed "Operations Manual" needs to be prepared, that would indicate who would do what, to whom and in what manner. Subsequently, a "Pilot Run" needs to be undertaken. Thereafter, the programme is launched in full swing – a pertinent point at this juncture would be to regularly obtain and analyze data on various aspects as the programme progresses, making changes if required.

The final step in this series of events would be to Evaluate the programme- this is done on various parameters, which include Relevance i.e. whether we need to conduct the program at all; this can be done by concurrent or terminal evaluation. The next parameter to be assessed for would be Adequacy i.e. to assess whether the required resources have been provided and suitably placed. Thereafter, the process itself would be assessed- quality, accessibility etc. The final parameters to be evaluated in conduct of a health care programme would be Efficacy (can the programme work in ideal / controlled settings), Effectiveness (does it work in real-life situations) and Efficiency (is this the most economical way- in terms of time or money).

## Study Exercises

**Long Question :** Epidemiology is an essential requirement at each step of planning and evaluating. Critically analyse this statement.

**Short Notes :** (1) SWOT analysis (2) Aim, objectives, targets and indicators (3) Planning cycle (4) Parameters on which evaluation is undertaken.

### Exercises and MCQs

1. The first step in the process of planning a health programme would be (a) SWOT analysis (b) resource analysis (c) Situational Analysis (d) Laying down the premises (scope).
2. Strengths are permanent phenomena that exist within the organization or community. Yes/ No.
3. Arrange the following steps in planning a health programme, in the sequential & ideal order : (a) Setting priorities (b) SWOT analysis (c) Evaluation of the programme (d) Enunciation of community needs (e) Identifying of "high-risk" groups.
4. Specific statements, through which the overall goal would be achieved, are known as (a) Objectives (b) Targets (c) Aims (d) Indicators.
5. In estimating the effectiveness of interventions, the number

of marks that would be given if interventions known to be very effective is (a) 1 (b) 2 (c) 3 (d) 4.

6. What the community members feel are their needs, are known as (a) Felt needs (b) Assessed needs (c) Professionally assessed needs (d) Minimum needs.
7. The conventional combination regime of Streptomycin, INH and Thioacetazone may give pretty good results for curing pulmonary tuberculosis if we were to treat patients admitted into the sanatoria for 18 months (say 90% cure), but in the real domiciliary settings, bring about only about 30% cure. This means that the regimen is (a) Both efficacious and effective (b) Efficacious but not effective (c) Effective but not efficacious (d) Neither efficacious nor effective.
8. Broadly, evaluation of a health care programme is undertaken for how many different facets? (a) 4 (b) 5 (c) 6 (d) 7.
9. During preparation of which particular document in the process of planning a health programme, it is to incorporate a time line i.e. a time frame for each objective, target and indicator, giving the date of each end point : (a) Operation manual (b) High-risk group register (c) Pilot run (d) Action plan.
10. The maximum possible score that can be given to a disease/ health event in according of priorities for purposes of planning and evaluation is (a) 09 (b) 10 (c) 11 (d) 12.
11. All of the following subset of data is analysed while doing a situational analysis, except (a) Demographic data (b) Socio- economic data (c) Disease data (d) Resource data.
12. "Threats" are permanent, mostly long-lasting, phenomena that exist in the external environment. Yes/ No.
13. A broad statement of the overall end-point which the programme intends to achieve is known as (a) Target (b) Indicator (c) Aim (d) Objective.
14. All of the following headings are taken into consideration for according priorities (through scoring system) in conduct of a health care programme, except (a) Importance of disease (b) Effectiveness of interventions (c) Cost of interventions (d) High risk groups.

**Answers :** (1) d; (2) Yes; (3) b-d-a-e-c; (4) a; (5) c; (6) a; (7) b; (8) c; (9) d; (10) a; (11) d; (12) No; (13) c; (14) d

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Kunal Chatterjee

Health has been at the centre of human concern since ancient times. Civilisations developed and perished due to wars, conflicts and raging diseases, which left none untouched, save those whose health was taken care of by an organised system. Ancient civilisations that developed in Indus valley, Greece, Rome and Mesopotamia had fairly advanced health systems for their times and the medical practitioners enjoyed a high status in the society due to their practice.

Two renowned medical systems developed in India in ancient times; Ayurveda and Siddha, which were quite similar in concept and practice. Indian systems sought knowledge by which life could be prolonged and some of the popular medical treatises of those times were the Charaka Samhita and the Sushruta Samhita. Medicine practiced in China was based on 'Yang' and 'Yin' principle and claimed to be the first organised body of medical knowledge. One of the oldest civilisations of the world developed on the banks of river Nile in Egypt. Ancient Egyptian medicine mingled with religion and enjoyed great patronage under their rulers. Nearby in the land between Tigris and Euphrates rivers, the Mesopotamian civilisation emerged, which was called the 'Cradle of the World'. Medical practice in this land was remarkable for a code of medical ethics created by the King Hammurabi, which though drastic was nevertheless the first of its kind. Greeks and Romans gave the world of medicine its modernity. They taught medical practitioners to think of 'why' and 'how' and raised medicine to the status of science.

The practice of medicine has come a long way since the time of magic, religion and supernatural thoughts to a modern science following evidence-based practice with a range of services extending from preventive, promotive, curative to rehabilitative offered to the individual and community.

### What is a Health System?

Health system covers a whole gamut of health activities, health programmes, institutions providing medical care such as hospitals, clinics and primary health care centres and the policies enunciated by governments to provide optimal health care for its citizens. A health system as described by WHO is the "sum total of all the organisations, institutions and resources whose primary purpose is to improve health." A health system needs staff, funds, information, supplies, transport, communications and overall guidance and direction. And it needs to provide services that are responsive and financially fair, while treating people decently. The government is ultimately responsible for the overall performance of a country's health system, however individual institutions, municipalities and regions need also to play an important role in its propagation and maintenance. Health systems affect the socio-economic status of a community in any region and in turn are affected by its poverty, development and stability.

*Health systems usually include the following :*

- Development of health policies, plan for their implementation and development of a system of regulation of health services.
- Define and develop the institutional framework to deliver the health services within the purview of this system.
- Allocate and mobilise financial and human resources for its functioning.
- Plan, manage and deliver the health services.

Health systems should be accessible, efficient, affordable and of a good quality. They should ultimately aim to improve, maintain and restore the health status of the community at a cost that an individual and the community can afford to spend without substantial change in their financial status.

### Goals of a Health System

A health system has to provide for much more than routine delivery of services. It has to protect the health of its community, treat them with dignity and ensure that it responds fairly to the expectations of the population. The WHO has thus identified three overall goals for the health systems to be effective, responsive and fair :

- Effective in contributing to better health throughout the entire population.
- Responsive to people's expectations, including safeguarding patient's dignity, confidentiality and autonomy and being sensitive to the specific needs and vulnerabilities of all population groups.
- Fair in how individuals contribute to funding the system so that everyone has access to the services available and is protected against potentially impoverishing levels of spending.

### Historical Evolution

The oldest known health system, since the time humans settled down to community living, is the family. Families came together since ancient times to care for the pregnant women, young and elderly and for basic survival needs such as nutrition, safety and care during sickness. The oldest known organised health efforts date back to the time when religion was identified with healing and deities were worshipped for seeking cure of a disease in the community. Some civilisations proffered sacrifices to appease the Gods. Worship, herbal medicines, medicines from animal sources and disciplined lifestyle were integral to the ancient medical systems. Thereafter, in the era when Buddhism and Christianity spread across countries, the first hospitals were constructed for the sick, destitute, old, orphans and lepers. Notable among them were the early sanatoria built by Emperor Ashoka in Indian subcontinent in 2nd century BC. Hospitals remained the domain of religious institutions such as churches till well into the 16th century in most parts of the world. State supported institutions developed subsequently when Europe awoke from the dark ages and superstition and dogma in medicine were challenged. Monarchs also lent their support to health care activities as a pious duty towards their people. In India modern hospitals were started by missionaries and later supported by the colonial government. Industrial revolution in Europe created conditions of overcrowding, rapid urbanisation and even rapid decline in the health of community. It brought



about an appreciation of the losses incurred by the state due to ill-health, especially of the workforce. This motivated them to work systematically towards improvement of health systems. Health was now perceived as a citizens' basic right.

### **The Rise of Modern System of Medicine**

In the second half of 19th century, several revolutionary breakthroughs were witnessed in the medical science. They heralded the coming of age of medicine making it one of the most researched sciences. Advances in the medical field continue unabated even today. Newer drugs, modalities of treatment, health systems and research have improved the quality of life of people. Life expectancy has risen, many diseases, which in early days caused significant morbidity and mortality have been controlled and some eradicated. Countries have witnessed an improvement in the health and quality of life indicators, which have added onto the rising economic prosperity.

This rise has however been associated with increase in the cost of newer technologies. Newer and deadlier diseases have emerged throughout the World. Microorganisms are increasingly showing resistance to the routine drug regimes and disease vectors have developed ability to survive in the environment despite using physical, chemical and biological methods to control them. Lifestyles of the human population are found to be associated with various chronic diseases and rising expectations of a relatively healthy and prosperous population have created the demand for immediate relief of illnesses often at the cost of rational drug policies and evidence based interventions. This milieu has created the impression of profitability of health care industry with health care providers, medical equipment manufacturers, insurance and pharmaceutical industry and the corporate world staking its claim of the pie. As a result there is a widening disparity in the quality of medical care being provided to different social status of population in the countries. The cost of medical care is growing out of the reach of common man.

### **Financing the Modern Health Care System**

The modern health care systems need funding from the state or citizen sources to create financial viability and enhance responsiveness, efficiency, equality and fairness in the delivery of health care. The following questions need to be asked to describe the financing of health care systems :

- Who is financing – Government, finance companies or employees?
- What are the services covered by this payment?
- Which financier pays for how much of the service provided?
- Who are the organisations or individuals receiving this funding?
- What is the basis for this payment – whether it is fee for service, capitation charges or both?

The primary source of funds is from the public, whether by direct cash for service or indirectly through the government contribution. There are generally five primary methods of financing health care systems as enumerated below.

- Direct or out-of-pocket payments
- General taxation

- Social health insurance
- Voluntary or private health insurance
- Donations or community health insurance

### **Private out-of-pocket Funds**

In most of the low-income countries, people pay a high proportion of their health costs directly to the health care providers out of their own pockets. While in the wealthiest countries in the world, few health care costs are paid by the individuals directly to providers. This system exposes the family in a poor country to exploitation and catastrophe in case of sickness. Some people are deterred from using health services or from continuing treatment because of unaffordability. The people who use these services have to cut expenditure on the more important needs of the family such as nutrition, clothing, housing and education. As per WHO, each year approximately 150 million people in the world are obliged to spend more than 40% of the income available to them on health care, after meeting their basic needs, which drives most of them below poverty line. To this scenario, market forces are added, which move the focus of health care from user benefit to vendor profitability. The formal health systems are thus seriously damaged and perception of effectiveness of a system gets linked to its cost. Traditional and cheaper alternatives are also pushed out. Though the system provides choices and control to the customers and also accelerates competition and research, most often all these efforts are oriented towards increased profitability.

### **General Taxation**

It is the responsibility of the governments to facilitate healthy and prosperous life for its citizens. A variety of functions are included to achieve this goal such as improvement of security, infrastructure, enforcement of laws and spending on education, health and nutrition. The health sector thus needs to compete with the others for resources out of the common government kitty. Governments of different countries have installed mechanisms to tax its citizens in various commodities and services, to fill the treasury from which it allocates a percentage share to develop health of its citizens. It is generally observed that in almost all the developed nations and some underdeveloped nations, governments spend heavily on health, even though a majority of its citizens are in a position to pay for health services. In the rest of the world, government spending is extremely low on healthcare and is unable to meet health needs, even though it remains the largest organised resource pool for health systems.

### **Health Insurance**

Here the basic tenet is that a large group of people are made to share the risk that they may need health care at any point of time, thus creating a 'risk pool'. The funds dedicated for health care are collected through prepayment and managed in such a way as to ensure that the risk of having to pay for health care is borne by all the members of the pool and not by each contributor individually.

### **Social Health Insurance**

In this finance scheme contributions targeted specifically for health care are collected from workers, self-employed people, businesses and the government. A pool of funds is thus created

and health care is financed through this source. The successful implementation of this scheme depends on the contributions of each member of the population. Often the government ends up contributing on behalf of people who cannot afford to pay themselves to this fund. An example of this type of insurance is the Employees State Insurance in India.

### Private Insurance

Private insurance companies operate in fairly big numbers in the developed countries such as USA. These collect contributions from its members and work for high profit margins due to the high insurance coverage amount and incentives that they create to increase appeal of their schemes. As a result the premiums paid for these schemes are also high and hence the private insurance players are more interested in the high income groups. In most countries part of the population is covered directly through general taxes, while others are required to make contributions to a social health insurance fund or another type of health insurance, which may be private.

### Donations

Donations play a very important role in the health systems such as during calamities and such emergencies in the affected areas. There is a lack of authentic data regarding the type and source of funds received during these situations especially when such catastrophes occur in lesser-developed countries. Similarly the availability of these funds are unpredictable and depends on the mobilisation and involvement of governments, non governmental organisations, corporate world and private donors.

## Health Care System Models

The health care systems in different countries are either purely private enterprises following the so called capitalistic model or the public insurance systems which enshrine the fact that health care is a fundamental right of every citizen and a basic responsibility of the government. Most often a country has a mix of the two systems to ensure equitable distribution of quality medical care.

### Private Systems

The purely private enterprises are relatively rare. In some countries where such systems exist, they cater to the requirements of a comparatively economically well-off population subgroup in a developing country. In such places the overall standard of health care is poor and private enterprises in the form of private clinics or nursing homes meet the requirements of wealthy expatriates. In most countries where the government health care system functions to provide health care, a parallel private system is also allowed to operate.

### Public Systems

The other model is the public insurance system where in the state covers the risks involved substantially. Here the citizens do not pay from their pockets to finance their treatment and mostly insurance is the medium of payment for health care. Among the methods of funding enumerated above, governments use taxation, social security measures and donations to fund this method of health care. Public insurance systems include social security model, publicly funded health care model and

the social health insurance models. In the social security model, workers and their families are insured by the state, while the residents of a country are insured by the state in a publicly funded health care model. Social health insurance scheme has been discussed before and includes a system where the population is a member of a sickness company. In India, the Employees State Insurance Corporation is an amalgamation of the social security model and social health insurance scheme. Some of the other social security models are practised in organisations such as Defence and Railways. A publicly health care model works in high-income countries and the small countries where government sources are mobilised to fund for the health care of its population such as in Cuba. A fall out of this model is that the quality of health care is compromised when the governments do not devote adequate resources for health care and private players take over.

## Planning & Development of Health Systems

### Planning

The earliest developed planning is where each individual or organisation makes decisions for definition and selection of relevant health problems, establishment of priorities among problems and allocate resources accordingly, establish coordination with other health system personnel and chose daily activities in the use and financing of health services. This is known as the *dispersed health planning*. Thus each physician selects his patients, area of practice, referral system, standard of performance and relationship with other health care workers and establishments. Similarly the consumer defines his health problem, which needs more priority and investment in time and money and ties up services of medical workers and laboratories and pharmacies he would utilise. A financing organisation also prioritises the services, facilities and disabilities for distribution of funds. Thus each individual or organisation balances its own self-interest with the self-interest of other individuals and organisations whose help and cooperation are required. While some important goals and standards are achieved with this planning, it results in creation of gaps and inconsistencies in distribution of health care especially among minority and disadvantaged who have not been able to participate in the planning process. Similarly each provider or consumer needs external help to solve all relevant health problems in the era of specialisation, population expansion, social mobility and rising expectations.

There have thus developed voluntary associations of persons and organisations to solve common problems and collectively attain goals, which were difficult to achieve individually. Such form of planning is known as *focused health planning*. These associations are established solely for purpose of organising voluntary efforts of persons interested in planning together to solve problems in organisation and financing of health care such as the health and welfare councils or comprehensive health planning councils in certain countries. These do not themselves provide health care nor allocate resources or engage in funding but facilitate the dispersed planning by individuals and organisations. The lack of control of resources, disagreements with those who control finances, domination by self-interest groups have limited the ability of these

organisations to implement recommendations arising out of planning processes.

The limitations of focused and dispersed planning to deal with certain kinds of issues, have resulted in development of another type of planning called as *central health planning*. Central health planning refers to the planned use of power controlled by an individual or organisation to force other individuals and organisations to use their own resources in accordance with their plans. Central health planning may be based on the legal or professional authority for health care, such as a physician in a clinical practice, or a health care financing organisation such as the medicare programme or state governments exercising their authority, which requires the hospitals to perform certain activities to improve these institutions.

### Development

The health systems need to respond to a variety of disease conditions, which have themselves been influenced by the social, demographic and epidemiological transition of communities. They require the financial means, organisation and procedures to efficiently manage the diversity of health conditions. Thus for development of health system in a country, the following key issues must be kept in mind that it should aim in :

- Improving health status.
- Reducing health inequalities.
- Enhancing responsiveness to legitimate expectations.
- Increasing efficiency.
- Protecting individuals, families and communities from financial loss.
- Enhancing fairness in the financing and delivery of health care.

A health system must aim at ensuring *universal coverage* of all the citizens of its country. To achieve this, the poorest, underprivileged and the sickest have to be reached by health promotion and prevention programmes. They have to be able to reach the nearest health post or clinic for treatment of locally prevalent and common health conditions. It also means that irrespective of the source of funds, the health care system must function like a national health insurance system, prepaid either through tax revenues or through social insurance. In this connection a historic WHO conference in Alma-Ata in 1978 established the goal of Health for All by the year 2000 defining the goal as 'attainment by all peoples of the world a level of health that permits them to lead a socially and economically productive life'. It suggested the achievement of this level by the extension of basic primary health care services to everyone as the major route to attain this goal.

*Efficiency* of a health system would vary with the amount of resources allocated to its development out of the total health budget of a country. The health status achieved with this kind of allocation would define efficiency in the macroeconomic terms. Most of the developed countries devote upto 9 percent of Gross Domestic Product for health care, which is considered optimal in view of the fact that the World Bank suggests US \$12 be allocated by a country for a combined package of per capita basic preventive and curative interventions. In most of the developing countries such as Cameroon, Sudan, Nigeria the percentage of GDP share for health is upto 2 percent, which

is grossly inadequate. Some countries such as USA spend upto 14 percent of GDP on health, which conversely could be an indicator of inefficiency. The scope of achieving greater efficiency out of the existing resources defines microeconomic efficiency. This includes issues such as overstaffing, spending large amount on health needs of diseases, which are absolutely preventable and so on.

*Establishment of priorities* in spending health resources is essential to ensure universal access to affordable and effective health care. Clear definition of priorities facilitates planning, training, monitoring and supervision of services in districts with inputs to build capacities at this level. In developed countries guidelines on priorities are debated and while several categories of priority are defined they differ among countries based on the need. In developing countries the debate on establishment of priorities is mostly led by the international agencies such as the focus on malaria control, diarrhoeal diseases or poliomyelitis. In such settings once the common conditions, with the maximum disease burden, are covered then the health facilities could be reorganised for improving patient waiting times, standardised dispensing of drugs and better communication with service users. Thus limited resources could be focused to have the greatest impact on service quality and health outcomes.

Lastly, *service quality* of a health system is influenced in the way service providers are paid. It is seen that when the providers are paid in the fee-for-service manner, it results in overspending, extravagant and wasteful care due to over-prescription, overuse of diagnostic services and excessive surgical interventions. This leads to an unproductive growth in health expenditure, hence a control on utilisation volume or quality of service is required. This control includes an arrangement between the funding agency, provider and the user. Referral process, profile of the health care personnel, performance and quality of care audit are such important measures to check the economic efficiency of health care. Appropriate incentive-disincentive process should be utilised for supervision of health care providers both in public and private sectors.

## Health Care Systems in the World

### France

The health care system in France is one of the best in the World. It permits all citizens access to treatment irrespective of their payment capacity, social class or any other disposition. The health care system is a combination of public, private (not for profit) and private profit making system. The doctor-population ratio at 3 : 1000 is among the highest in the world. The social security with regard to health care consists of several public organisations, with separate budgets that refund patients for health care. These budgets are generated by direct and indirect taxes such as that on tobacco and alcohol and contributions. Upto 70 percent of health care costs in most patients and 100 percent in long-term ailments is refunded by the social security. Supplementary insurance is also taken by the citizens, either from their employers or private organisations, mostly non-profit insurers. Insurance is compulsory for all employed and self-employed adults, besides which, social security also protects against economic losses incurred due to sickness and



provides maternal and child care services at home for women with new-born babies.

### United Kingdom

The United Kingdom established National Health Service (NHS) under the auspices of Department of Health in 1948 with the basic purpose of providing all British nationals with free physician and hospital services. Most health care facilities are owned by the state and the people working in NHS are employed by the state either directly or as independent contractors. The General Practitioners (GPs) are the mainstay of NHS and every patient has to be routed through them. They are paid by a nationally agreed contract, according to the number of patients registered with them and the range of additional services offered. The GPs refer the patients to specialists or secondary or tertiary level trust hospitals. Hospital staff are salaried employees according to nationally agreed contracts. Financing of health care is mainly through taxes and insurance. Private health care continues parallel to NHS, funded by private insurance and utilised by those who can afford it. The NHS has received its own share of criticism due to poor allocation of funds and long waiting lists despite being considered as the most cost effective health system in Europe.

### United States of America

The health care system of USA is alone among developed nations with the absence of universal coverage. It is a mix of public, private and charity hospitals and clinics. Majority of the health care expenses of its citizens are met by health insurance. Yet the US Census Bureau estimates that 16 percent of US population are uninsured, which mostly includes people less than 30 years of age who don't believe in the need to purchase health care and some eligible people who have not applied for insurance due to escalating costs. Some of the health insurance is provided by the government and includes Medicare covering people aged 65 years and above and those below that age with disabilities, Medicaid for low income groups mostly covering the dependant population and the State Children's Health Insurance Program (SCHIP) for all children upto 19 years of age. These state insurance schemes and those for serving or retired military personnel cover about 27 percent of population by government financed insurance. Besides this there are almost 50 private insurance companies, which offer medical insurance products to the citizens. The insurance systems in USA follow Diagnosis-Related Group (DRG) concept, that groups patients according to diagnosis, type of treatment, age and other relevant criteria. The health care establishments are paid a set fee for treating patients in a single DRG category, regardless of the actual cost of treatment for the individual.

### India

Health is a state subject in India, though the Centre plays an important role as a regulator, advisor and resource provider. The government is obligated to provide health care to every citizen of India. The total share of health costs of the government towards provision of free health care in India today is 17.6 percent, which is a quarter of what a country like USA spends on its citizens. As a result of this dismal spending on health, the government hospitals and primary care institutions are ailing.

There is a large and diverse private health care system including corporate hospitals, nursing homes and private clinics, which exist around urban areas and are utilised by people who can afford the out-of-pocket expenses. Medical insurance in India is in nascent stages and unavailable to majority of population. As a result majority of the lower economic groups cannot afford private health care and depend on government institutions or practitioners of indigenous or alternative health systems.

**Alternate systems of health care in India :** There is a large share of health practice in the country based on alternate systems of medicines, some indigenous and some, which were brought by the different invaders over the centuries. The scientific basis of these systems have been debated time and again, however it goes without saying that a vast majority of these systems are supporting health care in remote areas, for the disadvantaged groups and the poor who cannot afford the increase in health care costs in the country. Government of India has established a separate Department of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy) under the Ministry of Health & Family Welfare, to promote and regulate the practice of alternative medicine in the country. The more common ones are mentioned in the next paragraph.

The term Ayurveda means 'Science of Life', which is conceived as the union of body, senses, mind and soul. The living man is considered as a matrix of three humors; *Vata*, *Pitta* and *Kapha*, seven basic tissues and the waste products of the body. Besides this the body is considered to be composed of five basic elements namely earth, fire, water, air and vacuum (ether). Any disturbance in the balance in the matrix or the elements is considered to cause sickness and the aim of Ayurveda is to restore the balance. It employs treatment modalities such as purification treatment, palliative treatment, prescription of various diets, exercises, avoidance of disease causing factors and the use of psychotherapy and ayurvedic medicines. Siddha system of medicine is another ancient Indian system, which takes into account the patient, his surroundings, age, sex, race, habitat, diet, appetite, physical condition etc to arrive at the diagnosis. It uses minerals, metals & alloys and drugs & inorganic compounds to treat the patients. Unani medicine is another alternative system, which was introduced by the Greeks in ancient India. It considers that the body is made up of four basic elements, earth, air, water and fire which in turn form humors, blood, phlegm, yellow bile and black bile. Health is a state of equilibrium among these humors and when this is disturbed a person falls sick. The system treats a patient with diet, pharmacotherapy, exercise, massages and surgery somewhat similar to Ayurveda. Yoga is a tradition evolved over thousands of years by saints and sages. According to yoga, most of the diseases originate through wrong way of thinking, living and eating and its basic approach is to correct the lifestyle by cultivating a rational, positive and spiritual attitude towards all life situations. Among the other alternate systems practised in India is homeopathy, which was created by Dr Hahnemann in Germany and found great popularity in this country. It considers that symptoms are the best possible reaction of body's defence mechanism to a disease and aims to strengthen these reactions. It tries to find out the best possible



remedy that would be effective and uses minimum doses of drugs to cure diseases against the principles of dose-response effect.

## Summary

A health system as described by WHO is the “sum total of all the organisations, institutions and resources whose primary purpose is to improve health.” Health systems affect the socio-economic status of a community in any region and in turn are affected by its poverty, development and stability. Health systems usually include - Development of health policies, plan for implementation and regulation of health services; Define and develop the institutional framework to deliver the health services within the purview of this system; Allocate and mobilise financial and human resources for its functioning; Plan, manage and deliver the health services. Health systems should be accessible, efficient, affordable and of a good quality. They should ultimately aim to improve, maintain and restore the health status of the community at a cost that an individual and the community can afford. The WHO has identified three overall goals for the health systems to be effective in contributing to better health; responsive to people’s expectations, fair in how individuals contribute to funding the system.

Most often a country has a mix of the two health care systems, Public and Private, to ensure equitable distribution of quality medical care. The governments use taxation, social security measures and donations to fund public health care system. Public insurance systems include social security model, publicly funded health care model and the social health insurance models. Health insurance is also provided through Private insurance companies.

Health planning is of three types - Dispersed, Focused and Central. Central health planning refers to the planned use of power controlled by an individual or organisation to force other individuals and organisations to use their own resources in accordance with their plans. Planning efforts in a country shift from one type of planning to another as decisions made in one planning context create the need for other types of planning. For development of health system in a country key issues to be considered are improving health status; reducing health inequalities; enhancing responsiveness to legitimate

expectations; increasing efficiency; protecting individuals, families and communities from financial loss; and enhancing fairness in the financing and delivery of health care.

In India Health is a state subject, though the Centre plays an important role as a regulator, advisor and resource provider. The government is obligated to provide health care to every citizen of India. The total share of health costs of the government towards provision of free health care in India today is only 17.6 percent. There is a large and diverse private health care system including corporate hospitals, nursing homes and private clinics, which exist around urban areas and are utilised by people who can afford the out-of-pocket expenses. Medical insurance in India is in nascent stages and unavailable to majority of population. As a result majority of the lower economic groups cannot afford private health care and depend on government institutions or practitioners of indigenous or alternative health systems like Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy. In India, the Employees State Insurance corporation is an amalgamation of the social security model and social health insurance scheme. Some of the other social security models are practised in organisations such as Defence and Railways.

## Study Exercises

**Long Question :** Describe the health care system in India

**Short Notes :** (1) Health Insurance (2) Social security measures (3) Goals of a Health care system

**MCQs :**

1. The total share of health costs of the government towards provision of free health care in India today is (a) 17% (b) 7% (c) 37% (d) 50%
2. The following is not a method of financing health care systems (a) Direct or out-of-pocket payments (b) General taxation (c) Social health insurance (d) None of the above
3. The type of health planning which refers to the planned use of power controlled by an individual or organisation to force other individuals and organisations to use their own resources in accordance with their plans is (a) dispersed (b) focused (c) central (d) none

**Answers :** (1) a; (2) d; (3) c.

*Amitava Datta*

## Assessing “Health Status”

Assessing the health of a population is a fundamental part of many public health activities. Performing the assessment correctly is a challenging process as there are usually problems in obtaining the necessary data and in balancing alternative approaches.

### Reasons for Assessing Health Status

The usual circumstances under which assessing of health status of a community is conducted are as follows :

- To conduct a “health needs” assessment to establish whether particular health problems exist in a given population, describing the problems and identifying the magnitude of mortality and morbidity due to the problem.
- To conduct an audit into equitable distribution of resources, namely provision of health services by establishing the quantitative difference between “need” and “supply” for a defined population/service and bringing about necessary interventions.
- To assist in conducting a review of existing policy or plans to assist policy making decisions by decision-makers either directly or by informing the public, professional groups and other interested parties about the nature and distribution of health challenges and the definition of the problem; this may include a health impact assessment.
- To enable setting of targets for achievement and decide on quantum of resource allocation that is for better planning and implementation of health programs, improving resource allocation, target setting and helping targeting of health and other services.
- To conduct an evaluation of existing / proposed health services /interventions
- For research purposes by assisting in prioritizing the areas where research is needed.

### Steps in Assessing the Health Status of a Community/ Population

As indicated above, there may be many reasons for conduct of assessment of the health status of a community / population. The methodology varies depending on the objective. However the usual steps in performing a health status assessment are as follows :

- Define the purpose of the assessment.
- Define the population concerned including the populations which will be compared.
- Define the aspect / aspects of health to be considered.
- Identify and review existing data sources from which information can be obtained. In case good local data is already available or reliable local or national statistics already available or relevant published or unpublished surveys already available, there may be no need to conduct a fresh health assessment survey. The various sources of

secondary data are discussed in detail in the section of epidemiology.

- Determine the most appropriate existing data which can be used.
- Use of the available data, statistics or survey reports to appropriately analyze the aspects needed which includes adjusting for population composition, deriving suitable measures and modeling future trends if required.
- Determine if any issues / aspects require data to be specially collected in which case a special survey may need to be undertaken. Details of undertaking a survey are dealt with in the section on epidemiology.
- Determine the aspects of comparators which will be considered.
- If so needed issues of confidentiality of information and disclosure by the subjects will need consideration besides any ethical issues.
- Interpret and communicate the results of the assessment.
- Evaluate the results and efforts undertaken

**Step 1 - Clarity of purpose :** The starting point of the health assessment, defining the purpose, is very important. Many a times, a tendency to have an extensive unfocused list of objectives as well as the temptation to examine interesting but irrelevant issues may arise. These must be resisted.

**Step 2 - Define the population :** Defining the population to be assessed is extremely important. Population size, structure and the period of observation can have major effects on the numbers of cases of disease or disability observed. The data is therefore usually expressed as proportions (e.g. the number of children aged under five per thousand population at a particular point of time) or rates (the number of new cases of tuberculosis per thousand population per year). Adjustment for potential confounding variables (e.g. age, sex, socio-economic status, etc) to allow valid comparison with other populations will be needed. Often geographic locations are used to frame the population studied, for example district boundaries. Problems can arise with population estimates for small areas, especially those projected from a data source that is relatively distant in time. The smaller the areas being studied, the bigger the chance of errors in estimates of population numbers and composition which can result in dramatic but erroneous findings.

**Step 3 - Define the aspect / aspects of health to be considered :** Health as indicated above can have a variety of meanings which can range from the lofty definition of World Health Organization having physical, emotional and social dimensions. In practice a more restrictive definition should be used which can be easily measured, for example a particular group of diseases or certain summary measures of population health.

**Step 4 - Review the available data :** Comprehensive population health assessments are based on a wide range of data of different types. While local data are required for assessing the health of the local population, they may not be available and so national (or indeed international) data may be used if the local population is felt to be typical of the nation as a whole. Data from similar localities (e.g. from different developing countries sharing common boundaries) or national data may be used for comparative purposes.

Many data are collected routinely by periodic national census, health service providers, local and central government and others. In addition, some of the many ad hoc studies that have been carried out locally or elsewhere may be relevant to a particular issue. Weaknesses of routine data collection systems include non-standard or inconsistent approaches to coding and data collection and limited availability due to cost and privacy policies. Data can be Quantitative, which usually answer questions such as 'How many people have a particular condition?' or Qualitative, when exploring such issues as what it is like to be afflicted with a chronic disease like diabetes, or perceptions about the effects and tolerability of risks from industrial pollutants. Strengths and weaknesses of various data sources are discussed in the section on epidemiology

**Step 5 - Select data carefully** : At first sight there may seem to be so many data available that assessing health should not be much of a challenge. However, in this connection Finagle's law is usually proved correct in public health work, which can be roughly stated as, 'The information you have is not what you want; the information you want is not what you need; the information you need is not what you can get; the information you can get costs more than you want to pay'. Relevant, detailed and accurate data are seldom available directly and so data collected for other purposes have to be used appropriately to give an indirect assessment. In considering the use of any data, one must consider how they have been obtained. People often assume that the quality and relevance of the data is satisfactory for the intended purpose. While recording data consistent terms or criteria may not be used and this can have a major impact. The use of international data needs great care as different countries may use different definitions and data collection processes.

When the data source proposed to be used has been identified the following aspects of the data should be considered before utilizing it :

**Validity of data for the assessment** : The data must be relevant to the issue, the data items should have been defined, there should be no conceptual biases in the data source (e.g. data collection should not have been structured to benefit the organization that has produced the data), the data should still be relevant as per time and the data should be relevant to the defined population so that the findings can be generalizable.

**Technical quality of data** : The data should have been properly recorded according to the specified definitions, complete in all aspects (preferably all subjects included or a representative adequate random sample used), be free from classification or selection biases and appropriate for the assessment planned

**Quality of the analytic methods** : The data should be adjusted for the population structure, e.g. age, sex, social group or ethnic composition and the numbers should be big enough to allow a statistically adequate and precise estimate of the aspects being considered

**Other aspects** : The relevant use of the data should be possible in spite of confidentiality policies, whether the data is available in computer analyzable form and what the likely cost of obtaining the data is.

**Step 6 - Make good use of the existing data - Analyze and interpret the existing data** : In progressing from data to information, the purpose of the assessment will determine the nature of the analyses chosen. The results of the health assessment need to be communicated to the concerned people for who the assessment has been designed and executed. The usual aspects which may be planned to be communicated include :

- Comparison of findings on health aspects of the population with other similar populations or larger populations, or comparing health status observed with that expected for the type of population.
- Describing the relative health of groups of the population (based on defined areas or social groups) and identifying inequalities.
- Comparing the health trends over time.
- Estimating the extent of potentially preventable health problems or conditions.
- Describing the likely health impact of environmental and social factors.
- Describing the impact of health problems in terms of people's experience of health problems.

**Step 7 - Carry out a local study, if necessary** : The health aspect planned to be assessed can be sufficiently important and the available local data so limited that a case may exist for conducting a fresh data collection. At national or state level, this situation arises relatively frequently in the field of public health. Conduct of special survey is however usually constrained by the cost involved. At the local level, a special survey or longitudinal study should only be carried out if time is available and the value of the data likely to be provided justifies the cost. The purpose of the assessment must be clear. Attempting to answer too many interesting questions or record too many findings may become unnecessarily expensive, besides reducing the response rate, if a questionnaire is used which appears too complex. The key features of a successful survey are described in an exclusive chapter in the section on epidemiology.

**Step 8 - Consider the use of comparators** : Assessing the health of a population may be undertaken to assess what is the actual extent of a health problem and also to determine how it compares with previous years, other areas and other social groupings. For example in examining the need for initiatives to reduce smoking, all that may be required is the number of deaths and extent of ill health associated with smoking locally. Information that locally this data is 10% lower or higher than the national average may well be redundant and indeed may divert attention from the principal data. However on other occasions comparative data will be required to highlight problems that are becoming more important with the passage of time or are particularly acute locally and need to be addressed in ways that are different from those required for most other areas. For example, the proportion of school children smoking in the town surveyed has increased since the previous survey or is more as compared to national average. Comparisons are of particular relevance when considering inequalities and inequities.

**Step 9 - Address issues of confidentiality and disclosure** : Assessing the health status of a population, especially at a small

area level, increases the risk of inappropriate and unnecessary disclosure of personal data. For example, the assessment of the HIV positive status of commercial sex workers in a particular area. Social and other discrimination besides loss of clients may result from the publication of the survey results. This is a highly complex and evolving area, as there are both technical and ethical issues, concerning balancing the benefits to society being weighed with the risks to individuals. Informed consent of the participating subjects is an essential pre-requisite to their inclusion in the assessment process.

**Step 10 - Communicate results effectively** : Occasionally a large set of data is to be produced for reference purposes, for subsequent expert analysis. But usually the information is used to inform the process of identifying opportunities to improve health and while experts may be involved, the information usually needs to be communicated to a general audience. When communicating results, a full description of the analytic methods used together with their limitation and assumptions may well be inappropriate. If so the assessor must take great care to provide a fair assessment and ensure that the typical audience will gain the right impression. The assessor must, however, be prepared and able to justify the methods in detail if requested.

Key points about health status analyses to consider in a written or oral communication are :

- Think through its purpose.
- Don't leave it to the reader to relevant points from a mass of data-quote specific data to make a point.
- Ensure confidentiality for participants in survey and ensure this is made clear to everyone.
- Don't be too sophisticated-many people in the target audience will not have that much background knowledge of the issue.

**Step 11 - Evaluate your health status assessment** : Those who are engaged in public health need to emphasize the importance of assessment to others. This should begin at home. It is important that our work is assessed using correct tools such as audit.

## Assessing Health “Needs”

### Definition

“Health needs assessment” is a systematic method of identifying the unmet health and health-care needs of a population and making changes to meet these unmet needs. Health needs assessment is used to improve health and other service planning, priority setting and policy development. Most doctors are familiar with assessing the health needs of individual patients. Professional training and clinical experience imparts a systematic approach to this assessment before starting treatment that the health professional believes to be effective. Such a systematic approach has often been missing in assessing the health needs of local or practice populations. Case studies have revealed the importance of conducting scientific “health needs assessment” before planning appropriate interventions in society.

### Defining Need

An understanding of health needs assessment requires a

clear definition of need. Need, implies the capacity to benefit from an intervention. ‘To speak of a need is to imply a goal, a measurable deficiency from the goal and a means of achieving the goal.’

Health needs assessment is not the same as population health status assessment. It incorporates the concept of a capacity to benefit from an intervention. It therefore introduces an assessment of the effectiveness of relevant interventions to supplement the identification of health problems. Health needs assessment should also make explicit what benefits are being pursued by identifying particular interventions.

Health needs may be of two broad categories, viz. normative or professionally assessed needs, which are the needs which the expert health care providers think should be addressed, based on their professional assessment of the community. The second is the “felt needs” which the community feels to be important. Both the view points are important and need to be considered when assessing the health needs of a community.

### Approaches to Needs Assessment

Varied approaches to needs assessment have been suggested, which include ‘epidemiologically based’ needs assessment – thereby combining epidemiologic approaches (like specific health status assessments) with assessment of the effectiveness and possibly the cost-effectiveness of the potential interventions. It can also be a comparison of the levels of service receipt between different populations. Determining the demands and wishes of professionals, patients, politicians and other interested parties can also be an effective approach to needs assessment.

The epidemiologic and qualitative approach in determining priorities incorporates aspects of clinical effectiveness, cost-effectiveness and patients’ perspectives. Comparisons of health service usage are commonly used as indicators of need. However, often for unexplained reasons, population-based usage rates typically vary markedly between areas. The relation between usage rates and improved health outcomes is also often hard to demonstrate.

The distinction between individual needs and the wider needs of the community is important to consider when assessing needs. If individual needs are ignored then there is a danger of a top-down approach to providing health and other services, reflecting what a few people perceive to be the needs of the population, rather than what they actually are. In India, the present concept of decentralization through decision making by the panchayati raj institutions and implementation of National Rural Health Mission are clear examples of this concept.

It is important to appreciate that health needs assessment involves the active, explicit and systematic identification of needs rather than a passive, ad hoc, implicit response to demand. For example, evaluation of the pattern of referrals for specialist care from a health centre and then base the recommendation for posting of a particular specialist based on work load, rather than base the recommendation simply based on “demand” of the local politician. The assessment of health needs can be made clearer by classifying the issues into needs, demands and supply, considering that health needs is not restricted to health-care needs. Health needs include wider social and environmental determinants of health



such as social and economic deprivation, housing, nutrition, education and employment. Health needs should ideally be appropriately addressed ('met'), but these needs are too often unmet (e.g. waiting lists, undiagnosed anemia, ignored needs of contraception) or 'over met' (e.g. prescribing antibiotics for all diarrhea cases).

*Assessing of health needs provides the opportunity for :*

- Assessing the population's health status in terms of the patterns of disease or disorders in the local population and the differences from district, regional, or national disease patterns.
- Learning more about the needs and priorities of patients and the local population.
- Highlighting areas of unmet needs and working towards meeting these needs.
- Deciding rationally and appropriately how to use scarce resources to improve the health of the local population in the most effective and efficient way.
- Influencing government policy, inter-sector collaboration, as well as research and development priorities.
- It also provides a method of monitoring and promoting equity in the provision and use of health services and addressing inequalities in health.

### **Framework for Assessing the Health Needs of a Population**

There are eight steps involved in a formal health needs assessment project. However every assessment need not follow a simple linear progress through all the steps. Health needs assessment can be approached in much the same way as doing a jigsaw, so that different pieces are put together to give a complete picture of local health problem and thus the "need". The various steps involved are as follows :

**Step 1 :** Identify the health problem to be addressed in the defined population.

**Step 2 :** Carry out a health status assessment for the population, covering the relevant areas of ill-health and/or potential health to determine what is the size and nature of the problem.

**Step 3 :** Identify the existing services and interventions being delivered, including, where relevant, the service targeting, quality, effectiveness and efficiency.

**Step 4 :** Identify the interventions by determining what patients, professionals and other stakeholders want.

**Step 5 :** Identify interventions by reviewing the scientific knowledge and determine the most appropriate and cost-effective solutions.

**Step 6 :** Determine the resource implications. It may require to choose between competing ways of meeting needs (competing interventions) and decide on competing priorities – resources are always limited.

**Step 7 :** Enunciate the recommendations and the plan for implementation.

**Step 8 :** Determine whether assessing need is likely to lead to appropriate change by identifying expected health gains.

### **Needs Assessment Requires Careful Preparation**

The process of needs assessment involves identifying the right

issues, using the right technical methods and managing the process effectively. The task needs to be defined right in the beginning with the objectives as clear, simple and focused as possible. The right project team should be assembled and all relevant stakeholders included, which may include representatives from the likely funding agency, clinicians and the users. Good leadership is important besides providing a clear and effective communication during the project. This aspect is especially important if there are multiple agencies involved in the assessment process. Access to relevant available information and informants should be sought at an early stage.

### **Identify the Health Problem or Issue**

The health problem on which to focus the needs assessment exercise should be clearly identified. A health problem may come to attention from many sources, including the results of a population health status assessment, media reports, input from patients or stakeholders, government priority setting, or the scientific and professional literature.

The definition of the problem may involve a search of the health and social science databases besides review of the published health literature, which will provide a national and international perspective about the health topic and may provide already known methods, case definitions, disease incidence and prevalence, current provision of health services, etc, which may be applicable to the local population. In the absence of reliable published professional literature, a search of unpublished literature sources, for example reports of public health professional bodies and government health department databases, can also provide useful information. After initial analysis, it should become apparent whether the problem justifies a full and systematic needs assessment.

### **Dimension of the Problem**

With a working definition of the health problems in mind, relevant health data can then be collected by selected methodology – study of records or special survey. Although it would be desirable to be able to estimate the likely number of beneficiaries of the planned interventions, the assessment process should be able to establish the following :

- How many people in the studied population are likely to be suffering from the target condition or conditions ?
- What their socio-demographic and other characteristics are?
- To what extent they are already receiving appropriate interventions.

### **Availability of Services**

There are several sources of data on health care in a locality. Hospital data can provide information on OPD attendance and hospital admissions, diagnoses, length of stay, operations performed and patient characteristics to some extent. Clinical indicators can provide information on the comparative performance of hospitals and health authorities. Health-care provision indicators (e.g. number of doctors and nurses per capita, number of operations per capita) are often compared with national or international norms. There is however rarely evidence of a direct link between provision of health services and positive health outcome.

## What do Professionals, Patients and other Stake Holders want

A wide range of stakeholders can be consulted to describe local health needs. Local health professionals – both private practitioners as well as those in government run health care facilities will have valuable contributions to make about the health needs of their local community. Other stakeholders such as health administrators, local government agencies, local politicians and voluntary groups also provide important contributions. This not only obtains views on their knowledge and beliefs but also engages them in the assessment process and encourages ownership and eventual implementation of the results. It is important to include the general public in decision-making about local health care. With increasing recognition of the importance of obtaining greater public involvement, various methods have been used, including use of panchayati raj institutions in India.

## Determining the most Appropriate and Cost-Effective Interventions

An essential part of a health needs assessment is the review of the clinical effectiveness and cost-effectiveness of interventions that can address the identified health needs. Evidence about the effectiveness of health interventions or services can be found in databases of good-quality systematic reviews such as the Cochrane Library, or peer reviewed publications. Where there is a limited evidence of effectiveness of interventions then professional consensus about best practice may have to be relied on.

## Resource Implications

If needs are to be matched to the usually limited available resources so that as much need as possible is met, then economic appraisal, including cost-effectiveness or cost-benefit information, must be considered. This involves :

- Determining how resources are currently being spent (programme budgeting)
- Defining options for change by suggesting alternatives :
  - (a) identify potential services which require more resources
  - (b) identify services which could be provided at the same level of effectiveness but at reduced cost.
  - (c) identify services which are less cost-effective than those identified.
- Assessing the costs and benefits of the principal options.
- Decide on the best option, aiming to increase investment in (a) and reduce investment in services identified in (b) and (c).

## Implementation of Recommendations

In a needs assessment program, the collected information should be collated, analyzed and presented, usually in a report form. A summary of key findings is very useful in communicating the results to the decision-makers and those who will be affected by the decisions. Reporting results, however, is not an end in itself. Building agreement to a practical implementation plan for meeting the unmet needs is an essential part of needs assessment.

**The Demarcation Between Health Needs Assessment (HNA) and Health Impact Assessment (HIA) :** Health needs

assessment starts from the health of a defined population and result in proposals (for policy, programmes, strategy, plans or other developments). Health impact assessments (HIAs) and Integrated Impact Assessment (IIA) start from proposals and compare how they may impact on health. HIA has been dealt with in detail in a subsequent chapter in this section.

## Summary

Assessing health status of a community is a challenging process but is required for numerous reasons viz- to conduct a health needs assessment; to audit equitable distribution of resources; to assist in conducting review of existing policy; to enable setting of targets for achievement; to evaluate existing / proposed health services / intervention and for research purpose as well. The methodology varies depending on objective; however mentioned steps could be followed to achieve the same. Needs implies the capacity to benefit from an intervention. The concept of felt needs- what people consider and/or say they need, expressed needs - needs expressed by action and normative needs-what health professionals define as need are very important to understand and apply. Health Needs Assessment is a systematic method of identifying the unmet health and health care needs of a population and making changes to meet these unmet needs. Approaches used commonly for need assessment are epidemiological and qualitative in nature. Health needs are not static and therefore any assessment will only provide snapshot of current needs of population concerned. Thus health need assessment is a continuous process which is to be reviewed, updated and evaluate concurrently.

## Study Exercises

### Exercises

- (1) Give WHO's definition of health and its drawback.
- (2) Enumerate the limitations of hospital based data.
- (3) What is Finagle's law in public health work?
- (4) Name a difficulty with use of international data.
- (5) What are the aims of health need assessment?
- (6) Name approaches utilized for needs assessment.
- (7) State the ethos of health needs assessment.

### Answers

1. WHO has defined Health as a state of complete physical, mental and social well being and not merely absence of disease. This is an idealistic definition which does not lend itself easy measurement.
2. (a) Although voluminous, needs to be evaluated with care as not all people with a disease/ disability receive treatment. (b) Data is recorded for clinical purpose rather for analytic purpose. (c) Definition of a condition vary substantially from clinician to clinician, from clinician to researcher. (d) Issues related to patient confidentiality.
3. 'The information you have is not what you want; the information you want is not what you need; the information you need is not what you get; the information you get costs more than you want to pay'.
4. The use of international data needs great care as different countries may use different definition and data collection processes.
5. (a) To identify unmet health and health care needs of

- a population. (b) To improve health and other service planning, priority setting and policy development.
6. (a) Epidemiologic method. (b) Qualitative method.
  7. Health needs assessment starts from the health of a defined population and result in proposals- for policy, programmes, strategy, plans or other developments.

## Further Suggested Reading

1. Assessing health needs. John Wright and Dee Kyle in Oxford Handbook of Public Health Practice. 2nd ed, 2007. 20-31
2. Assessing health status. Peter Gentle, David Pencheon and Julian Flowers in Oxford Handbook of Public Health Practice. 2nd ed, 2007. 146-159
3. Measuring health needs. Gavin Mooney, Stephen Jan and Virginia Wiseman in Oxford Textbook of Public Health. 4th ed, 2002. 1765-1772

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## Assessing the “Health Impact”

*Amitava Datta*

### Definition, Scope and Need for HIA

The word “Impact” in public health parlance means the overall, totalistic effect of an intervention. It does not restrict itself to specific outcomes. For example, the specific outcome measure in the case of an intervention like polio vaccination is reduction in the incidence of paralytic polio cases. However assessment of “impact” will go much beyond this and include wider range of outcomes both positive like, improvements in quality of life, increase in productivity as well as negative outcomes like community apprehensions, misconceptions, etc. Health impact assessment is a combination of procedures, methods and tools by which a policy, programme or project may be judged as to its potential effects on the health of a population and the distribution of those effects within the population. Health impact assessment may focus on projects such as new industry, hospital or health centre, programmes such as women's empowerment or immunization of children, or policies such as ban on advertisement on tobacco in movies. On an international level, HIA can be employed to assess global public policies in areas such as international trade, war and human rights.

Health Impact Assessment (HIA) is based on four values- Democracy, Equity, Sustainable development and Ethical use of evidence. These values provide the foundation based on which the benefits of HIA can be derived and link HIA to the policy environment in which HIA is being undertaken.

Elucidation of these values explains the concept of HIA. By democracy is meant allowing people to participate in the development and implementation of policies, programmes or projects that may impact on their lives. By assessing the distribution of impact from a proposal or policy on the whole population, with a particular reference to how the proposal will affect vulnerable people (in terms of age, gender, ethnic background and socio-economic status), equity is ensured. By assessing short and long term impacts, sustainable development is ensured. The ethical use of evidence ensures the best available quantitative and qualitative evidence must be identified and used in the assessment. A wide variety of

evidence should be collected using the best possible methods.

Health impact assessment builds on the fact that a wide range of economic, social, psychological, environmental and organizational influences determines a community's health. It is important to try to estimate these influences on health prospectively and so HIA should precede the start of the project, programme, or policy concerned.

*The aims of prospective HIA are :*

- To systematically assess the potential health impacts, both positive and negative, of projects, programmes and policies.
- To improve the quality of public policy decisions by making recommendations that are likely to enhance predicted positive health impacts and minimize negative ones.

The key output of a HIA is a set of recommendations for beneficially modifying a proposal so that its overall health impacts are enhanced and any potential health inequalities are minimized.

### The Importance of Health Impact Assessment

Health impact assessment is an important public health method because of the following reasons :

- It promotes equity, sustainability and healthy public policies in a world which has unequal and different levels and perceptions of health.
- The quality of decision-making in health sector and of its partner organizations is improved by incorporating into the planning and policy-making process the need to address health issues.
- It emphasizes social and environmental justice as the disadvantaged sections of society and the world suffer the most from negative health impacts.
- It involves a multidisciplinary approach.
- Participation by the public is encouraged in debates about public health, planning and other public policy issues.
- Gives equal status to qualitative and quantitative assessment methods.
- Makes values and politics explicit and opens all issues to scrutiny.
- Demonstrates that health is a subject which is far broader than only health-care issues.
- Health impact assessment is used in public policy decision-making in a wide and rapidly increasing range of developed and less developed countries throughout the world.



## Methods for Assessing Health Impacts

There are a wide range of methods used for HIAs which clearly reflect the nature and complexity of the subject. It is very important to use all methods and involve all disciplines that may contribute to the overall tasks. The methods commonly used are :

- Analysis of policies.
- Assessing the health profiles of affected areas/populations.
- Identification of potential positive and negative health impacts.
- Assessment of perceived health risks.
- Quantification and valuation of health impacts.
- Ranking the most important impacts.
- Consideration of alternative options and recommendations for management of desired impacts.

## Participation in HIAs

The process of HIA requires broad participation of all disciplines and all stake holders to enable obtaining of a comprehensive picture of potential health impacts. Public participation throughout the HIA is essential, both to ensure that local concerns are addressed and for ethical reasons of social justice. The commonly sought participation includes :

- Those involved at all levels in the project.
- Those likely to be directly affected by the project.
- Others who have knowledge or information of relevance to the project and its outcomes
- Local or outside experts whose knowledge is relevant to the project.
- Relevant professionals including medical and paramedical workers, social workers or community workers.
- Voluntary organizations working in the field under assessment.
- Community participation adds value and credibility to HIA recommendations. The experiences of the local community are more important than routinely collected statistics. Undue reliance on quantitative methods may oversimplify the complexity of real life situations.

## Reasons to Use HIA

**Promotes cross-sectoral working** : The health and wellbeing of people is determined by a wide range of economic, social and environmental influences. Activities in many sectors beyond the health sector influence these determinants of health. HIA is a participatory approach that helps people from multiple sectors to work together. HIA participants consider the impacts of the proposed action on their individual sector and other related sectors – and the potential impact on health from any change. Overlaps with other policy and project initiatives are often identified, providing a more integrated approach to policy making.

**A participatory approach that values the views of the community** : An initial stage within the HIA process is to identify the relevant stakeholders to the HIA. This process usually produces a large number of relevant people, groups and organisations. The HIA can be used as a framework to consult meaningfully with stakeholders, allowing their messages to be heard. The common stakeholders besides those who

commissioned the HIA are network of people and organisations who will carry out the HIA include the local community / public, specially the vulnerable groups, developers, planners, local/national government officials, voluntary agencies / NGOs, health workers at local, national or international levels, employers and representatives of workers' unions and representatives of other sectors that are affected by the proposal.

### **The best available evidence provided to decision makers:**

The purpose of an HIA is to provide decision makers with a set of evidence-based recommendations about the proposal. The decision makers can then make decisions about accepting, rejecting, or amending the proposal secure in the knowledge that they have the best available evidence before them. HIA should consider a range of different types of evidence – going beyond published reviews and research papers, to include the views and opinions of key players who are involved or affected by a proposal. Often, evidence of the quality and quantity demanded by decision makers is not available, this is noted within the HIA and the best available evidence is provided.

**Improves health and reduces inequalities** : Addressing inequalities and improving the health of its community or population is a goal for many organisations and all Governments. One way of contributing to the planning of policies to improve health and overcome inequalities is through the use of HIA. It also ensures that proposals do not inadvertently damage health or reinforce inequalities. HIA provides a systematic approach for assessing how any new proposal can affect a population - specially, the distribution of those effects among the different subgroups of the population. Recommendations can specifically target improvement of health, particularly for vulnerable groups.

**Appropriate for policies, programmes and projects** : HIA is suitable for use at many different levels. HIA can be used on projects, programmes and policies, though it has most commonly been used on projects. The flexibility of HIA allows these projects, programmes and policies to be assessed at either a local, regional, national or international level – making HIA suitable for almost any proposal. Therefore, choosing when to carry out an HIA is important.

**Timeliness** : In order to be able to influence the decision making process, the HIA recommendations must reach the decision makers well before any decisions about the proposal will be made. This basic principle of HIA highlights the practical nature of the approach. Experienced HIA practitioners can work with most timeframes, undertaking comprehensive HIAs, which may take a longer time or a rapid HIAs.

**Links with sustainable development and resource management** : When HIA is undertaken early in the development process of a proposal it can be used as a key tool for sustainable development. For example, for an HIA on road building, it enables the inclusion of health and other sustainability aspects to be built in from the very beginning, such as cycle lanes, noise and speed reduction interventions, crossings, pedestrian over bridges, etc rather than solving the health impacts like accidents at a later date. This enables health objectives to be considered on a par with socio-economic and environmental objectives, bringing sustainable development closer.



**Many people can use HIA** : HIA because of being participatory in approach, has many potential users which include decision makers who may use the information for making decisions; Commissioners of the HIA, who use it to consult widely and gather differing views to build capacity and develop strong partnerships; HIA workers, who actually carry out the individual components of the HIA, which may include consultants, local staff from a wide variety of organisations and the community and finally the Stakeholders, who want their views to be considered by decision makers.

## The HIA Procedure

**1. Identifying if an HIA should occur – Screening** : It is not possible to carry out an HIA on every project, policy or programme. Therefore screening is used to systematically decide when to do an HIA. Although ideally screening of each planned proposal should be conducted to assess whether an HIA should be conducted, in practice it is usually not followed due to resource and organisational issues. Screening only works when there is organisational commitment to HIA – where management allows the time and resource to screen each project, policy or programme. Typically, the decision to carry out an HIA occurs because a significant project is occurring and someone (the developer, the public, local public health, planners, etc) thinks an HIA would be a good idea. At other times funding is received for carrying out an HIA and a single topic is chosen.

**2. Identifying what to do and how to do it - Scoping** : Scoping sets the boundaries for and considers how the HIA appraisal stage should be undertaken. Some typical scoping issues which need to be considered are :

- Who will do the HIA and who will be in charge.
- Are there any specialists or practitioners who could be involved ?
- What monitoring and evaluation of the HIA will occur.
- When does the HIA have to be done by, to influence key decision makers (often influencing the choice of whether a rapid or comprehensive HIA is undertaken).
- Setting and agreeing the aims and objectives of the HIA

The terms of reference for the HIA are often drawn up at this stage to clarify exactly what is expected from whom. The HIA may be conducted as a Rapid HIA where the appraisal stage is carried out quickly (often only in days/weeks) with a limited amount of resource, or else a Comprehensive HIA, in which an extensive appraisal is conducted, where new information is generated, significant literature reviews undertaken and comprehensive involvement of stakeholders often occurs. This may take several months or longer.

**3. Identifying the health hazards and considering the evidence of impact - Appraisal** : This is where a large amount of HIA work is carried out. The work usually begins with a panel of experts to guide the assessment process who examine the proposal in detail. The panel can draw on a variety of documents that may include information on a number of determinants of health including social and economic issues, besides other relevant issues. Specific health hazards and diseases in the defined area would also need to be listed. The relationships between the determinants of health and key elements of the

proposal are then investigated (often laid out in a table/grid like fashion for clarity). Normal procedures for collecting field data may not be used at all times and improvisations conducted to suit the specific requirements. Normally within an HIA the best available qualitative and quantitative evidence would be collated using a range of methods, including interviews, focus groups, surveys and community profiling. However, if these are not possible for various reasons or constraints, secondary analysis of existing data to estimate the likely number of deaths per year from the most important health and safety risks can be conducted to rank important health risks. Identification and description of the type and size of health impacts (both positive and negative) is typical of the appraisal stage of HIA.

**4. Developing recommendations to reduce hazards and / or improvement of health- Reporting** : A key output of HIA is the set of recommended changes to the proposal. Recommendations are provided in a formal report to the decision-maker and delivered in good time. The stakeholders' views are clearly set out within the recommendations made. Decision makers are provided with recommendations that cover all of the possible decisions that could have been taken. If there are any conflicting impacts, these are acknowledged. Consideration is also given to provide a feed back of the outcome of the HIA to the community.

**5. Evaluation and monitoring - Monitoring** : Evaluating whether the HIA has influenced the decision making process (and the subsequent proposal) is an important component of HIA. As with any intervention, evaluation is required to see if it has worked. Monitoring the implementation of the proposal is critical to ensure that any recommendations that decision-makers agreed to, actually occur. Longer term monitoring of the health of populations is sometimes a component of larger proposals. This long term monitoring can be used to see if the predictions made during the appraisal were accurate and to see if the health, or health promoting behaviours, of the community have improved.

## The Impact of HIA

Health impact assessment has now been carried out on a number of major policies, programmes and projects and has had significant influence on policy-making and planning. Examples include the Greater London Assembly's HIA programme, the Fittingly airport study conducted by Doncaster Health Authority (which for the first time in the UK incorporated the establishment of an independent airport health impact group into the regulatory framework for an airport) and the St Helens and Knowsley PFI study which was instrumental in attracting significant additional financial investment in the scheme at reduced interest rates from the European Investment Bank. At a global level, the World Health Organisation has appointed a HIA adviser at its Geneva Headquarters and has published a special issue of its Bulletin on HIA. The WHO has also played a major role in promoting the consideration of health within Strategic Environmental Assessment (SEA). These actions reflect the importance ascribed to HIA in health care management by the world body.

Health impact assessment is also increasingly used by global agencies such as the World Bank and by multinational corporations.

Even in developing countries, poverty reduction strategies are among the most structured ways of developing investment policies and HIA has been recommended to be an ideal way to support these strategies and integrate economic and social activities with health concerns.

## Summary

'Impact' in public health refers to overall totalistic effect of an intervention. Assessment of health impact combines procedures, methods and tools by which a policy, programme or project may be judged as to its potential effects on the health of a population. HIA is based on 4 values - Democracy, Equity, Sustainable development and Ethical use of evidence. Ideally, HIA should precede start of project, programme or policy concerned. The aims of prospective HIA are to systematically assess potential health impacts and to improve quality of public policy decisions by making suitable recommendations. The methods commonly employed for HIA are- analysis of policies, assessing the health profiles of affected population, identification of potential positive and negative health impacts, assessment of perceived health risks, quantification & valuation of health impacts, ranking impacts and consideration of alternative options. HIA requires broad participation of all disciplines concerned to obtain comprehensive picture of potential health impacts. HIA has now been carried out on number of major policies, program and projects and has had significant influence on policy making and planning. It is being increasingly used by global agencies viz WHO, World Bank and by multinational corporations. HIA has been recommended to be ideal way to support strategies used by most of them.

## Study Exercises

### MCQs and Exercises

1. Which are the four values on which health impact assessment is based ?
2. Enumerate the aims of prospective HIA.

3. What are the possible methods of assessing health impacts?
4. Health Impact assessment is a \_\_\_\_\_ approach.
5. Potential users of HIA includes \_\_\_\_\_  
(a) Decision makers (b) Commissioners of HIA (c) HIA workers (d) Stake holders (e) All the above
6. Highlight the difference between Rapid HIA and Comprehensive HIA
7. Strategic environmental assessment is a concept of HIA implemented by which international organization?

### Answers

1. Democracy, Equity, Sustainable development and Ethical use of evidence.
2. (I) Systematic Assessment of potential health impacts  
(II) Improve quality of public policy decisions by making suitable recommendations
3. Methods commonly used are : Analysis of policies; Assessing the health profiles of affected areas/ populations; Identification of potential positive and negative health impacts; Assessment of perceived health risks; Quantification and valuation of health impacts; Ranking the most important impacts; Consideration of alternative options; Recommendations for management of desired impacts.
4. Participatory
5. e.
6. Rapid HIA is one in which appraisal stage is carried out quickly- in days and weeks with limited resources where as comprehensive HIA is the one in which extensive appraisal is conducted, new information is generated, significant literature reviews are undertaken and there is comprehensive involvement of stakeholders.
7. WHO.

## Further Suggested Reading

1. Assessing health impacts on a population. Alex Scott-Samuel, Kate Ardern and Martin Birley in Oxford Handbook of Public Health Practice. 2nd ed, 2007. 42-55

The definition of a community can have many interpretations such as a neighbourhood, or a collection of people in similar geographical circumstances. A community also refers to a group of people who share the same stakes and common interests. Epidemiological methods can be used to assess the condition of the people living in a community or defined geographical area. Indices can be produced of the health and wellbeing and

the character and dimensions of the problems can be charted. The process of diagnosing the health, health related problems and their determinants, in a community is called community diagnosis. In some contexts it has also been considered to be the methods which enable communities in developing a consensus about the priority health problems in their individual communities and developing strategies to address the issues identified. The completion of the *Community Diagnosis process* should answer the following questions for the community :

- Where is the community now?
- Where does it want to be?
- How will it get there?

There are several ways to obtain information for the diagnosis of communities including routine health facility reporting, screening, surveillance, special large scale surveys, contact tracing and population census. These methods vary depending on the objectives, investment and utilities available.

The overall objective of community diagnosis is to estimate the magnitude of the health problems and the determinants as well as to analyse trends and changing paradigms of these problems and determinants. Because the community consists of heterogeneous groups, the overall objective may need to be expanded to include many value laden issues such as health needs and determinants, equity, responsiveness to expectation, efficacy, protection of individuals and fairness. The diagnosis of the state of health of a community must also be dynamic as there are continuous changes happening. The results of the community diagnosis process can then be used as evidence for discussion among the stakeholders in the community, balancing the views of the stakeholders in setting priorities and making decisions for resource allocation which are acceptable to the community. The priorities and decisions for control should take into account not only the current status but also the impact that controls may have on health of future generations. The priorities and decisions for control depend not only on the indicators used for the diagnosis but also on the expressed values of a health system.

### **Types of Health Information Needed for Planning Health Care**

**Health situations and needs** : Planning of health care of any community will need to start from simple descriptions of the state of health of the community or presence of illnesses. The socio- demographic distribution of the diseases and conditions will help assess the “needs”.

**Availability of resources to deal with those needs including the various approaches to organizing and financing of the resources** : The availability of health resources determines the relative ability to cope with the requirement and “needs” of the community and setting of priorities for allocation of resources.

**The accessibility and utilization of existing health resources**: This is important to determine the type of services which will be most appropriate for the community and therefore can be considered for provision.

**Impact on health outcomes** : The planned outcome will play an important role in determining what health services or facilities need to be provisioned.

**Consequences of health care financing on politics, economy and society as well as on the welfare of the entire population**: Health is central to the overall development of any community. The outcomes in the non – health field in a community which can be also expected because of improved health can provide additional bargaining support while requesting for resources for the planned health interventions.

### **General Framework for Community Diagnosis**

**Defining the community** : The first task to be considered when it is planned to define health and disease in a community is to define the target community – country, province, district, or

state but might be a more defined geographical region such as urban inner city or a socially defined group such as poor communities, women in reproductive group, pregnant mothers, infants, young adults, elderly, etc. If not properly defined there may be a chance of over representation of sub groups from who it is easy to obtain data.

**Health indicators** : Definition of indicators is a pre-requisite for the development of an effective information system in community diagnosis. They should reflect both the positive (as SMPH) and negative (as IMR) aspects of health status. Positive health measures have been less used in developing countries as these populations are more likely to be satisfied with poorer health. Concept of burden of risk can be brought to the notice of public health officers. Mostly the health indicators are oriented to the negative aspect of health because of ease of measurement. Details of various indicators in community health practice are dealt with in another chapter on “measures of health and disease in community health”.

**Sources of information and the methods that can be used for community diagnosis** : A variety of information regarding the health status of a community is available from existing health system records. Depending on the type of information required specific surveys may need to be conducted to gain the desired information if not available from existing health system records. Some of the sources which can be considered for obtaining information about the community are as follows:

- Routine reporting from health facilities
- Surveillance – active and passive and sentinel surveillance
- Screening of the community
- Surveys
- Vital registration of events
- Combination of several methods

**Trend analysis** : Information regarding various health parameters can be obtained and analysed regarding changes over a period of time. Various aspects like demographic transition, urbanization, economic transformation, politics, globalization, etc may impact on the health status of a community. Trend analysis can be conducted to assess the changes in a community of the health situation, burden of illness, prevalence of risk factors and many other factors.

**Characteristics of community diagnosis** : Basis of Community Diagnosis is to assess the health situation in the community including its dimensions and determinants besides whether the community has achieved the objectives proposed by the health policies and programmes in use. There are several desirable characteristics in the Community Diagnosis process which are enumerated as follows :

- Ability to address important community problems which are amenable to practical control.
- Ability to identify most of the targeted health events.
- Adequacy in reflecting changes in distribution of events over time, place and person.
- Having a clearly defined population, data collection, data flow, analysis, interpretation and feedback.
- Orientation towards appropriate action.
- Being participatory, uncomplicated, sensitive, timely and inexpensive.



## Sources of Information and Methods for Community Diagnosis

The various important sources of obtaining information have been enumerated above and have been dealt with in detail in an exclusive chapter on “sources of information in epidemiology”. Readers are advised to go through the same.

### Steps in Conduct of Community Diagnosis

There are no clearly laid down chronological steps in the conduct of a community diagnosis program. Several short cuts can be easily taken to achieve the desired results. However, when time and resources permit a thorough study, the various steps involved may be considered to be as follows :

**Step 1 - Establishing a Community Diagnosis Team** : The first step is to establish a Community Diagnosis Team who will lead the assessment process. This group should consist of motivated individuals who can act as advocates for a broad range of community members and can represent appropriately the concerns of various populations within the community.

**Step 2 - Analyzing the existing Health Data** : The Community Diagnosis Team will compare the community’s health statistics with those of the district, state or national figures to identify possible health problems in the community.

**Step 3 - Collecting Community Data** : Data will be collected from the community on health issues of interest, especially those that go beyond the information available in the existing community or health system records. The necessary data can be collected using specially devised Community Health and Opinion Survey Questionnaire, conducting Focus Group Discussions with community members and obtaining data from the Health Resources Inventory (if it exists). Community surveys take a lot of time and it may not be possible to implement all of these data collection efforts before the reporting deadlines. These tools may be employed at any time, since community health assessment should be an ongoing process.

**Step 4 - Combining existing Health Statistics With Community Data** : The Community Diagnosis Team will review the data from Steps 2 and 3 in detail. By the end of this phase, one will have a basic understanding of the community’s major health issues including comparison with other communities.

**Step 5 - Choosing Health Priorities** : Community Diagnosis Team will determine the priority health issues which will need to be addressed in the community based on the data collected and analysed.

**Step 6 - Developing the Community Health Action Plan** : Community Diagnosis Team will develop a plan of action for addressing the health issues deemed as priorities in Step 5. Developing of appropriate and effective health interventions and prevention activities is the basic idea behind the community diagnosis exercise.

**Step 7 - Measuring Environmental and Policy Changes** : The Community Diagnosis Team will do some advance planning about evaluating the success of the interventions developed in Step 6. A particular focus of this step is on collecting community-level indicator data to document the extent to which the community is making changes to improve health.

### Step 8 - Creating the Community Diagnosis Document :

Community Diagnosis Team will develop a stand-alone report to document the process as well as the findings of the entire assessment effort. The purpose of this report is to share the assessment results and plans with the entire community and other interested stakeholders. At the end of this step, the community will be ready to move from assessment to action by implementing the Community Health Action Plan developed in Step 6.

### Limitations of Community Diagnosis

The process of community diagnosis as a solution to assessing the problems of the community and instituting appropriate interventions based on the findings has its limitation in ability to provide valid inputs to enable prioritizing health care facilities and interventions. The effects of health problems of individuals on their relatives cannot be assessed so simply. For example, all deaths are not equal in effect. Death of a person who is the sole earning member in the family has catastrophic effects which cannot be compared with the death of any other member of the family. The community will need to be consulted regarding their perceptions of values to assess the correctness of community diagnosis in these circumstances. The principles of community diagnosis are however valid in laying the foundation for appropriate public health interventions specially in the settings of developing countries where multiple health problems are vying for attention of politicians and health administrators for allocation of scarce resources.

### Summary

The process of diagnosing the health and health related problems of a community is called community diagnosis. The overall objective of community diagnosis is to estimate the magnitude of health problems and the determinants as well as to analyze changing trends of these problems and determinants. There are several ways to obtain information for the diagnosis of communities including routine health facility reporting, screening, surveillance, special large scale surveys, contact tracing and population census. The health information required for planning health care includes information on health situations and needs, available resources, organizational capacity, impact on health outcomes and consequences of health care financing on politics, economy and society as well as on the welfare of entire population. Various sources of information commonly utilized are routine reporting from health facilities, active and passive surveillance, screening of community, special and rapid surveys conducted to obtain same. The priorities for policy decisions should take into account not only the current status but also the impact that policies may have on health of future generations.

### Study Exercises

#### Exercises

1. The process of diagnosing the health, health related problems and their determinants, in a community is called \_\_\_\_\_ .
2. The overall objective of community diagnosis is to estimate the magnitude of the health problems and the determinants as well as to analyse trends and changing paradigms of



- these problems and determinants. True/False
3. The diagnosis of the state of health of a community is static as there are no changes happening. True/False
  4. Positive health measures have been less used in developing countries as these populations are more likely to be satisfied with poorer health. True/False
  5. Information regarding various health parameters can be obtained and analysed regarding changes over a period of time, this is referred to as

**Answers :** (1) Community diagnosis; (2) True; (3) False; (4) True; (5) Trend analysis

### Further Suggested Reading

*Readers are advised to also go through the following chapters in this book*

1. Epidemiological basis of planning and evaluation of a health programme
2. Planning a Health Education Programme
3. Measuring the level of Health and disease of a Community
4. Sources of data in Epidemiology

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## Ethics in Public Health, Health and Human Rights

*Amitava Datta*

Ethics has been defined as “a set of principles of right conduct”. In the medical sense, it has also been defined as “the principles and norms of proper professional conduct concerning the rights and duties of health care professionals themselves and their conduct toward patients and fellow practitioners, including the actions taken in the care of patients and family members”.

The ethical practice of health dates back to ancient times. The Hippocrates oath administered to all practitioners of medicine was the start of the formalization of ethical medical practice. The concept of “bioethics” however took birth due to the experiences of the Second World War and the atrocities conducted in the name of medical research by Nazis among inmates of concentration camps. The vulnerability of human beings to being subjected to medical research against their wishes was highlighted by the experiences of the inmates and findings of the Allies after Germany surrendered in 1945. A code of conduct for human research, namely the Nuremberg Code was established. In 1964, the World Medical Association Declaration of Helsinki took this process a step further and underscored 12 basic principles for the conduct of human biomedical research (Details are given in Box-1 towards the end of this chapter). However, these principles were largely physician oriented and did not directly address the issue of research in developing countries. The issue of research in developing countries was eventually taken up by the Council for International Organization of Medical Sciences (CIOMS), which in collaboration with WHO, proposed guidelines for international research. The guidelines were further amended in 1993 as the International Ethical Guidelines for Biomedical Research involving human subjects. The rapid advances in medicine, including reproductive health, organ transplantation and genetics, raised questions about the purpose and limits of medical technology. In recent years, there have been efforts to broaden the scope of ethical analysis in health care to focus more directly on public-health issues.

### What is Public Health Ethics

Public health ethics can be subdivided into a field of study and a field of practice. As a field of study, public health ethics seeks to understand and clarify principles and values which guide public health actions. Principles and values provide a framework for decision making and a means of justifying decisions. Because public health actions are often undertaken by governments and are directed at the population level, the principles and values which guide public health can differ from those which guide actions in biology and clinical medicine (bioethics and medical ethics) which are more patient or individual-centered.

As a field of practice, public health ethics is the application of relevant principles and values to public health decision making. In applying an ethics framework, public health ethics inquiry carries out three core functions :

- Identifying and clarifying the ethical dilemma posed.
- Analyzing it in terms of alternative courses of action and their consequences.
- Resolving the dilemma by deciding which course of action best incorporates and balances the guiding principles and values.

Public health ethics thus focuses on the design and implementation of measures to monitor and improve the health of populations. This is in contrast to the traditional emphasis of bio-ethicists on the physician–patient relationship. Public-health ethics also looks beyond health care to consider the structural conditions that promote or inhibit the development of healthy societies.

### Issues in Public Health Ethics

#### Who is Responsible for Health?

The conflicting views on ethics in the field of public health arise due to differing perceptions regarding responsibility for health. The wide spectrum of views has at one end the view, that it could be purely a matter of individual choice. On the other extreme, responsibility for health could be completely delegated to government. The central dilemma, therefore in public health is to balance respect for individual freedom and liberty with the responsibility of governments to provide their citizens with some degree of protection in relation to health.

The role of the government has been evolving over a period of time. Today, very few would argue against state sponsored fortification of bread or pasteurization of milk. However many of the interventions to prevent the so called “lifestyle choices” leading to arising of risk factors of killer diseases like ischemic heart disease, lung cancer, chronic obstructive pulmonary disease and diabetes mellitus are still contentious depending on the country involved. It is common knowledge that the so called “choices of lifestyle” are often constrained by actions of others like industry and government as well as socio-economic, environmental and genetic factors. In traditional bioethics, much emphasis is placed on the freedom of the individual. However, in public health policy, some measures might constitute minor infringements of a person's freedom but bring about significant benefit for a large number of people. The western world with democratic traditions would recommend that governments should not coerce their people or restrict their freedom unnecessarily. However, these same governments are also expected to provide the conditions under which people can lead healthy lives. “Tobacco smoking” lends itself easily as an example. By banning advertisements by tobacco companies and restricting the availability to children, the governments are discharging their role in harm reduction to vulnerable citizens while still permitting their citizens their right to smoke tobacco.

### **Disparities in Health Status in Different Parts of the World**

It is an accepted fact that resource allocation depends in part on value judgments about the relative importance of small improvements in quality of life for a large portion of the population as compared with a life-saving intervention that would benefit only a few people. Most of the developing countries have very poor state of health of their citizens. They look towards the affluent nations and philanthropic agencies for economic and technological aid to alleviate the sufferings of their citizens. Most inter governmental economic aid is however conditional to the use of services provided through companies of the donor country, which may exploit the situation for economic gain rather than philanthropy. The astronomical and unjustifiable gains of some pharmaceutical companies, from sale of life saving drugs, are well documented. Governmental health policies may become dictated by the donor of funds rather than from perceived need.

### **Disparities in Access to Quality Health Care and the Benefits of Medical Research**

Many of the clinical researches being conducted in the world have used subjects who may have nothing to gain from the research. Medical research is one of the most contentious issues in public health today. Even in the developed world, discriminations against the deprived communities have been documented in literature and have raised ethical concerns. The existing ethical norms need to be guided more by the need and circumstances of individual nations (especially developing countries) rather than be exceedingly idealistic and moralistic in their approach. The Global Forum for Health Research has pointed out that less than 10% of the world's research resources are earmarked for 90% of the health problems. If a country's

health research system could be regarded as the “brain” of its health system, then ethics would constitute its “conscience”. It is imperative that health research systems function to the highest aspirations of ethics and distributive justice.

### **Responding to the Threat of Infectious Diseases**

Efforts to contain the spread of infectious diseases raise difficult questions about the appropriateness of restricting individual choices to safeguard other people's welfare. Examples include the use of isolation and quarantine for tuberculosis, yellow fever, SARS and pandemic influenza.

### **International Co-operation in Health-Monitoring and Surveillance**

The international context also matters in the case of infectious diseases, since infections do not respect national borders. Countries also differ in their capacities to monitor and respond to outbreaks. Therefore, developed countries have obligations to assist developing ones, for example in terms of enhancing surveillance capacity. At the same time, developing countries have obligations to cooperate with international surveillance and control efforts. The implementation of the International Health Regulations reflects the commitment of countries to collective action in the face of public-health emergencies. Defining the scope of countries' obligations to act collectively and determining how those obligations should be enforced, will inevitably raise difficult ethical dilemmas.

### **Exploitation of Individuals in Low-Income Countries**

Current practices in medical research, for example, may expose participants to significant risks without a benefit for themselves or their communities. Defining and enforcing foreign research sponsors' obligations to local participants is therefore a critical ethical issue. In the area of organ transplantation, the growing practice of “transplant tourism” exposes individuals living in poverty to significant health risks while also raising broader questions about the commodification of the human body.

### **Participation, Transparency and Accountability**

As an ethical matter, the process by which decisions are made is as important as the outcome of the decisions. In the area of medical research, much attention has been devoted in recent years to strengthening systems for informed consent and community oversight. Once such systems are in place, the next step will be to develop mechanisms for evaluating their effectiveness.

### **Medical Research in Developing Countries**

The ethical issues in conduct of medical research on public health in developing countries need special attention. This aspect is deliberated in detail in the section on epidemiology and research methodology.

The recent landmark trial in Gadchiroli, India, makes an interesting case in point which clearly elucidates the above concerns. The trial evaluated domiciliary neonatal care with community-based health workers administering oral trimethoprim-sulfamethoxazole and twice-daily gentamicin to newborn infants with suspected sepsis. A control population was used for comparison and the researchers were able to demonstrate a 72% reduction in neonatal mortality using this

approach. This study would have raised ethical questions by most existing standards, since it involved a control population and also used an experimental protocol, when the “national standard of care” for suspected neonatal sepsis was intravenous antibiotics and supportive care. The authors, Bang et al, went through an elaborate scientific and ethical review process prior to the study, involving national experts and the Indian Council for Medical Research. The researchers were also able to get community concurrence to participate in this study, in a situation where even the national “standard of care” was not available to the participants. The benefits of the study for the local people (in terms of improved neonatal survival) and its impact on national and global programmes for neonatal care have been enormous. Taking an extreme position on the “standards of care” would have required that the study only be conducted with a control arm that received neonatal intensive care and expensive intravenous antibiotics, neither of which are sustainable even in urban settings in India. Thus, the study could not have taken place. The Gadchiroli trial vindicates the position of public health researchers that each developing country deserves the chance to develop health care interventions that suit local socio-cultural and economic means.

## Principles of Ethical Public Health Practice

The Public Health Leadership Society in 2002 has published a code of ethics for the ethical practice of public health based on the definition of health as advocated by WHO. The salient features which explicitly enunciate the current basic understanding of the ethical practice of public health are as follows. The detailed elaboration of each of these principles is being given in detail subsequently.

1. Public health should address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes.
2. Public health should achieve community health in a way that respects the rights of individuals in the community.
3. Public health policies, programs and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members.
4. Public health should advocate and work for the empowerment of disenfranchised community members, aiming to ensure that the basic resources and conditions necessary for health are accessible to all.
5. Public health should seek the information needed to implement effective policies and programs that protect and promote health.
6. Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs and should obtain the community's consent for their implementation.
7. Public health institutions should act in a timely manner on the information they have within the resources and the mandate given to them by the public.
8. Public health programs and policies should incorporate a variety of approaches that anticipate and respect diverse values, beliefs and cultures in the community.
9. Public health programs and policies should be implemented in a manner that most enhances the physical and social

environment.

10. Public health institutions should protect the confidentiality of information that can bring harm to an individual or community if made public. Exceptions must be justified on the basis of the high likelihood of significant harm to the individual or others.
11. Public health institutions should ensure the professional competence of their employees.
12. Public health institutions and their employees should engage in collaborations and affiliations in ways that build the public's trust and the institution's effectiveness.

## Notes on the Individual Ethical Principles

1. This principle gives priority not only to prevention of disease or promotion of health, but also at the most fundamental levels. Yet the principle acknowledges that public health will also concern itself with some immediate causes and some curative roles. For example, the treatment of curable infections is important to the prevention of transmission of infection to others. The term “public health” is used here and elsewhere in the Code to represent the entire field of public health, including but not limited to government institutions and schools of public health.
2. This principle identifies the common need in public health to weigh the concerns of both the individual and the community. There is no ethical principle that can provide a solution to this perennial tension in public health. We can highlight, however, that the interest of the community is part of the equation and for public health it is the starting place in the equation; it is the primary interest of public health. Still, there remains the need to pay attention to the rights of individuals when exercising the police powers of public health.
3. A process for input can be direct or representative. In either case, it involves processes that work to establish a consensus. While democratic processes can be cumbersome, once a policy is established, public health institutions have the mandate to respond quickly to urgent situations. Input from the community should not end once a policy or program is implemented. There remains a need for the community to evaluate whether the institution is implementing the program as planned and whether it is having the intended effect. The ability for the public to provide this input and sense that it is being heard is critical in the development and maintenance of public trust in the institution.
4. This principle speaks to two issues : Ensuring that all in a community have a voice; and underscoring that public health has a particular interest in those members of a community that are underserved or marginalized. While a society cannot provide resources for health at a level enjoyed by the wealthy, it can ensure a decent minimum standard of resources. The Code cannot prescribe action when it comes to ensuring the health of those who are marginalized because of illegal behaviors. It can only underscore the principle of ensuring the resources necessary for health to all. Each institution must decide for itself what risks it will take to achieve that.
5. This principle is a mandate to seek information to inform



actions. The importance of information to evaluate programs is also implied.

6. This principle is linked to the third one about democratic processes. Such processes depend upon an informed community. The information obtained by public health institutions is to be considered public property and made available to the public. This statement is also the community-level corollary of the individual-level ethical principle of informed consent. Particularly when a program has not been duly developed with evaluation, the community should be informed of the potential risks and benefits and implementation of the program should be premised on the consent of the community (though this principle does not specify how that consent should be obtained).
7. Public health is active rather than passive and information is not to be gathered for idle interest. Yet the ability to act is conditioned by available resources and opportunities and by competing needs. Moreover, the ability to respond to urgent situations depends on having established a mandate to do so through the democratic processes of Ethical Principle number three.
8. Public health programs should have built into them a flexibility that anticipates diversity in those needs and perspectives having a significant impact on the effectiveness of the program. Types of diversity, such as culture and gender, were intentionally not mentioned. Any list would be arbitrary and inadequate.
9. This principle stems from the assumptions of interdependence among people and between people and their physical environment. It is like the ethical principle from medicine, "do no harm", but it is worded in a positive way.
10. This statement begs the question of which information needs to be protected and what the criteria are for making the information public. The aims of this statement are modest : to state explicitly the responsibility inherent to the "possession" of information. It is the complement to Ethical Principles 6 and 7, about acting on and sharing information.
11. The criteria for professional competence would have to be specified by individual professions, such as epidemiology and health education.
12. This statement underscores the collaborative nature of public health while also stating in a positive way the need to avoid any conflicts of interest that would undermine the trust of the public or the effectiveness of a program.

## Summary

Ethics has been defined as a 'set of principles of right conduct'. The landmarks in ethical practice of health dates back to the Hippocratic oath, 'Concept of Bioethics' arising out of atrocities of Nazi doctors and Germans during Second World War in the name of medical research, setting up of Nuremberg code for human research, followed by Declaration of Helsinki adopted at World Medical Assembly, Finland, 1964. The Council of International Organization of Medical Sciences (CIOMS) in collaboration with WHO established International Ethical Guidelines for Biomedical Research last amended in

1993. There are 3 core functions of public health ethics viz identifying the ethical dilemma posed, analyzing it in terms of alternative course of action and deciding best course of action. The Public Health Leadership Society in 2002 has published a code of ethics for ethical practice of public health based on definition of health as advocated by WHO constituting the 12 basic principles of ethical public health practice. Ethics has also been at the heart of WHO mission to protect & promote global community health. WHO's General Dr. Gro Harlem Brundtland created an 'Ethics and Intelligence Initiative', which has since served as a focal point for ethics activities throughout the organization.

## Study Exercises

### MCQs and Exercises

1. The Code of conduct for human research is called the \_\_\_\_.
2. The World Medical association Declaration of Helsinki took place in : (a) 1954 (b) 1964 (c) 1974 (d) 1984.
3. The Global forum for health research has pointed out that < \_\_\_\_\_ % of the world's research resources are earmarked for \_\_\_\_\_ % of the health problems.
4. Clinical research cannot be legitimately carried out unless the importance of the objective is in proportion to the inherent risk to the subject. True/False.
5. The responsibility for clinical research is both for the researcher & the subject once the consent has been obtained from the subject. True/False.

**Answers :** (1) Nuremberg Code; (2) b; (3) <10%, 90%; (4) True; (5) False.

## Further Suggested Reading

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### **Box - 1 : Declaration of Helsinki**

#### **Recommendations Guiding Doctors in Clinical Research**

Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964

It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfillment of this mission. The Declaration of Geneva of The World Medical Association binds the doctor with the words : "The health of my patient will be my first consideration" and the International Code of Medical Ethics declares that "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest. "

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, The World Medical Association has prepared the following recommendations as a guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

In the field of clinical research a fundamental distinction must be recognized between clinical research in which the aim is essentially therapeutic for a patient and the clinical research, the essential object of which is purely scientific and without therapeutic value to the person subjected to the research.

#### ***I. Basic Principles***

1. Clinical research must conform to the moral and scientific principles that justify medical research; and should be based on laboratory and animal experiments or other scientifically established facts.
2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.
3. Clinical research cannot legitimately be carried out unless the importance of the objective is out of proportion to the inherent risk to the subject.
4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.
5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

#### ***II. Clinical Research Combined with Professional Care***

1. In the treatment of the sick person, the doctor must be free to use a new therapeutic measure, if in his judgment it offers hope of saving life, reestablishing health, or alleviating suffering.  
If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.
2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

#### ***III. Non-Therapeutic Clinical Research***

1. In the purely scientific application of clinical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.
2. The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.
- 3a. Clinical research on a human being cannot be undertaken without his free consent after he has been informed; if he is legally incompetent, the consent of the legal guardian should be procured.
- 3b. The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice.
- 3c. Consent should, as a rule, be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained.
- 4a. The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.
- 4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued.  
The investigator or the investigating team should discontinue the research if in his or their judgment, it may, if continued, be harmful to the individual.

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Information is the basis for all planning processes and planning of public health measures for a community is no exception. Health information is generated both at the individual level (patient records from hospitals) as well as at the community level (surveillance systems, population surveys, outbreak reports, etc). The clinician requires detailed information about limited number of persons for clinical follow up. The needs of the public health analyst differs from that of his clinical colleague in that he needs information from large number of persons or patients but comparatively limited information about each person or patient. By the word data, we usually mean numerical information that is collected routinely and that is used to monitor health of the populations (surveillance data) or the activity of health-related services. In general, data tends to refer to numerical information which expresses information in terms of 'how many' and 'how much'. However epidemiology has clearly taught us that simply 'counts' do not allow meaningful comparisons. Public health data invariably has a numerator and a denominator besides preferably having a time dimension and is expressed as rates to enable comparisons with other communities or periods of time. Information can be considered to be the outcome of processing and evaluating raw data. The degree of processing required to turn data into information may depend on the level of expertise of the recipient.

The term evidence is used mainly in legal terms where it is used to describe the material which shows beyond a reasonable doubt that something has occurred. In public health, it is applied to knowledge obtained from research. It can be used for providing support to theory regarding etiology; for example, does iodine deficiency produce hypothyroidism or to what extent does the absence of fluorine in drinking water lead to dental caries. It can also be providing support for some planned or existing intervention; for example does the fortification of salt with iodine lead to reduction in number of mentally retarded children in a community. Evidence can be a mixture of numbers and words as compared to data which has only numbers. Evidence comes from many sources, is of variable quality and requires interpretation. This is also the case when considering empirical evidence, arising from observation or experiment.

Public health policy makers and health care managers require timely, useful and balanced information which is quantifiable and tangible for the diagnosis of health needs of a community, their trends and determinants with a view to achieve effective planning and monitoring of health care interventions. This information can be of three types - derived from research, that is evidence; derived from routinely collected data, that is statistics or derived from experience either from patients or of fellow professionals or other partner organizations.

## **Components of Information Systems for Planning Health Care**

The major components of health care which will need systematic information for planning activities include information about health situations and needs, availability of resources to deal with those needs, organization and capacity to take those resources and convert them into services (that is conduction of system efficacy, effectiveness, efficiency, quality and decision analysis), variation of use and practice with their implication on equity to access and coverage, impact on health outcome and consequences of health care financing on politics, economy and society as well as on the welfare of the entire population. The users and contributors of information for health planning can be policy analysts, health care providers, epidemiologists, social scientists, economists, etc. Those who provide health services and have the task of being accountable for the services they provide should be involved with the development of information system. There are differences in the emphasis shown to the different components of health information system between developing and developed countries as well as depending upon the political system in the respective country.

## **Important Considerations in Providing Data and Evidence for Policy Makers**

It is common knowledge that in the field of public health, as in other planning processes, there had been many occasions when there has been a mismatch between the generation of evidence and data and their communication to the right people in the right way at the right time. The many known reasons for this incongruity can be overcome with careful organization and preparation.

In the field of public health when we attempt to solve serious problems there is often a wealth of descriptive data about a population (like data obtained from routine surveillance system, data from special survey as well as anecdotal evidence from practitioners or professional bodies). However some times, (especially when a new disease appears), there may be too little information available, for example during the initial stages of the AIDS epidemic. In both circumstances however, rarely is information made available in a way that makes it easy for policy makers to take effective action. Some of the problems which have been identified in providing data and evidence for policy makers and needs consideration are as follows :

**Availability of many types of knowledge :** Data, evidence and best practice (obtained from professional bodies) often leads to confusion. The present confusion to decide which drugs to use in prevention of parent to child transmission of HIV is clearly an apt example. It is necessary to develop an organized approach to considering problems and suggesting solutions using a combination of 'content' and 'process'. Although there can be different sorts of knowledge, all of which can help in different ways, however, these must be critically evaluated before they are assembled and articulated in a clear balanced way. Anecdotes are powerful ways to raise issues but they need to be validated by data and evidence before they can be used to direct significant policy and action.

**Information is not available in time :** To be able to plan and implement public health policies information is required within

stipulated time frame. Most policy makers are constrained by time schedule beyond which the policy making cannot be kept pending. In India for example, wherever governmental funds are to be committed, the information required to formulate policy and commit funds has to start several months before the start of a financial year and in case of major fund requirement, as much as five years before – in case the policy decision is required to be funded through the five year planning system. In the present age of computers, it is sometimes expected that simply on the click of a button, data and evidence will be generated. Unfortunately, this is far from reality except to generate data regarding some highly prevalent communicable diseases. Most public health data are expensive to collect but expense must not be made an excuse not to collect, analyse and present required data.

**Lack of consistency in information definitions** : The field of public health is extremely dynamic. The common examples are definitions for hypertension and diabetes mellitus. With better understanding of the risk posed, the definition of what is to be considered “hypertension” and “diabetes” needing therapeutic or other interventions has changed over the last decade. What may have been a mild problem in several geographical areas like states has suddenly become a “burning public health issue” once the new definition is applied. Similarly, there are debates and disagreements among professional bodies to arrive at consensus definitions. .

**Lack of meaningful comparators** : Many public health problems do not have adequate or appropriate comparators or indicators which allow comparison of the state of health due to the condition under consideration. This may be due to basic problems of ethnicity. The lack of protective effect due to BCG vaccine among Indians as compared with the demonstrated protective effect in other countries is based on evidence. The continued use of BCG in the national immunization program based on evidence of “reasonable” protection from childhood forms of tuberculosis provided by certain surveys does not allow for meaningful comparisons as there is paucity of data on this aspect. Comparators can be the crux of any analysis. The presentation of data should clearly indicate whether we need to be increasingly concerned, whether the magnitude of the problem is less or more than other comparable places, whether time trends are available, whether the change if any or rate of change is satisfactory, etc.

**Solution-focused approach of knowledge** : There are at times attempts to stress the ‘solution’ rather than the ‘problem’ while presenting analysis of data. For example in a bid to introduce Pneumococcal immunization in the national immunization schedule in India, the protective efficacy of one or more vaccines only is projected without assessing the magnitude and determinants of pneumonia in the country. The initiation of debate should have been with an assessment whether Pneumococcal pneumonia is indeed a problem in our country.

**Lack of common language to describe domains** : Concern for the health of their citizens is common among practitioners of public health as well as policy makers. However they may have different ideas of the relative importance of different health related problems as well as the means of overcoming them. It would be helpful if all concerned could be aligned in a similar

manner to address the public health problems. Communication of the information therefore has to be consistent in various presentations.

**Communication of evidence in unhelpful ways** : Even the most committed policy makers will be unable to generate the required policy change if problems are provided to them in a manner which is not conducive to easy understanding of the seriousness of the problem as well as the quantification of the improvement likely. Technical epidemiological terminology, like ‘absolute risk reduction’ though appropriate when used among professionals may be counter productive if used among not so knowledgeable professionals or non- medical persons. Use of simple terms like ‘how many children out of 1000 immunized with the proposed vaccine will be saved’ is likely to be as effective or even more than use of terminology like ‘risk reduction’. An inappropriate stress on evidence can be as damaging to a desired policy outcome as the wrong dose of a drug to a patient. The full range of available evidence (statistics, charts, meta-analyses, etc. ) does not always need to be marshaled while communicating the seriousness of the public health problem and its suggested solution. The timing of the presentation of evidence is also very important. Provision of ‘exhaustive evidence’ after the negative policy making decision has occurred is of lesser use as compared to ‘adequate evidence’ before the decision making process. It would be appropriate to present the latter form in time rather than wait too long for the ‘perfect evidence’. It will also be pertinent to know who will receive the evidence- a public health specialist, a clinician, non-medical official or politician before deciding how to package and communicate the evidence. This will ensure a better appreciation of the problem at hand by the receiver of evidence.

**Poor communication of information** : The ability to convert data into evidence and subsequently convey it in an acceptable manner depends on many factors including capability, training, motivation and other interests of the persons responsible. Even though a problem may be considered to be requiring continued communication, there is a real danger of ‘over exposure’. The danger of military commanders becoming immune to the repeated pleas for attention to curb the STD and malaria incidence among soldiers, as documented to have happened during second world war are apt examples of this aspect needing consideration. Unforeseen reactions like some sub-sections of society rebelling and actually increasing their tobacco use only as an expression of their rebellion is also to be warded against. When economic considerations are likely to play an important role in the policy making process, it may be wiser to have fewer experts propounding the issues at regular intervals rather than attempting to rope in as many and diverse personalities. The use of cinema personalities, sports persons, politicians, etc in the campaign against tobacco use can be considered in this light.

**Inability to balance harm, benefit and cost explicitly** : The method of communicating data, information or evidence needs to be able to clearly elucidate the harm caused by an element, the benefit on removal of the element from society and the costs involved - direct and indirect in the intervention proposed. The most apt example is the continued debate on tobacco use over



a period of nearly half a century throughout the world. Tobacco does not cause immediate harm and hence users, lay public and policy makers need to have evidence of the cause and effect relationship of tobacco leading to harm, the gains from cessation of use of tobacco as well as stopping the initiation of tobacco use, besides the costs involved in implementing a policy for stopping the use of tobacco which needs to consider the losses to industry, the tobacco farmers, related industry as well as government (in terms of easy taxes). Similarly charging a token sum for the purchase of highly subsidized condoms in the family planning program needs to be considered before implementation. There is evidence that introducing user charges may reduce inappropriate attendance, but it might lead to an adverse impact on the most disadvantaged. At the clinical level, the well known example of suppressing ventricular ectopics in post myocardial infarction period actually increased the risk of sudden death rather than decreasing it. This was established only after careful research and stressed the importance of considering all potential harm as compared to benefits in any intervention.

**Inadequate listening to the users :** Many a times, information is provided in a sensational manner which attracts the attention of important community persons as well as policy makers. The discussion of HIV / AIDS among the women of a community who are more concerned about the problem of inadequate child health care facilities in the community is hardly likely to succeed. Similarly discussing the problem of child labour in an area with abject poverty may make for good media coverage to identify industries which employ child labour. This may in fact result in the denial of employment to a child but does nothing to take care of his need for this employment as a means of earning money for his and possibly also his family's needs. In the absence of organized social security, implementation of such public policies may only harm the individuals concerned and provide for exploitation of needy children. The key issue with data is to choose the right data (with the right comparators) that will change the particular minds (and hearts) of the people to who we communicate. Before planning any health related communication, it is almost always a good investment of time and effort to seek to understand the perspective, anxieties and motivations of the people who are the targeted beneficiaries.

**Policy makers often don't want evidence :** In the field of public health especially, evidence may be unwelcome. It would be politically inappropriate for some evidences in the public health domain to be overlooked. However, constraints of funds may not permit allocations and hence delays in even consideration of needed policies. There are various organisations and individuals who focus their research and other activities only on certain fields of public health. The problems of lobbying activities are well established in western countries. Even in India, lobbies for assisted reproductive therapy vie for funds from policy makers in a country where the problem due to too many births is well recognized. However, good-quality evidence, well generated and explicitly disseminated, can make an issue less political as there may be less debate in the face of scientifically generated information. In case the available evidence is clearly against the known beliefs of the policy maker, then it will need careful planning by the public health

specialists about how you change the belief. However, in no case must spurious or biased evidence be fabricated to merely satisfy a policy position.

Evidence and data are usually, though not exclusively, provided to change and improve the quality of decision-making. A public health professional armed with good data and evidence and presenting in a well organized, skillful and confident fashion to raise and debate issues opportunistically, without the need to berate, harangue, or sermonize the audience, can be very effective in bringing about policy change. In the absence of good evidence on how best the available evidence can best be used to effect policy change, it is one of the major challenges in public health.

## Summary

Information is the basis for all planning processes including public health. Health information is generated at the individual & the community level. The Public health analyst needs information from large number of persons, but needs limited information. Data refers to numerical information but to enable comparisons, information can be considered to be the outcome of processing & evaluation of raw data. Evidence refers to knowledge obtained from research, which can be used to provide support to theory regarding etiology or to some planned or existing intervention. It can be a mixture of numbers & words, come from many sources, is of variable quality & requires interpretation. Public health policy makers & health care managers require quantifiable & tangible information in the form of evidence, statistics or experience.

The components of information systems for planning health care need systematic information about health situations & needs, resources, organization, capacity to convert resources into services, impact on health outcome & consequences of health care financing.

In the field of Public health, rarely is information available in a way that it is easy for policy makers to take effective action. The problems that need consideration are :

- Availability of many types of knowledge
- Information not available in time
- Lack of consistency in information definitions
- Lack of meaningful comparators
- Solution – focused approach of knowledge
- Lack of common language to describe domains
- Communication of evidence in unhelpful ways
- Poor communication of information
- Inability to balance harm, benefit & cost explicitly
- Inadequate listening to the users
- Policy makers often don't want evidence

Evidence & data are usually provided to change & improve the quality of decision making. One of the major challenges in public health is to effect policy change in the absence of good evidence.

## Study Exercises

### MCQs & Exercises

1. Patient records from the hospitals is health information generation at community level : True/False



2. Health information generation at community level includes all except : (a) Surveillance system (b) Population surveys (c) Outbreak reports (d) None
3. Numerical information which expresses information in terms of 'how many' & 'how much' is referred to as \_\_\_\_\_
4. The outcome of processing & evaluating raw data is referred to as \_\_\_\_\_
5. The knowledge obtained from research is referred to as \_\_\_\_\_
6. Information can be in the form of : (a) Evidence (b) Statistics (c) Experience (d) All of the above
7. Information is rarely made available in a way that makes it easy for policy makers to take effective action : True/False
8. Which of the following are powerful ways to raise issues but aren't valid on their own : (a) Data (b) Evidence (c) Anecdotes (d) Policy
9. Spurious or biased evidence may be fabricated to satisfy a policy position : True/False
10. Policy makers often don't want evidence : True/False
11. 'Solution-focused' approach to knowledge is better than 'Problem-focused' approach : True/False

#### Answers

- (1) False; (2) d; (3) Data; (4) Information; (5) Evidence; (6) d; (7) True; (8) c; (9) False; (10) True; (11) False.

#### Further Suggested Reading

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## 72 Making Public Health Policies

*Amitava Datta*

A policy is a deliberate plan of action to guide decisions and achieve rational outcomes. The term may apply to government, private sector organizations and groups and individuals. According to the Oxford English Dictionary, policy is 'a course of action or principle adopted or proposed by a government, party, individual, etc. , or any course of action adopted as advantageous or expedient'. Policy or policy study may also refer to the process of making important organizational decisions, including the identification of different alternatives such as programs or spending priorities and choosing among them on the basis of the impact they will have. Policies can thus be understood as political, management, financial and administrative mechanisms arranged to reach explicit goals.

Policy differs from rules or law. While law can compel or prohibit behaviors (e.g. a law requiring the payment of taxes on income) policy merely guides actions toward those that are most likely to achieve a desired outcome. Science and logic may help to identify public health problems and potential solutions, but emotion and power relationships determine whether anything is done about them.

Public policy-making is accepted to be 'political' and seldom driven by public health evidence. To achieve healthy public policy, it is necessary that timing and the relevance of evidence to policy are crucial. Evidence needs to support a practical programme of actions, but much public health research can be criticized for providing elaborate descriptions of problems rather than possible solutions. There is need for public servants who are equipped with critical appraisal skills to use evidence in policy development. The methodology of presenting evidence

for health policy use has been discussed in a different chapter. Many of the public debate on health issues is converted by the media into simplified notions of what each issue is really about. For example, to public health practitioners in USA, gun control is about saving lives, but to the gun lobby, opposing gun control is about limiting the power of the state and preserving the freedom of the individual. Framing of issues in the media is critical to how they are dealt with and understanding this process and responding directly to an adverse framing of an issue, can be critical to influencing policy and politicians.

Multi-national companies and global organizations can now have major influences on 'local' public health problems and public health practitioners must now both think and act locally and globally. Appreciating the full international picture behind modern public health challenges can help us focus on cause rather than symptoms.

Globally, public opinion and the media can be critical to getting public health issues onto the policy agenda and keeping them there. The importance of recognizing the task of influencing policy as a specific challenge of public health practice, as a challenge that requires an understanding of the policy-making process and the adoption of specific attitudes and skills are important considerations in framing public health policy. At most levels, getting public health issues into the mainstream of public debate and influencing public opinion is seen as a major challenge to public health practitioners.

#### Policy Making Process

**Intended Effects** : The goals of policy may vary widely according to the organization and the context in which they are made. Broadly, policies are typically instituted in order to avoid some negative effect that has been noticed in the organization, or to seek some positive benefit.

Policies frequently have side effects or unintended

consequences. Because the environments that policies seek to influence or manipulate are typically complex adaptive systems (e.g. Governments, societies, large companies), making a policy change can have counter-intuitive results. For example, a government may make a policy decision to raise taxes, in hopes of increasing overall tax revenue. Depending on the size of the tax increase, this may have the overall effect of reducing tax revenue by causing capital flight or by creating a rate so high; citizens may lose incentive to earn the money that is taxed.

The policy formulation process typically includes an attempt to assess as many areas of potential policy impact as possible, to lessen the chances that a given policy will have unexpected or unintended consequences. Because of the nature of some complex adaptive systems such as societies and governments, it may not be possible to assess all possible impacts of a given policy.

**Policy cycle** : In political science the policy cycle is a tool used for the analyzing of the development of a policy item. It usually includes the following stages :

- Agenda setting (Problem identification)
- Policy formulation
- Decision-making
- Policy implementation
- Policy analysis and evaluation (continue or terminate)

**Agenda setting** : Agenda setting, the most crucial step in initiation of new policy, occurs when policy makers identify a problem and develop broad goals to address it. In health care, examples of potential problems include rising health expenditures, an unexpected increase in problems include rising health expenditures, an unexpected increase in infant mortality, or an unexpected increase in the prevalence of a disease (e.g. AIDS). Health-care issues such as these must compete against other policy issues (such as national defence) to become national priorities and specific health issues must compete for attention with other health issues. Policy makers can focus on only a limited number of problems at any one time.

A considerable amount of effort is required to place an issue at the forefront of the policy-making agenda. Although different issues may be influenced by different ways and means, however in general, factors known to help place an issue on the political agenda are the following :

- Large number of people perceiving the existence of the problem.
- Perception of the severity of the problem by many.
- If the problem has occurred recently and is very unique or novel.
- Likely to affect individuals personally.

Simply generating public interest alone does not guarantee that an issue will be placed on the public agenda. Policy makers should consider that the issue is within the purview of government action and deserving of public attention before they will accept it being placed on the public agenda. Many policy issues that have only long-term consequences or only minor consequences for an individual are unlikely to become health-care policy concerns. Unfortunately, many public health issues fall into this category.

Many different approaches are used to place an issue at the forefront of the public policy agenda. One method is to use 'Inside access' to try to influence policy making. This is the aspect which in western countries especially USA, is delegated to lobbyists. Another method is to influence public opinion. This can be done through the media, personal appeals by public officials and celebrities, advertising to raise public awareness and many other approaches including to interest groups and political parties. Public opinion has its greatest impact on government decision-making when people feel strongly about clear-cut preferences. Impact of public opinion is also highest during the period close to elections in democracies. Although government policy usually tends to coincide with public opinion, however if well-organized interest groups intervene, this may not be the case, particularly when public apathy is evident. Special interests can have a particularly important role in technical issues or issues that involve only a few people.

In health care, there is an unequal distribution of information; doctors and other health professionals have specialized knowledge. As a result, individuals must often place their trust in health-care professionals. These health-care professionals who hold and control information have considerable leverage over public opinion.

The media can have a strong influence on public opinion and a short well orchestrated media campaign can provide exceedingly successful results. Interest groups, politicians and others are all trying to influence how the media frame issues and report the news. Favourable media reporting has had very significant impact on decision making. Political leaders and media persons often share a symbiotic relationship. Politicians rely on the media to provide them with information (feedback from their constituency) and to convey their messages to the public. The media, in turn, rely heavily on politicians and public officials for information they use as the basis for their reporting.

Political parties serve as linkages or intermediaries between the citizens and their government. Officially and unofficially political parties have a major role in agenda setting. Party leaders have major roles in determining the agenda of the party in advance of an election and then balancing the conflicting priorities of various interest groups between elections.

**Policy formulation** : Once it is widely recognized that a problem requires government attention, policy makers must develop a broad policy agenda into specific policy options. Policy formulation involves developing alternative proposals and then collecting, analyzing and communicating the information necessary to assess the alternatives and begin to persuade people to support one proposal or another. The analysis process may involve cost-benefit or cost-effectiveness studies in case the proposals require substantial financial support. Policy formulation involves compromising and bargaining in order to satisfy various interests and build a coalition of support and ideally a consensus among the opposing interests.

Next step involves adoption of specific policies. Known by political scientists as legitimization, government policy must conform to the public's perception of the proper way to do things to enable its wide acceptance. Frequently, previous policies of the government are good predictors of future policies,

since people tend to prefer incremental changes over major or revolutionary changes.

In policy formulation, information is gathered, arguments developed and alternatives shaped towards winning the approval of policy makers. Sometimes this is accomplished through rational analyses of the advantages and disadvantages of various alternatives. At other times, policy formulation is a more flexible process that is likely to be influenced by which specific policy maker is involved at specific times and unexpected opportunities to affect change that arise suddenly.

Once the policy has been formulated, statements of government policies and programmes are promulgated. These can be laws, regulations, decisions on resource allocation, court decisions, etc. Equally important, the government can decide that the best alternative is in action.

**Policy content** : Policies are typically promulgated through official written documents. Policy documents often come with the endorsement or signature of the executive powers within an organization to legitimize the policy and demonstrate that it is considered in force. Such documents often have standard formats that are particular to the organization issuing the policy. While such formats differ in form, policy documents usually contain certain standard components including :

- A purpose statement, outlining the reasons for issuing the policy and what its desired effect or outcome of the policy should be.
- Applicability and scope statement, describing who the policy affects and which actions are impacted by the policy.
- An effective date which indicates when the policy comes into force. Policies with retrospective effect are rare.
- A responsibilities section, indicating which parties and organizations are responsible for carrying out individual policy statements.

Policy statements indicating the specific regulations, requirements, or modifications to organizational behavior that the policy is creating.

**Policy Implementation** : Few government policies are self-implementing. Once a policy has been formulated and promulgated, it must be implemented. Even the most brilliantly crafted law, executive order, or court decision will fail to meet the planned goals if it is poorly implemented. Implementation involves three activities directed towards putting a policy into effect. The three activities required for implementation are interpretation, organization and application

**Interpretation** : It requires the translation of the program language into acceptable and feasible administrative directives. Administrators need to understand the policy-makers intent and fill in the details about how the goals will be accomplished. In many instances, legislation or court decisions are purposefully left somewhat vague to allow administrators wide latitude to respond to changing conditions and conflicting demands.

**Organization** : This requires the establishment of administrative units and methods necessary to put a program into effect. Resources (money, buildings, staff and equipment) are required to implement a program. Implementers may choose

to organize a new policy through an existing agency, or create a new agency to administer the policy.

**Application** : Application requires the services to be routinely administered.

The entire process of interpreting policy and designing the organization to implement it is sometimes referred to as 'strategic planning'. This refers to setting out the broad approaches and methods for achieving the policy goals in practice. It must then be followed by 'operational planning' and management in the application phase of implementation.

**Policy Evaluation** : The last step in Policy formulation is evaluation. The policy is evaluated with the view to assess how well it was implemented including whether the goals and objectives were achieved and what impact was achieved. The results can determine whether the program is to be maintained, expanded, changed, or even terminated. Inputs are provided by the general public, providers and special interest groups. The inputs may range from anecdotal to formal evaluation surveys. The results of the evaluation process will lead to actions similar to that of policy making with the formulation of a revised policy based on the results of the evaluation.

### Successful Public Health Policy Formulation

Public health evidence and a population based perspective do not adequately influence public policy in many cases, particularly in sectors other than health. Public health professionals are therefore often frustrated at their apparent failure. Such lack of success should only serve as a motivating factor to generate more support needed from all stakeholders and interest groups to exert a successful influence on the policy makers. Policy making is rarely an event, or even an explicit set of decisions. Policy tends to evolve, subject to continuous review and incremental change. Policy making as it impacts on a large population, is an inherently 'political process' and the timing of decisions is usually dictated as much by political considerations as the evidence. As such, policy making requires appraisal of aspects that are scientifically plausible and acceptable besides being possible to implement practically.

**Potential pitfalls** : A public health practitioner wishing to succeed in ensuring policy formulation must be wary of certain known pitfalls which have been mentioned earlier and take appropriate proactive actions which are reiterated for emphasis as follows :

- Prevent failure to understand the intense political nature of the policy making.
- Be realistic about the possible contribution of their evidences.
- Look for rare windows of opportunities for the uptake of evidence into policy which may occur when policy maker's interest and the social climate coincide to support public health evidence in policy making. These need to be recognized early and successfully exploited.
- Be in possession of appropriate advocacy and communication skills.
- Build relationships with civil servants and policy makers.
- Engaging with media.

## Summary

A Policy is a deliberate plan of action to guide decisions & achieve rational outcomes, which can be applied to Govt. , private sector organizations & groups, & individuals. Policies are therefore political, management, financial & administrative mechanisms arranged to reach explicit goals. It differs from rules or law in that law can compel or prohibit behaviors while policy merely guides actions.

Public policy-making is accepted to be political & seldom driven by public health evidence. To achieve healthy public policy, timing & relevance of evidence are crucial. Good policy is designed for successful implementation & one approach to focus attention on progress of policy implementation is to set targets followed by local action. Framing of issues in the media is critical to how they are dealt with, influencing policy & politicians. Actions at the local level are essential, although, international developments are increasingly gaining importance. Globally, public opinion & the media can be critical in getting public health issues onto the policy agenda.

Policies are generally instituted to avoid some negative effect noticed in the organization, or to seek some positive benefit. Policies frequently have unintended consequences or counter-intuitive results. The Policy formulation process typically includes an attempt to assess as many areas of potential policy impact as possible.

Policy cycle is a tool used for analyzing the development of a policy item, having the following stages :

- Agenda setting (Problem identification)
- Policy formulation
- Decision making – Regarding Implementation & Policy content
- Policy implementation (Requires Interpretation, Organisation & Application)

- Policy analysis & evaluation (to continue or terminate)
- Successful public health policy requires appraisal of aspects that are scientifically plausible & acceptable, being possible to implement practically, besides being wary of certain potential pitfalls & take appropriate proactive actions.

## Study Exercises

### MCQs and Exercises

1. A deliberate plan of action to guide decisions & achieve rational outcomes, which can be applied to govt. , private sector organizations & groups, & individuals is referred to as \_\_\_\_\_.
2. Policies are political, management, financial & administrative mechanisms arranged to reach explicit goals : True/False
3. Policies are same as rules or law : True/False
4. Public policy-making is accepted to be political & is always driven by public health evidence : True/False
5. The tool used in Political Science for analyzing the development of a policy item is referred to as \_\_\_\_\_.
6. The steps in implementation of a Policy are : (a) Interpretation (b) Organization (c) Application (d) All of the above
7. The entire process of interpreting policy & designing the organization to implement it is referred to as \_\_\_\_\_.

**Answers :** (1) Policy; (2) True; (3) False; (4) False; (5) Policy cycle; (6) d; (7) Strategic Planning.

## Further Suggested Reading

1. Developing healthy public policy. Don Nutbeam in Oxford Handbook of Public Health Practice. 2nd ed, 2007. 312-320
2. Public health Policy at a European level. Martin McKee in Oxford Handbook of Public Health Practice. 2nd ed, 2007. 354-363
3. Policy development. Helen H Schauffler in Maxcy-Rosenau-Last. Public Health & Preventive Medicine. Appleton & Lange. 14th ed, 1998. 1069-1080. 14th ed, 1998. 1159-1161

### What is “Strategy”?

Strategies are plans or methods that are relatively broad in scope, are usually long term in nature and often involve a significant expenditure of resources. Strategy is about where we want to be in say 5 years from now. It can be considered to be a process as well as a product which enunciates the methodological framework for achieving a vision. The changes or steps which are necessary to be undertaken to enable achievement of this vision should be part of the strategy.

Planning without consideration of strategy is unlikely to be successful. Roughly speaking, strategies are likely to be used in attaining goals, whereas tactics are likely to be used in attaining objectives. Strategies can also be considered to be like other tools used in management for the purpose of helping us achieve the designated task better. Strategies provide us the framework for executing tasks needed for achieving stated goals laid down in the plan.

Health care strategy once enunciated as a statement, helps the wide range of like minded partners to understand, appreciate and address the ways of achieving health care goals by ensuring that they share common priorities which are similarly clearly elucidated. Devising strategies in public health have been recommended as public health projects involve expenditure of large amount of resources for the benefit of large population



groups. Involvement of public health practitioners in devising health strategy also adequately addresses concerns regarding needs, equity, effectiveness, etc of the health interventions. The strategy process is dynamic and has been likened to a 'journey' rather than a static single point statement of intent or purpose.

The planning process is guided by strategy. Good strategies are based on the principles inherent in the relevant policy. However, the strategies proposed to be adopted to achieve the policy goals inform the policy planners of the practicability of putting the policy into action. Strategy thus provides the practical road map, based on practical considerations of opportunities and obstacles, which will be needed to make the vision of the policy achievable. Planning concerns the day-to-day details of how the key steps of strategy are achieved over months and years. The linkage between policy, strategy and planning can be understood better with an example – The Indian government while developing national highways may consider it necessary to state a policy that trauma victims of accidents on the highways must be provided care at a fully functional trauma care centre as soon as possible on occurrence of an accident to save life and limb. The state governments, who are responsible for provision of health services, will then need to develop strategy that within a period of five years trauma care centres are provided in such a manner that the maximum distance from any site of accident on the highway is not more than 30 minutes driving distance to ensure observance of the 'golden hour' concept in trauma management. Detailed plans will therefore need to be developed of how the trauma care centres will be developed including upgrading of existing primary health centres and even seeking assistance of private hospitals.

The factors associated in general with successful strategy development have been understood with experience. Any strategy needs to incorporate the values and vision of the people who will actually implement it. The strategy must provide an impetus for forward movement towards achieving goals and the key issues clearly identifiable by planners who will need to address these issues. The uncertainties in the initial stages need to be overcome by ensuring that all participants are focused in their thinking without any constraining lateral thinking. Involvement of dedicated and correctly selected persons, right from inception stage, who will acknowledge the policy context and the needs of planners are essential to successful strategy development. Clarity of purpose, engaging of the right people and right policy context, continued evaluation and appropriate implementation are needed to avoid floundering of strategies which may have sounded grand initially. Similarly, the strategy development needs to avoid becoming too complex by attempting to keep the strategy simple and practical as far as possible without constraining thought.

### Health Care Planning

Planning is the future oriented, systematic process of determining a direction, setting a goal and taking actions to reach that goal. Planning is considered a basic management function essential to the functioning of all levels of an organization. While planning can be described in terms of techniques and tools, it is also a very complicated social

process that must be mastered by the successful manager and any thriving organization. While every manager must realize the need to plan, there are few prescriptions available for effective planning. Gaps that exist between public expectations and how an institution, sector of government or the society actually functions may point to inadequate planning or lack of planning, rather than poor leadership and implementation.

Planning is as much a social and political process as a technical process. It is essential to recognize that all participatory planning takes place in the context of an organizational culture and a history of relationships between the planning parties (both organizations and individuals). Complications and conflicts often arise over disagreements on the scope of planning strategies and specific actions necessary to achieve goals. Unfortunately, policies sometimes set out grand principles and the courses of action suggested are frequently with scant details and occasionally with little apparent thought as to how they will be implemented.

In the field of public health, even in the present developed world, planning was not common until the 1920s. The increase in funds allotted to public health over the years has created a need to plan for and be accountable for the expenditure of the funds. The planning process was developed especially in countries with socialistic forms of government. India started its development program after independence and adopted the Soviet model of a command economy. The planning structure was enshrined in the Planning Commission which prepared plans for development, recommended funding mechanism through government allocation and monitored the implementation in a "top down" approach. The health sector was also included in the planning process and public health facilities were all funded through governmental sources. Since the execution of the 1st five year plan, India is now into the 11th five year plan. The funding situation till today has not seen much change as regards the public health sector is concerned.

Planning is a form of rational decision making and can be considered to be executed in a step wise manner as follows :

**Step 1 :** Decide on goals and objectives.

**Step 2 :** Determine the constraints on the planning process and the likely changes in the environment that may affect how easy the goals and objectives are to achieve.

**Step 3 :** Figure out what actions, policies and programs to implement.

The details of planning process are discussed in an exclusive chapter in the section on health management.

The term 'strategic planning' derives from military jargon. It implies a planning process of significance, usually done by high-level decision makers, that will result in setting the organization's overall direction. It is often coupled with the term 'long term' or 'long range' to create an important sounding term 'long range strategic planning' which implies a systematic periodic process that sets the overall business strategy of the organization for the years ahead.

### Steps in Strategic Planning

Strategic planning is planning directed at the achievement of the planned goals, which are the significant or even ultimate

ends. As such, it is an extremely important task and falls largely on the shoulders of the leadership. The steps are :

**Step 1 :** “Planning for plan” stage – the reasons for choosing strategic planning, needs to be clear and communicated to potential stakeholders to lay the groundwork for a shared vision. It can however be an expensive process and funds will be needed for conducting it.

**Step 2 :** This involves the clarification of organizational mandates.

**Step 3 :** Agency leaders begin to investigate the values that will govern the agency and the agency’s community relationship. It may include conduct of a stakeholder analysis.

**Step 4 :** Assessment of the internal and external environments in order to identify the opportunities and the challenges arising from the change process, called the SWOT analysis. The internal assessment looks at the agency’s resources, the process of carrying out the agency activities and the performance outputs.

**Step 5 :** Identification of the issues to be addressed by the plan. Identify the critical issues and why they are critical and the consequences of not addressing these issues.

**Step 6 :** Development of strategies to address the issues delineated in step 5.

**Step 7 :** Stakeholders review, modify and adopt the strategic plan developed in step 6.

**Step 8 :** Creation or revision of the organizational vision. Strategic planning may lead to changes that impact the vision and thus visioning is tied to each step.

**Step 9 :** Implementation of the plan.

**Step 10 :** Monitoring the implementation and making necessary mid-course corrections.

**Operational planning :** This is the most common type of planning is engaged in by managers, supervisors and every member of an organization in routine yet essential, day-to-day activities. Besides being most common, it is crucial to providing the services and products in health and human service organisations. When objectives are clearly defined and resources known, operational planning is straight forward. The presently available tools like office automation, computerized scheduling systems, spread sheets, voice mail and electronic mail all provide for better planning and implementation.

**Tactical planning :** Its an another term having military origins, is “how to” or implementation planning. ‘Program planning’ and ‘project planning’ are other planning types that deal with implementation. Tactical planning implies a broader scope and somewhat longer time horizon than operational planning. Projects can be as massive as a new hospital or a nationwide immunization campaign or as limited as implementing a re-engineered care process or new computer software system. Numerous management tools and techniques, such as a decision support and project planning software, exist to aid in monitoring progress and optimizing project implementation. Planning process can be formal or informal. Formal planning leaves a paper trail with all critical decisions being documented. Informal planning is less organized and more guided by social interactions.

## Methods and Tools for Planning

**Planning information and the scientific method :** Information is at the core of all planning and a variety of collection techniques may be useful. Gathering and transforming data that is useful in making decisions is at the core of any systematic planning process. Information may come from formal or informal sources or systems.

**Mathematical modelling and quality planning :** In recent years, various methods / models for improving the quality of products and services have become popular in health care settings. In many situations, organisations and communities must make decisions for the future with little information. Statistical modeling is among the useful techniques in such situations. Mathematical models are often essential because we may be unable to wait for even preliminary empirical data that could aid our decisions.

**Integrated planning, budgeting and improvement approaches :** Over the years management science, industrial engineering and organizational development specialists have developed systems designed to integrate and improve various management functions including planning. Management By Objectives (MBO) swept businesses in the 1970s with the promise of quantitatively linking the performance of every member of the organization with the organization’s goals by using a system of quantifiable objectives. Large organisations developed their own approaches including zero-based budgeting, which America tried to introduce to the public sector. Many management systems have proved to be short term fads. However, other systems and management tools have been successful and worthy of long term adoption.

## Role of Public Health Practitioner in Health Care Planning

As a public health practitioner it is likely that he will need to work with the following in the field of health planning :

- Managers and clinicians in organizations who are involved in purchasing and providing health care services.
- Patients and users who will have experienced most of the good and bad aspects of any system. In western countries, citizens panels can be a good way to do this, but are time-consuming and expensive. In India the role of members of the ‘panchayati samiti’ or ‘rogi kalayan samitis’ serve a similar purpose.
- There are likely to be existing planning groups and one will need to work with these to be effective, but to be useful these planning groups need to be part of the power structure, with authority over budgets.

The public health practitioner may need to help develop specific options for implementing policy, including new ‘models of health care’, involving changes to inputs or processes. The role will involve presenting to health sector civil servants or politicians and other health care professionals, research evidence on the effectiveness of relevant health interventions.

They may be tasked to also provide information for planning. This includes quantifying how the new models of health care will affect health services - patterns of provision, activity, budgets and outcomes. Based on the output from the above mentioned three tasks, usually an implementation plan for a

strategy or project proposal is developed using an agreed work plan.

The public health practitioner will also be called upon for dissemination and supporting decision-making. It is necessary to analyze thoroughly the implications of the policy options produced in earlier tasks. The planning cycle then begins again with the monitoring and evaluation tasks, to determine what effect the implemented changes are having on the existing health system.

### Potential Pitfalls and Fallacies in Health Planning

Completing the implementation of planning decisions may usually take several years. Often there will be inadequate time but based on the suggested framework, it should be possible to reap the most benefit in the time available for health planning.

It must be appreciated that Planning rarely goes 'according to plan' as circumstances and personnel change. The intended objectives in planning are usually only partially attained and there are often unintended consequences. Therefore, monitoring the effects of planning and making adjustment are crucial. The public health practitioner should therefore be ready to accept only partial implementation of the planned intervention on the basis of changed circumstances, be ready with the evaluation process to assess the needs for changes in the plan which can be then presented to the decision makers and not become emotionally attached with the original plan.

Success in the planning process is usually not absolute. Although there should be specific objectives and measurement of their attainment, however, success, like the planning process, usually comes little by-little. That implies that monitoring and evaluation are essential to successful planning. Similarly, discussions with colleagues and formal evaluations, including workshops, are important.

It is clear that the terms policy, strategy and planning are linked and seen as being part of hierarchy of time-scale, but definitely not a hierarchy of challenge or importance in achieving aims. It is therefore important for public health practitioners to possess a clear understanding of the procedures involved in devising health care strategy and health care planning to meet the stipulated goals in public health.

### Summary

Strategies are plans or methods that are relatively broad in scope, long term & often involve a significant expenditure of resources. It is a process as well as a product. Strategies are likely to be used in attaining goals, whereas tactics are likely to be used in attaining objectives. Devising strategies in Public health have been recommended. Planning without strategy is unlikely to be successful.

Planning needs to be compared to the process of strategy development as both the processes have distinct entities although they are linked. Good strategies are based on the principles inherent in the relevant policy. Strategy thus provides the practical road map, based on practical considerations of opportunities & obstacles, which will be needed to make the vision of the policy achievable. It must provide an impetus for forward movement towards achieving goals & the key issues

clearly identifiable by planners who need to address them.

Planning is the future oriented, systematic process of determining a direction, setting a goal and taking actions to reach that goal. It is as much a social & political process as a technical process. This process was developed especially in countries with socialistic form of government.

Planning is a form of rational decision making & can be considered to be executed in a stepwise manner as follows :

- Decide on goals & objectives.
- Determine the constraints on the planning process.
- Figure out what actions, policies & programs to implement.

Roher describes three planning models that are typically used in public health - Rational planning model, Community development model and Activist model. The 'Strategic planning model' applies to both organizational reform & community health planning & Bryson developed a ten step procedure for it. 'Operational Planning' is the most common type & is crucial to providing services & products in health. 'Tactical Planning', 'Program Planning' & 'Project Planning' are other planning types that deal with implementation.

The methods & tools for planning include the following :

- Planning information & the scientific method.
- Mathematical modeling & quality planning.
- Integrated planning, budgeting & improvement approaches.
- Funding of plan.

A Public health worker needs to work with managers, clinicians, patients, users & existing planning groups to be effective. Besides he is also required to help develop specific options for implementing policy, provide information for planning & disseminate & support decision making.

Planning rarely goes 'according to plan', as circumstances & personnel change. Therefore monitoring the effects of planning & making adjustments are crucial. It is a continuous process & evolves as it unravels. Success in the process is usually not absolute. Policy, strategy & planning are linked & seen as being part of hierarchy of time-scale, but definitely not a hierarchy of challenge in achieving aims.

### Study Exercises

#### MCQS & Exercises

1. Plans or methods that are relatively broad in scope, long term & often involve a significant expenditure of resources are referred to as \_\_\_\_\_.
2. \_\_\_\_\_ are likely to be used in attaining goals, whereas \_\_\_\_\_ are likely to be used in attaining objectives.
3. The planning process is guided by strategy : True/False.
4. Strategy development ensures progression in small incremental but predictable steps : True/False.
5. Health care priorities need not be examined & debated, but can be hidden or accidental : True/False.
6. India adopted the \_\_\_\_\_ model of a command economy after starting its development program.
7. The planning which is empowerment oriented & promotes local citizen partnership in planning activities is :  
(a) Rational planning model (b) Community development model (c) Activist model (d) Strategic planning model.



8. The model that has the advantage that it applies to both organizational reform & community health planning is the: (a) Rational planning model (b) Community development model (c) Activist model (d) Strategic planning model.
9. The ten step procedure for strategic planning was given by \_\_\_\_\_.
10. The form of planning which is a type of implementation planning is : (a) Tactical Planning (b) Program Planning (c) Project Planning (d) All of the above.

**Answers :** (1) Strategies; (2) Strategies, tactics; (3) True; (4) False; (5) False; (6) Soviet; (7) b; (8) d; (9) Bryson; (10) d.

### Further Suggested Readings

1. An introduction to health care strategy. David Puncheon in Oxford Handbook of Public Health Practice. 2nd ed, 2007. 376-381
2. Strategies for health services. Martin McKee and Josep Figueras in Maxcy-Rosenau-Last. Public Health & Preventive Medicine. Appleton & Lange. 14th ed, 1998. 1069-1080. 14th ed, 1998. 1889-1910
3. Structures and Strategies for public health intervention. Don Nutbeam and Marilyn Wise in Maxcy-Rosenau-Last. Public Health & Preventive Medicine. Appleton & Lange. 14th ed, 1998. 1069-1080. 14th ed, 1998. 1873-1888

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## Bringing about Equality in Health Care

*Amitava Datta*

### Concepts of Equity

The concept of equity dates back to early human civilization and is linked to disadvantaged, impoverished, deprived human beings. Equity has been discussed by politicians and statesmen from ancient times when comparing the 'haves' with the 'have nots'. The central dogma of the socialist pattern of politics is "To each as per his need" and "from each as per his ability". Equity includes the concepts of fairness, justice and equality which have been the central theme of modern day democracies. In the health sector, it is assessed by comparing levels of health of individuals or a community, or the ability of individuals and communities to obtain health care.

There are two forms of health equity. "Horizontal" equity refers to equal treatment for equal needs, for example, the devotion of equal resources to patients with similar conditions, or equal access to care for people with equal needs. The components of horizontal equity in health are described as providing equal resources for people with equal needs, providing equal access to health care for people with equal needs, providing equal utilization of health care by those with equal need and providing equal health aimed at reducing inequalities in health status between populations.

"Vertical equity" refers to unequal treatment for unequal needs; that is treating individuals who are unequal in society in different ways in order to overcome the effects of differences in their social or clinical situation. Vertical equity can be achieved by ensuring that individuals with more need should have more treatment to bring them up to the same level as others with less need. This might include devoting more resources to patients with serious conditions than to those with trivial conditions or financing health care according to the ability to pay. The alternative perspective points out that equal use for equal need does not necessarily always result in unequal use

of unequal need. If mildly diabetic persons are treated in the same way regardless of gender, age or ethnicity, but severely diabetic men are more likely to receive treatment than severely diabetic women, then equal use for equal need (- the concept of horizontal equity) occurs for mild diabetes but not for severe diabetes (where there is vertical inequity). The central theme of "need" therefore determines equity.

It must be recognized that differences in health care use are not biased if they are due to differences in need. Such differences demonstrate equal but fair care. The fair distribution of health care should be considered from two related perspectives. The first is that people with equal needs should be treated the same (equal use for equal needs). This is referred to as the achievement of horizontal equity. For example, if we consider differences in clinical need, such as differences in disease severity or presence of co-morbidity, then patients with similar levels of disease severity should be equally likely to receive an effective intervention regardless. The alternative perspective is that people with greater clinical needs should have more treatment than those with lesser needs (unequal use for unequal need). This is referred to as the achievement of vertical equity. Thus, patients with severe disease should be more likely to receive an effective intervention compared with patients with a milder form of the same disease, regardless of age or gender.

### Theories of Equity

Although defining equity is relatively easy, however it becomes difficult to decide what is fair or just. Most of the health and health care issues related to equity come under the broad category of "distributive justice" – that is, how benefits, resources and burdens of society are distributed to each individual. The manner in which members of the society cooperate and the value system in the society determine its theory of equity. Theories of distributive justice differ in different political systems and societies. Some of these known theories of distributive justice can be broadly divided into libertarian, liberal and collectivist.

**Libertarian theory :** The 'Libertarians' believe in the protection of individual freedom, namely, political liberty, freedom of speech



and economic freedom. People are considered to be entitled to what they have, provided it was acquired justly. It has been propagated that for the state to raise taxes from individuals in order to provide services for the least advantaged class is a form of theft by the state against the private citizen. One obvious limitation to libertarian theory is that biological and genetic influences mean that the distribution of health cannot be described as fair. This has implications for the allocation of health care under a libertarian system.

**Liberal theory** : It also emphasizes individual liberty, but also includes the concept of “need” in its definition. Liberal theory also relies on the free market to allocate resources, but also recognizes the unequal distribution of assets among individuals. State intervention is therefore deemed appropriate when the market fails to safeguard the needs of all the members of society. Public health interventions such as universal immunization for measles or polio are based on utilitarianism principles.

**Collectivist theory** : This theory is based on 3 main rules—equality, freedom and fraternity, though the dominant concern is equality. Collectivist theories are therefore egalitarian and are in favour of positive, equalizing measures to re-distribute rights and wealth.

### **The Concern for Removal of Health Inequalities**

In the recent years, interest in equality, equity and health of the poor has begun to assume a more important place in international agenda. The 1970s ended in the declaration for “Health for All” movement. The Alma-Ata conference in 1978, led to a strong focus on community orientation with governments supporting or encouraging the development of free health care services. The ‘primary health care’ approach was advocated by WHO to achieve provision by all countries of basic health care services to all their citizens.

Pragmatic examination of the various facets of primary health care approach created doubts whether this approach was capable of providing the dramatic improvements ascribed to it. “Health sector reform” became the new buzzword. The focus shifted to sustainability and efficiency rather than only concern for the health of the poor people living in developing countries. Importance was also given to health, nutrition and population by WHO during the late 1990s. The focus still remained on the poor – World Health Report for 1999 laid stress on reducing the burden of excess of mortality and morbidity of the poor. Overall, the situation in the recent times has become encouraging for those concerned with health equity and the health of the poor. However, it is uncertain whether it will be enough to guarantee significant improvements in health equity in a sustainable manner. The dispute ridden areas in Africa and Asia, which are taking their toll in terms of worsening human misery, are a major source of health inequity today in the world.

### **The Problem of Poverty and Health**

Poverty and ill-health are interlinked. It is known that poor countries tend to have worse health outcomes than better-off countries. Within individual countries, poor people have worse health outcomes than better off people. The association between poverty and ill-health reflects causality running in both directions. Illness or excessively high fertility may have a

substantial impact on household income and may even make the difference between being above and being below the poverty line. Furthermore, ill-health is often associated with substantial health care costs. But poverty and low income also cause ill-health. Poor countries and poor people within countries, suffer from a multiplicity of deprivations that translate into high levels of ill-health. Poor people are thus caught in a vicious circle—poverty breeds ill health, ill-health maintains poverty.

Latin America appears to have higher inequalities in child health between poor and non-poor than other parts of the developing world, whatever health indicator is used. By contrast, inequalities in child mortality and malnutrition are less pronounced in sub-Saharan Africa than in North Africa, Asia and the Near East, but the opposite is true of inequalities concerning diarrhoea and acute respiratory infections. Socioeconomic inequalities in health seem to be widening rather than narrowing. This is true of both the developing and developed world. Three points are worth highlighting.

*First*, the world today knows a good deal about the extent of health inequalities between poor and non-poor in developing countries and a reasonable amount about inequalities in health determinants. Most striking in this connection is the failure of publicly financed health care to reach the poor in almost all developing countries.

*Second*, too little is known about the relative importance of inequalities in the determinants of health and health service utilization. Present knowledge suggests that inequalities in health and most probably in service utilization, largely reflect inequalities in variables at the individual and household levels, such as education, income, location and housing characteristics. Policies aimed at combating health sector inequalities should therefore aim to reduce both inequalities in the quality and availability of health services and inequalities in income, knowledge (especially health-specific knowledge), accessibility of health services, availability of safe drinking-water and sanitation, etc.

*Third*, too little is known about the impact of programmes and policies on health sector inequalities. There is undoubtedly a large gap in our knowledge on how best to reach the poor in the health sector. In order to fill this gap, more work is needed along the lines of the above studies related to health sector inequalities and public policy.

### **Action to Overcome Health Inequity**

Having accepted that poverty is linked to almost all health inequity, it is necessary to attempt to overcome health inequity. The different approaches which may be considered are measures to improve the health of the poor, reducing poor-rich health inequalities or redressing health inequities. The approaches may be individually different. Those who approach health from a poverty viewpoint are typically concerned with improving the health of the poor alone rather than with reducing the poor-rich health differences. To improve the poverty status, the concept of ‘poverty line’ is used. While the concern for lessening poverty and improving the health of the poor is widespread, it is not necessarily the most preferred way. Many focus on inequalities in general and with respect to health in particular. Health inequalities have played a more central role than the

health of the poor alone in European concern. There appears to be different views on the most appropriate strategies for the reduction of inequalities. The aspects which must be borne in mind while considering the strategies are – how is the inequality to be measured, what aspects of inequality are most important and whether the focus should be local or global.

The concern for attaining of health equity is no longer the domain of health professionals only. It has been well appreciated that reduction in health inequity can be attained by the world through comprehensive multi-disciplinary action involving diverse resources. The adoption of the Millennium Development Goals by World Assembly in 2000, is the latest international initiative to attempt at equity including health equity. This aspect has been discussed in detail in an earlier chapter on health for all, primary health care and MDGs and the readers are advised to refer to the same. It is considered necessary to clearly highlight the appreciation by the world community of the prevalent causes of inequity and health inequity not only between countries but also within countries and the proposed means to reduce this inequity. The salient features of MDGs in relation to health equity are as follows :

**Goal 1 - Eradicate extreme poverty and hunger :** The fundamental problem affecting equity among mankind being poverty and its related fact, hunger, it is extremely apt that this fact has been stressed by United Nations in stating it as the first goal of all nations. It has been proposed to reduce by the year 2015, the number of people who earn less than \$ 1 per day by 50% in low and middle income countries and also reduce by 50% the persons who suffer from hunger.

**Goal 2 - Achieve universal primary education :** Illiteracy has rightly been considered as a major impediment to attainment of equity by all people. Hence the stress to at least attain primary education by all children of the world. To reach the education goal, countries must first enroll all school-age children. Then they must keep them in school. Although not officially included as one of the MDG indicators, primary completion rate is increasingly used as a core indicator of an education system's performance.

**Goal 3 - Promote gender equality and empower women :** Women have an enormous impact on the well-being of their families and societies – yet their potential is not realized because of discriminatory social norms, incentives and legal institutions. And while their status has improved in recent decades, gender inequalities remain pervasive. Gender inequality starts early and keeps women at a disadvantage throughout their lives. Educating women and giving them equal rights is important for many reasons- It increases their productivity, raising output and reducing poverty; it promotes gender equality, within households and removes constraints on women's decision making thus reducing fertility rates and improving maternal health; and educated women do a better job caring for children, increasing children's chances of surviving to become healthier and better educated.

**Goal 4 - Reduce child mortality :** The target is to reduce by two-thirds the under- 5 years mortality rate by 2015. Immunization is an essential component of activities to reduce child mortality. Child mortality is also closely linked to poverty. In 2002, the average under-five mortality rate was 121 deaths

per 1,000 live births in low-income countries, 40 in lower-middle-income countries and 7 in high-income countries.

**Goal 5 - Improve maternal health :** The target is reduce by three-quarters the maternal mortality ratio. Women in high-fertility countries in Sub-Saharan Africa have a 1-in-16 lifetime risk of dying from maternal causes, compared with women in low-fertility countries in Europe, who have a 1-in-2, 000 risk and in North America, who have a 1-in-3, 500 risk of dying. Greater access to family planning, providing rapid access to emergency obstetrical care, including treatment of hemorrhages, infections, hypertension and obstructed labor and supported by the right environment are suggested interventions.

**Goal 6 - Combat HIV/AIDS, malaria and other diseases :** The economic burden of epidemics such as tuberculosis, malaria and HIV/AIDS on families and communities is enormous. Estimates suggest that tuberculosis costs the average patient three or four months of lost earnings, which can represent up to 30 percent of annual household income; Malaria slows economic growth in Africa by about 1.3 percent a year; and when the prevalence of HIV/AIDS reaches 8 percent the cost in growth is estimated at about 1 percent a year. The targets are that by 2015, halt and start reversing the spread of HIV/AIDS and the incidence of malaria and other diseases.

**Goal 7 - Ensure environmental sustainability :** Improved water and sanitation reduce child mortality and better drainage reduces malaria. It also reduces the risk of disaster from floods. Managing and protecting the environment thus contributes to reaching the other Millennium Development Goals. Fortunately, good policies and economic growth, which work to improve people's lives, can also work to improve the environment. The targets are to halve by 2015 the proportion of people without sustainable access to safe drinking water and basic sanitation, besides achieving by 2020 a significant improvement in the lives of at least 100 million slum dwellers. The interventions suggested include reversing the denudation of forests, reduce the existing pressures on biodiversity by declaring protected areas and species, change in use of energy sources away from fossil fuels and reducing carbon dioxide emission by use of better technology

**Goal 8 - Build a global partnership for development :** It is advocated to have an open, rule-based trading and financial system, more generous aid to countries committed to poverty reduction and relief for the debt problems of developing countries. It draws attention to the problems of the least developed countries, which have greater difficulty competing in the global economy. It also calls for cooperation with the private sector to address youth unemployment, ensure access to affordable, essential drugs and make available the benefits of new technologies. In March 2002 leaders from developing and high-income countries came together in Monterrey, Mexico, to discuss new strategies for attacking global poverty. Rich countries made new commitments that would increase official development assistance in real terms by about \$16 billion a year by 2006.

Health inequity has come to the forefront of international concern in recent years. With globalization, boom in information technology and communication, besides relative affluence and overall development in many parts of the

world, there is greater awareness of the existing disparity in health equity in different parts of the world. This awareness exists at the individual, governmental and institutional levels. Philanthropic institutions and professional bodies are investing their own resources in developing and implementing strategies to overcome many of the identified inequities. It can be reasonably anticipated that the pace of reduction of health inequities will proceed in a sustained manner as planned by the international agencies like United Nations with the full participation of national governments and assisted by like minded donor agencies.

## Summary

Equity includes the concepts of fairness, justice & equality, which in the health sector is assessed by comparing levels of health of individuals or a community or their ability to obtain health care. The two forms of health equity are 'Horizontal equity' which refers to equal treatment for equal needs & 'Vertical equity' which refers to unequal treatment for unequal needs. The central theme of "need" therefore determines equity.

Differences in health care use are not biased if they are due to differences in need. Such differences demonstrate equal but fair care. It is essential to take account of different levels of clinical need in order to measure the fair use of health care.

Most of the health & health care issues related to equity come under the broad category of "distributive justice". Theories of "distributive justice" can broadly be divided into : Libertarian theory, Liberal theory and Collectivist theory

Poverty has long been associated with health inequities. Also poverty & ill-health are interlinked. The international community has an increasing concern over health inequities in recent times. The different approaches which may be considered to overcome this are to improve the health of the poor, reducing poor-rich health inequities or redressing them. The priority need at present is to begin applying what is already known to obtain political commitment & develop effective intervention strategies, besides redefining health goals.

The adoption of Millennium Development Goals by World Assembly in 2000, is the latest international initiative to attempt at equity including health equity. It may be expected that the pace of reduction of health inequities will proceed in a sustained manner as by the international agencies with participation of national Govts. & assistance by like minded donor agencies.

## Study Exercises

### MCQs and Exercises

1. The equity which refers to equal treatment for equal needs is referred to as \_\_\_\_\_
2. 'Vertical equity' refers to equal treatment for unequal needs : True/False
3. The central theme of "need" determines equity. True/False
4. The theory of equity which emphasizes individual liberty with the concept of need is : (a) Libertarian (b) Freedom (c) Liberal (d) Collectivist
5. The theory of equity which is based on 3 main rules of equality, freedom & fraternity is : (a) Libertarian (b) Freedom (c) Liberal (d) Collectivist
6. The adoption of Millennium Development Goals by World Assembly took place in the year : (a) 1999 (b) 2000 (c) 2001 (d) 2002
7. As per the MDGs, the target of Goal 4 is to reduce under - 5 mortality by \_\_\_\_\_ by the year \_\_\_\_\_.
8. As per the MDGs, the target of Goal 5 is to reduce maternal mortality ratio by one-fourth : True/False

**Answers :** (1) Horizontal equity; (2) False; (3) True; (4) c; (5) d; (6) b; (7) Two-thirds, 2015; (8) False.

## Further Suggested Readings

1. Measuring and monitoring health inequalities and auditing inequity. Julian Flowers in Oxford Handbook of Public Health Practice. 2nd ed, 2007. 170-183
2. Improving equity in health care. Anna Donald in Oxford Handbook of Public Health Practice. 2nd ed, 2007. 412-419
3. Reducing health inequalities in developing countries. Davidson R Gwatkin in Oxford Textbook of Public Health. 4th ed, 2002. 1791-1810.

## 75 Health Care Quality

*Amitava Datta*

The word "quality" can convey different meanings. It can convey a high degree of excellence, e.g. "a quality product", or a degree of excellence or the lack of it e.g. "work of average quality", or a property of something, e.g. "the addictive quality of alcohol". Usually however the word is used in the world of business where it is subjective term for which each person has

his or her own definition. In technical usage, quality can have two meanings – first, the characteristics of a product or service that bear on its ability to satisfy stated or implied needs and second, a product or service free of deficiencies. It has been opined that "Quality in a product or service is not what the supplier puts in. It is what the customer gets out and is willing to pay for." Quality thus has no specific meaning unless related to a specific function and/or object. Quality is a perceptual, conditional and somewhat subjective attribute.

Health care Quality also has many facets which are needed to be understood as the health care manager, usually a public



health specialist is expected to assess the quality of health care in given community. According to the United States Institute of Medicine, 'Quality of health care' is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. This definition explicitly acknowledges that 'Quality' is measured as a scale or degree, encompasses all aspects of care and can be observed from an individual as well as a population perspective. The quality 'outcomes' do not specify for whom, thus allowing differing perspectives on which aspects of quality are most important (professional, patient, public, political, etc). There is rarely a causal link between the quality of care and outcome. The phrase 'consistency with current professional knowledge' indicates that the quality of care can only be judged relative to what is known at that moment in time.

## Defining and Measuring the Quality of Health Care

Although it is apparent that quality often being perceived as difficult to define, however the quality of a service is the degree to which it conforms to certain preset standards of good care. An important dimension of measuring quality is to make the standards against which one is assessing quality absolutely explicit and preset. It has been expounded that there are six dimensions of quality which can be considered while measuring the quality of a product or practice – effectiveness, efficiency, acceptability, access, equity and relevance which are explained as follows :

**Effectiveness** : measures the desired effect.

**Efficiency** : measures the cost of the input as compared with the cost elsewhere for the same requirement (treatment) / service.

**Acceptability** : measures how humanely and considerately the treatment/service is delivered. What does the patient think of it? What does an observant third party like his attendant think? To what extent does the treatment /service conform to patient/public expectations and how much are they utilizing it.

**Access** : measures whether people get this treatment/service when they need it. Identifiable barriers like large distances to travel, inability to pay and waiting times also influence the access.

**Equity** : measures whether all groups of patients are being fairly treated compared to others or is there discrimination in who gets the service / treatment.

**Relevance** : compares the treatment / service with the best that could be achieved, taking account the needs and wants of the population.

### Measurement of 'Quality'

The quality of health care can be assessed by measuring the structure, process, or outcomes. "Structure" (often also referred to as "inputs" in certain managerial parlances) refers to the components of the health-care system like number of health centres, the number of beds in the health centre, the ratio of the number of nurses and doctors to the number of beds in a centre, the presence of laboratory, x-ray machine, etc.

Although the absence of adequate health structure has strong negative influence on health, however, mere presence of health care structure cannot necessarily improve the health of the population.

The "processes" of health care are those things which are delivered to individual patients in specific clinical circumstances, such as prescription of certain medications, conduct of diagnostic tests and therapeutic procedures, etc.

"Outcomes" refer to health states such as recovery, death, disability, improvements in functional status, etc. Measuring outcomes appears logically to be the best measure of the quality of health care but there are serious limitations because of the following reasons :

Many determinants of outcome are poorly understood or not under the control of the health-care system. For example the recovery of a patient treated with angioplasty after a heart attack cannot be clearly measured. His functional state may not be an indication of the competence of the cardiologist or the hospital as various other factors like the severity of the disease process, socio-economic support system of the patient and his age, occupation, etc may play a major role on his complete physical, social, mental and economic rehabilitation

For many chronic conditions, the time between the key processes of care and the outcomes may be very long. For example, untreated diabetes may be asymptomatic for years before leading to retinal damage or kidney failure.

Therefore, use of outcome measures of quality is usually restricted to areas where the above problems are not present, for example in measuring mortality following major surgical procedures in a hospital.

By assessing the health processes as indicators of health care quality, we measure what is delivered to patients under specific circumstances and they must be strongly linked to subsequent outcomes, preferably by good evidence from epidemiological studies like randomized clinical trials, or professional consensus. A good example to study the effect of a "process" is an immunization campaign as a means of reducing morbidity and mortality due to an infectious disease like measles.

For all of these reasons, measures of health-care quality are dominated by "process" measures rather than "outcome" measures.

### Measuring Quality of Care

In order to assess and improve the quality of health care provided to a community, it first must be measured. For example, let us examine an operational statement about a specific health-care process – "if a patient has diabetes and is over the age of 55 and is at increased risk for cardiovascular disease then he should be offered treatment with an ACE inhibitor". To be a quality measure it will need to be applied to a specific population and data sources and spell out precisely how patients with diabetes are to be identified, what factors (and how they are measured) are considered to be evidence of increased cardiovascular risk and what efforts count in terms of offering ACE inhibitor therapy.

Criticisms of the use of quality indicators or measures include that the selected items aren't necessarily related to improved



health outcomes and that focusing attention on certain measures will lead to decreasing attention on other aspects of health care, which may be as much or more important. Therefore, development of measures should aim to be as rigorous as possible and cover a broad array of aspects of health care, to better represent care and minimize the ability to distort or game the measurement system.

### **The Appropriateness of Clinical Interventions**

The 'appropriateness' of health-care interventions have been defined as the degree to which benefit of care exceeds the expected negative consequences. Through this concept it is possible to establish a set of rules or standards of care based on identifying appropriate interventions which should be used (or not used) in a specific clinical situation.

The 'appropriateness method' was developed as a pragmatic solution to the problem of trying to assess for which patients certain surgical and medical procedures are 'appropriate'. For example, it may be stated that in the case of middle aged male patients detected to have single or double vessel blockage on coronary angiography, they be offered angioplasty. However for triple vessel blockage in similar age group of patients, coronary bypass graft surgery be offered. Attempts are made to determine 'appropriateness' with a thorough literature review, but this may prove insufficient for developing comprehensive, clinically detailed measures of appropriateness in some cases. Several fundamental concepts assist in developing the 'appropriateness'. Some of these are :

- Clinical judgment is required to supplement findings published in medical literature which on its own is insufficient.
- All relevant clinical disciplines must be involved
- Indicators must be specific and described in sufficient clinical details specially with respect to risks and benefits of the procedure.
- The definitions of appropriate care should be comprehensive and applicable to a very large number of the possible clinical situations relevant to the procedure.
- Applying the method must be feasible in terms of resources.

The key elements of the appropriateness method are somewhat arbitrary and hence the method has been criticized because there is potential for variability in the process due to the composition of the panel or the actual panel members themselves as well as the role of the moderator. There is a possibility of misclassification bias of individual scenarios and the process lacks specificity about what outcomes are being considered for individual scenarios. The ratings may reflect nothing more than codifying existing clinical dogma. A substantial amount of methodological research has been done to try and assess these criticisms which have determined that clinicians who perform the procedure are more enthusiastic about its use. Favourable predictive validity for appropriateness ratings have been reported for several procedures, including coronary angiography and coronary revascularization. The sensitivity and specificity of the method for identifying inappropriate over use has been estimated at varying between 68% and 99% and under use 94% and 97% respectively.

### **Comparative Quality Standards**

In contrast to the 'appropriateness method' for specific patients and interventions a variety of standards have been set by comparing performance of different clinicians or services. Take the example of normal delivery by gynecologists. It may be that after an uneventful period of recovery in hospital and discharge in the case of 100 such primi-gravida cases, there are unplanned readmission rate for post delivery reproductive tract infection which varies from 1% to 5% in different hospitals. What rate of unplanned readmission should we adopt as an indicator of high-quality care? If we adopt the lowest, we may be ignoring avoidable problems even in the best units. On the other hand, we may be setting impossible targets that cannot be achieved.

The different levels of standards usually used are

- Excellent standards- these are typically standards achieved by the 'best' services, such standards can identify what's possible and challenging excuses.
- Minimal acceptable standards- are those below which no service should fall; this may arbitrarily be what 90% of hospitals are achieving.

In practice, the standards must be such that it is clear what individuals need to do to achieve them and they must be attainable. i.e. a balance needs to be struck between standards of excellence and achievable standards. These standards must be agreed to, implemented and achieved preferably locally. Standards developed in one country may not necessarily be applied in another. Most standards applied in medicine are based on achievements in western countries like USA. However adaptation for local conditions may be needed before its acceptance. The standards may also vary. For example, exacting standard of sterility will be required in a cardiology OT or orthopedic OT. However it may not be necessary or cost effective to insist on same standards in a general surgery OT. Not only do different people value different dimensions differently but the same individual may value different dimensions over time or depending on the condition that needs attention.

### **Perspectives on Improving Quality**

Assessing quality through mechanisms such as monitoring, audit and evaluation is essential. However, there are different philosophical and practical approaches to how a system's quality is maintained and improved. Comparison in medical care giving will invariably identify bad doctors or bad procedures. It is difficult to identify the other end of the spectrum – good doctors or good procedures which can be the standard which is aimed to be achieved. After assessment, If a 'punitive' attitude is taken, it need not necessarily lead to improvement in standards. In the 'system improvement' approach, emphasis is laid on learning from mistakes but some mistakes will have to be permitted although all efforts made to lessen their chance of occurrence.

### **Highlights of Measurement of Health Quality**

The issues which must be considered when measuring quality of health care are :

- The need to measure quality
- Definition of the aspects which have been planned to be measured

- Choice of investigators involved in the assessment process. Care to consult all those with a stake in the issue and their perspective on quality understood.
- Aspect of quality planned to be assessed may need to have been analysed before deciding on which ones will be measured.
- Perspective of quality which will be considered needs to be decided based on rational understanding of advantages and limitations of each.
- Aspects of Population appropriateness and Individual appropriateness
- Approach planned to be used
- Dimension planned to be assessed - structure, process or outcome

### Taking Action to Improve Quality

After conducting an assessment of quality of health care, the logical sequelae must be to improve the quality of health care. By definition, a quality improvement project is a clearly articulated plan to improve the quality of health care. Commonly, the quality improvement will be attempted to incorporate one or more aspects and include Safety, Timeliness, Effectiveness, Efficiency, Equity and Patient-centeredness.

To implement a successful improvement project it is necessary to develop 'will' (that is support of senior leaders and clinicians), have good ideas and have a carefully thought out strategy for execution. The 'ideas', or 'change package', may be a strategy for implementing clinical practice guidelines that has already been tested and is ready for local adoption and adaptation, or may require innovation if no one has achieved quality improvement in a similar setting before.

### Obtaining the Support of Senior Leaders and Clinicians

Senior leaders and clinicians may not be directly involved in the day-to-day work of improvement, but their support is crucial to success. 'Not all change is improvement, but all improvement is change' and organizations tend to resist change. By getting the leaders to agree to the changes will help remove obstacles to change. This can be achieved by use data to demonstrate the opportunities for improvement, build a business case for improvement, periodically get reports on safety and quality for consideration of leaders and if available use stories of real patients to reinforce the suggested change.

### The Business Case for Improvement

To project a business case for improvement it will be necessary to use data to show how the projected changes will improve results either directly or indirectly besides reduction of wastage in the system or other business parameters which either increase efficiency or reduce losses.

### Forming Quality Improvement Team

The team should to implement the quality improvement must include representatives from all disciplines and departments involved in the improvement work, who are preferably enthusiastic about the changes which have been demonstrated to them. The important stakeholders must be incorporated and not necessarily all senior persons. The team must be encouraged to study the existing process and help identify opportunities

for improvement. They must collaborate and share ideas with institutions with similar problems or where similar problems have been solved to arrive at an appropriate improvement strategy. While implementing the improvement project, it is necessary to set clear measurable goals, like, 'to reduce hospital acquired infections among newborn by 50 percent over a six months period of time'. The measures of the outcome must be specified so that the improvement can be measured, documented and communicated in the form of graphs, charts, etc. The team must be motivated and prepared for hard work and provided required commitment and support from the leadership in order to be able to succeed in implementing the desired changes.

### Summary

The term 'quality' refers to perceptual, conditional and a subjective attribute of a product or service, to satisfy stated or implied needs. According to United States Institute of Medicine, 'Quality of health care' is the degree to which health services for individuals and population increase the likelihood of desired health outcomes and are consistent with current professional knowledge. In order to assess, improve and compare the quality of health care provided to the community, it must first be measured against defined standards, to assess the quality. There are six dimensions to measure the quality of health care services viz- effectiveness, efficiency, acceptability, access, equity and relevance. The quality of health care can be assessed by measuring the structure, process or outcomes. The appropriateness method of health care interventions is the degree to which benefits of care exceed the expected negative consequences. This method has been criticized because of potential for variability, besides lacking specificity. Comparative method utilizes comparing performance of different clinicians and services either by using established excellent standards or minimal acceptable standards. Assessing quality through mechanisms such as monitoring, audit and evaluation is the heart of system improvement approach. Quality improvement has to incorporate aspects of safety, timeliness, effectiveness, efficiency, equity and patient centeredness.

### Study Exercises

#### MCQs

1. Which dimension of Health Care Quality measure, assesses the cost of input compared with cost elsewhere for the same reqmt : (a) Effectiveness (b) Efficiency (c) Relevance (d) Acceptability.
2. The quality of health care can be assessed by measuring : (a) Structure (b) Process (c) Outcome (d) All.
3. Measures of health care quality are dominated by "process" measures rather than "outcome" measures : True/False

Answers : 1. (b); 2. (d); 3. True.

### Further Suggested Reading

1. Understanding health care quality. Paul Shekelle, David Pencheon and David Melzer in in Oxford Handbook of Public Health Practice. 2nd ed, 2007. 430-441
2. Taking action to improve quality. Charlie Tomson and Rashid Massoud in in Oxford Handbook of Public Health Practice. 2nd ed, 2007. 442-451
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Social marketing can be described as the process of motivating people (through application of marketing techniques) to voluntarily adopt behaviour which is beneficial to them, over other 'potentially' harmful behaviour. It can be defined as 'the design, implementation and control of programs seeking to increase acceptability of a beneficial social idea or practice in target group(s) (Philip Kotler 1975). Social marketing is a means to assist in gaining acceptance and willingness on the part of the concerned individuals to adopt a particular behaviour. For example, for a new vaccine to be successful, it should first be developed and produced, then social marketing should be used to create acceptance of need for the vaccine among physicians and public, so that it is used by the target groups. The term 'Social Marketing' gained popularity when the Journal of Marketing brought out an issue on the topic in July 1971 (Kotler 1971). Around the same time, it was being increasingly felt that health professionals should assume more responsibility for health education in community.

The objective of social marketing is to promote public health with the overall aim of improving health for all. It therefore relies heavily on preventive medicine. Moreover, social marketing should not be confused with marketing of new commercial health & hospital establishments since these promote curative services for profit of shares holders and the resultant benefits may not always be beneficial to public health. Social Marketing offers a unique opportunity for public health specialists to bridge the gap between the health care delivery systems and those who are unaware or unwilling to use it.

### Principles & Techniques of Social Marketing

As a health planner, one must be aware that like commercial marketing, Social Marketing also consists of four marketing elements (marketing mix) of Product, Place, Price and Promotion.

**The Product** : In health care setting, the product may be a tangible material (such as a therapeutic drug or an educational pamphlet) or an intangible/non-standardised service (such as a training course on HIV counselling or nursing care in ICU). Social marketing of health products also involves issues like product/service branding, packaging, positioning, form, life cycle and product development. For example, if the packaging and quality of a condom is poor, there is bound to be poor response and low acceptability of such condoms. Thus, pretesting and obtaining feedback from users can reduce some obstacles in social marketing.

**The Place** : It is important for success of social marketing that the product/service should be located where users are most likely to find them without any stigma. Marketing of STD clinics as a separate entity has largely been a failure because of stigma attached to such clinics, hence poor utilisation of such services. On the other hand, some countries have very successfully increased utilisation of condoms by making them

available in areas where the potential users can find them easily, such as in 'red light' areas, on bus stands, on highways etc. Similarly, a public health specialist should realise that the best place to undertake social marketing of immunisation and breast feeding would perhaps be an antenatal clinic of a hospital which is visited by expecting mothers.

**The Price** : In ordinary curative or promotive health care scenario, the demand for health care is dependent on the price and personal income, in comparison with life threatening situations, where an individual seeks the required surgical/medical care at whatever cost it is available, irrespective of his personal income. For promotive/preventive health care, demand is more if the price is low and personal income is high. In addition, the 'perceived value' of the health service/behaviour also determines the demand. For example, use of helmets among two-wheeler users would be higher if cost of good quality helmets is affordable and also if driver perceives the benefit of using a helmet, which may be as a safety measure or even as a fashion statement.

In addition, a public health specialist should realise that social marketing is also associated with 'convenience costs' (cost of loss of work, pay or travel if the individual has to visit a clinic) and 'response costs' (embarrassment in case of purchase of condoms in market place or exposure of a particular personal problem in case of visit to a STD clinic in the neighbourhood). Such costs are often intangible since they are personal to the individual and thus are difficult to accurately quantify.

**Promotion (Visibility & Timing)** : High visibility constantly reminds the user of the existence of a product/service. Timing, on the other hand, pertains to presenting the reminder when the user is most likely to accept the idea, product or the service. People at different times vary in their readiness to receive information and accept new ideas. A new message should thus be promoted to people when they are most likely to accept it and it should be in a form and from a source most acceptable. For example, social marketing of Oral Rehydration Solution (ORS) is best undertaken by doctors in a paediatric OPD or by Village Health Guides during home visits, especially when a child is suffering from diarrhoea. Educating a woman about ORS when she is about to go into labour would be of no consequence since the felt-need is not present at that time and the woman is thus not receptive to the idea.

**Designing the message** : A message for any social marketing endeavour depends on local sensitivities rather than on any strict rules. Social marketing messages should be able to educate the target group about the existence of the health problem and its understanding, empower the group to undertake action/behaviour recommended and explain to the target group about benefits of a particular recommended behaviour. The social message must also overcome any cultural, social and traditional practices, which resist change. Repeated message for Pulse Polio Immunisation on mass media by leading film stars in India is an excellent example of an effectively designed and presented social message. A social message needs to be short, correct and delivered to target audience at most opportune moment when they are most likely to accept and adopt new behaviour, by overcoming existing resistance.



## A Step-Wise Approach to Social Marketing

**Step 1 - Identification of health problem & establishing methods for social marketing** : Effective social marketing needs an in-depth identification of the health problem. In addition, rigid customs and opinions of community have to be considered. Consensus building among public (to minimise conflicting opinions) through operational and political cooperation with community is essential. The decision makers in government and community should be identified at the earliest since their cooperation is essential for success of social marketing. In addition, social marketing for healthy behaviour will require identification of traditional health measures, demographic & population studies including mortality/ morbidity patterns and economic impact etc. The causes of the problem have to be established clearly and the required & available resources like mass media, marketing & design expertise should also be identified.

**Step 2 - Identification of priorities and implementation of affordable efforts** : Organising priorities saves time, energy and money for a social marketer. The health problem and desired objectives should be assessed from the viewpoint of the consumer and should ideally be quantified. Cost estimates for media, material & delivery, personnel and other resources should be assessed in advance. It is essential to project realistic and achievable goals & objectives and prepare realistic budgets.

**Step 3 - Analysis of marketing activities, including social message** : The strategy of social marketing needs to be evaluated regularly. There may be a need to adopt different messages and message styles for effectively communicating the message for a particular target group. For example, messages and their style of delivery for HIV prevention would be different for college students, commercial sex workers, MSM groups, truck drivers and housewives.

**Step 4 - Identification of target audience for each marketing component** : 'Market segmentation' involves accurate identification of the group or individual who is not doing what they should be doing, in terms of health related behaviour (for example, identification of clients of CSWs who are not using condoms when they should be using). Accurate market segmentation will result in better and effective social marketing & better message delivery since a health message needs to be designed and delivered differently for different socio-economic and demographic groups.

**Step 5 - Analysing each marketing strategy to determine attitudes and potential resistance among target groups** : A public health specialist should identify all possible cultural, social and religious resistance points, which will differ in strength within each target group. Attitude testing techniques are used to isolate beliefs and values which offer resistance to healthy behaviour. Instead of countering such beliefs head-on (which will result in rejection of the social message), it is more appropriate to build consensus and strategy to overcome the resistance.

**Step 6 - Identification of objectives for each target group** : The proposed behaviour change in each target group should be accurately identified and preferably quantified. For example, we may define our objective as "raising condom use among

clients of CSWs in a geographical area from 40% to 90% in next one year" or "increasing household use of iodised salt in a given district from 60% to 95% in next 2 years". All necessary and relevant information should be provided according to understanding abilities of the target group and effect of each message should be evaluated periodically to assess if it has been understood properly or not.

**Step 7 - Designing and testing the social message** : The social message should be pretested on samples of target audience for acceptability, comprehension, believability and conviction. Even the best designed social message is of no utility if it is not understood or believed by the target audience. After pre testing, messages should be revised and retested as necessary.

**Step 8 - Selection of marketing/distribution system** : Media and distribution system for the message should be in a manner which ensures maximum coverage among target audience. Introduction of statutory warnings on tobacco products is one such way to ensure that the anti-smoking message reaches all target audience.

**Step 9 - Evaluate the impact of social messages** : Quantifiable variables should be identified which indicate impact of the social messages over a certain period of time. These should be assessed periodically to evaluate the impact of social marketing and mid-term corrections should be made wherever required. For example, incidence of sexually transmitted diseases as ascertained from a busy STD clinic or hospital in a district is a good indicator of the impact of social marketing for condoms in that district.

## Limitations of Social Marketing

A public health specialist should realise that social marketing techniques are only appropriate in certain circumstances and have certain limitations. It is most often focussed on change in individual behaviour whereas other health education techniques aim intervention at families, villages and communities. Social marketing may lead people to believe that a particular marketed behaviour is better than other health promoting behaviours, which are not being marketed intensively. For example, use of condoms for multi partner sex may be perceived by some as better than abstinence and avoidance of multi partner sex due to intensive social marketing for promoting condom use. Social marketing often proves ineffective where major barriers (such as poverty, lack of health facilities, social discrimination and lack of political will) resist change in individual behaviour. It is also ineffective where individual efforts are inadequate to achieve the desired behaviour. Social marketing must ideally involve the consumer in decision making as there are often ethical and social difficulties in determining who must make the decisions or what behaviour must be promoted. For example, the decision to promote condoms in India still faces resistance from some sections, who favour promotion of single-partner sex and avoidance of sex outside marriage. Social marketing is often a labour and time intensive activity and obtaining adequate funds may be a problem. Actual social marketing programs are very few due to high demand of manpower & resources. Since the target population of social marketing is traditionally devoid of cash, the process of behaviour change is culturally, socially and psychologically different from commercial marketing. As a result, progress is slow and results are difficult to achieve,



making social marketing efforts low priority activities even within government channels. Mass media too is mostly aimed at an audience capable of paying, thus social marketing efforts by mass media are often poor in quality & ineffective. In addition, social marketing faces greater challenges as compared to commercial marketing as highlighted under :

(a) Accurate market analysis is most often not possible. Primary data collection, besides being expensive and time consuming, is also inaccurate due to incorrect or socially desirable responses of subjects. Secondary data is inaccurate, simplistic and not easily available, since social behaviour is complex and can not be objectively measured.

(b) Market segmentation, which is essential for targeting efforts towards the target audience, may itself be detrimental to efforts because of discrimination & stigma attached to such segmented behaviour. For example, clients of commercial sex workers for targeted intervention for promoting condoms or patients of sexually transmitted diseases (STDs) when they visit designated & well advertised STD clinics may be discriminated against due to their high visibility & stigma. Such kind of stigma and discrimination is contrary to audience response in conventional commercial marketing scenario.

(c) Product strategy in the form of developing complex behaviour which is acceptable to target audience and which meets their felt needs is difficult in social marketing.

(d) Pricing strategy in social marketing is also a challenge since a social marketer aims to reduce monetary barriers which prevent consumers from adopting healthy behaviour, rather than maximising the tangible financial gains for the consumer. Social marketing often has no control over (and cannot address) issues of intangible consumer costs such as cost of personal embarrassment (as in case of examination by a male doctor for cervical cancer) or fear (as in voluntary testing for HIV).

(e) Strategy for selecting channels for dissemination of social messages is a challenge since incentives & financial returns for the medium of distribution (such as a doctor or a hospital) are minimal, intangible and often non- financial. In addition, indirect dissemination of social message is often associated with misinformation.

(f) Communication options in social marketing are limited because paid advertising is often not possible and large amount of information needs to be conveyed to target audience before behaviour can be changed.

(g) Social marketing programs often face failure due to limited knowledge of marketing principles among health planners. Such programs also often face opposition from competing groups (such as tobacco companies in anti-smoking campaigns and baby food manufactures in breast feeding campaigns).

(h) Evaluation of impact is especially difficult in case of social marketing because change in social & individual behaviour & attitude is complex and intangible with very few objective variables.

## Summary

Social marketing involves the research, product design, distribution, information, communication & often introduction of a new product / concept /service, with the aim of changing

behaviour. The basic differences between commercial and social marketing are summarised as under :

**Commercial marketing** : (1) Meets identified needs & wants of target market segment. (2) Aims to make a profit by serving the interests of target market. (3) Marketing of products/services mostly through ideas.

**Social marketing** : (1) Aims to change attitudes & behaviour to a healthier behaviour. (2) Serves interests of target market without personal profit. (3) Mostly marketing of ideas and concepts rather than tangible products.

A social marketer primarily acts in the benefit of targets group. Social marketing aims to broadly bring about social changes as under :

(a) **Cognitive changes** : are relatively easy to market where groups which need information are identified through market research, their media habits are identified and messages are carried to the target audience through appropriate channels.

(b) **Action changes** : involves that the target audience should understand the social message and take specific action based on it. Action change may be hampered by factors such as distance & non-availability of product/service hence the social marketer has to often facilitate action for target group by making the products/services easily available, accessible & acceptable.

(c) **Behaviour change** : is still more difficult than action change as it requires careful segmentation of target audience and specifically tailored 'solutions' for each segment; to enable them to alter their behaviour consistently.

(d) **Value change** : attempts to alter the deeply held beliefs of an individual & thus is most difficult. A prolonged and intense indoctrination program is required to change an individual from one basic value - orientation to another.

Social marketing uses scientific evidence on health and creates education and action programs for healthier habits & behaviour through methods of marketing. Social marketing can be used to help combat many major fatal diseases, especially in children in developing countries, that can be prevented by vaccination, nutrition or hygiene. Even in developed societies, social marketing finds place in diet education programs to lower cholesterol levels or anti-smoking campaigns.

## Study Exercises

**Long Questions** : (1) You are posted as a Medical Officer in a PHC. Plan a step-wise approach for "Social marketing of new Oral Rehydration Solution (ORS)" in a particular Village. (2) What is Social Marketing? What are the principles, techniques and Limitations of Social Marketing?

**Short Notes** : (1) Differentiate Social marketing from Commercial marketing. (2) Principles of Social marketing (3) Enumerate Steps for Social marketing (4) Limitations of Social Marketing.

## MCQs

- Which of the following is true about Social marketing?  
(a) Meets identified needs & wants of target market segment. (b) Aims to make a profit by serving the interests of target market. (c) Marketing of products/services mostly through ideas. (d) Marketing of ideas and concepts rather than tangible products.

2. Social marketing aims to broadly bring about the following changes except (a) Cognitive Changes among people (b) Behaviour changes among people (c) Price value changes of that particular product (d) changes in false beliefs of an individual.
3. All of the following are the elements of commercial marketing which are also used in social Marketing except (a) Product (b) Place (c) Price (d) None of the above.
4. The accurate identification of the group or individual who is not doing what they should be doing, in terms of health

related behaviour is known as (a) Marketing Analysis (b) Market segmentation (c) Commercial marketing (d) None of the above.

5. Social Marketing can be used for (a) Health education (b) Behaviour change (c) Combating many major fatal diseases, especially in children, that can be prevented by vaccination and nutrition (d) All of the above.

**Answers :** (1) d; (2) c; (3) d; (4) b; (5) d.

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## Public Health Aspects of Disaster Management

*Ashok K. Jindal & Puja Dudeja*

*It is the people who matter most and without the people we have no disasters.*

Disasters have existed ever since the existence of mankind and no community is immune to the emergence caused by natural and man-made disasters. Worldwide, natural disasters have been known to be one of the major problems in terms of mortality, number of people adversely affected and economic losses. The spectrum of occurrence of disasters indicates that the Asian region is one of the most disaster prone regions as 60% of the major natural disasters reported in the world occur in this region. India is amongst the most disaster prone countries in the world due to high vulnerability to natural disasters like floods, earthquakes, cyclones and droughts. In India, flood affects over 9 million hectares area annually, 56% of landmass is vulnerable to seismic activity of varying degree and 5700 kms long coastline is prone to severe cyclones with very severe loss of life and economic damage. Besides the natural disasters, India is also vulnerable to man-made disasters like transportation accidents, chemical and technological disasters and other such events.

It is evident from the spectrum of occurrence that adequate procedures to deal with disaster situations are necessary. Disaster management requires well-coordinated public policy for disaster prevention, mitigation, preparedness, emergency response and reconstruction. Health care in disaster is one of the critical elements (1). The issue becomes even more relevant since proper foresight and planning is of considerable importance for disaster management. Often, in disaster situations, a lot of resources have been wasted due to improper planning and impulsive actions (2).

### Definition

Commonly disasters are defined as an 'overwhelming ecological disruption which exceeds the capacity of a community to adjust

and consequently requires assistance from outside'. W Nick Carter defined it as 'an event, natural or man-made, sudden or progressive, which impacts with such severity that the affected community has to respond by taking exceptional measures'(3). As per the Disaster Management Act 2005, 'Disaster means a catastrophe, mishap, calamity or grave occurrence in any area, arising from natural or man-made causes, or by accident or negligence which in substantial loss of life of human suffering or damage to and destruction of property, or damage to, or degradation of environment and is such a nature or magnitude as to be beyond the coping capacity of the community of the affected area (4).

### Classification of Disasters

#### (i) Natural Disasters

**(a) Meteorological Disasters :** Storms, cyclones, hailstorms, hurricanes, tornados, typhoons, snow storms, cold spells, heat waves and droughts.

**(b) Topological Disasters :** Earthquake, avalanches, landslides and floods

**(c) Biological Disasters :** Epidemics of communicable diseases and insect swarms (e.g. locust swarms)

#### (ii) Man-made Disasters

**(a) Accidents :** Transportation accidents (Land, air and sea), collapse of buildings, dams and other structures, mine disasters and technological failures such as mishap at a nuclear power station or leak at a chemical plant causing pollution of atmosphere (5).

**(b) Civil disturbances :** Riots and demonstrations.

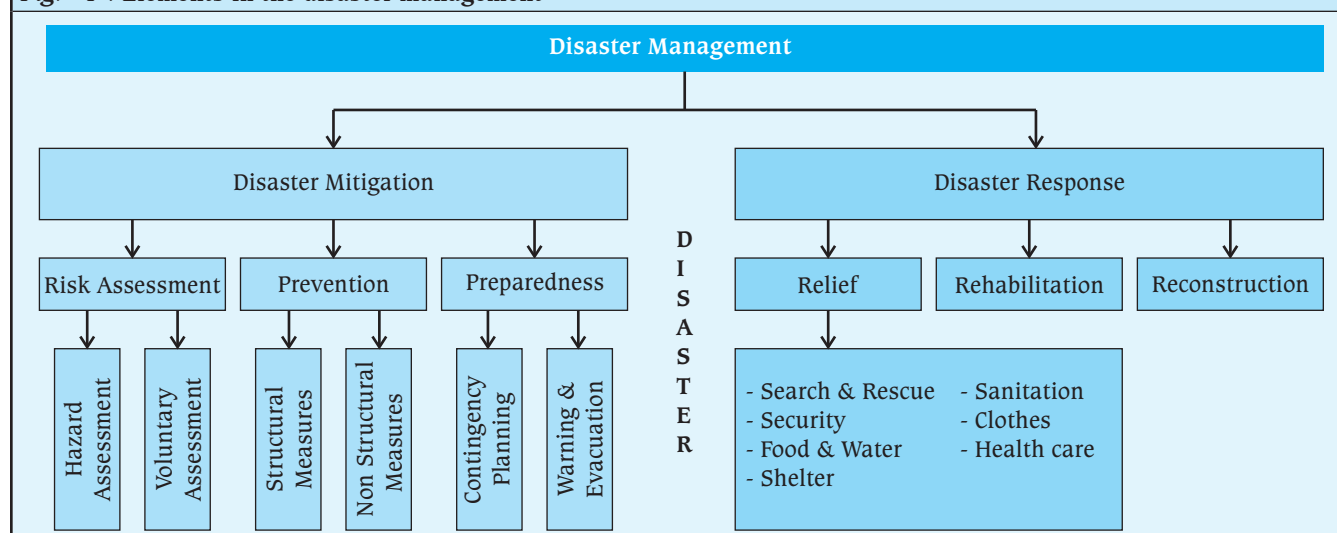
**(c) Warfare :** Conventional warfare (Bombardment, blockage or siege); Non - conventional warfare (Nuclear, Biological and Chemical warfare, guerrilla warfare including terrorism).

**(d) Refugees :** Forced movements of large number of people usually across the frontiers.

### Elements of Disaster Management

The spectrum of disaster management involves disaster prevention, mitigation, preparedness, response and recovery (Fig. - 1).

**Fig. - 1 : Elements in the disaster management**



**(a) Disaster Prevention** : It covers those measures, which are aimed at impeding the occurrence of a disaster event and/or preventing such an occurrence having harmful effects on communities. It is concerned with the formulations and implementation of long-range policies and programs.

**(b) Disaster Mitigation** : Measures aimed at reducing the impact of a natural or man-made disaster on a nation or community.

**(c) Disaster Preparedness** : Measures, which enable governments, organizations, communities and individuals to respond rapidly and effectively to disaster situations. Preparedness measures include the formulation of viable disaster plans, the maintenance of resources and the training of personnel. Organizing, planning coordinating, resources planning and training are its major concerns.

**(d) Disaster Response** : Response measures are those, which are taken immediately, prior to and following disasters. Such measures are directed towards saving life and protecting property and dealing with the immediate damage caused by the disaster. Its success depends vitally on good preparedness.

**(e) Disaster Recovery** : Recovery is the process by which communities and the nations are assisted in returning to their proper level of functioning following a disaster. Disaster

situation has been conceptualized as a process with differing phases. In each different phase, the information needed, the action required, the problem encountered and people involved may be quite different.

### Principles of Disaster Planning

Disaster Management means a planned and systematic approach towards understanding and solving problems in the wake of disasters. Disaster planning cannot prevent disasters but its effect could be minimized by appropriate plans and preparedness. The key issues in disaster management are communication, coordination and control. Important issues in pre-disaster management are prediction, prevention, planning and preparedness. The critical issues when disaster event occurs are the immediate response, rescue, relief and rehabilitation. Fig. 1 shows elements in the management of a disaster.

### Effects of Disaster

These are summarised in Table - 1.

### Health Problems Common to all Disasters

**(a) Social reactions** : These could be grouped as follows :

- Spontaneous behavioral reactions e.g. generalized panic or stunned waiting.
- Widespread looting

**Table - 1 : Effects of Disaster**

Effects	Type of Disaster			
	<i>Earth-quakes</i>	<i>High Winds (Without Flooding)</i>	<i>Tidal waves (Flash Floods)</i>	<i>Floods</i>
Death	Many	Few	Many	Few
Severe injuries requires extensive care	Overwhelming	Moderate	Few	Few
Increased communicable disease load	Potential risk following all major disaster (Probably rising with overcrowding and declining sanitary conditions)			
Food scarcity	Rare	Rare	Common	Common
Population displacements and movements	Rare	Rare	Common	Common

- (iii) Rumors regarding spread of epidemic
- (iv) Population displacements leading to excessive burden on relatives and friends, parks city squares, vacant lots and government buildings in urban areas where public services can't cope resulting in increased morbidity and mortality.

**(b) Exposure to elements** : The need to provide emergency shelter varies greatly with local conditions.

**(c) Food and Nutrition** : Food shortages in the immediate aftermath may arise in two ways. Food stock destruction within the disaster area may reduce the absolute amount of food available, or disruption of distribution system may curtail access to food even if there is no absolute shortage.

**(d) Communicable Diseases** : The transmission of communicable diseases after natural disasters may be influenced by following factors :

**(i) Pre existing Diseases in the Population** : The risk of epidemic after a disaster is related to the endemic levels of diseases in the population. Where a disease agent did not exist in a population before a disaster, there is generally no risk of an outbreak occurring. These include diarrhea and dysentery, cholera, measles, whooping cough, meningococcal meningitis, tuberculosis, malaria, intestinal parasites, scabies and other skin diseases, louse borne typhus and relapsing fever.

**(ii) Ecological Changes resulting from Natural Disasters** : Natural disasters may alter the potential for disease transmission by altering the ecological conditions. In this context, the most important diseases are those transmitted by mosquito vectors and by water. The breakdown in living conditions following disasters may increase the hazard of transmission of plague, louse borne typhus and relapsing fever. The incidence of dog bite and risk of rabies may increase as neglected strays come in close contact with persons living in temporary shelters.

**(iii) Population Movements** : Population movements may influence the transmission of diseases by increasing population density causing burden on the water supply and other services in the receiving areas and/or introducing susceptible population to a new disease or disease vector. The important diseases to occur in temporary settlements are diarrheal diseases and dysentery, viral hepatitis, measles, whooping cough, malaria, tuberculosis, scabies and other skin infections.

**(iv) Damage to public Utilities** : Damage to water supplies and sewage disposal systems may increase water borne and excremental diseases.

**(v) Interruption in Public Health Services** : The important services interrupted in this context are vector control programme, which might lead to resurgence of malaria and other vector borne diseases, routine immunization programme against measles, whooping cough, poliomyelitis, tuberculosis and diphtheria.

**(vi) Altered Individual Resistance to diseases** : Protein Energy Malnutrition, which affects children in poorer population of most of the developing countries, increases susceptibility to many communicable diseases including malaria and tuberculosis.

### Medical Care for Disaster

The principles of mass casualty management are universal and can be applied in any mass casualty situation, natural

or man-made. The importance of triage, first aid, life saving measures, transport and evacuation for definitive care to hospital has been recognized the world over. The mass casualty management demands standard simple therapeutic procedures and standardized drugs & medical supplies. On site care demands establishment of a command post triage team, first aid team, mobile hospital (if required), evacuation team, transport and communication.

### Disaster Preparedness

Disaster plan should be realistic, adaptable and harmonized at all levels. It must be clearly written and periodically tested. It should include

- (a) Resources plans for health care.
- (b) Role and responsibility of resources organization.
- (c) Logistics, equipment and supplies required.
- (d) Arrangement for communication, transportation and evacuation.
- (e) Coordination and control.
- (f) Disaster drills.

### Disaster Management Plan for Natural Disasters

All disasters are unique in that they affect areas with different social, medical and economic backgrounds. The peculiar problems associated with disasters are essentially due to increased load of communicable diseases, food scarcity and mass population displacements and movements. Disaster management includes certain interventions namely good site planning, provision of basic clinical services, shelter, clean water, good sanitation, vaccination and control of disease vectors. The diseases prevented by these interventions are given in Table - 2.

Table - 2 : Preventive measures in a disaster	
Preventive measures	Impact on spread of
Site planning	Diarrhoeal diseases, acute respiratory infections
Clean water	Diarrhoeal diseases, typhoid fever, hepatitis A and E
Good Sanitation	Diarrhoeal diseases, vector-borne diseases, scabies
Adequate nutrition	Tuberculosis, measles, acute respiratory infections
Vaccination	Measles, meningitis, Japanese encephalitis, diphtheria
Vector control	Malaria, plague, dengue, Japanese encephalitis, other viral haemorrhagic fevers
Personal protection (insecticide-treated nets, clothing, shoes)	Malaria, leishmaniasis, leptospirosis
Personal hygiene	Louse-borne diseases, typhus
Health education	Diarrhoeal diseases



## Organisation of Medical Setup

The State Chief Secretary should be overall incharge of Disaster Management in the State. The medical aspects will be coordinated by the State DGHS. He will ensure that adequate manpower reserves are rushed from non affected areas in the State to those which are worst affected so that medical manpower is properly augmented.

At the District Level, the District Collector will be the Chief Executive of the Disaster management cell. He will be in a position to coordinate all relief efforts with various departments including ensuring NGO participation. The medical team will be headed by the Chief Medical Officer (CMO) of the district. The various programme officers under him like the District Malaria Officer, the District Immunisation Officer, etc will ensure availability of equipment, stores and manpower required for disaster activities. The District hospital will be responsible for providing referral services for curative care as well as outreach teams to be deployed at short notice in affected remote areas. These teams should have medical officers, surgeon, anesthetists and adequate paramedical staff. The nodal peripheral unit for providing medical relief will be the PHC of the area and the MO i/c PHC will coordinate all efforts and seek assistance of the CMO as and when required. The sub-centre staff will support him in all the activities.

## Public Health Aspects

The important aspects include provisioning of appropriate shelter for displaced population, potable water supply, food and nutrition and sanitation.

**Excreta Disposal** : Improper excreta disposal contaminates soil and water sources. It also often serves as a breeding ground for certain species of flies and mosquitoes, giving them the opportunity to lay their eggs and multiply or to feed and transmit the infection. It also attracts domestic animals and rodents which carry fecal matter on them and with it, potential diseases. Furthermore, this situation usually creates unsightly areas and disagreeable odors. The goal of sanitary excreta disposal is to isolate excrement so the infectious agents in it cannot reach a new host. The method selected for a given area or region will depend on many factors, including local geology and hydrogeology, the communities' culture and preferences, the materials available locally and the cost.

The aim is to develop physical barriers against the transmissions of diseases, in order to protect the health of the disaster affected population. These barriers include both engineering measures and personal hygiene measures. The provision of latrine and the development of methods of waste disposal are essential elements of the programme. These measures are only fully effective, when complemented by a sanitation education programme. The efficient and safe disposal of human excreta is as important as the provision of water in its positive effect on the health of the emergency affected population. Human excreta are more likely to transmit diseases than animal waste. It contributes to the transmission of numerous diseases (particularly when combined with low levels of nutrition) and can also be a breeding ground for flies and other insects. In the acute phase of an emergency, any form of excreta disposal is better than none. The simplest and quickest methods should be

adopted; these can later be improved on and changed initially speedy action is important in averting human catastrophe.

### *What to do :*

- If there are no sanitation services, latrines must be built (individual, collective, portable).
- Before installing a latrine, the soil at the site must be evaluated along with topographical conditions, user access and the presence of surface and ground water in the surrounding area.
- If the land is not appropriate for latrine construction (rocky soil or high water table) aboveground latrines with removable tanks must be built. The excreta must be transported to a pit located on appropriate ground, for immediate burial.
- Estimate the number of latrines to be installed, based on the number of persons in the shelter (1 waterless toilet/25 women and 1 waterless toilet and 1 urinal/35 men).
- Provide information and instructions to the population on throwing used toilet paper into the latrine.
  - Using the sanitation services only for defecating or urinating (do not store tools or other items in the latrine)
  - Washing their hands with soap and water after urinating or defecating.
  - Keeping the floor, walls and area surrounding the latrine clean.

Not defecating or urinating outdoors in the area around the sanitation services or near bodies of water, since this encourages the proliferation of flies and larvae and water contamination through water runoff.

### *What not to do :*

- Install excreta disposal systems without first assessing the situation (existence of sanitation services, number of users and characteristics of the site, among others)
- Select the location of the sanitation services without taking into account the characteristics of the site (soil type, topography, accessibility, presence of bodies of water, etc.)
- Try to implement sophisticated excreta disposal technologies without having facilities to operate / maintain.

**Accommodation** : In natural disaster, the displaced population must be sheltered in temporary settlements or camps. The selections of sites must be well planned to avoid risk factors for communicable diseases transmission, such as overcrowding, poor hygiene and inadequate water supply, insanitary disposal of excreta vector, inadequate sites and lack of adequate shelter. Such conditions favour the transmission of diseases such as measles, meningitis and cholera. Critical factors to consider when planning a site are : water availability, means of transport, access to fuel and access to fertile soil. The guidelines are given in Table - 3. The surrounding environment may also pose a threat to health in the form of vectors not encountered in the population's previous place of residence. In order to reduce such risks it is essential that site selections, planning and organization be undertaken as soon as possible.

**Water supply** : Water and sanitation are vital elements in the transmission of communicable diseases and in the spread of diseases prone to cause epidemic. Diarrheal diseases are

**Table - 3 : Guidelines to provide accommodation for displaced**

Area per person for collective activities	30 m <sup>2</sup>
Shelter space per persons	3.4 m <sup>2</sup> (4.5 -5.5 m <sup>2</sup> in cold climates)
Distance between shelters	2m minimum
Area for support services	7.5 m <sup>2</sup> /persons
Number of people per water point	250
Number of people per latrine	20
Distance to water point	150 m maximum
Distance to latrine	30m
Distance between water point and latrine	100m
Firebreaks	75m every 300m

a major cause of morbidity and mortality among affected populations, most being caused by a lack of safe water, inadequate excreta disposal facilities and poor hygiene. The goal of proper water and sanitation facilities is to minimize risks to the health of a population, particularly one caught up in the difficult circumstances of an emergency with its attendant displacement and dangers. Such a programme is an integral part of preventive health activities. The main focus of such a programme is on the following :

- The provision of a safe and sufficient water supply
- Provision for excreta disposal and the establishment of other waste control and hygiene measures
- A programme of public education of the affected population on the issue of hygiene and water use.

In a natural disaster, the affected population need immediate access to a water supply in order to maintain health and to reduce the risk of epidemics. If the emergency affected populations have to be sheltered in temporary settlements or camps, water supply is an essential consideration in choosing the site location. An adequate amount of safe drinking water must be provided for the entire displaced population. The first objective is to provide sufficient water; quality can be addressed later, sufficient water of low quality is better than very little water of high quality. During the rapid assessment of a proposed site it is essential to protect existing water sources from possible contamination. If the population has already moved into the area in question, then immediate measures should be taken to isolate and protect the water sources, if it is on or near the site. Table - 4 gives the recommended doses of Chlorine tablets that can be distributed to the affected population to prevent diarrheal diseases. Location, design and number of water distribution points are given in Table - 5.

**Solid Waste** : Solid waste may be refuse, manure for animal cadavers. There is a correlation between improper solid waste disposal and the incidence of vector-borne diseases. As a result, arrangements must be made to collect, store and dispose of solid waste.

#### **What to do**

- Assess the situation, considering the number of people in the shelter, existing services, collection service, topographic conditions, accessibility and soil type (if the waste must be disposed of on site).

- Estimate the quantity, type and capacity of the water storage containers, based on the number of persons and existing services. For a short time, empty food containers, plastic or water-resistant paper bags and disposable packaging can be used. The capacity of the containers should be 50-100 liters and should not exceed 20-25 kg when full.
- Provide three or four containers per 100 persons and distribute them so that every family has access to a container (or plastic bag).
- The containers should not touch the ground, for example they should be on a wooden platform. They must be emptied and washed daily.
- If there is regular waste collection and final disposal service :
  - Coordinate with the responsible entity to cover refuse collection from the shelter or camp.
  - Check the accessibility of the regular collection service and take the appropriate steps for the shelter or camp.
  - If the regular service does not have access to the shelter or camp, place waste pick-up sites in the surrounding area and locate storage bins or containers away from water sources.
- If there is no regular waste collection and final disposal service :
  - Organize collection, transport and final waste disposal service, involving the persons living in the shelter or camp.
  - For final disposal, bury the waste by building pits 1.5 meters wide, 1.5 meters long and 2 meters deep. At the end of each day, cover the refuse with 15 cm of dirt and pack it down. This pit will last 10 days for a population of 200. For larger populations, increase pit size proportionately, up to a maximum of 3 meters x 3 meters. Before the pit is full, cover it with a layer of packed dirt 40 cm thick, so that it is level with the ground. Then dig a new pit.
- Dead animals and excrement from domestic animals must be buried immediately, since they can be a source of contamination.
- Provide information and training to the population on sanitary refuse handling.

#### **What not to do**

- Request tools, containers, bins, plastic containers or other devices without first assessing the situation.

<b>Table - 4 : Recommended dosage of chlorine</b>					
		Type of water source			
		<i>Clear piped water</i>	<i>Protected tube wells, ring wells, clear rain water</i>	<i>Unprotected wells and cloudy water (filtered before purifying)</i>	<i>Water known to have faecal contamination (filtered before purifying)</i>
Tablet Size	Chlorine per tablet (mg)	Volume of water treated per tablet (Litres)			
8.5mg	5	5	2.5	1	0.5
17mg	10	10	5	2	1
67 mg	39.41	39.41	19.7	7.77	3.94
340mg	200	200	10	40	20
500mg	294	294	147	58.5	29.4
Free available chlorine content after treatment (Residual)		1mg/Litre	2mg/Litre	5mg/Litre	10mg/Litre

<b>Table - 5 : Location, design and number of water distribution points</b>	
Location	Water distribution point must be set up in suitable places around the camp. A good location is an elevated spot in the centre of a living area. If the water points are from ground sources, no sanitation facilities should be within 50 meters and definitely not closer than 30 meters. If the water point is too far away, people will not collect.
Design	<p>When designing water points consider the following :</p> <ul style="list-style-type: none"> <li>- Traditional water carrying methods</li> <li>- The containers used : for example, a raised area is suitable for people who carry the bucket on their heads</li> <li>- Persons collecting and carrying the water (it is usually the women and children)</li> <li>- The availability of spare parts.</li> <li>- There should be enough space on the concrete slab around the water point for laundry and bathing areas. If sanitation is compromised, it may be felt necessary to locate bathing and washing areas away from collection points. However, traditional practices and habits need to be accommodated as much as possible. Animals must certainly be kept away. If they are mobile herds, watering facilities should be established some distance away and a fence erected around the eater point.</li> </ul>
Number	One tap per 200-250 people is the ration recommended by the United Nations High Commissioner for Refugees (UNHCR). The more the people per tap, the more would be wear and tear. Nobody should have to wait longer than a few minutes : if collection takes a long time, people will return to old, contaminated but quicker sources.

- b. Mix common waste with medical waste, thus endangering the population.
- c. Accept or request sophisticated technology for treating medical waste without having the facilities or trained personnel to operate it.

**Vector control** : The purpose of a vector control programme is to reduce disease transmission by rendering the environment unfavourable for the development and survival of the vector. Prevention is better than cure and when the planning and construction of camps is undertaken, preventing the development of vector problems should be taken into account. The vector population and its life expectancy should be kept to a minimum. Community adhesion and participation in a vector control programme is essential for its success. Early diagnosis and treatment are needed to prevent severe forms of the disease (especially for malaria) when transmission control is needed to reduce incidence. Both are complementary and

two essential components of any effective vector borne disease control programme.

**Types of vectors** : The major biological vectors are mosquitoes, sand flies, ticks, fleas, lice, mites. Important carrier reservoirs or intermediary hosts are synanthropic flies and rodents.

**Diseases spread** : The diseases most commonly spread by vectors are malaria, filariasis, dengue fever, leishmaniasis, typhus and plague. Major diseases transmitted by intermediate hosts or carriers are schistosomiasis, diarrhoeal diseases and trachoma.

**Prevention** : The main methods of control in emergency situations can be classified into the following groups :

- Residual spraying,
- Personal protection,
- Environmental control,
- Camp site and shelter design and layout,
- Community awareness.

**Indoor Residual Spraying** : This is a recommended technique for controlling mosquitoes and sandflies. It is the most common method in the post-emergency phase when the displaced population is living in more permanent dwellings such as huts or houses. IRS is very effective in almost all epidemiological settings and recommended as the first line intervention to control epidemics. *Ground space spraying*, either Ultra-Low-Volume (ULV) cold mist or thermal fogging, is not the preferred intervention for malaria vector control in emergency situations. In the context of camps, especially in crowded areas, ground space spraying can be resorted to if residual spraying is delayed or cannot be implemented. Pyrethrins or pyrethroids are the best choice for such application but organophosphate insecticides are also suitable.

**Personal protection** : Personal protection against the spread of disease includes a variety of methods : insecticide-treated nets, treated sheets and blankets, personal hygiene, insect repellents and clothing and dusting powder. *Insecticide-Treated Nets* (ITNs) are primarily used to protect against mosquito. Daily bathing, washing of hands after using the latrine, regular washing of clothes and good food and water storage practices can prevent the spread of fly-borne diseases. Biting by mosquitoes, flies and ticks can be reduced by wearing long-sleeved shirts and long trousers and by using insect repellents. Appropriate *dusting powders* can be used in the treatment of flea and louse infestations.

**Environmental control** : Environmental control strategies aim to minimize the spread of disease by reducing the number of vector breeding sites. Some of the most important measures, namely the provision of clean water, the provision and maintenance of sanitary latrines and the efficient and safe disposal of waste water are other important aspects to be looked into. Larvicides may be applied via hand-carried, vehicle-mounted or aerial equipment. The larvicide is added to water at sites that are recognized breeding grounds, such as ponds or water jars, in areas where the breeding sites are limited in number. Long-term measures, such as land drainage or filling, should be planned and implemented to avoid future spraying.

**Community awareness and health education** : Community participation in a vector control programme is essential for its success. It allows the implementing agency to develop an awareness of community practices that prevent or encourage the spread of disease. Both the community and the vector control team can develop strategies that can be implemented with some degree of success. Information on the spread of disease can be disseminated in a culturally sensitive manner.

**Food and nutrition** : Food shortages and malnutrition are common features of emergency situations. Ensuring that the food and nutritional needs of an emergency-affected population are met is often the principal component of the humanitarian response to an emergency. When the nutritional needs of a population are not met, this may result in protein-energy malnutrition and micronutrient deficiencies such as iron-deficiency anaemia, pellagra, scurvy and vitamin A deficiency. There is also a marked increase in the incidence of communicable diseases, especially among vulnerable groups such as infants and young children and these contribute further

to the deterioration of their nutritional status.

The mean daily per capita energy requirements for some population groups vary depending on the weight, age, gender and physical activity of the individual. Energy requirements increase during certain specific situations, such as the second and third trimesters of pregnancy, lactation, infection (e.g. tuberculosis) and recovery from illness (for every 1°C rise in body temperature there is a 10% increase in energy requirements), cold temperatures (an increase of 100 kcal per person for every 5 °C below 20 °C), moderate or heavy labour. The mean energy requirement is 2100Kcal per person per day, out of which 17-20% of energy should be in the form of fats or oils and 10-12% from proteins.

Food is an important source of pathogens and there is a risk of diarrhoeal disease epidemics when basic food safety principles are not followed. It is estimated that 70% of diarrhoeal episodes in children under the age of 5 years are due to the consumption of contaminated food. There are a number of routine practices that should be adhered to when preparing food, in both the household and in health facilities. To overcome this menace following actions are recommended :

- Ensure an adequate water supply.
- When preparing food or washing utensils, use a chlorinated water supply.
- Store food in sealed containers.
- Ensure that food is covered during cooking and prior to serving.
- Ensure that cooked food is consumed once prepared.
- Cover food when served, if left unattended.
- Place hand-washing facilities outside latrines, living areas and kitchens.
- Ensure that people use them.
- Ensure an adequate number of sanitary latrines and that they are maintained and used.
- All areas in a feeding centre must be cleaned daily using chlorine as a disinfectant.
- Cover water containers at all times.
- Ensure that water is taken either from a tap or from a clean container.
- Disposal of garbage safely.

**Prevention & control of communicable diseases**: The prevention and control measures of communicable diseases should be on the following broad principles.

**(a) Setting up a Surveillance System** : It is established to collect, collate and interpret the data, It will need the services of an epidemiologist/public health specialist, paramedical and health personal and clerical staff.

**(b) Disease Surveillance** : The objective of disease surveillance after disaster is to identify disease outbreak, in order to investigate them and to instigate appropriate disease control measures. The diseases considered for surveillance include those known to be endemic to the area, those, which represent a serious health hazard and those, which are amenable to control. A more focused, system based surveillance system should be instituted. This system complex, which might be important, include fever, fever and diarrhea, fever and cough, trauma, burns, measles etc. This data should be analyzed, interpreted and presented to the higher authorities (6, 7).



(c) **Laboratory Services** : Lab for basic diagnostic tests of stool and blood may be established by field reporting units but for specific bacteriological and virological tests, the referral labs in nearby cities or areas will have to be marked (7, 8, 9).

(d) **Vaccinations and Vaccination Programs** : Mass vaccination campaigns against Tetanus and Measles will be helpful, as well as some other vaccines for specific diseases, depending on the threat perception (7, 8, 9). However mass vaccination campaign against typhoid and cholera should be avoided because of the following reasons :

- (i) Offer low and little individual protection.
- (ii) Complete coverage of population is probably impossible
- (iii) Require large number of workers who could be better employed elsewhere.
- (iv) Could lead to reuse of inadequately sterilized needles that may transmit Hepatitis B/HIV.
- (v) May lead to false sense of security about the risk of diseases and to neglect effective control measures.

**Surveillance system** : The objectives of a surveillance system in a disaster are to :

- (a) Identify public health priorities.
- (b) Monitor the severity of an emergency by collecting and analyzing mortality and morbidity data.
- (c) Detect outbreaks and monitor response.
- (d) Monitor trends in incidence and case-fatality from major diseases.
- (e) Monitor the impact of specific health interventions (e.g. a reduction in malaria incidence rates after the implementation of vector control programmes).
- (f) Provide information to the Ministry of Health, agency headquarters and donors to assist in health programme planning, implementation and adaptation and resources mobilization.

Experience from many disaster situations has shown that certain diseases/syndromes must always be considered as priorities and monitored systematically. In the acute phase of an emergency, the major diseases/syndromes that should be reported are : Bloody diarrhoea; Acute watery diarrhea; Suspected cholera; Lower respiratory tract infections; Measles; and Meningitis. After the second/third week the following diseases should be added on : Malaria; Dengue/DHF; JE; Leptospirosis; and Septic dermatological complications. Lab for basic diagnostic tests of stool and blood may be established by field reporting units but for specific bacteriological and virological tests, the referral labs in nearby cities or areas will have to be marked.

**Burial / Disposal of the Dead** : Bodies are unlikely to cause outbreaks of diseases such as typhoid fever, cholera, if death resulted from trauma. However, they may transmit gastroenteritis or food poisoning syndrome to survivors if they contaminate water sources. Despite the negligible risk, dead bodies represent a delicate social problem. The normal local method of burial or cremation should be used although mass cremation requires large amounts of fuel. Before disposal, bodies must be identified and the identifications recorded.

### Suggested Logistics Planning

The suggested (approximate) requirements of drugs, vaccines and insecticides / hygiene chemicals for a displaced population

for a period of 30 days are laid down in Table 6a, b & c. Readers may please note that these are only suggestions for logistic planning and the actual requirement should be worked out after actual on-ground assessment of the displaced population.

<b>Table - 6a : Requirements of Vaccines &amp; related items</b>	
<b>Vaccine</b>	<b>Doses</b>
Typhoid oral	600
Cholera	400
Measles	250
Japanese Encephalitis	250
Tetanus Toxoid	300
Tetanus immunoglobulin	300
Meningococcal vaccine	300
Vaccine Carrier	15
Cold boxes	10

<b>Table - 6b : Requirements of Insecticides, hygiene chemicals &amp; equipment</b>	
Thermal fogger	01
Knapsack sprayer(16L)	02
Compression sprayer(12L)	03
ULV fogger	01
Malathion EC 50% DDP WP	300 l/Kg
Temephos/Baytex EC	10L
Aquatabs (17 mg)	1,00,000
DMP oil	25L
Impregnated bed nets*	600
Bleaching powder (33# Available Chlorine)	30 Kg
Cresoli Black	150L
* alternatively, 6 ltrs of 2.5% deltamethrin solution will be required to impregnate 600 bed nets	

<b>Table - 6c : Requirements of Drugs and expendables</b>	
<b>Nomenclature</b>	<b>Quantity</b>
Inj Lignocaine	02
Inj Atropine	02
Tab Common Cold	2, 000
Inj Morphine	50
Inj Ranitidine	10
Inj Fortwin	50
Inj Adrenaline	30
Tab Cetrizine	800
Tab Periacin	100
Tab Dexamethasone	200
Inj Dexamethasone	10

<i>Table - 6c (Contd.)</i>	
Nomenclature	Quantity
Inj Hydro Cortisone	20
Inj Avil	20
Tab Avil	400
Inj Phenargan	20
Inj Diazepam	20
Tablets Anti Inflammatory	1000
Cap Antibiotics	5000
Tab Antipyretic	1000
Tab Anti malarials	2000
Syp Antitussives	10L
Tab Antispasmodics	300
ORS	1500
Hydrogen Peroxide	5.000L
Liq Antiseptic	1.000L
Eye Drops	15
IV Fluids Normal Saline	576 Bott
IV Fluids DNS	576 Bott
IV Fluids Ringer Lactate	2, 256 Bott
Haemaccel	900 Bott
IV Set	576
IV Catheter	576
Cotton Absorbent	10 Kg

## Summary

Worldwide, natural disasters have been known to be one of the major problems. India is amongst the most disaster prone countries in the world. Adequate procedures to deal with disaster situations are necessary. Disaster management requires well-coordinated public policy for disaster prevention, mitigation, preparedness, emergency response and reconstruction. Health care in disaster is one of the critical elements. Disasters are defined as an 'overwhelming ecological disruption which exceeds the capacity of a community to adjust and consequently requires assistance from outside. Disasters can be classified into natural disasters (which would include Meteorological, Topological & Biological disasters) and Manmade disasters (that would include Accidents, Civil disturbances & Warfare). The spectrum of disaster management involves disaster prevention, mitigation, preparedness, response and recovery. Disaster Management means a planned and systematic approach towards understanding and solving problems in the wake of disasters. The key issues in disaster management are communication, coordination and control. Important issue in pre-disaster management is prediction, prevention, planning and preparedness.

There are some health problems which are common to all types of disasters. These include Social reactions (such as looting,

rumor spreading etc.), Exposure to elements - depending on local conditions and issues of Food and Nutrition. Also prominent among the health problems would be risk of spread of communicable diseases, the occurrence of which would depend on factors such as pre-existing Diseases in the Population, Ecological Changes Resulting from Natural Disasters, Population Movements, Damage to public Utilities, Interruption in Public Health Services and Altered Individual Resistance to diseases. The principles of mass casualty management during disaster include the vital elements of triage, first aid, life saving measures, transport and evacuation for definitive care to hospital has been recognized the world over. Disaster plan for preparedness should be unambiguous, well-rehearsed and must specify Resources plans for health care and Coordination and control, among other essentials. Disaster management plan should include good site planning, provision of basic clinical services, shelter, clean water, good sanitation, vaccination, healthy food and nutrition and control of disease vectors. In organization of medical set-up, the nodal point(s)/ personnel in-charge of co-ordination and execution of activities would be : State Chief Secretary & District Collector at respective levels for overall administration, State DGHS, Chief Medical Officer (CMO) of the district and MO i/c PHC at respective levels for the medical aspects. The aim of hygienic excreta disposal is to develop physical barriers against the transmissions of diseases, in order to protect the health of the disaster affected population. These barriers include both engineering measures and personal hygiene measures. The simplest and most effective measure in this context would be construction of appropriate latrines (catering to aspects such as topography, numbers) and also educating the public on relevant aspects. Temporary settlements or camps would form the best possible mode of accommodation in disaster scenario. The selection of sites must be well planned to avoid risk factors for communicable diseases transmission and keeping in mind water availability means of transport, access to fuel and access to fertile soil. The goal of proper water and sanitation facilities is to minimize risks of water-borne diseases such as diarrheal diseases to the population. In a disaster, the affected populations need immediate access to a water supply in order to maintain health and to reduce the risk of epidemics. The first objective is to provide sufficient water; quality can be addressed later. Appropriate chlorination, proper location of water distribution points and health education are inevitable steps in this regard. Necessary arrangements must be made for collection, storage and disposal of solid waste. The vital steps would be assessment of the situation, tailor-making the supplies- quantity and quality-wise; according to the need (a thumb-rule could be 03 or 04 containers per 100 persons) and proper disposal, depending on whether regular waste collection and final disposal service are available or not. Preventing the development of vector problems should be taken into account, when the planning and construction of camps is undertaken. Community adhesion and participation in a vector control programme is essential for its success. The main methods of vector control in emergency situations would include residual spraying (preferably Indoor Residual spraying with pyrethrin or pyrethroids), personal protective measures [using Insecticide-Treated Nets (ITNs) and/or dusting powders], environmental

control (measures such as provision of clean water, provision and maintenance of sanitary latrines for short-term purposes and land drainage or filling for long-term), campsite and shelter design and layout and creation of community awareness. Ensuring that the food and nutritional needs of an emergency-affected population are met is often the principal component of the humanitarian response to an emergency, since protein-energy malnutrition, micronutrient deficiencies and a marked increase in the incidence of communicable diseases, especially among vulnerable groups will result if due care is not accorded to provision of adequate healthy food. The mean daily per capita energy requirements for some population groups vary depending on the weight, age, gender and physical activity of the individual. There are a number of routine practices that should be adhered to when preparing food, in both the household and in health facilities. Some useful measures in this regard would include, among other points, ensuring an adequate and safe water supply, placing hand-washing facilities outside latrines, living areas and kitchens and so on. The prevention and control measures of communicable diseases during disasters should be on the broad principles of Setting up a Surveillance System, Disease Surveillance, establishment of Lab facilities for basic diagnostic tests of stool and blood, mass vaccinations and Vaccination Programs (definitely targeting Tetanus and Measles, but never against Typhoid or Cholera). The normal local method of burial or cremation should be used, after proper identification and recording. Requirements of drugs, vaccines and insecticides / hygiene chemicals should be worked out after actual on-ground assessment of the displaced population.

## Study Exercises

### MCQs and Exercises

- All of the following are examples of natural disasters except (a) Meteorological Disasters (b) Topological Disasters (c) Accidents (d) Biological Disasters.
- All of the following are Elements of Disaster Management, except : (a) Disaster Treatment (b) Disaster Preparedness (c) Disaster Response (d) Disaster Recovery .
- Measures aimed at reducing the impact of a natural or man-made disaster on a nation or community, is collectively known by the term (a) Disaster Response (b) Disaster Mitigation (c) Disaster Recovery (d) Disaster Prevention.
- Relief, Rehabilitation and reconstruction are essential components of (a) Disaster Mitigation (b) Disaster Response (c) Both of the above (d) None of the above.
- Overwhelming number of Severe injuries which require extensive care, when compare to other disasters, take place in (a) Flooding (b) Tidal waves (c) High winds (d) Earthquakes.
- All of the following factors influence the transmission of communicable diseases after natural disasters, except (a) Damage to public Utilities (b) Population Movements (c) Interruption in Public Health Services (d) Social reactions.
- The nodal peripheral unit for providing medical relief in times of disasters, will be (a) Sub-centre (b) Anganwadi (c) Primary Health Centre (d) District hospital.
- At the District Level, the CMO (Chief Medical Officer) will

be the Chief Executive of the Disaster management cell. Yes/ No.

- Among the following choices, the most appropriate one while constructing toilets in disaster scenario, will be (a) 1 waterless toilet/25 women (b) 1 waterless toilet/25 men (c) 1 waterless toilet/35 women (d) 1 waterless toilet/45 men.
- While considering factors for proper accommodation of homeless persons in disaster situation, the distance from the site to the water point should be not more than (a) 50 meters (b) 100 meters (c) 150 meters (d) 250 meters.
- Sufficient water of low quality is better than very little water of high quality, in disaster scenarios. Yes /No.
- While locating water points during times of disasters, if the water points are from ground sources, no sanitation facilities should be definitely not closer than a distance of (a) 50 meters (b) 100 meters (c) 10 meters (d) 30 meters.
- The ratio of taps to persons as recommended by the United Nations High Commissioner for Refugees (UNHCR), especially in setting of disasters, is (a) One tap per 100-150 people (b) One tap per 200-250 people (c) One tap per 250-300 people (d) One tap per 50-100 people.
- The maximum permissible weight of solid waste that can be collected in a single container, (i. e weight of a single container, when full), is (a) 20-25 kg (b) 30-35 kg (c) 40-45 kg (d) 50-55 kg.
- The Insecticidal method of choice for controlling mosquitoes and sandflies during disaster situations is (a) Space spraying (b) Knockdown spraying (c) Indoor residual spraying (d) Ground spraying.
- The mean energy requirement per person per day, that has to be catered for by provision of appropriate food, at times of disasters, is (a) 2500 Kcal (b) 2000 Kcal (c) 2100 Kcal (d) 2300 Kcal.
- Mass vaccination campaigns against one of the following diseases would be imperative and helpful in times of disasters (a) Typhoid (b) Cholera (c) Scrub Typhus (d) Measles.
- Match the following features in column A with that in Column B.

Column A	Column B
<i>Type of water at source</i>	<i>Recommended Free available chlorine content after treatment (Residual)</i>
(a) Clear rain water	(i) 5mg/Litre
(b) Unprotected wells	(ii) 1mg/Litre
(c) Water known to have faecal contamination	(iii) 2mg/Litre
(d) Clear piped water	(iv) 10mg/Litre

**Answers :** (1) c; (2) a; (3) b; (4) b; (5) d; (6) d; (7) c; (8) No; (9) a; (10) c; (11) Yes; (12) d; (13) b; (14) a; (15) Yes; (16) c; (17) d; (18) (a) iii; (b) i; (c) iv; (d) ii.

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## Principles & Practice of Hospital Management

Anuj Bhatnagar

World Health Organisation (WHO) has defined a 'hospital' as *'an integral part of a social and medical organization, the functions of which are to provide to the population, complete health care, both curative and preventive including out-patient services which reach out to the family in its own environment and also carry out training of health workers/functionaries and undertake bio-social research'*. Besides this comprehensive WHO definition, a hospital has also been described as an institution which is operated for medical, surgical and/or obstetrical care of in-patients and which is deemed to be a hospital by the government or local licensing bodies (Directory of Hospitals in India, 1988)

*Hospitals* are generally considered as institutions where the sick and injured are treated as indoor patients, in comparison to *dispensaries* where primarily out-door patients are treated and medicines are distributed. Thus, a hospital can be described as an organisation which provides health care services (preventive, promotive and curative) by pooling in the various skills & services of health professionals, supportive staff and ancillary staff, with the overall objective to provide health care to patients.

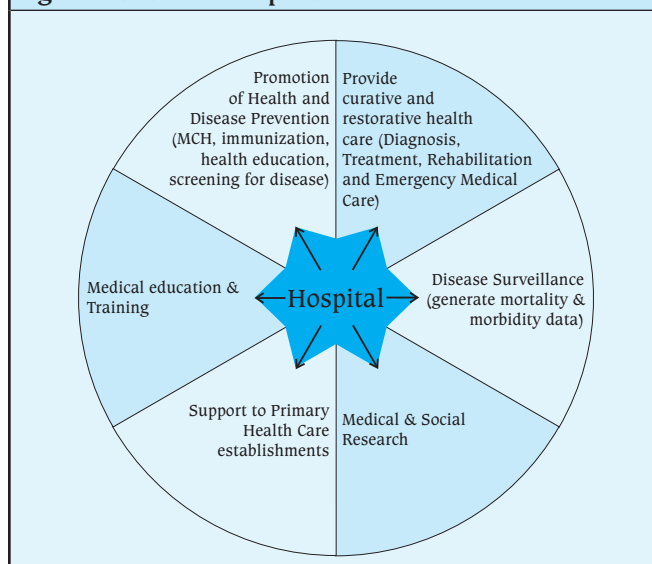
### Role of a Hospital

The role of a hospital in a community can be summarized graphically as shown in Fig. - 1.

### Peculiarities of a Hospital as an Organisation

As a health manager, one should be acutely aware that a hospital differs greatly from any other organisation. It is a highly complex institution which brings together highly qualified and highly technical professionals for common cause of providing comprehensive health care and medical care to patients, in the most cost-effective manner, within the limited available resources. The peculiarity of a hospital as an organisation is enhanced since the 'product' in a hospital is 'medical care',

Fig. - 1 : Role of a Hospital



which is highly personalized, professional and technical in nature and hence can not be assessed in quality by a lay person.

This 'service' provided by a hospital can not be quantified in any economic/financial terms and can not be evaluated on any objective criteria for quality and standard. Hospital care and service differs for every patient depending on his/her condition & requirements and thus standardization of such medical care is not possible. Pre-planning at micro level is not possible in a hospital and most often, hospital management is *management by crisis* wherein each patient is unique requiring highly professional and personalized medical care, provided by the entire team rather than any one individual. A hospital also employs a wide variety of people, from highly trained professionals to unskilled individuals. It is thus a challenge for any hospital manager to manage people of such wide ranging skills as a team and to make them work together. In addition, staff in a hospital is always under dual control, with *professional control* vested with heads of respective departments and



*administrative control* vested with the hospital administrators, which often leads to conflict of interest among the various members of the team.

### Work Areas of a Hospital

A hospital can be broadly divided into :

(a) **Clinical Areas** : A&E Dept, OPD, Operation Theatre, ICU & inpatient services

(b) **Diagnostic Areas** : Laboratory, radiological services, blood transfusion & pharmacy services

(c) **Support Services** : CSSD, medical records dept, laundry services & dietary services

(d) **Auxiliary Services** : Basic and allied engineering services.

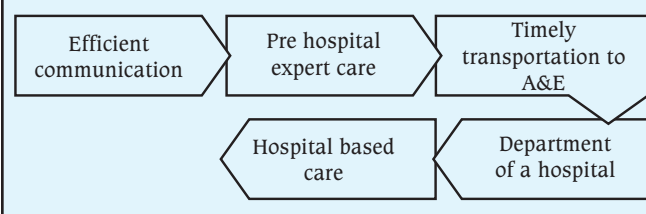
### Clinical Areas of a Hospital

A hospital comprises of certain key clinical areas which are engaged in the primary task of providing medical care to the patients. These clinical areas are vital areas in hospitals where the actual objective of the hospital (of treating the sick and injured) is achieved through various categories of health care providers. A description of these areas is as follows :

#### Accident and Emergency Services (A & E Services)

The term "Accident and Emergency Department" was suggested to be used in all hospitals by Platt Committee in UK in 1960s and in India, the Central Council of Health, as early as 1963, recommended the setting up of 'emergency medical services' in all States. *Emergency Medical Services* (EMS) can be described as medical services undertaken with the aim to transport the right patient to the right hospital at the right time so that right treatment can be given, thereby preventing death & disability among such patients. The essential components of EMS are described as in Fig. - 2.

**Fig. - 2 : Essential components of EMS**



#### Planning considerations for A&E facilities of a hospital

(i) Patient load (ii) Morbidity pattern (iii) Time of maximum patient load (iv) Location of main roads (v) Communication facilities (vi) Similar facilities for population (vii) Architecture of hospital (viii) Industries / infrastructure in the area.

#### Role of A&E Services in a Hospital

1. Provisioning of prompt life/limb saving medical care (including surgeries) to patients in need, at all times.
2. Liaise with police and assist the courts in medico-legal cases, but without compromising on the primary duty of providing life saving medical care.
3. To provide ambulance services equipped with trained

manpower and adequate life saving equipment for transport of patient to & from the hospitals.

4. To function as an information centre about seriously injured patient, especially in case of large scale disasters.
5. To sensitively and maturely cater to the emotional needs of relatives of seriously ill/ injured patients brought to the hospital.
6. Continuous training of medical staff in trauma care and emergency medical care.

**Planning of an A&E Dept** : The basic principle while planning an A&E Dept in a hospital must be remembered that 'design should follow function' that means that various areas should be planned and designed according to their intended function, as under :

(a) **Location** : The A&E Dept should be separated from the main hospital but with access to dependent areas like ICU, OT, laboratories and mortuary etc. It should be situated on ground floor with direct access from main road and a porch for patients to alight from ambulances. There should be adequate facility for parking of ambulances and other patient vehicles. Adequate sign posting (both at day & night) should exist.

(b) **Space requirements** : The A&E Dept should have an average space of 10 square meters per patient visiting the Dept, with an additional 50% of space to avoid overcrowding. For example, if the A&E Dept of a hospital is visited every day by an average of 50 patients, the required space would be 500 square meters + 250 square meters = 750 sq m. There should be facility for expansion of A&E Dept without affecting functioning or form of any other department. Approximately 10% of all patients coming to the hospital visit A&E Dept during any given time; hence there should be 6 parking spaces for every 10, 000 annual visits. All A&E Depts should have a Trolley/Wheel chair bay (1 wheelchair & trolley per 1000 annual visits).

(c) **Planning of facilities** : The A&E Dept of a hospital should be planned to ensure availability of Reception, Registration and Waiting areas. There should also be a police and mass media room. The Dept should have a separate entrance 1.6 meter wide with two-way doors with glass panel at eye height. Triage area, separate examination and treatment areas, resuscitation cubicles, observation beds, plaster room (1 per 15, 000 annual visits), burns room, radiography unit, ECG room, isolation room and an emergency laboratory should also be catered for.

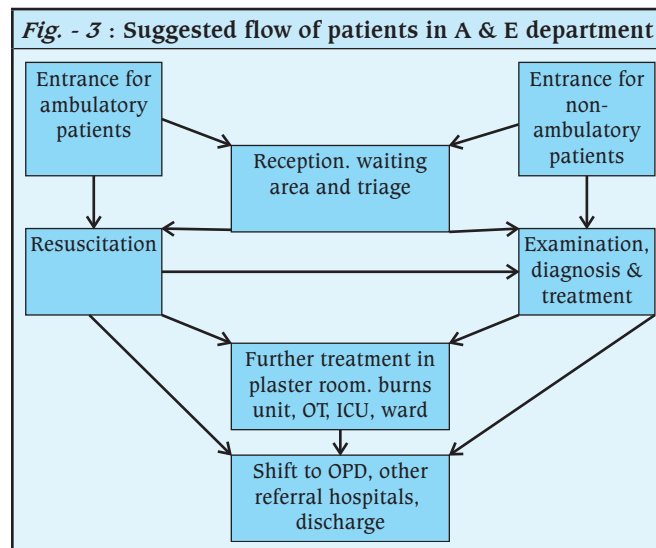
(d) **Architectural design** : While planning the architectural design of an A&E Dept, the following aspects should be kept in mind.

- (i) Entrance should be separate for ambulatory and stretcher-borne patients with two-way swinging doors 1.6 meters wide with glass at eye level. There should be no steps, only ramps with side railings should be provided at the entrance.
- (ii) Waiting area should be in form of a large lobby, including the waiting area which may also be used for triage of patients. Toilets should be located near the main entrance and every specialist cubicle or special investigation should have its own sub-waiting area.
- (iii) Reception, Registration & Records should have an office adjacent to main entrance which should be manned

24 hours. This office should be used for admissions, discharges, billing, record keeping and safe keeping of patients' valuables. There should also be an adjacent Nurses Station and work room.

- (iv) Examination & Treatment area should be in form of cubicles (7mx13.4m) with temporary partitions which can be removed to expand the area. There should be examination beds which permit access to patients from all sides. Loose hanging wires or clutter of unwanted equipment should be avoided.
- (v) Resuscitation Room should ideally have an area of 30 square meters with all resuscitative equipment & standby emergency electricity supply system. All shelves, drawers & cabinets should be properly labeled.
- (vi) X Ray facility in A&E Dept is desirable if more than 1000 patients undergo radiological investigations in A&E Dept per month. It should have an area of 180 square feet.

**Suggested flow of patients in A & E department :** It is described in Fig. - 3



### Out - Patient Department

An out-patient department (OPD) can be defined as that part of the hospital with allotted physical and medical facilities and staff in adequate numbers, with regularly scheduled hours, to provide care for patients who are not registered as indoor patients. The present magnitude and importance can be gauged from the fact that a hospital OPD load is around 500 patients per bed per year against an inpatient load of 25 patients per bed per year.

Out patients Departments are also called the 'show windows' of hospitals. They are the first point of contact between the patients/their relatives and the hospital staff and the facilities and the care provided in OPDs often are the true reflection and determine the image of the hospital. The important functions of an OPD in a hospital are summarized as under :

- (a) To provide day care investigative, diagnostic and treatment specialist procedures to the community.
- (b) To undertake day care surgical procedures (e.g. vasectomy) for ambulatory patients.

- (c) To conserve hospital beds (and inpatient resources) by acting as an admission filter and admitting only those patients who are actually in need of admission.

- (d) Undertake health education and thus promote health.

- (e) To carry out medical follow up and rehabilitation of patient after discharge from the hospital.

- (f) To undertake various promotive and preventive measures such as antenatal care, vaccination, well baby clinics etc.

Broadly, the OPD Services can be classified into two types. Firstly, the decentralized type in which the specialist services are located in the respective departments (specialty clinics). All specialist services are usually located in a compact area, including all diagnostic and therapeutic facilities (polyclinic).

**Planning Considerations and Principles for OPD :** The planning of an OPD facility in a hospital would be determined by many key factors. The range of services to be offered (investigative and therapeutic services offered) would determine the space requirement and the capacity of the OPD being planned. Other important considerations for planning an OPD are the number of medical and paramedical personnel available to the hospital for OPD, the service time for patients, type of patients expected, rate of arrival of patients, holding capacity expected & the number of admissions to the hospital. The following principles should be observed for planning an OPD :

- (a) **Location :** The OPD of a hospital should be located near the main road and near the main entrance of the hospital with adequate space for parking of vehicles including ambulances. The OPD should ideally be separate from in-patient wards but connected to them, especially vital investigative centers like pathology laboratory and radiological services.

- (b) **Patient flow :** It should be only in one logical direction with minimal cross traffic. This can be ensured by planning the various facilities in a logical sequence of possible utilization by the patients.

- (c) **Interdepartmental Resource Sharing :** All OPDs should be so located that they are all able to share common and interdepartmental resources of the hospital such as pharmacy, radiological services, pathology services, hospital records, billing etc.

- (d) **Facility for expansion :** All OPDs should be planned and laid so that they can be expanded in future without disrupting the routine functioning.

- (e) **Physical facilities**

- (i) **Space provisions :** The Bureau of Indian Standards (BIS) has laid down the space specifications of 2 square meters per bed for entrance zone, 10 square meters per bed for ambulatory area, 6 square meter per bed for diagnostic zone for OPD area out of a total OPD space specification of 60 square meter per bed for the entire hospital area.

- (ii) **Public areas in OPD :** An OPD should have a wide entrance with double swinging doors with glass at eye level, ramps and steps. Reception and information desk should be located near the entrance in the public area. There should be registration counters (01 desk per 20 patients per hour) with a counter for storing files etc. The waiting area should be at the scale of 0.1 square meter per patient (minimum of 4 square meter) adjacent to Reception/Registration. Sub-waiting areas should

also be provided for specialist consulting rooms & special investigations. Public toilets should be provided separately for males and females at the rate of one toilet each for 200 patients/ visitors. Snack bar should be conveniently located in the waiting area in for large OPD.

(iii) **Clinical areas of OPD** : These include various specialist consulting areas such as surgical OPD, Ophthalmic OPD, Medical OPD, Dental OPD, Pediatric OPD etc. and may also include certain super specialty OPDs such as cardiology, neurology etc. These specialist and super specialist OPDs should have separate sub-waiting areas and at any given time should not have more than one thirds of the total patients of OPD in each sub-waiting area. The consultation room should have a space of 14-28 square meter, should accommodate all furniture and equipment necessary for examination of patients and each consultation room should be able to cater for examination of 100 cases per day.

(iv) **Additional clinical areas** : These include

- Injection room with 12-40 square meter area and waiting area for 10-20 patients, depending on the patient load.
- Dressing and Treatment Room with an area of 12-16 square meter.
- Pharmacy is generally the last point to be visited by OPD patients, by which time they are tired, hence it should have multiple dispensing windows & adequate staff to reduce waiting time, in addition to comfortable seating arrangements for the patients.

(v) **Auxiliary facilities for OPD** : These should be able to provide care both to inpatients and outpatients and thus should be easily approachable from OPD and various wards. The important auxiliary facilities in any hospital are :

- Pathology laboratory with separate male and female toilets (15 square meters) and bleeding room (20 sq mt).
- Radiology Services.
- Blood Bank with adequate waiting area, reception, bleeding room, laboratory, recovery room and storage facility for blood and blood components.
- Health Education Facility with adequate audiovisual aids.
- Medico-Social Service Facility with adequate number of counselors, located in OPD.
- Screening Clinic should be located near the reception with adequate equipment for examining patients where all patients would be initially screened and referred to the appropriate specialist OPD. This reduces the load on specialist OPDs, guides the patients correctly and improves the quality of OPD services.
- Preventive & Promotive Health Care facility with an area of at least 15 square meter, would be the centre for advice on preventive and promotive health aspects such as immunization, nutrition, family welfare & counseling, sanitation etc.

(vi) **Administrative Areas of an OPD** : These areas should consist of an administrator's office, a business office for personnel section, record keeping, requisitions etc, a janitor's closet for house keeping and adequate storage facility for general stores, drugs (including dangerous and controlled drugs) and linen etc.

(vii) **Circulation Areas** : These include corridors, lifts and stairs and would occupy almost 30% of the total area of an OPD complex. These areas, esp corridors and doors should be at least 1.8 mt wide to allow the passage of a stretcher with a person on either side. Adequate communication facilities, lighting, public address system and fire fighting facilities should also be provided.

**Common problems faced in OPDs :**

- (a) Overcrowding at screening OPDs, specialist OPDs and special investigation centres.
- (b) Timings of OPDs and auxiliary/ supportive services may not be same.
- (c) Jumping of queue by influential patients/ staff members.
- (d) Long waiting time.
- (e) Investigation results not available centrally and on time.
- (f) Lack of communication (absence of PA system and patient call system).

### Operation Theatre

An Operation Theatre (OT) is defined as a specialized facility of the hospital where life saving / life improving procedures are carried under strict aseptic conditions in a controlled environment by specially trained personnel, to promote healing and cure with maximum safety, comfort and economy. Surgical operations have been classified broadly as emergency surgeries (which must be carried out as soon as the diagnosis has been made and patient prepared for surgery in a proper manner) and elective surgeries (undertaken some time after the diagnosis has been made and when best suited to the patient & hospital). An OT in a hospital should be planned with the following objectives in mind :

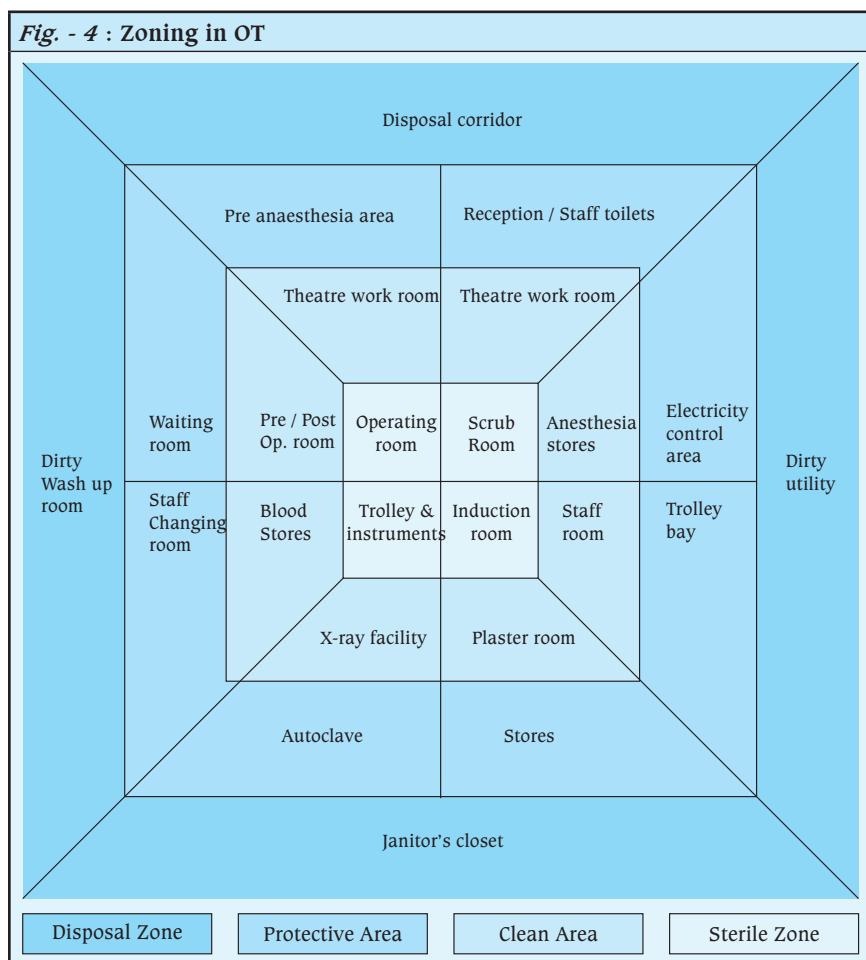
- (a) Ensure complete asepsis during surgeries.
- (b) Ensure maximum safety for patients and medical personnel from bio-medical, engineering, electrical and radiological hazards in the OT environment.
- (c) Optimal utilization of trained manpower and other resources in OT.
- (d) To optimize working condition for OT staff.
- (e) Allow for flexibility.
- (f) Minimize maintenance and regulate flow of traffic through OT.

**The Concept of 'Zoning' in an OT** : The OT has to be divided into four distinct zones based on bacteriological cleanliness, in order to attain maximum asepsis for surgeries. Bacteriological contamination progressively diminishes from outer zone to the core zone (100% sterile) where all surgeries are performed. The following zones are identified in an OT (Fig. 4):

- (a) **Disposal zone** with facilities like patient closet, disposal corridor for solid linen and surgical waste and dirty wash up room.
- (b) **Protective zone** includes areas in OT like Reception, waiting room, stores, trolley bay, autoclave, TSSU, control area of electricity, changing rooms for staff with toilets and pre-anesthesia room.
- (c) **Clean Zone** includes areas in OT such as theatre work room, plaster room, recovery room, surgeons'/ nurses' staff rooms, anesthesia stores, X Ray facility, blood stores, pre and post operative rooms.



**Fig. - 4 : Zoning in OT**



- (d) **Sterile Zone** (innermost) consists of facilities like operating room, scrub room for staff, anesthesia induction room and instruments/trolley area.

### Intensive Care Unit

The intensive care unit (ICU) of a hospital is one of the most important places in a hospital. It can be defined as a specific area in a hospital where sophisticated monitoring, titrated life support, specific therapy and specialized nursing are provided for potentially salvageable, critically ill patients with life threatening illness or injuries. ICU is a place where seriously sick patients, highly skilled medical and nursing staff with knowledge and experience & sophisticated medical equipment are brought together for better health care at an optimum cost. One of the major objectives of ICU is to identify patients who require intensive medical care and close monitoring round the clock. Broadly, such patients are classified as :

- Patients expected to survive.
- Potentially recoverable patients.
- Patients with uncertain prognosis.
- Patients not likely to survive irrespective of whatever is done.
- Patients for whom death is imminent.

**Classification of ICU :** (based on organizational structure)

- Open unit** is available for admission to all patients by any attending physician but the triage decision and allotment

of a bed is the decision of the medical officer in charge of the intensive care unit.

(ii) **Semi closed unit** is where the medical team in charge of the intensive care unit must review and approve all admissions into ICU. Concerned specialists recommend ICU admissions but all final decisions rest with administrators.

(iii) **Closed unit** is one where Heads of Departments and treating physicians are responsible for all admissions and discharges but after admission, the ICU team along with the treating physicians is responsible for providing health care.

**Staffing requirements in ICU :** Since ICU is one of the most sensitive places in a hospital, it is necessary to be staffed accordingly by medical and nursing personnel. Ideally, ICU should have a medical officer in charge who should provide continuity and direction to ICU services. The ICU should also be staffed by one Resident round the clock in addition to a junior resident who is pursuing post graduate studies. ICU has extensive nursing and paramedical requirements. The acceptable staff : patient ratio are as under :

Nurse : patient ratio - 1 : 1 during day & 1 : 2 during night

Staff : Patient ratio - 2 : 1 for a 6-8 bedded ICU

Any ICU for constant patient care requires a nurse : bed ratio of 4 : 2 allowing for leave and other absences of nursing staff.

### Physical facilities and design of ICU

(a) **Location** : ICU should be ideally located near operation theatre and should have access from other departments. The movement areas in ICU should be spacious and corridors should be at least 2.4 m wide.

(b) **Space requirement** : The should have a space of 50 sq m per bed. There should be facility for removing shoes and wearing masks /gowns and entrance should have air curtains to prevent dust from entering. Every patient should have at least 15 sq ft of clear space (with minimum head wall width of 1-2 ft / bed) excluding service areas like toilets. ICU should have a nursing station equipped with patient monitoring equipment (including an alarm system and telephone to call for assistance from outside). At least one hand washing facility should also be provided for every three beds in ICU.

(c) **Patient services** : ICU should have piped oxygen supply and suction facility. Adequate electric sockets should be available for every bed. Each bed in ICU should be isolated by mobile partition to form a small cubicle for each bed.

(d) **Nursing station in ICU** : It should have adequate storage space for documents and should have adequate counter space. Since all patients in ICU need to be monitored round the clock, nursing station in ICU should be so oriented so that every



patient can be directly observed from central nursing station without being able to see other patients in ICU.

**(e) Miscellaneous :** ICU should be well illuminated without reflective or bright lights. It should stock all necessary routine and emergency medicines, should have refrigerator for storing medicines which require to be stored at low temperature. In addition, every ICU should have a clean supply room, clean linen store, soiled linen holding room, X-Ray viewing facility and equipment storage space. Laboratory, radiological and pharmacy services should be available to ICU round the clock.

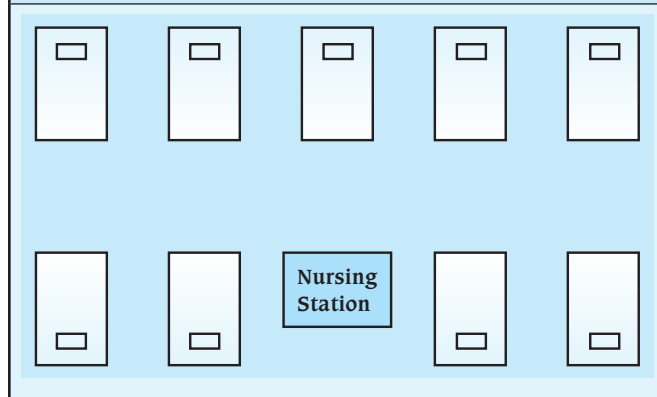
### In-Patient Services

The inpatient services of a hospital provide clinical care to non-critical patients who need to be admitted to the hospital for investigations, diagnosis and treatment. The hospital wards (which accommodate the inpatients) and their ancillary areas & services thus are the most vital areas of any hospital, occupying as much as 50% of the entire hospital area. The inpatient areas consist of various wards (including the nursing station) the patient beds and the entire necessary support services and areas. Since inpatients are required to be monitored and are mostly dependent on nursing staff, these areas also witness non-stop patient related activities. A 'ward' in a hospital can be defined as a section of a hospital, including a nursing station, bed and necessary storage service, work and public areas, where nursing care is provided to in patients.

**Various types of wards :** The main factor to be kept in mind while designing a ward is that nursing staff should be able to hear & see all patients and should be able to react accordingly with maximum efficiency and least stress and strain.

**(a) Open ward (pavilion type) :** It was first constructed in 1770 by a Frenchman and later modified by Florence Nightingale in 1850's. Such wards have patients' beds in two rows at right angles to the longitudinal walls. Bathrooms and toilets are located at one end while the nursing station and doctor's room is located at the other end. The usual length of such open ward was 96 feet, where 30-35 patients were admitted (Fig. - 5).

**Fig. 5 : Open ward**

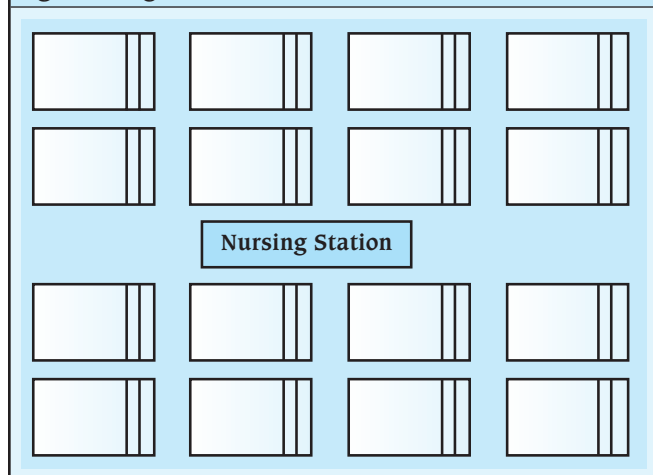


Sun glare in tropical countries was prevented by constructing covered verandas on either side of wards. After 1925, the nursing station was shifted to center of the ward to reduce nurse fatigue. Similarly, service areas were also shifted to a central annexe to reduce the distance traveled by each patient.

Open wards offer the advantages that all patients are directly visible to nurses on duty, adequate ventilation and natural light is available to all patients and it is economical to construct and maintain. It however suffers from certain disadvantages like lack of privacy, danger of cross infection and constant glare for all patients. Moreover, seriously ill patients requiring constant attention have to be placed in the center close to the nursing station which is also the area for maximum movement in the ward.

**(b) Rig's ward :** In Denmark, Rig's Hospital first adopted a design where patient beds were arranged in small cubicles along the longitudinal walls of the wards. This has the advantages that patients have privacy, cross infection can be contained to some extent, infectious patients can be partially isolated in cubicles and patients of both sexes can be accommodated in the same ward since privacy is offered by cubicles. However Rig's pattern of ward suffers the disadvantages that patients are not under direct supervision of nurse, there is difficulty in communication between patients and nurse, additional nurses are required since wards became larger and it is costly to construct and maintain (Fig. - 6).

**Fig. - 6 : Rig's Ward**



The Committee On Plan Projects (Buildings Projects Team) of the Planning Commission (COPP) has recommended 20-30 beds per ward with 2-3 single-bed rooms for patients requiring special nursing care. In addition there may be 2-3 additional beds for patients on payment. The rest of the ward should be divided into cubicles with 6-8 hospital beds each. Outer verandas are no longer recommended. Recent studies have indicated that Nightingale pattern is more acceptable and appropriate for inpatients in India since it was easier to observe all patients at all types. The nurse fatigue is less and hence job satisfaction is higher among nurses. Open type wards offer a subtle form of group therapy for admitted patients and ambulatory patients are less likely to feel bored.

The primary area in a ward consists of patient space, with generally 7 square meter space per bed. The size of the bed is 1 meter X 2 meter and the minimum distance between centre of adjacent beds should be 2.5 meters. The distance from centre of the aisle to the foot end of bed should be 0.9 meter and distance from wall to head end of the bed should be 0.25 meter.

**Ward Management** : The objective of Ward Management is to provide the best possible medical & nursing care to patients by using the abilities of every member of the staff to fullest extent possible & by providing close supervision of both patient care & of the individuals who provide the health care. The common problems in ward management are summarised in Table - 1.

**Table - 1 : Common problems in Ward Management**

- Over crowding
- Inadequate staff
- Untrained staff
- Excessive use of student nurses
- Lack of equipment /supplies/ stores
- Multiplicity of units
- Pilferage of stores & medicines
- Undue paper work/ inventory
- Lack of discipline in staff
- Lack of supervision
- Lack of incentives for staff
- Lack of coordination

Ward management would consist of the following :

**(a) Patient Management**

- Admission & orientation of the patient
- Realistic assessment of patients' needs
- Observation and recording
- Monitoring the progress & reporting
- Assignment of patient care
- Planning of work schedule
- Ward rounds
- Disposal & rehabilitation of patient

**(b) Management of Supplies & Equipment**

- Indent, receipt & issue of supply
- Accounting of drugs & med stores
- Requisition of diets & its distribution
- Provision of linen & its exchange
- Maintenance of equipment

**(c) Management of Environment**

- Adequate lighting, ventilation, prevention of noise, dust control, regulation of temp & humidity, adequate privacy, control of visitors & control of infection

**(d) Management of personnel**

- Junior Doctors & interns, Nurses, paramedicals and ancillary staff

## Diagnostic Services

The diagnostic and supportive services in any hospital broadly consist of the laboratory services, radio-diagnostic and imaging services, blood transfusion services and pharmacy services, which are described in detail subsequently.

### Laboratory Services

The functions of a laboratory can be described as :

- Provision of comprehensive & accurate analytical test results
- Collective consultation with clinicians regarding most useful application of scientific procedures for patient care
- Training of professional & technical staff

- Research (e.g. types of diseases, social, genetic, nutritional, environmental etc. )
- Adaptation of Laboratory Medicine to useful advances in basic science
- Preventive (through examination of food handlers, personnel, materials for delivery rooms, nursery, OT, examination of food, water & milk)

### Major considerations while planning a hospital laboratory

**(a) Space** : The total area of a hospital laboratory should be 10.3 to 14.4 square feet per bed depending on the load and the type of hospital. A hospital laboratory broadly consists of three areas. Primary space is the area occupied by technical & professional staff and should be ideally 3.5 Laboratory Space Unit (LSU) (1 LSU = 200 square feet). Secondary space (1.4 LSU) is the area for non-professional activities of those personnel who occupy the primary space. Circulation space (0.4 LSU) is the area for movement of personnel and goods.

**(b) Staffing** : The suggested staffing pattern is as summarised in Table - 2.

The average number of tests which can be performed by a technician, depending on the automation of the laboratory is as under :

- Semi automated laboratory : 1800 tests per year
- Partial automated laboratory : 25,000 tests per year
- Totally automated laboratory : 2,85,000 tests per year

**Table - 2 : Staffing pattern in a laboratory**

Beds	Pathologist	Technicians	Steno
<50	1 (part time)	2-3	As needed
50-100	1 (part time)	3-5	Part time
100-200	1	5-8	Part Time
200-300	1 or more	8-10	1
300-500	3	20-30	2-3

### Blood Transfusion Services

A blood bank is defined as a organisation for carrying out all or any of the operations pertaining to collection, aphaeresis, storage, processing & distribution of blood drawn from a donor &/or preparation, storage & distribution of blood components, with the aim to provide adequate quantity of safe blood & blood products or components for patients in a cost effective & coordinated manner. The role and functions of a blood bank can be summarized as under :

- Selection of donors & maintenance of donor records
- Collection of blood in an aseptic manner
- Screening for HIV, Hepatitis B & C, Malaria & Syphilis
- Component preparation
- Optimum storage of blood and blood components
- Carry out emergency matching, cross matching
- Record all Blood Bank procedures
- Training of medical & paramedical staff
- Conduct camps in community for voluntary donation of blood

Blood banks can be broadly classified into three categories based on consumption of blood :

- (a) Category I : Hosp consuming 3-7 units of blood/yr/bed (100-400 beds) (100 sq m space)
- (b) Category II : Hosp consuming 8-15 units of blood/yr/bed (400-1000 beds) (300 sq m space)
- (c) Category III : Hosp consuming >16 units of blood/yr/bed (>1000 beds) (895 sq m space)

#### Planning considerations for establishing blood transfusion services :

The location should be preferably on ground floor and easily accessible from Operation Theatre & A&E Dept. There should be proper signage and parking facilities for donors and ambulances. The *public access areas* should consist of donor reception office, counseling room, medical examination room, bleeding room and refreshment / rest room (including toilet & pantry). The *laboratory areas* (accessible only by professional staff consists of a transfusion lab, a component lab and facilities for disposal of biomedical waste. The *storage & issue areas* consist of storage facilities for blood and blood components and issue counter, which should be prominently marked and located near A&E Dept/OT. *Administrative areas* in a transfusion facility would include offices for medical officer & paramedical staff, rest rooms for technicians, conference room & library etc. Equipment required for blood transfusion services are described in Table - 3.

Table - 3: Equipment required for blood transfusion services	
For Routine Work	For Blood Component work
<ul style="list-style-type: none"> <li>● Refrigerators</li> <li>● Centrifuges</li> <li>● Dielectric tube sealers</li> <li>● Plasma separators</li> <li>● Hot air oven</li> <li>● Microscope</li> <li>● Tube stripper / cutter/ sealer</li> <li>● Blood Bags</li> </ul>	<ul style="list-style-type: none"> <li>● Refrigerated Centrifuge (5000Xg)</li> <li>● Deep freezers with power back up Water baths</li> <li>● Incubators</li> <li>● Platelet agitators</li> <li>● Cryo precipitate thawing bath</li> <li>● Laminar flow</li> <li>● Weighing scales</li> </ul>

## Supportive Services

### Central Sterile Supply Department (CSSD)

The Central Sterile Supply Department is responsible for collecting & receiving used patient care items with the view to decontaminate, process, sterilize, store and dispose these items to all other parts of the hospital (Mayhall). Thus the Central Sterile Supply Department (CSSD) comprises of the services within the hospital which receives, stores, processes, sterilizes, distributes and controls professional supplies and equipments, both sterile and non sterile, to all departments of the hospital for the care and safety of patients. The CSSD is a central agency in a hospital which ensures quality control of sterilized material, economy of scale (since it dispenses optimum requirements of various wards) and better utilization of trained nursing manpower. CSSD is set up in hospital with the aim of providing sterilized materials from a central department where sterilizing practices is conducted under conditions which can be properly controlled (thereby reducing incidence of hospital infections)

and to take some of the work off the nursing staff so that they can devote more time to patient care. The objectives of a CSSD are thus,

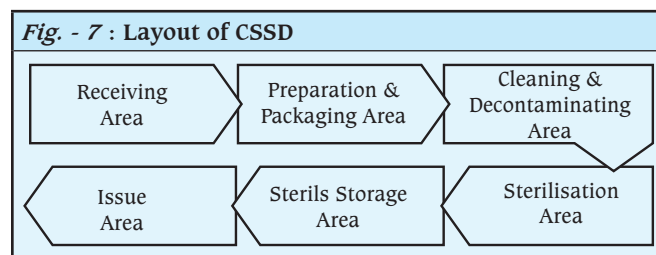
- To provide sterile supplies centrally
- To provide assistance to purchasing dept in selection and pretesting of goods
- Advisory role to Hosp Infection Control Committee (HICCOM)
- Ensure quality control measures in sterilization of various items
- Impart training to hospital personnel

CSSD caters for sterilization of items such as needles & glass syringes, rubber goods, including catheters & tubings, treatment & diagnostic sets (such as lumbar puncture sets), dressings, intravenous sets and infusion fluid for renal dialysis. Normally, CSSD does NOT include sterilization of surgical instruments used in OT, bed pans & urinals, bedding of patients, diets, medicines including blood & crystalloids and laundry.

**Planning considerations** : CSSD must be located close to and be easily accessible to areas which it serves most frequently such as Operation Theatre, ICU, acute wards & labour room. The space requirements recommended for CSSD (based on number of beds) are as shown in Table - 4 :

Table - 4 : Space requirement recommendation for CSSD	
Up to 100 beds	10 square feet per bed
101 - 200 beds	9-10 square feet per bed.
201 - 300 beds	8-9 square feet per bed
301 beds and above	7-8 square feet per bed

The *functional layout* of CSSD should be so planned so that sterile and contaminated items do not come in contact and are not handled in the same area. Functional areas are thus divided into Receiving area, Cleaning and washing area, Unsterile area for inspection and maintenance, Work area for assembly and packing, Work area for sterilization, Sterile storage area, Gloves and rubber goods processing area and Issue area. Broad layout of a CSSD is as shown in Fig. - 7:



**The concept of 'Zoning' in CSSD** : Zoning is essential to ensure that contaminated items do not mix with sterile items in CSSD. Broadly the CSSD is divided into (i) Dirty Zone (receiving area, cleaning area and repair place); (ii) Clean Zone (Assembly and packing place) and (iii) Sterile Zone (Sterilisation, storage and issue areas). Accordingly the flow of items inside CSSD should be in such a manner that dirty items and sterile items do not mix.

**Distribution System** : CSSDs in various hospitals may follow any one of the distribution systems in vogue, as under :

- Clean for Dirty Exchange system* in which one used item is exchanged for sterile one on an exchange basis. This method of distribution is mostly used in cases where the demand for sterile items is less, such as in chronic wards.
- Topping system* where stocks of each ward, OT, ICU etc. are topped up daily to a predetermined level by making rounds and topping up the stocks. It is recommended that 50% extra items (more than the average daily consumption) should be added when one daily round is made and 25% extra items should be added when two daily rounds are made.
- Requisition system* where the requirements of each ward, ICU, OT etc are intimated to CSSD in advance and sterile items from CSSD are supplied based on the demand from each ward.
- Exchange Trolley system* wherein entire trolley is exchanged which has a fixed number of items. Such a system is followed where demand is substantial, such as a busy OT, ICU or acute surgical wards.

### Medical Records Department

A medical record is defined as a clinical, scientific, administrative and legal document related to patient care in which is recorded sufficient data in sequence of events to justify the diagnosis, warrant the treatment given to the patient and results (McGibony 1969). Medical records are thus clear, concise & accurate history of patient's life & illness, written from medical point of view (Mac Eachern 1957). They are the sequentially recorded findings, observations and prescriptions of all medical & paramedical health care providers who attend to a patient during his / her interaction with health care facility.

### Types of Medical Records

- Directly related to patient care* such as admission forms, medical history sheets, medical record forms, nurses' bedside records like TPR charts, consultations, investigations ordered & their results, OT notes and discharge summaries etc.
- Indirectly related to patient care* such as budget, accounts and financial transactions during patient's stay in hospital.

### Importance of medical records

- For the patient, medical records help in continuity of medical care, prevent omission / duplication of investigations, support or refute medico-legal issues, provide reliable information for health insurance and disability entitlements for the patients.
- For the treating physician, accurate medical records provide a quality check regarding the adequacy and continuity of medical care, helps in evaluation of medical care provided and protects from legal suits of medical malpractice or medical negligence.
- For the hospital, medical records serve as evidence for evaluation of medical & nursing care, helps the management in planning & allocation of resources for the future and protects in case of legal suits.
- For medical research, accurate medical records assist in deriving conclusions or investigating them, aids informal

education, forms basis for clinical research and provides reliable source for advancement of medicine.

- For public health, medical records provide reliable info regarding mortality & morbidity profile of population, assists in planning preventive & social measures and provides early warning of incidence of communicable diseases.

### Some commonly used terms in medical records

**(a) Hospital Death** : Death of a patient admitted as an inpatient in the hospital is considered as a hospital death. Death of a patient in casualty, OPD, ambulance or anywhere in the hospital before actual admission is not termed as hospital death. Gross Hospital Deaths are hospital deaths irrespective of duration of admission, whereas Net Hospital Deaths are deaths of inpatients after 48 hours of admission.

$$\text{Gross death rate} = \frac{\text{Total number of hospital deaths during the given period}}{\text{Total discharges (Including deaths) during the same period}} \times 100$$

$$\text{Net death rate} = \frac{\text{Total number of deaths of inpatients after 48 hours of admission during a given period}}{\text{Total discharges (including deaths) during the same period}} \times 100$$

Net Death Rate of a hospital serves as an accurate indicator of quality of medical care provided by that hospital. It is natural that net death rate (hospital deaths after 48 hours of admission) will be low where quality of medical care is good. Excessive net death rates indicate poor quality of hospital care and should be investigated.

**(b) Patient Day** : It is defined as the duration of medical care rendered to an inpatient between the census taking hours of two successive days. While counting the patient days, the day of admission is always counted (irrespective of the time of admission) and the day of discharge is always excluded (irrespective of the time of discharge). Patient day is a useful unit of time for assessing various hospital related activities such as patient days of health care provided, cost incurred on ICU bed per patient day, cost of hospital food per patient day etc.

**(c) Average Daily Census** : It is the average number of patients in the hospital at any given time of the day and is expressed as:

$$\frac{\text{Sum of daily census for a given period}}{\text{Number of calendar days in the period}}$$

**(d) Occupancy Rate** : It is the ratio of actual patient days expressed as a percentage of the maximum possible patient days (based on bed complement) in a hospital during any given period. It is :

$$\frac{\text{Number of patient days (based on discharges) during a given period}}{\text{Bed complement} \times \text{days during the same period}} \times 100$$



(e) **Average length of stay** : It is the average number of days of medical care rendered to each discharged patient during a given period of time and can be compiled from the discharge summary of patients. It is expressed as :

$$\frac{\text{Total patient days during a given period}}{\text{Total discharges (including deaths) during the same period}}$$

(f) **Turnover Interval (T interval)** : It is the average number of days that bed remains vacant between a discharge and subsequent admission. It is expressed as :

$$\frac{\text{Maximum possible patient days -- Actual patient days (bed complement x days) during a given period}}{\text{Number of discharges (including deaths) during that period}}$$

A negative value of T interval indicates a scarcity of hospital beds whereas a prolonged positive T interval indicates under-utilization of hospital beds (vacant beds) due to inadequate admissions or poor quality of medical care offered by the hospital. T interval is a sensitive index of hospital bed utilization and a short positive T interval indicates optimum utilization of beds.

**Legal aspects of Medical Records** : Medical Records, besides recording the complete diagnosis, treatment and outcome of a patient in a hospital, is also an important legal document and hence must be complete (must contain adequate data to identify the patient, justify diagnosis & treatment and outcome and must contain all bedside recordings of various medical & nursing procedures), adequate (must contain all necessary clinical information), accurate (information recorded should be quantifiable and assessable for correctness and legible (records must be legible and names of all medical professionals endorsing the records should be recorded clearly). The medical records are property of the hospital and not of the patient or the treating doctor. Since a medical record pertaining to an individual is a personal document, the contents ordinarily should not be divulged to anyone without consent of the patient. However, details may be divulged to the patient concerned in form of brief summary and findings of investigations. Relevant details may be released to press under exceptional circumstances only by the administrator of the hospital. Details of hospitalization can be released to LIC even without consent of patient to dispose claims arising from insurance policies and to police in case of medico-legal cases, injury reports etc. Police should ordinarily not be allowed to record a patient's statement without prior certification by MO (compos mentis). According to Indian Evidence Act, hospital documents including medical records are admissible as evidence. Courts can subpoena any document or medical record and can summon any doctor for evidence under law of torts. Medical documents can also be used for education, research & public health when used as impersonal details. At times, some personal information has to be divulged in public interest for communication & notification of certain diseases.

**Safety & retention of medical documents** : It is the responsibility of hospital administration to safely store medical records pertaining to patients. Medico-legal documents should be especially kept safely as these are required in courts of law subsequently. The general guideline for retention of hospital

documents is that OPD records should be stored for 5 years, indoor records for upto 10 years and medico-legal documents should be stored permanently.

### Linen & Laundry Services

Linen & laundry services are one of the important support services of a hospital, which not only contributes to patient satisfaction, but also assists in healing by reducing cross infection among patients. Hospital linen can be defined as all clothing made of cotton, linen, wool or synthetic fabrics which are used by the patient or used for him while in hospital.

#### Importance of laundry services for a hospital

(a) **Prevention of cross infection among patients** : Frequent change & adequate cleaning of patient linen reduces the chances of cross infection among patients, thereby assisting in faster healing of wounds.

(b) **Comfort & patient satisfaction** : Clean and appropriate clothing for patients invariably leads higher levels of comfort and satisfaction among patients.

(c) **Aesthetic aspect** : Clean linen in hospital wards provide a neat and cheerful look to the wards, which makes the patients stay more comfortable. In addition, clean linen in hospital also improves the job satisfaction of nursing and paramedical staff in the hospital, by providing a clean working environment.

(d) **Public Relations** : A clean ward serves as an important public relation factor wherein all visitors and patients carry a favorable impression of the services and medical care rendered at the hospital.

#### Types of Laundry Services

- In-plant System** is a hospital owned laundry and is best suited for large teaching or referral hospitals with large number of beds and adequate patient turnover. It is costly to maintain but better control over quality can be exercised by the administration.
- Rental System** is where a hospital hires linen from a contractor who is also responsible for replacement and laundering of the linen. Though less costly for the hospital, quality control has to be monitored closely as it is dependent on the contractor.
- Contract System** is where the hospital owned linen is laundered by a contractor because the hospital does not have facilities for laundry.
- Cooperative System** is one of the most cost-effective methods for smaller hospitals where a single laundry is shared by more than one hospital.

**Classification of linen** : Laundry linen is classified as under based on the cleaning process required for the linen.

- Soiled linen** that has been used by patients and has to be cleaned by routine procedures of washing, conditioning and ironing.
- Infected linen** which has been contaminated by infective material such as blood or Pus. Such linen is collected in polythene bags, is handled least and has to be first disinfected before routine washing.
- Foul linen** is linen which is contaminated with faeces, excreta or blood and has to be passed through sluicing before washing.

- (d) *Radio-active linen* is linen contaminated with radioactive substances and has to be suitably decontaminated & monitored before washing and re-using for patients.

Life of hospital linen is a major concern for administrators since it involves a recurring expenditure. Generally, 15-20% of linen becomes unusable after 35 washes (or after 3 months) and has to be replaced. The overall life of hospital linen would depend on availability of linen in adequate quantity type of laundry system (in-plant system will lead to longer life) and type of detergents used etc.

**Types of Linen Distribution System** : One out of the following systems of linen distribution is followed in all hospitals.

**(a) Centralized linen services**

- (i) *'Clean for Dirty' exchange system* where laundered linen is issued whenever used/soiled linen is deposited in laundry by user departments.
- (ii) *Topping up system* where a pre-decided laundry stock (calculated on the basis of one day's requirement) is replenished every morning by laundry staff in each user department.
- (iii) *Exchange Trolley system* where daily stock of linen is supplied to each ward in a trolley and replaced the next day. This reduces handling of clean laundry by too many people in the hospital.
- (iv) *Pack system* where complete requirement of linen patient-wise is prepared in laundry itself in form of packs and supplied to user departments.

**(b) Decentralized linen services** : Linen is issued to wards on their inventory and used linen is sent to a central laundry by the ward nursing staff. Every linen is marked to identify the user department and laundered linen is issued to user wards out of the stock maintained for each department.

**(c) Mixed linen services** : These are followed where some key areas like Operation Theatre, ICU etc. are issued with their own linen as in decentralized system but rest of the hospital follows the centralized system of laundry.

**Hospital Dietary Services**

Dietary services of a hospital is one of the main supportive services, which contributes to recovery of health through scientifically prepared diets, dietary counseling of patients and training of health care providers in dietary requirement & planning. Hospital dietary services can be described as supportive services which cater to the needs of outpatients regarding diet counseling and provision of appropriate diets to the inpatients, as per their requirements.

Conventional dietary system in most hospitals consists of menu items prepared in a kitchen on the premises where meals are prepared and held for a short time and maintained either hot or cold until serving time. This system is more adaptable to regional, ethnic & individual preferences and ensures quality control. However, because of differences in menu, this system is more stressful for workers. In addition, skilled workers may be assigned tasks that could be done by non-skilled workers and the system needs two shifts of employees.

In the Commissary (large central kitchen) system, there is centralized food purchasing & delivery of prepared food to

satellite units located in different hospital areas for final preparation and service to patients. This system is economical because of bulk cooking & quality control is better because there is only one unit to supervise. However, poor food safety during distribution may result in contamination. In the ready prepared (Cook & Chill) system, foods are prepared in advance & stored under refrigeration. There is thus no peak period pressure & no delay in preparation. But the system needs cold storage and freezers for chilling the food items immediately after they are prepared.

**Summary**

A hospital can be described as an organisation which provides health care services (preventive, promotive and curative) by pooling in the various skills & services of health professionals, supportive staff and ancillary staff, with the overall objective to provide health care to patients. It is a highly complex institution which brings together highly qualified and highly technical professionals for common cause of providing comprehensive health care and medical care to patients, in the most cost-effective manner, within the limited available resources. A hospital can be broadly divided into Clinical Areas, Diagnostic Areas, Auxiliary Services and Support Services. Emergency Medical Services (EMS) can be described as medical services undertaken with the aim to transport the right patient to the right hospital at the right time so that right treatment can be given. Role of A&E services in a hospital includes such functions as to function as an information centre about seriously injured patient, to provide ambulance services and so on.

Location, Space requirements, Planning of facilities and Architectural design (such as considerations on Entrance, Waiting area, Reception, Registration & Records, Examination & Treatment area) are the vital considerations while planning an A&E Dept. An Out-Patient Department (OPD) can be defined as that part of the hospital with allotted physical and medical facilities and staff in adequate numbers, with regularly scheduled hours, to provide care for patients who are not registered as indoor patients. They are the first point of contact between the patients/their relatives and the hospital staff. Functions of OPD include provision of day care investigative, diagnostic and treatment specialist procedures, health education and health promotion and so on. Location, Patient flow, Interdepartmental Resource Sharing, Physical facilities, Space provisions, Clinical areas, Pathology laboratory & Auxiliary facilities are some of the factors that have to be considered while planning an OPD. Overcrowding and long waiting time are some of the problems faced in OPDs.

An Operation Theatre (OT) is a specialized facility of the hospital where life saving / life improving procedures are carried under strict aseptic conditions. Surgical operations have been classified broadly as emergency surgeries and elective surgeries. Objectives to remember while planning an OT include flexibility, complete asepsis and maximum safety. In order to attain maximum asepsis, an OT should ideally include Disposal zone, Protective zone, Clean Zone, Sterile Zone. The intensive care unit (ICU) is a place where seriously sick patients, highly skilled medical and nursing staff with knowledge and experience & sophisticated medical

equipment are brought together for better health care at an optimum cost. Based on organizational structure, ICUs can be classified into Open unit, closed unit and Semi- Closed unit. ICU should have a medical officer, one Resident round the clock and a junior resident, apart from nursing staff. Physical facilities and design of ICU should factor in the appropriate location, space requirement, patient services and facilities for nursing station in ICU. Illumination, ventilation etc. are the other considerations in designing an ICU. A 'ward' in a hospital can be defined as a section of a hospital, including a nursing station, bed and necessary storage service, work and public areas, where nursing care is provided to in patients. The main factor to be kept in mind while designing a ward is that nursing staff should be able to hear & see all patients and should be able to react accordingly with maximum efficiency and least stress and strain. Open ward (pavilion type) and Rig's ward are some of the types of wards. 20-30 beds per ward with 2-3 single-bed rooms for patients requiring special nursing care has been prescribed as a norm. The objective of Ward Management is to provide the best possible medical & nursing care to patients by using the abilities of every member of the staff to fullest extent possible. Ward management comprises of Patient Management (including assignment of patient care, planning of work schedule) and management of Supplies, Equipment, Environment and personnel. Common problems in Ward Management include inadequate staff, untrained staff, lack of supervision and the like. The diagnostic and supportive services in any hospital broadly consist of the laboratory services, radio-diagnostic and imaging services, blood transfusion services and pharmacy services. The functions of a laboratory would include training of professional & technical staff and provision of comprehensive & accurate analytical test results, among others. Major considerations while planning a hospital laboratory would include Space, Staffing etc.. A blood bank is an organisation for carrying out all or any of the operations pertaining to storage processing & distribution of blood drawn from a donor &/or preparation, storage & distribution of blood components. Component preparation, collection of blood in an aseptic manner and screening are the main functions of a blood bank. Blood banks can be broadly classified into three categories based on consumption of blood. Planning considerations for establishing blood transfusion services should cater for proper public access areas, laboratory areas, storage & issue areas and administrative areas. The Central Sterile Supply Department is responsible for collecting & receiving used patient care items with the view to decontaminate, process, sterilize, store and dispose these items to all other parts of the hospital comprises of the services within the hospital which receives, stores, processes, sterilizes, distributes and controls professional supplies and equipments, both sterile and non sterile, to all departments of the hospital for the care and safety of patients. The objectives of a CSSD includes provision of sterile supplies centrally, Advisory role to Hosp Infection Control Committee (HICCOM) and the like. CSSD must be located close to and be easily accessible to areas which it serves. The functional layout of CSSD should be so planned so that sterile and contaminated items do not come in contact and are not handled in the same area. CSSD is divided into Dirty Zone, Clean Zone and Sterile Zone. CSSDs in various hospitals may follow any one of the

distribution systems like Clean for Dirty Exchange system, Topping system, Requisition system or Exchange Trolley system. A medical record is defined as a clinical, scientific, administrative and legal document related to patient care in which is recorded sufficient data in sequence of events to justify the diagnosis, warrant the treatment given to the patient and results. The various types of Medical Records are those that are Directly or indirectly related to patient care. The Importance of medical records is manifold, like for the patient, for public health and so on. Death of a patient admitted as an inpatient in the hospital is considered as a hospital death. Patient Day is defined as the duration of medical care rendered to an inpatient between the census taking hours of two successive days. Average Daily Census is the average number of patients in the hospital at any given time of the day and Occupancy Rate is the ratio of actual patient days expressed as a percentage of the maximum possible patient days. Average length of stay is the average number of days of medical care rendered to each discharged patient during a given period of time. Turnover Interval (T interval) is the average number of days that bed remains vacant between a discharge and subsequent admission is also an important legal document. Medical Records should be complete, accurate, legible and adequate. It is the responsibility of hospital administration to safely store medical records pertaining to patients. Hospital linen can be defined as all clothing made of cotton, linen, wool or synthetic fabrics which are used by the patient or used for him while in hospital. The Importance of laundry services for a hospital includes mainly aesthetic aspect, public relations and the like. Types of Laundry Services include In-plant System, Rental System, Contract System and Cooperative System. Soiled linen, infected linen, foul linen and radio-active linen are the various types of Linen. Distribution System for linen includes Centralized linen services & Decentralized linen services. Dietary services of a hospital is one of the main supportive services, which contributes to recovery of health through scientifically prepared diets, dietary counseling of patients and training of health care providers in dietary requirement & planning. Conventional dietary system and Commissary (large central kitchen) system are the main types of hospital dietary services.

## Study Exercises

### MCQs and Exercises

1. The word 'product' in a hospital setting would actually mean (a) number of patients (b) income generated (c) medical care (d) variety of specialists.
2. All of the following are types of Support Services in a hospital except : (a) laundry services (b) medical records dept (c) dietary services (d) pharmacy services.
3. Average recommended space per patient visiting the A&E (Accident & Emergency) Dept in a hospital is (a) 10 square meters (b) 20 square meters (c) 30 square meters (d) 40 square meters.
4. Against an inpatient load of 25 patients per bed per year, a hospital OPD load on an average, is around (a) 400 patients per bed per year (b) 500 patients per bed per year (c) 600 patients per bed per year (d) 800 patients per bed per year.
5. Public toilets should be provided in hospitals separately



- for males and females at the rate of one toilet each for (a) 200 patients/ visitors (b) 100 patients/ visitors (c) 300 patients/ visitors (d) 400 patients/ visitors.
6. The following are the zones are identified in an Operation Theatre, except (a) Disposal zone (b) Protective zone (c) Clean Zone (d) Fertile zone.
  7. The type of Intensive Care Unit (ICU) where the medical team in charge of the intensive care unit must review and approve all admissions into ICU, is known as (a) Open unit (b) Semi-closed unit (c) closed unit (d) Quasi- open unit.
  8. The open type of ward is also known as the Rig's ward. Yes/ No.
  9. The minimum distance between centre of adjacent beds in a ward should be at least (a) 2.4 metres (b) 1.0 metres (c) 0.4 metres (d) 1.4 metres.
  10. A hospital laboratory broadly consists of all of the following areas, except (a) Primary space (b) Secondary space (c) Tertiary space (d) Circulation space.

11. The space requirements recommended for CSSD (Central Sterile Supply Department) in a hospital with 201 - 300 beds is (a) 10 square feet per bed (b) 08-09 square feet per bed (c) 07-08 square feet per bed (d) 06-07 square feet per bed.
12. The duration of medical care rendered to an inpatient between the census taking hours of two successive days, is known as (a) Patient Day (b) Hospital Day (c) Average length of stay (d) Bed occupancy duration.
13. Where a single laundry is shared by more than one hospital, the type of laundry service system is known as (a) In-plant System (b) Rental System (c) Contract System (d) Co-operative System.
14. Large central kitchen system in hospital dietary system, is also known as (a) Commissary system (b) Conventional dietary system (c) Ready Prepared system (d) Cook & Chill system.

**Answers :** (1) c; (2) d; (3) a; (4) b; (5) a; (6) d; (7) d; (8) No; (9) a; (10) c; (11) c; (12) a; (13) d; (14) a.

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## Advanced Diagnostic Technologies in Public Health

*Rohit Tewari*

A diagnostic test is any kind of medical test performed to aid in the diagnosis or detection of disease. It may be used to diagnose diseases or measure the progress or recovery from disease or confirm that a person is free from disease.

Some medical tests are parts of a simple physical examination which require only simple tools in the hands of a skilled practitioner and can be performed in an office environment. Some other tests require elaborate equipment used by medical technologists or the use of a sterile operating theatre environment. Some tests require samples of tissue or body fluids to be sent off to a pathology lab for further analysis. Some simple chemical tests such as urine pH, can be measured directly in the physicians office. However, with advancements in health care, a large array of diagnostic tests have become available. The aim of this chapter is to provide an introductory overview of the various modern (and often, expensive) diagnostic modalities which are often discussed routinely in contemporary medical world.

According to IPHS standards stated as a part of NRHM, the laboratory facilities which should be available at various levels are (Table-1) :

**Table - 1 : IPHS Standards for Availability of laboratory Services at various levels of care (31-50 Bedded Hospital)**

Speciality	Diagnostic Services / Tests
Haematology	Haemoglobin estimation, Total Leucocyte count, Differential Leucocyte count, Absolute Eosinophil count, Reticulocyte count, Total RBC count, E. S. R. , Bleeding time, Clotting time, Peripheral Blood Smear, Malaria/Filaria Parasite, Platelet count, Packed Cell volume, Blood grouping, Rh typing, Blood Cross matching
Urine Analysis	Urine for Albumin, Sugar, Deposits, Bile salts, Bile pigments, Acetone, Specific gravity, Reaction (pH)
Stool Analysis	Stool for Ova cyst (Eh), Hanging drop for V. Cholera, Occult blood
Sputum	Sputum cytology
Microbiology	Smear for AFB, KLB (Diphtheria), Grams Stain for Throat swab, sputum etc. KOH study for fungus
Serology	RPR Card test for Syphilis, Pregnancy test (Urine gravindex), WIDAL test, Rapid Test for HIV, HBs Ag, HCV
Biochemistry	Blood Sugar, Urea, Serum Bilirubin, Liver function tests, Kidney function tests, Blood Cholesterol, Blood Uric acid



For 51-100 Bedded (All as in 31-50 bedded with the following additional facilities) (Table - 2)

<b>Table - 2 : For 51-100 Bedded</b>	
<b>Speciality</b>	<b>Diagnostic Services / Tests</b>
Haematology	Prothrombin time, ELISA for HIV, HBsAg and HCV
Semen Analysis	For count, morphology and motility
CSF Analysis	Cell count cytology
Aspirated fluids	Cell count cytology
Others	Stocking of rapid H2S based test for bacteriological examination of water, Stocking of OT test for residual chlorine in water

For 201-300 Bedded (All as in 51-100 bedded with the following additional facilities) (Table - 3)

<b>Table - 3 : For 201-300 Bedded</b>	
<b>Speciality</b>	<b>Diagnostic Services / Tests</b>
Haematology	Prothrombin time
Semen Analysis	For count, morphology and motility
CSF Analysis	Cell count cytology
Aspirated fluids	Cell count cytology
Others	Stocking of rapid H2S based test for bacteriological examination of water, Stocking of OT test for residual chlorine in water.
Microbiology	Culture and sensitivity for blood, sputum, pus, urine etc., Stool culture for Entero pathogen, Supply of different Specimen collection and transportation media for peripheral Laboratories, KOH Study for Fungus
Biochemistry	Lipid Profile, Serum calcium, sodium, potassium, Serum Phosphorous, Serum Magnesium, Blood gas analysis, Thyroid T3 T4 TSH, CPK, Chloride

The various modern diagnostic technologies that shall be discussed in this chapter can be classified under the following groups :

- Immunopathology
- Molecular Biology
- Clinical Chemistry
- Haematology
- Cytopathology
- Histopathology
- Radiology
- Electrophysiology

## Diagnostic Technologies in Immunopathology

Antigens can be defined as any substance that can represent antigenic sites (epitopes) to produce corresponding antibodies, from small molecules such as haptens and hormones to macromolecules such as proteins and glycoproteins. Antibodies are produced in response to antigenic stimulation. Immunoassays (antigen antibody reactions) can be used for detection of either antigens or antibodies. For detecting antigens, the corresponding specific antibody should be used as one of the reagents and vice versa.

The technologies available are –

**Precipitation immunoassays** : It is based on the occurrence of precipitation when large complexes of antigens and antibodies combine to form an insoluble lattice. These techniques suffer from poor sensitivity. The lower limit of sensitivity remains in the range of 0.1-0.4 mg/dl. Typical examples of precipitation immunoassay are the Widal test and the Weil-Felix test.

**Particle immunoassay** : Here specific antigens are coated onto a particle and on reaction with antibody under test, the agglutination is made more visible. Reverse agglutination where the antibody is coated onto the particle is also performed. The particle used may be RBC, latex or gelatin. The sensitivity of hemagglutination tests is upto 50 ng/ml for antigen detection.

**Applications in public health** : Hemagglutination test using RBC as the particle is widely used for Treponema pallidum called as the TPHA (Treponema pallidum Hemagglutination). Hemagglutination tests for hepatitis B and hepatitis C are also widely used. (for detection of antibody). Reverse passive hemagglutination (RPHA) has extensive application in detection of hepatitis B surface antigen (HBsAg). Latex agglutination is widely used in measurement of hCG for qualitative pregnancy tests.

**Radioimmunoassay** : Radioimmunoassay (RIA) is a scientific method used to test antigens (for example, hormone levels in the blood). Although the RIA technique is extremely sensitive and extremely specific, it requires a sophisticated apparatus and is costly. It also requires special precautions, since radioactive substances are used. Therefore, today it has been largely supplanted by the ELISA method, where the antigen-antibody reaction is measured using colorimetric signals instead of a radioactive signal. To perform a radioimmunoassay, a known quantity of an antigen is made radioactive, frequently by labeling it with gamma-radioactive isotopes of iodine attached to tyrosine. This radiolabeled antigen is then mixed with a known amount of antibody for that antigen and as a result, the two chemically bind to one another. Then, a sample of serum from a patient containing an unknown quantity of that same antigen is added. This causes the unlabeled (or “cold”) antigen from the serum to compete with the radiolabeled antigen for antibody binding sites.

**Applications in public health** : These are limited to hormonal assays for example thyroid hormone levels in goiter endemic areas.

**Enzyme Linked Immunosorbent Assay (ELISA)** : This is a technique used mainly in immunology to detect the presence of an antibody or an antigen in a sample. In simple terms, in ELISA an unknown amount of antigen is affixed to a surface

and then a specific antibody is washed over the surface so that it can bind to the antigen. This antibody is linked to an enzyme and in the final step a substance is added that the enzyme can convert to some detectable signal.

**Applications in public health :** ELISA can be performed to evaluate either the presence of antigen or the presence of antibody in a sample, hence it is a useful tool both for determining serum antibody concentrations (such as with the HIV test or West Nile Virus) and also for detecting the presence of antigen. ELISA can also be used in toxicology as a rapid presumptive screen for certain classes of drugs. ELISA can be used for detecting tumour markers for certain cancers, e.g. Prostate Specific Antigen (PSA) in carcinoma prostate.

**Fluorescent immunoassay :** When fluorescent molecules are irradiated with light at appropriate wavelengths, an electron in the ground state is transitioned into the excited state. As the electron returns to the ground state, physical energy is released in the form of a photon which is detectable.

**Applications in public health :** Immunofluorescence assays have been extensively used for detecting antigens in tissue sections, e.g. kidney biopsies. Use of Auramine rhodamine stain in detection of tubercle bacilli in smears is well documented and shown to have better sensitivity than the conventional ZN stain. They have also been developed to detect the concentration of drugs, hormones and proteins and polypeptides.

**Chemiluminescent immunoassay :** These assays use chemiluminescence generating molecules as labels, such as luminol derivatives.

**Applications :** Assays of hormones and tumour markers can be performed. The detection limit has been reported as 0.2 to 0.4 ng/ml for Carcino-Embryonic Antigen (CEA) and 0.4 ng/ml for Alfa Feto Protein (AFP).

### Diagnostic Technologies in Molecular Biology

Molecular biology is the study of biology at a molecular level. Molecular biology chiefly concerns itself with understanding the interactions between the various systems of a cell, including the interactions between DNA, RNA and protein biosynthesis and learning how these interactions are regulated. The tools of molecular biology have proven readily adaptable for use in the clinical diagnostic laboratory and promise to be extremely useful in diagnosis, therapy, epidemiologic investigations and infection control [8, 9]. Although technical issues such as ease of performance, reproducibility, sensitivity and specificity of molecular tests are important, cost and potential contribution to patient care are also of concern [10]. Molecular methods may be an improvement over conventional microbiologic testing in many ways. Currently, their most practical and useful application is in detecting and identifying infectious agents for which routine growth-based culture and microscopy methods may not be adequate

**Gel electrophoresis :** Gel electrophoresis is one of the principal tools of molecular biology. The basic principle is that DNA, RNA and proteins can all be separated by means of an electric field. In agarose gel electrophoresis, DNA and RNA can be separated on the basis of size by running the DNA through an agarose gel. Proteins can be separated on the basis of size by using an

SDS-PAGE gel, or on the basis of size and their electric charge by using what is known as a 2D gel electrophoresis.

**Hybridisation assays :** When the hybridization reaction is used to analyse the nucleic acid content of an unknown sample, the process is known as a hybridization assay. The property of complementary base pairing allows fragments of known composition (the probes) to interrogate an unknown for the presence of matching (complementary) sequences. The detection of the hybrids can be done a variety of technologies including radioisotope labels, fluorochrome based detection and enzyme based systems.

**Liquid phase hybridization :** When both sample and probe are in solution.

**Solid support hybridization :** In these assays, hybridization occurs in a biphasic environment, a solid phase (usually sample) and a liquid phase (usually probe).

**Southern and Northern hybridization assays :** These combine electrophoretic separation of test nucleic acids with transfer to a solid support and subsequent hybridization. Hence these assays give information of hybridization as well as the molecular weight of the hybridizing species. The original procedure was described by EM Southern and the test nucleic acid was DNA [11]. When RNA is the nucleic acid under test, the technique is called northern blotting by analogy. A further extension to the analogy is western blotting where proteins are subjected to the same procedure.

**In situ hybridization :** This is the detection of specific genetic information within a morphological context (intact tissue, cells or chromosomes affixed to glass slides).

**Amplification technology :** All the target amplification systems are enzyme based processes in which a single enzyme or multiple enzymes synthesize copies of target nucleic acid. All result in production of billions of copies of the amplified product in a few hours. These techniques are subject to contamination from product molecules of previous amplifications and hence false positivity is high. However, special lab design, practices and workflow have helped to reduce false positives to an acceptable range.

**Polymerase Chain Reaction (PCR) :** It is a simple in vitro chemical reaction that permits synthesis of large quantities of nucleic acid. This is brought about by heating the reaction mixture to separate the strands of the DNA, then cooled to permit the primers to anneal to the target DNA in a sequence specific manner. The DNA polymerase then initiates extension from 3' end. Thus the whole process is carried out in a programmable thermocycler which controls the temperatures at which various steps occur.

**Reverse transcriptase PCR (RT-PCR) :** PCR was initially described to amplify DNA. RT-PCR was developed to amplify RNA targets

**Nested PCR :** This variation increases the sensitivity and specificity of PCR. The products of the first round of amplification are subject to second round of amplification with a second set of primers.

**Real time PCR :** Here the target amplification and detection occur simultaneously. The computer software supporting the

thermocycler monitors the data throughout the PCR at every cycle and generates a plot.

**Restriction Fragment Length Polymorphism (RFLP) based assays** : Assays that utilize the sequence recognition property of restriction enzymes to demonstrate variations or polymorphisms in the DNA sequence of two samples are known as RFLP assays.

**Arrays** : A DNA array is a collection of spots attached to a solid support such as a microscope slide where each spot contains one or more single-stranded DNA oligonucleotide fragment. Arrays make it possible to put down a large quantity of very small (100 micrometre diameter) spots on a single slide. Each spot has a DNA fragment molecule that is complementary to a single DNA sequence (similar to Southern blotting). A variation of this technique allows the gene expression of an organism at a particular stage in development to be qualified (expression profiling). Since multiple arrays can be made with the exact same position of fragments they are particularly useful for comparing the gene expression of two different tissues, such as a healthy and cancerous tissue. Arrays can also be made with molecules other than DNA. For example, an antibody array can be used to determine what proteins or bacteria are present in a blood sample.

#### **Applications of molecular biology in Public Health**

**Pathogen detection by hybridisation** : The DNA of the infectious agent is detected directly in the clinical specimens by DNA probes. The disadvantage is that at least  $10^4$  or more copies are required for detection. In infectious diseases hybridization assays are unlikely to be a significant tool for diagnosis in the future due to low sensitivity. These formats are more applicable to batch processing of large numbers of specimens as in research labs.

**DNA probes for culture identification** : Probes are available for various organisms like *Mycobacterium tuberculosis*, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Human papilloma virus*, *Hepatitis C virus*, *Cytomegalovirus* and *Herpes simplex virus*.

This is especially important for slow growing organisms like Mycobacteria, fungi etc. Identification of cultured Mycobacteria by conventional methods is slow and time consuming. The use of probes for this purpose permits identification from cultures within one working day and sensitivity (95.4%) and specificity (99%) are excellent [12].

**DNA amplification for diagnosis** : Hepatitis C Virus-Detection of the virus by reverse transcriptase PCR confirms current infection and has a role in diagnosis and monitoring response to therapy [13]. Development of Quantitative PCR allows quantification of HCV which is important in prognosis and monitoring of therapy.

**HIV** : Molecular diagnosis is required in cases where serological testing results are indeterminate and neonates where serological detection of antibodies may be positive due to transplacental transfer of maternal antibodies and a prolonged follow up period (18 mths) may be needed to confirm infection by serologic methods. Quantitation of HIV virus is widely used for prognosis and for evaluation of response to antiretroviral therapy [14].

***Mycobacterium tuberculosis*** : In general the sensitivity of these assays for specimens for which the smear for acid fast bacilli (AFB) is positive is excellent (95-100%). It is lower for specimens that are AFB smear negative (50-80%) [15]. Currently, the amplification processes cannot replace the AFB smear because the latter is used to determine the level of infectivity of patients and in gauging the initial response to therapy. At present the role of amplification assays remains complimentary to microscopy and culture.

**Sexually Transmitted Diseases** : Amplification assays have been developed for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*.

**Fungi** : PCR assays for diagnosis of invasive Candidiasis and Aspergillosis have been developed.

**Detection of antimicrobial resistance** : Resistance of microbes to antimicrobials is one of the major public health problems of this decade. Molecular methods have contributed towards understanding of the genetics of antimicrobial resistance and the spread of resistance determinants. e.g. Molecular detection of the *Mec-A* gene is now considered a reference method for assessing Methicillin resistance in Staphylococci [16]. PCR amplification of DNA sequences from the *rpoB* (rifampicin resistance) and the *kat G*, *inh A* and *ahp C* genes (isoniazid resistance) followed by detection of mutations associated with resistance has a high sensitivity for detection of resistance to rifampicin (>96%) and isoniazid (87%) [17].

**Molecular Epidemiology** : The techniques of molecular typing are useful not only in research settings but also in real life clinical and public health problems. e.g. prediction of response to interferon therapy is important in patients with Hepatitis C virus infection. HCV genotypes 1b and 1a appear less likely to respond to interferons [18]. If molecular evidence of identity of multiple isolates of *Staphylococcus epidermidis* isolated from a single patient at different times can be shown, it indicates that the isolate is clinically significant.

#### **Diagnostic Technologies in Clinical Chemistry**

**Colorimetry** : This is performed in a device that measures the absorbance of particular wavelengths of light by a specific solution. This device, invented by Jan Szczepanik, is most commonly used to determine the concentration of a known solute in a given solution by the application of the Beer-Lambert law, which states that the concentration of a solute is proportional to the absorbance. Changeable optic filters are used in the colorimeter to select the wavelength of light which the solute absorbs the most, in order to maximize accuracy. The usual wavelength range is from 400 to 700 nanometres (nm). In modern colorimeters the filament lamp and filters may be replaced by several light-emitting diodes of different colors.

**Applications in public health** : These are far reaching and extensive since colorimetry forms the basis of assessing almost all parameters in clinical chemistry (including routine analytes like urea, creatinine, glucose, uric acid etc) and also hemoglobin in hematology. The technology involved is simple and made available at almost all levels of health care. Levels in blood of routine analytes forms the basis of the diagnosis of diabetes, hyperlipidemia, metabolic syndrome etc.



**Nephelometry** : This is a method for measuring the concentration of a solution that contains particles that are too large for colorimetry/ absorption spectroscopy. When a collimated light beam strikes a particle in suspension, portions of the light are absorbed, reflected, scattered and transmitted. Nephelometry is the measurement of the light scattered by a particulate solution.

**Applications in public health** : This is useful in measurement of antigen antibody complexes formed in immunoassays.

**Electrophoresis** : Electrophoresis is the separation of charged compounds based on their electrical charge. Common support media for electrophoresis in clinical work include cellulose acetate, agarose and polyacrylamide gel. Once separation has occurred, the support medium is treated with dyes to stain and identify the separated fractions. To obtain a quantitative profile of the separated fractions, densitometry is performed on the stained support medium.

**Applications in public health** :

**Separation of serum proteins** : Patterns of hypoproteinemia in malnutrition or gross loss of protein show decreases in all fractions with dramatic reduction in albumin. Cirrhosis of the liver shows a specific pattern with severe reduction of albumin and increased immunoglobulins. The pattern in monoclonal gammopathies (multiple myeloma) is very characteristic and shows an M band due to high levels of paraprotein secreted by a monoclonal proliferation of plasma cells.

**Separation of hemoglobins** : This is important in the diagnosis of various abnormal hemoglobins like thalassemia, sickle cell anemia etc.

**Chromatography** : Chromatography is a separation method based on the different interaction methods of the specimen compounds with the mobile phase and with the stationary phase, as the compounds travel through a support medium. The compounds interacting more strongly with the stationary phase are retained longer in the medium than those that favor the mobile phase.

**Gas chromatography** : It is a procedure used for compounds which are naturally volatile or those which can be easily converted to a volatile form.

**Liquid chromatography** : It is used for compounds that are too unstable or insufficiently volatile for gas chromatography.

**Applications in public health** : Routinely, chromatography is used for determination of drugs and chemicals in body fluids (toxicology). Detection of additives / chemicals in food is possible through High performance liquid chromatography. Environmental and water pollutants can be detected with accuracy through the use of various chromatographic procedures.

**Automation in clinical chemistry** : Automated analyzers allow labs to process a large volume of tests quickly. This is possible through the increased speed of testing. The increase in test throughput is possible by automating many steps involved. Most automated chemistry analyzers, photometric methods of analysis such as colorimetry, spectrophotometry or nephelometry etc. calculations, calibration curves and quality control are performed by the computers, thus reducing errors

and providing more accurate results. The testing pathway in an analyser may be

- Sequential testing- Multiple tests analysed one after another on a single specimen.
- Batch testing- All samples are loaded at the same time and a single test is conducted on each sample.
- Parallel testing- More than one test is analysed concurrently on a given clinical specimen.
- Random access testing- Any test can be performed on any sample in any sequence.

## Diagnostic Technologies in Hematology

**Automated Instruments** : These instruments have many different components to analyze different elements in the blood. The cell counting components count the numbers and types of different cells within the blood. The results are printed out or sent to a computer for review. Blood counting machines aspirate a very small amount of the specimen through narrow tubing. Within this tubing, there are sensors that count the number of cells going through it and can identify the type of cell; this is flow cytometry. The two main sensors used are light detectors and electrical impedance. One way the instrument can tell what type of blood cell is present is by size. Other instruments measure different characteristics of the cells to categorize them. Because an automated cell counter samples and counts so many cells, the results are very precise. However, certain abnormal cells in the blood may be identified incorrectly and require manual review of the instrument's results and identify any abnormal cells the instrument could not categorize. In addition to counting, measuring and analyzing red blood cells, white blood cells and platelets, automated hematology analyzers also measure the amount of hemoglobin in the blood and within each red blood cell.

## Diagnostic Technologies in Cytopathology

**Exfoliative cytology** : The microscopic examination of cells that have been shed from a lesion or have been recovered from a tissue for the diagnosis of disease.

**Applications in public health**

**Cervical cytology** : Exfoliative cytology from the uterine cervix is valuable in picking up premalignant lesions of the cervix and goes a long way in early detection of cervical cancer. Cervical cytology has been perhaps the most successful cancer screening technique of the 20th century. Technology used may be conventional i.e. where the smear is taken on a glass slide directly by the sampling device which may be an Ayres spatula or an endocervical brush or it may be Liquid based where the cells are suspended in a liquid fixative and subsequently spread onto a glass slide by a centrifugation process. In general, it has an overall sensitivity of 80% and a specificity of 99.4% for cytologic screening for cervical cancer. The sensitivity was slightly lower for mild and moderate dysplasia (78.1%) and slightly higher for carcinoma in situ and severe dysplasia (81.4%) and invasive carcinoma (82.3%) [19].

**Fine Needle Aspiration Cytology** : Fine Needle Aspiration Cytology (FNAC) is a technique where a fine needle is introduced into a lesion and with aspiration from a syringe, cellular material is obtained which can be spread on to glass slide, stained and evaluated cytologically. It is a technique



which is applicable not only to superficial accessible lesions but also to deep seated lesions under imaging guidance. A needle aspiration biopsy is safer and less traumatic than an open surgical biopsy and significant complications are usually rare, depending on the body site. Common complications include bruising and soreness. There is a risk, because the biopsy is very small (only a few cells), that the problematic cells will be missed, resulting in a false negative result. There is also a risk that the cells taken do not enable a definitive diagnosis. The technique is suitable to evaluation of lesions/nodules arising from breast, lymph nodes, thyroid, liver, kidney and soft tissue. The sensitivity and specificity varies according to the organ involved and also depends on the aspiration of a representativeness of the sample.

### **Diagnostic Technologies in Histopathology**

Histopathology from the Greek *histos* (tissue) and *pathos* (suffering) refers to the microscopic examination of tissue in order to study the manifestations of disease. Specifically, in clinical medicine, histopathology refers to the examination of a biopsy or surgical specimen by a pathologist, after the specimen has been processed and histological sections have been placed onto glass slides. This is the most important tool of the anatomical pathologist in routine clinical diagnosis of cancer and other diseases. Histopathological examination of tissues starts with surgery, biopsy or autopsy. The tissue is removed from the body and then placed in a fixative which stabilizes the tissues to prevent autolysis. The samples are transferred to a cassette, a container designed to allow reagents to freely act on the tissue inside. This process is known as tissue processing. The processed tissue is then taken out of the cassette and set in a mold. Through this process of embedding, additional paraffin is added to create a paraffin block. The process of embedding then allows the sectioning of tissues into very thin (2 - 7 micrometer) sections using a microtome. The microtome slices the tissue ready for microscopic examination. The slices are thinner than the average cell and are layered on a glass slide for staining. To see the tissue under a microscope, the sections are stained with one or more pigments. The most commonly used stain in histopathology is a combination of hematoxylin and eosin.

**Applications in public health** : Histopathology is the gold standard of diagnosis in clinical medicine. It is eminently suited to diagnosis of diseases and conditions like malignancies and also some non neoplastic conditions like tuberculosis and other infections.

**Immunohistochemistry** : Immunohistochemistry or IHC refers to the process of localizing proteins in cells of a tissue section exploiting the principle of antibodies binding specifically to antigens in biological tissues. Immunohistochemical staining is widely used in the diagnosis of abnormal cells such as those found in cancerous tumors. IHC is also widely used in basic research to understand the distribution and localization of biomarkers and differentially expressed proteins in different parts of a biological tissue.

**Applications in public health** : Diagnosis of tumours/ non neoplastic conditions by histopathology occasionally is hampered by similar morphological appearances and hence

recognition of specific molecular markers by IHC like S100, Cytokeratin etc. helps in identifying the origin and hence the diagnosis of various tumours and conditions.

### **Radiological Techniques**

**X-ray** : X-radiation (composed of X-rays) is a form of electromagnetic radiation, used primarily used for diagnostic radiography and crystallography. As a result, the term “X-ray” is metonymically used to refer to a radiographic image produced using this method, in addition to the method itself. X rays are produced by accelerating electrons which collide with a metal target (Tungsten/Molybdenum). These short X-ray pulses are shot through a body with radiographic film behind. The bones absorb the most photons by the photoelectric process, because they are more electron-dense. The X-rays that do not get absorbed turn the photographic film from white to black, leaving a white shadow of bones on the film. This technique is useful not only in the detection of pathology of the skeletal system, but also for detecting some disease processes in soft tissue. Some notable examples are the very common chest X-ray, which can be used to identify lung diseases such as pneumonia, lung cancer or pulmonary edema and the abdominal X-ray, which can detect ileus (blockage of the intestine), free air (from visceral perforations) and free fluid (in ascites). However they have a very little use in the imaging of soft tissues such as the brain or muscle.

**Applications in public health** : Chest x ray was the backbone of National Tuberculosis Control Programme in 1962 and had been an important component of battle against Tuberculosis in our country. But unfortunately it did not meet the criteria of being “Appropriate Technology” being expensive, requiring infrastructure and trained professionals for reporting and was left out in formulating the components of DOTS. However it is included in the diagnostic algorithm of RNTCP where one sputum sample is positive/ three negative smears in a symptomatic patient. In occupational health the ILO criterion for diagnosis of pneumoconiosis uses findings of x ray chest only.

**DEXAScan** : DEXA Scan stands for Dual Energy X-Ray Absorptiometry. Two different types of X- ray scan the body and the images are subtracted by the computer giving a very accurate estimation of bone density/body fat. It is used to detect the presence of osteoporosis in men and women with particular risk factors, screen for osteoporosis, particularly in women making decisions about hormone replacement therapy at menopause, predict future fracture risk and monitor bone density in those with low normal levels and in those with osteoporosis. Dual energy X-ray absorptiometry or DXA (formerly DEXA), is a good method for estimating body fat percentage.

**Angiography** : It is the study of blood vessels with a contrast medium. It has a great role in study of coronaries to detect the status of these vessels and decide the treatment modality for the patient. With the epidemic of coronary artery disease in the country this investigation will go a long way in the final management of the patients.

**Digital Subtraction Angiography (DSA)** : In traditional angiography, we acquire images of blood vessels on films by

exposing the area of interest with time-controlled x-ray energy while injecting contrast medium into the blood vessels. The images thus obtained would also record other structure besides blood vessels as the x-ray beam passes through the body. In order to remove these distracting structures to see the vessels better, we need to acquire a mask images for subtraction. The mask image is simply an image of the same area without contrast administration. So, using manual darkroom technique, clear pictures of blood vessels are obtained by taking away the overlying background. In DSA, the images are acquired through digital format in computer. With the help of computer the images are subtracted automatically. As a result a near instantaneous film show of the blood vessel can be obtained.

**Mammography** : Mammography is the process of using low-dose X-rays, high contrast, high-resolution film and an X-ray system designed specifically for imaging the breasts to examine the human breast. The goal of mammography is the early detection of breast cancer, typically through detection of characteristic masses and/or micro calcifications. Mammography has been shown to reduce mortality from breast cancer.

**Ultrasound** : Medical sonography (ultrasonography) is an ultrasound-based diagnostic medical imaging technique used to visualize muscles, tendons and many internal organs, their size, structure and any pathological lesions. It is also used to visualize a fetus during routine and emergency prenatal care. Other uses include cardiac scan (echocardiography), renal, liver and gallbladder scans. It is also used for musculo-skeletal imaging of muscles, ligaments and tendons, ophthalmic ultrasound (eye) scans and superficial structures such as testicle, thyroid, salivary glands and lymph nodes. Because of the real time nature of ultrasound, it is often used to guide interventional procedures such as fine needle aspiration FNA or biopsy of masses for cytology or histology testing in the breast, thyroid, liver, kidney, lymph nodes, muscles and joints. Modifications of ultrasound include 3-D and 4-D ultrasonography for better visualization of the anatomy.

**Applications in Public Health** : This technique in antenatal cases is practiced to date the pregnancy (gestational age), confirm fetal viability, determine location of fetus, intrauterine vs ectopic, check the location of the placenta in relation to the cervix, check for the number of fetuses (multiple pregnancy), check for major physical abnormalities, assess fetal growth (for evidence of intrauterine growth restriction (IUGR), check for fetal movement and heartbeat and determine the sex of the baby. However it has been wrongly used extensively to find the sex of unborn child. This malpractice has altered the child sex ratio (0-6 yrs) of the nation to an abnormally low level of 819 in 2001 and 849 in 2008 and inhuman killing of unborn girl child. Ultrasound is also increasingly being used in trauma and first aid cases, with emergency ultrasound becoming a staple of most emergency response teams.

**CT scan** : CT scan works on the principle that cross sectional slices of the body are produced using X rays, followed by processing by the computers to study detailed anatomy of the specific location or slice. The modification of conventional CT is spiral where the X-ray tube/ detector combination rotates continuously around the patient creating a spiral and helps in generating high quality images.

**Magnetic Resonance Imaging** : Charged spinning particles such as protons behave like tiny bar magnets and are used to produce image of biological tissue in black and white depending upon the type of tissue and the specific imaging technique used. It does not use ionizing radiation hence is safe with no known biological hazards. It provides excellent tissue contrast with good spatial resolution. Images can be obtained in any plane (Multiplanar Imaging) and does not produce artifacts due to bone and is an ideal imaging modality for spine, posterior fossa and musculoskeletal system.

Applications of CT Scan and MRI in public health and clinical practice are shown in Tables - 4 and 5.

**Radionuclide scan** : A radionuclide scan is a way of imaging bones, organs and other parts of the body by using a small dose of a radioactive chemical. There are different types of radionuclide chemicals. The one used depends on which organ or part of the body is to be scanned. Radionuclide is put into the body, usually by a injection into a vein. Sometimes it is breathed in, or swallowed, depending on the test. Cells which are most 'active' in the target tissue or organ will take up more of the radionuclide. So, active parts of the tissue will emit more gamma rays than less active or inactive parts. The gamma rays which are emitted from inside the body are detected by the gamma camera, are converted into an electrical signal and sent to a computer. The computer builds a picture by converting the differing intensities of radioactivity emitted into different colours or shades of grey.

#### Public Health Importance

**Bone scan** : Used to detect areas of bone where there is cancer, infection or damage.

**Kidney scan** : Used to detect scars on the kidney and how well urine drains from the kidney to the bladder.

**Lung Perfusion Scan ('VQ scan')** : Detects pulmonary embolus.

**IPHS Standards for Provision of Radiological Techniques**: According to IPHS standards in NRHM radiological facilities which should be available at various levels are given in Table - 6.

#### Electrophysical Technologies

Despite existence of modern diagnostic imaging, biochemical and other techniques that enable detection of morphological and chemical changes within the body, there are also various functional disturbances sometimes detectable only via analysis of electric potentials produced by some organs (tissues) as a manifestation of their function (ECG, EEG, EMG, ERG, EOG and others). These methods can also be preferable in some cases because of their non-invasive character and economical efficiency.

Evaluation of these signals is performed either in the "time domain" (detection of particular specific peaks and wave complexes - "grapho-elements" - and description of their time and amplitude characteristics) or in the "frequency domain" (frequency spectrum characteristics). At present this is done almost exclusively with the use of computers. Since electrical activity analysis serves mainly for recognition of functional changes, pathophysiology deals with some of these signals

<b>Table - 4 : CT scan, its modifications and their use in public health</b>		
<b>Modality</b>	<b>Remarks</b>	<b>Public health field</b>
CT Angiography	Arteries and veins of any part of the body are visualized by giving a contrast medium.	Coronary Artery Disease Venous Thrombosis in smokers Diabetics
CT of Musculo-skeletal System	Musculoskeletal system is visualized and is used in detecting congenital anomalies and in trauma cases.	Trauma cases
CT Colonography	Thin CT sections of the abdomen are taken and is a useful tool over direct colonoscopy in detecting lesions specially in geriatric cases.	Geriatric field
CT Bronchoscopy	CT sections of the tracheobronchial tree are taken.	Smokers with lung cancer
Cardiac CT	Used as a marker of atherosclerosis and risk indicator for coronary event and coronary artery disease.	Coronary Artery Disease
Coronary Calcium scoring	Can be used to follow progression of Coronary atherosclerosis.	
CT Coronary angiography	Contrast medium is used to visualize the Coronary Artery Disease (CAD) to detect and study blockage.	
CT Perfusion of Brain	IV contrast is used to study Cerebral Blood Flow, Cerebral Blood Volume and Mean Transit time which can indicate presence of acute cerebral ischemia. It helps in early diagnosis of ischemic stroke.	Stroke

<b>Table - 5 : MRI : Clinical uses</b>	
<b>Technique</b>	<b>Remarks</b>
MR Angiography	Used for display of vascular anatomy
MR Spectroscopy	Used in diagnosis of disorders of central nervous system
Diffusion Weighted MR imaging	Used for diagnosing ischaemic injury
Perfusion weighted MR imaging	Evaluation of viable but ischaemic brain tissue in stroke, assessment of cerebral blood volume and in patients with brain tumors Alzheimer's disease
BOLD Imaging	Useful in seizure evaluation
Cardiac MRI	Its applications include evaluation of congenital heart diseases, acquired heart diseases like pericardial effusion, pericarditis and pericardial masses. Cardiac MRI can be used to evaluate the myocardium cardiomyopathy and to assess myocardial viability in coronary artery disease.

<b>Table - 6 : IPHS Standards : Suggested Availability of radiological techniques</b>	
<b>Level of hospital (No of beds)</b>	<b>Facilities available</b>
31-50	X-ray, Ultrasonography
51-100	X-ray, Ultrasonography, Colour Doppler, CT
101-200	X-ray, Ultrasonography, Colour Doppler, CT
201-300	X ray, OPG, HSG Ultrasonography Colour Doppler, Spiral CT scan, MRI 0.4 TESSLA
301-500	X-ray, Barium swallow, Barium meal, Barium enema, IVP, HSG, Dental X-ray, Ultrasonography, CT scan

(mainly with ECG, EEG) and instructs basic interpretation of some pathological findings.

**Electroencephalography** : This is the neurophysiologic measurement of the electrical activity of the brain by recording from electrodes placed on the scalp or in special cases, subdurally or in the cerebral cortex. The resulting traces are

known as an electroencephalogram (EEG) and represent an electrical signal (postsynaptic potentials) from a large number of neurons. In conventional scalp EEG, the recording is obtained by placing electrodes on the scalp, usually after preparing the scalp area by light abrasion and application of a conductive gel to reduce impedance. Each electrode is connected to an input of a differential amplifier, which amplifies the voltage between

them (typically 1,000-100,000 times). The resulting voltage signal is filtered which is shown on paper (in older systems), or displayed on a computer screen. It is widely used as a tool for monitoring and diagnosis in certain clinical situations :

- Epilepsy and syncope
- Sleep disorders
- Coma and brain death

**Electrocardiography** : An electrocardiogram (ECG or EKG, abbreviated from the German *Elektrokardiogramm*) is a noninvasive transthoracic graphic produced by an electrocardiograph, which records the electrical activity of the heart over time. Electrodes on different sides of the heart measure the activity of different parts of the heart muscle. An ECG displays the voltage between pairs of these electrodes and the muscle activity that they measure, from different directions, also understood as vectors. This display indicates the overall rhythm of the heart and weaknesses in different parts of the heart muscle.

**Applications in public health** : It is the best way to measure and diagnose abnormal rhythms of the heart, particularly abnormal rhythms caused by damage to the conductive tissue that carries electrical signals, or abnormal rhythms caused by levels of dissolved salts (electrolytes), such as potassium, that are too high or low. In myocardial infarction (MI), the ECG can identify damaged heart muscle.

**Electromyography** : Electromyography (EMG) is a technique for evaluating and recording the activation signal of muscles. EMG is performed using an instrument called an electromyograph, to produce a record called an electromyogram. An electromyograph detects the electrical potential generated by muscle cells when these cells contract and also when the cells are at rest. EMG is used to diagnose two general categories of disease : neuropathies and myopathies.

## Summary

IPHS prescribed various standards for the availability of laboratory facilities as per the bed status of Health care setting and are stated as a part of NRHM. The various modern diagnostic technologies can be classified into various categories like Immunopathology, Molecular Biology, Clinical Chemistry, Haematology, Cytopathology, Histopathology, Radiology and Electrophysiology.

The available Diagnostic Technologies in Immunopathology are Precipitation immunoassays (Widal test and the Weil-Felix test), Particle immunoassay (hemagglutination tests), Radioimmunoassay (ELISA) and Immunofluorescence assays.

Hemagglutination tests are used for diagnosis of Syphilis, hepatitis B and hepatitis C and Latex agglutination is widely used in measurement of hCG for qualitative pregnancy tests. ELISA can be used for diagnosing HIV and detecting tumour markers for certain cancers, e.g. Prostate specific antigen (PSA) in carcinoma prostate. Immunofluorescence assays have been extensively used for ZN staining in TB and in detecting antigens in tissue sections, e.g. kidney biopsies.

The available Diagnostic Technologies in Molecular Biology are Gel electrophoresis, Hybridisation assays, Amplification technology, PCR (Polymerase chain reaction) and Restriction

Fragment Length Polymorphism (RFLP) based assays. DNA Probes are available for various organisms like Mycobacterium tuberculosis, Chlamydia trachomatis, Neisseria gonorrhoeae, Human papilloma virus, Hepatitis C virus, Cytomegalovirus and Herpes simplex virus. This is especially important for slow growing organisms like Mycobacteria, fungi etc. DNA amplification is used for diagnosis of Hepatitis C Virus, HIV, TB, STDs and for Detection of antimicrobial resistance.

The available Diagnostic Technologies in Clinical Chemistry are Colorimetry, Nephelometry, Electrophoresis, Chromatography and Automation in clinical chemistry.

Colorimetry forms the basis of assessing almost all parameters in clinical chemistry. Nephelometry is useful in measurement of antigen antibody complexes formed in immunoassays. Electrophoresis is used for Separation of serum proteins and Separation of hemoglobins, which is important in the diagnosis of various abnormal hemoglobins like thalassemia, sickle cell anemia etc. Chromatography is used for determination of drugs and chemicals in body fluids (toxicology). Detection of additives / chemicals in food is possible through High performance liquid chromatography. Environmental and water pollutants can be detected with accuracy through the use of various chromatographic procedures.

The available Diagnostic Technologies in Hematology are Automated Instruments like the cell counting components, Blood counting machines, flow cytometry etc. In addition to counting, measuring and analyzing red blood cells, white blood cells and platelets, automated hematology analyzers also measure the amount of hemoglobin in the blood and within each red blood cell. The available Diagnostic Technologies in Cytopathology are Exfoliative cytology (used for cytologic screening for cervical cancer), Fine Needle Aspiration Cytology (used for evaluation of lesions/ nodules arising from breast, lymph nodes, thyroid, liver, kidney and soft tissue). The available Diagnostic technologies in Histopathology are Histopathological staining and Immunohistochemistry. Histopathology (the most commonly used stain in histopathology is a combination of hematoxylin and eosin) is used as gold standard of diagnosis in clinical medicine and it is eminently suited to diagnosis of diseases and conditions like malignancies and also some non neoplastic conditions like tuberculosis and other infections. Immunohistochemistry is used for diagnosis of tumours/ non neoplastic conditions by specific molecular markers like S100, Cytokeratin.

The available Radiological techniques are X-ray (e.g. for diagnosis of Chronic infections like TB), DEXA Scan (used for screening of osteoporosis, particularly in women), Angiography and Digital Subtraction Angiography(DSA) (mainly used for Cardiovascular diseases), Mammography (screening of Breast Ca), Ultrasound (e.g. Antenatal care), Radionuclide scan (used for Bone scan, Kidney scan, Lung Perfusion scan), CT scan and Magnetic Resonance Imaging (mainly used for Cardiovascular diseases).

The available Electrophysical Technologies are Electroencephalography, Electrocardiography and Electromyography. EEG is widely used as a tool for monitoring and diagnosis. Epilepsy and syncope, Sleep disorders, Coma and brain death.



ECG is widely used for diagnosis of Arrhythmias and CAD. EMG is used to diagnose neuropathies and myopathies.

## Study Exercises

**Short Notes :** (1) Applications of Radiological techniques in Public Health (2) Applications of Immunopathology techniques in Public Health (3) Applications of Hematological techniques in Public Health (4) Applications of Electrophysical techniques in Public Health.

### MCQs

- Which of the following is not a electrophysiological diagnostic technique : (a) EEG (b) EMG (c) DEXA SCAN (d) a & b.
- Which of the following is usually used as gold standard of diagnosis in clinical medicine (a) Histopathology (b) Electrophysiology (c) X-ray (d) Clinical Chemistry.

**Answers :** (1) c; (2) a.

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## Accreditation of Health Care Facilities

*Udai Bhaskar Misra*

External assessment of healthcare has attained an ever increasing dimension globally. There are various models of External Assessment like ISO certification, business excellence, peer review, statutory inspection and accreditation. Accreditation can be regarded as one of the most attractive form of tool for External Quality Assessment of healthcare organizations. The concept was started in USA and at present many countries world over are practising this model of External Quality assessment (1).

### Evolution of Accreditation

The inception of the process began with the development of Minimum Standards for Hospitals by American College of Surgeons in 1917. In 1951, the American College of Physicians, the American Hospital Association, the American Medical

Association and the Canadian Medical Association joined with the American College of Surgeons to create the Joint Commission on Accreditation of Hospitals (JCAH). The Canadian Medical association withdrew from the JCAH in 1959. In 1971, the JCAH established the Accreditation Council for Long-Term Care and subsequently Accreditation for ambulatory care began in 1975. In 1987, since the scope was further expanded, the name of the organization was changed to the Joint Commission on Accreditation of Healthcare Organizations (2). Accreditation for healthcare networks began in 1994 and JCAHO and Quality Healthcare Resources formed the Joint Commission International with the goal of serving hospitals in other countries. Joint Commission Resources now provides consultation worldwide on healthcare issues and Joint Commission International is the largest Accreditation organisation, concerned with global accreditation. Gradually, accreditation has become a national yardstick for healthcare organisations in many countries including Australia, UK and European Countries. In developing countries, though, some beginning has been made but it is still in infancy.

## Definition

Accreditation may be defined as a formal process by which a recognized body, usually a non-governmental organization (NGO), assesses and recognizes that a healthcare organization meets pre-determined standards. It can also be defined as a system of external peer review of an organization for determining compliance against predetermined standards, usually as a voluntary process.

Accreditation standards are usually regarded as optimal and achievable and are designed to encourage continuous improvement in delivery of healthcare within accredited organizations. An accreditation decision about a specific healthcare organization is made following a periodic on-site evaluation by a team of peer reviewers, typically conducted every two to three years. It is usually a voluntary process in which organizations choose to participate, rather than one required by law and regulation. Accreditation has following principal components :

- (a) It is based on written and published standards.
- (b) Reviews are conducted by professional peers.
- (c) The accreditation process is administered by an independent body.
- (d) The aim of accreditation is to encourage organisational development.
- (e) It is usually a voluntary process.

The effectiveness of accreditation is dependent on its voluntary nature, non-threatening process and interaction with external reviewers as a means of attaining desired quality improvements. Accreditation programmes, if undertaken with careful planning, strong government support and organizational commitment have the potential to improve the quality of care available in hospitals and medical laboratories in many developing countries.

## Purpose

Purpose of Accreditation is to :

- (a) Improve the quality of healthcare by establishing optimal achievement goals in meeting standards for healthcare organizations.
- (b) Stimulate and improve the integration and management of health services.
- (c) Establish a comparative database of healthcare organizations able to meet selected structure, process and outcome standards or criteria.
- (d) Reduce healthcare costs by focusing on increased efficiency and effectiveness of services.
- (e) Provide education and consultation to healthcare organizations, managers and health professionals on quality improvement strategies and “best practices” in healthcare.
- (f) Strengthen the public's confidence in the quality of healthcare and reduce risks associated with injury and infections for patients and staff.
- (g) Accountability to professional bodies.

## Accreditation Procedure

There are many recognized bodies providing Accreditation to Healthcare Institutions. These have diverse policies and procedures (3, 4). However, the common elements in a typical

Accreditation procedure are as under :

(a) Setting and publication of standards and elements of performance by a recognized body :

**(i) Standard** : A Standard is a Statement that defines the performance expectations and /or structure or processes that must be in place in order for an organization to provide safe, high quality care, treatment and services.

**(ii) Elements of performance** : The specific performance expectations and /or structures or processes that must be in place in order for an organization to provide safe, high-quality care, treatment and services.

**(iii) Rationale** : Some of the accrediting bodies have also included rationale for having standards in their document. Rationale is a statement that provides background, justification or additional information about a standard.

- (b) Application for registration by the healthcare institution.
- (c) Payment of fees.
- (d) Pre-survey activities.
- (e) Survey by the multidisciplinary team of Accreditation Body.
- (f) Resurvey, if the Institution is found deficient in certain areas of delivery of care.
- (g) Accreditation report and award of Accreditation.
- (h) Resurvey after a fixed period.

Health care accrediting bodies use a variety of evaluation approaches during the on-site survey in order to determine the healthcare organization's performance with predetermined standards. These methods include any combination of the following (5) :

- (a) Interviews of the top level Administrators or the Managers of the organization
- (b) Clinical and support staff interviews.
- (c) Patient and family interviews.
- (d) Observation of patient care and services provided.
- (e) Tour of the building facilities, observation of patient care areas, equipment management and diagnostic testing services.
- (f) Review of written documents such as policies and procedures, training documents, financial documents and quality assurance plans.
- (g) Evaluation of the organization's achievement of specific outcome measures (e.g. Immunization rates, hospital-acquired infection rates, patient satisfaction).
- (h) Evaluation of patients' medical records.

## Advantages of Accreditation

Although this area requires more research but many studies have indicated the advantages of Accreditation to the hospitals, staff and the patients. It forms an essential basis for Quality Assurance Programme in a healthcare organization (6, 7). The advantages of accreditation can be grouped as under :

### Benefits to the Hospital

- (a) It Improves delivery of medical care and enhances the image of the hospital. Thus, for private healthcare organizations it also results in more business.
- (b) It stimulates a process of continuous improvement in delivery of medical care.

### Benefits for the employees

- (a) It helps in education, training and development of professional staff.
- (b) Provides leadership for quality improvement within medical profession and nursing.
- (c) Increases satisfaction of employees with working conditions and leadership.
- (d) It aims for improved employee safety and security.
- (e) It promotes team work.

### Benefits for Patients

- (a) Provides access to organizations providing quality medical care.
- (b) Patient's rights are respected and protected.
- (c) It increases patient's Involvement in medical care decisions.
- (d) Focuses on patient safety.

### Review of Accreditation Systems in selected countries

The discussion on accreditation will not be completed without a review of status in selected countries, the same is appended below :

**Accreditation System in USA :** There are a number of organizations in US performing the function of accreditation of healthcare institutions as given below (8) :

- (a) The Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
- (b) The National Committee for Quality Assurance (NCQA).
- (c) The American Medical Accreditation Program (AMAP).
- (d) The American Accreditation Health Care Commission / Utilization Review Accreditation Commission (AAHC/URAC).
- (e) Accreditation Association for Ambulatory Health Care (AAAHC).

JCAHO is the largest and oldest accrediting body of USA. It is an independent, non government and not-for-profit organization. It has provided accreditation to more than 20,000 healthcare organizations both in US and outside. It has a board of Commissioners including 28 members. The constitution of the board includes :

- (a) Administrators, Physicians, Medical directors and Nurses
- (b) Consumers
- (c) Providers of care
- (d) Employers, Human Resource and quality expert
- (e) Health Insurance expert and expert in Ethics
- (f) Corporate and Public Members.

The Corporate members include American College of Surgeons, the American College of Physicians, the American Dental Association, the American Hospital Association and the American Medical Association. JCAHO hospital standards can be grouped as under :

**(a) Patient focused functions :** These include standards on following :

- (i) Ethics, Rights and Responsibilities
- (ii) Provision of care, treatment and services
- (iii) Medication management
- (iv) Surveillance, Prevention and Control of Infection

**(b) Organisational functions :** Standards pertaining to following aspects are included in this section :

- (i) Improving organization performance
- (ii) Leadership
- (iii) Management of the environment of care
- (iv) Management of human resources
- (v) Management of Information

**(c) Structures with functions :** This section includes standards on following aspects :

- (i) Medical Staff
- (ii) Nursing

In 1997 Joint Commission initiated first step in establishing a link between accreditation and the outcomes of patient care, treatment and service issues using an ORYX tool. In order to apply this tool, initial core measure focus conditions for patient in a given location are identified in consultation with various professional bodies and field assessment. Subsequently, accredited hospitals choose 3 core measures out of the list earlier decided for example Acute Myocardial Infarction, Pneumonia and Heart failure.

During on site survey, the Joint Commission team assesses performance improvement in conditions related to selected core measures with the help of data from the hospital. ORYX Plus is a voluntary option, the requirements of which far exceeds those of ORYX. It is used by organizations that intend to contribute to a national database. The JCAHO expects home health agencies to establish their own performance measures, which gives these organizations the freedom to develop their own quality assurance programs and outcome measures (9).

**Accreditation system in Australia (10, 11) :** The Australian Council on Healthcare Standards (ACHS) is an institutional accreditation body established in 1974. At present Ninety percent of the country's healthcare organisations are its members. ACHS conducts a voluntary program of health facility accreditation modeled along the lines of the Joint Commission. To increase clinician involvement in the accreditation process, also in quality assurance programs and to enable some assessment of the outcome of care in a facility at the time of survey, the ACHS, together with the medical colleges, is developing objective measures of care (clinical indicators).

Ten medical colleges were incorporated in developing the clinical indicators. The first set of measures, the Hospital-Wide Medical Indicators (HWMIs) developed in conjunction with the Royal Australian College of Medical Administrators, was formally introduced into the accreditation process in January 1993. These indicators were developed by a combined working party of the Care Evaluation Program and the Royal Australian College of Medical Administrators. The HWMIs address the areas of trauma, postoperative pulmonary embolism, readmissions to hospital, returns to the operating room, hospital-acquired infection, medication errors, etc. Development of objective measures of care (clinical indicators) will facilitate the accreditation process. It will also enable Australian physicians to compare patient care throughout the healthcare system.

**Accreditation system in UK (12) :** The royal commission on the NHS recommended in 1979 that a special health authority be set up to develop and institutionalise standards for healthcare



organizations. In the early 1980s several monitoring agencies were suggested but, despite favourable response from national professional bodies, no such national agency featured in the government's white paper of 1989 "Working for Patients". In the absence of any governmental lead, several small and large peer review accreditation programmes emerged as external voluntary mechanisms for organisational development. There are now more than 35 such programmes equipped with standards and trained assessors. However, integration and consistency between these programmes are lacking.

NHS institutions also have their visits from clinical training programmes, inspectors (such as for fire regulations, environmental health, etc). In addition the NHS Information Authority and Information Management Centre for data quality, Controls Assurance for risk management. The Clinical Standard Board for Scotland, the National Institute for Clinical Excellence (NICE) and Commission for Health Improvement (CHI) for England and Wales have been established to improve standards in the NHS. At present the requirement is to provide public access to the valid standards, reliable assessment and fair judgment. The NHS system also suffers from duplication and inconsistency.

### Accreditation System in India

**Accreditation Boards under Quality Council of India (QCI) :** QCI is an autonomous body set up jointly by Government of India and Industry to establish and operate accreditation structure in the country. Initially it started with product certification and inspection under ISO 9001 series. Subsequently QCI developed standards for accreditation of laboratories and the Hospital as different boards. The same are discussed below.

**National Accreditation Board for Testing and Calibration Laboratories (NABL) :** National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the aegis of Department of Science & Technology, Government of India and is registered under the Societies Act. Government of India has authorised NABL as the sole accreditation body for Testing and Calibration laboratories.

NABL provides laboratory accreditation services to laboratories that are performing tests / calibrations in accordance with ISO/IEC 17025 : 1999 General Requirements for the Competence of Testing and Calibration Laboratories. These services are offered in a non-discriminatory manner and are accessible to all testing and calibration laboratories in India and abroad, regardless of their ownership, legal status, size and degree of independence.

**Scope and duration :** NABL Accreditation is currently given for Testing Laboratories like Electronics, Calibration Laboratories like Optical and Radiological, Clinical Laboratories and Forensic Laboratories. The accreditation granted to a laboratory is valid for a period of 3 years subject to satisfactory annual surveillance.

**National Accreditation Board for Hospitals and Healthcare providers (NABH) :** NABH is a constituent board of QCI set up with cooperation of the Ministry of Health and Family Welfare, Government of India and the health Industry. However, the Board has complete autonomy in its operation. NABH is a member of International Society for Quality in healthcare

(ISQua). The Technical Committee of NABH had formulated first edition of standards for hospitals in 2005 which have been revised and in November 2007 second edition of standards have been published.

**Standards of NABH :** There are 10 chapters in NABH document including 100 standards. The standards can be classified as :

**(a) Patient Centered standards :** These include :

- (i) Access, Assessment and Continuity of Care
- (ii) Care of patients
- (iii) Management of medication
- (iv) Patient Rights and Education
- (v) Hospital Infection Control

**(b) Organisation Centered Standards :** These include :

- (i) Continuous Quality Improvement
- (ii) Responsibilities of Management
- (iii) Facility Management and Safety
- (iv) Human Resource Management
- (v) Information management System

Each standard is further divided into variable number of objective elements. There are 515 objective elements for accomplishment of 100 standards. Objective elements frame the guidelines for achieving a particular standard.

**Indian Confederation for Healthcare Accreditation (ICHA):**

ICHA is a body of national associations / institutions in healthcare sector. The basic objective of ICHA is to establish a mechanism of comprehensive healthcare accreditation system. It is an autonomous not-for-profit but self sustaining organisation driven by healthcare professionals. In August 2002 ICHA was constituted with the members from major healthcare associations of the country like the National Associations of Physicians (API), Surgeons (ASI), Anaesthetists (ISA), Ophthalmologists (AIOS), Pharmacists (IPA), Hospital administrators (AHA) and Hospital Pharmacists (IHPA). At present there are about 25 National Associations as members, 4 affiliate associations, 12 Individual organisational affiliates and 179 individual affiliates. The basic methodology of ICHA in granting accreditation is similar to NABH, however, the system is not as comprehensive and popular as NABH. .

### Future Challenges

**Competitive rivalry amongst the healthcare organizations:**

Accreditation is an important method for Healthcare Organizations to distinguish themselves amongst their competitors in India. This will promote competitive rivalry amongst Healthcare Organisations, to obtain Accreditation. It is intimated that about 20 Hospitals have already applied for Accreditation to NABH and 40 more are preparing for it in India (16). After obtaining Accreditation, our Healthcare Organisations will become tough competitors to International Hospitals as they will be delivering quality care at much lower cost compared to other countries.

However, considering the giant size of healthcare sector in our country, it is suggested that the development of infrastructure of Accreditation Agencies like NABH should keep pace with the number of Healthcare Organizations applying for accreditation; otherwise the process may continue more than a decade before the healthcare organizations are accredited. This will require



meticulous planning for trained assessors to undertake the survey.

**Technological Boom** : There will be increasing acquisition of high cost and advanced technology to over ensure the implementation of accreditation standards and to satisfy competitive rivalry amongst healthcare organisations. This will result into technological boom and haphazard mushrooming of equipment Industries. Such trends may lead to a requirement of accreditation of equipment agencies / OEM providing medical technology. Accreditation agencies like JCAHO are not only concerned with the proper technology but also whether the use information with regards to the equipment has been transferred to the ultimate users. Thus it is imperative on our part to work out some regulatory mechanism so that quality equipment is provided to users with assured after sale maintenance. Accreditation of equipment agencies will discourage mushrooming of substandard technology and facilitate the implementation of technology related standards of Accreditation for healthcare organizations.

**Promotion of medical tourism** : Many countries are already suffering with sky rocketing cost of care and long waiting line for definitive care. India has about 20 million individuals living abroad as NRIs or otherwise. They function as best of marketing ambassadors of medical care for brand India when they return to the Nation they are settled, after spending their leave back home. This is one of the major factors which have led to the promotion of Medical Tourism. The phenomenon can be further supported if our hospitals are accredited by a comprehensive Accreditation System and regulation of Tourism Industry. In some countries Medical Tourism is having an economic impact and similar predictions are made for our country in McKinsey Report submitted by the commission engaged for Study on Health care under the aegis of Confederation of Indian industry. Countries like USA are in an advantageous position for health tourism as about Ninety six percent of the hospital beds are in accredited hospitals. However, the cost of treatment in US is inhibitory for patients which is a definite advantage with Indian hospitals.

**Accreditation of miscellaneous healthcare organisations other than hospitals and part-facilities** : It is evident that the “first takers” for the Accreditation will be the Corporate Hospitals for the obvious reasons. Subsequently, other facilities like Ambulatory Care Centers, Nursing Homes and Clinics may come forward for obtaining Accreditation. Thus in the subsequent phase the Accreditation body should be ready with standards which are applicable to variety of healthcare organizations. However, Indian Accrediting bodies are not ready with the standards for various healthcare organizations. A workable solution could be to evolve the standards in the form of modules which are applicable to different organizations with addition / deletion of certain items.

**Accreditation of disease specific care** : Once the process of Accreditation is established in India, the Disease Specific Accreditation may be developed. The common diseases like Diabetes, Hypertension, Tuberculosis, COPD and IHD may be identified which cover about 80 to 90% population. The willing organisations which may not afford for Comprehensive

Accreditation may be considered for Disease Specific Accreditation Programme. JCAHO has already started with Disease Specific Accreditation in 2002. However, it may have both positive and negative aspects. For example the organisations may obtain Accreditation for limited number of diseases but this transparency may not be maintained during marketing campaigns. Thus it needs further deliberation and formulation of policies accordingly (4).

**Accreditation of Clinical Care** : Once the Accreditation process is well firmed up in India, a possible ramification of the process to introduce the Clinical Accreditation programme may be initiated in collaboration with apex Medical Institutions / experts. Initially, particular aspect of care for example Acute Care may be chosen for programme and gradually it may be extended. Australian Council of Healthcare Standards has already started an Accreditation Programme for Acute Care by identifying about 200 Indicators which are utilised to monitor the clinical services. The growth of this programme has been overwhelming and many nations have joined this programme. Such programmes can be beneficial in improving the clinical processes and the outcome aspect of care.

**Accreditation of healthcare organisations providing alternative care** : A large amount of Indian population is seeking healthcare from healthcare providers dealing in alternative medicine. With increasing awareness of clients, these healthcare organizations may also like to apply for Accreditation. This may involve further efforts at the part of Accreditation Providing Agencies in the form of formulation of policies, designing different set of Standards and other resources. In developed countries there are many agencies providing accreditation for alternative systems of medicine for example Royal College of Alternative Medicine UK, British Medical Acupuncture Society, The American Alternative Medicine Association and so on.

**Accreditation of Public sector healthcare organization** : It is contemplated that the Public Sector Healthcare organizations may be the last one to seek the Accreditation. However, with increasing awareness of clientele about the Accreditation of Healthcare organizations in Corporate Sector, the client pressure will compel the Public Sector Organisations to seek the accreditation. It is suggested that our ultimate goal should be to ensure reasonable standard of care at the grass root level by accreditation of Primary Health Care Centers through involvement of Central and State Governments.

**Increasing empanelment of accredited organisations by Insurance agencies** : It is evident that there will be rising trend for Insurance agencies to empanel the hospitals which are accredited. Insurance companies may use accreditation as a tool to decide which healthcare organisations to reimburse.

**Cost Escalation** : There may be miscellaneous reasons for escalation of the cost for healthcare during the process of accreditation. It is documented that the cost of accreditation by NABH is about one tenth of Joint Commission International (JCI). The cost of Accreditation process for a 500 bedded hospital is about 7 lakh. However, additional cost will be incurred in implementing the structure, process and outcome in accordance with NABH standards and then maintaining it. The question is

who will bear this cost ? Most likely this cost may be shifted to the patients. Secondly, the increase in paying capacity can also lead to rise in cost. The influx of foreign patients has already resulted in cost escalation in some of the areas of our country.

**Care of unaffordable class :** Accreditation of healthcare organisations does not provide an answer for the medical care of unaffordable class. If the accreditation process is not monitored / regulated in a disciplined way it may result in escalation of cost of care which will further hurt the poor class. There is a need for Government intervention in this regard to formulate adequate policies. The feasibility for cross subsidisation of the medical care of the poor class from the revenue earned by accredited hospitals through Medical Tourism should be worked out.

**Medical trade :** With growing recognition of Indian Hospitals having an accreditation tag and influx of foreign nationals for healthcare, doors of miscellaneous trade ventures will be opened. Sooner or later there will be involvement of third party between the patient and the hospital. Such agencies may offer different types of packages, starting from identification of a hospital to provision of transport and other administrative and logistics aspects including the hospice services if required at any point of time. It will be very essential to regulate such trade so that the image of our healthcare sector is not tarnished in the eyes of the other Nations.

To conclude, Accreditation is an International phenomenon. It is catching up in India in the right time as many countries are looking for alternative destinations to their healthcare organisations either due to cost escalation or due to a long waiting line for the procedures. However, it should be designed, regulated and monitored properly.

It is suggested that design of standards should be such so as to provide high inter assessor reliability and validity. Standards which are low on inter-assessor reliability should be revised or discarded. Similarly, assessing which factors contribute to inter-rater reliability and understanding how attitudes and behaviours of surveyors contribute to an effective system will influence the choice and training of surveyors.

While many claims are made about the benefits of accreditation processes, empirical evidence to sustain many such claims is currently lacking. Researching the impact of accreditation on individual and organisational performance is an important undertaking. The question arises as to how best to research the validity, impact and value of accreditation processes in healthcare. In countries where most healthcare organisations participate in some sort of accreditation process it may not be possible to study its merits using a randomised controlled strategy.

However, In India it is the right time for such research. As the sample will be available for a randomized controlled trials from the hospitals which are accredited and those without accreditation. Thus, research studies are necessarily required in India to discover the overall impact of Accreditation.

## Summary

Accreditation can be regarded as one of the most attractive form of tool for External Quality Assessment of healthcare

organizations. Accreditation for healthcare networks began in 1994 and JCAHO and Quality Healthcare Resources formed the Joint Commission International with the goal of serving hospitals in other countries. Joint Commission Resources now provides consultation by Joint Commission worldwide on healthcare issues and Joint Commission International is the largest Accreditation body, concerned with global accreditation. One of the chief purposes of Accreditation is to Improve the quality of healthcare by establishing optimal achievement goals in meeting standards for healthcare organizations. Health care accrediting bodies use a variety of evaluation approaches during the on-site survey in order to determine the healthcare organization's performance with predetermined standards.

The advantages of accreditation can be grouped as benefits to the Hospital, which include improvement of delivery of medical care, benefits for the employees in providing education, training and development of professional staff and benefits for Patients which include provision of access to organizations providing quality medical care. There are a number of organizations in US performing the function of accreditation of healthcare institutions. JCAHO is the largest and oldest accrediting body of USA. It has provided accreditation to more than 20,000 healthcare organizations both in US and outside. It has a board of Commissioners including 28 members. JCAHO hospital standards can be grouped as Patient- focused functions and Organisational functions. The Australian Council on Healthcare Standards (ACHS) is an institutional accreditation body established in 1974. At present Ninety percent of the country's healthcare organisations are its members. The first set of measures, the Hospital-Wide Medical Indicators (HWMIs) developed in conjunction with the Royal Australian College of Medical Administrators, was formally introduced into the accreditation process in January 1993.

The royal commission on the NHS recommended in 1979 that a special health authority be set up to develop and institutionalize standards for healthcare organizations. There are now more than 35 such programmes equipped with standards and trained assessors. The Clinical Standard Board for Scotland, the National Institute for Clinical Excellence (NICE) and Commission for Health Improvement (CHI) for England and Wales have been established to improve standards in the NHS.

QCI is an autonomous body set up jointly by Government of India and Industry to establish and operate accreditation structure in the country. National Accreditation Board for Testing and Calibration Laboratories (NABL) provides laboratory accreditation services to laboratories that are performing tests/ calibrations in accordance with ISO/ IEC 17025. Indian Confederation for Healthcare Accreditation (ICHA) : ICHA is a body of national associations / institutions in healthcare sector. The basic methodology of ICHA in granting accreditation is similar to NABH. It is imperative on our part to work out some regulatory mechanism so that quality equipment is provided to users with assured after sale maintenance. In some countries Medical Tourism is having an economic impact and similar predictions are made for our country. A workable solution could be to evolve the standards in the form of modules which are applicable to different organizations with addition / deletion of certain items.

Once the Accreditation process is well firmed up in India, a possible ramification of the process to introduce the Clinical Accreditation programme may be initiated in collaboration with apex Medical Institutions / experts. With increasing awareness of clients, alternative medicine healthcare organizations may also like to apply for Accreditation. It is contemplated that the Public Sector Healthcare organizations may be the last one to seek the Accreditation.

There are miscellaneous reasons for escalation of the cost for healthcare during the process of accreditation. The feasibility for cross subsidisation of the medical care of the poor class from the revenue earned by accredited hospitals through Medical Tourism should be worked out.

With growing recognition of Indian Hospitals having an accreditation tag and influx of foreign nationals for healthcare, doors of miscellaneous trade ventures will be opened.

Accreditation is an International phenomenon. It is catching up in India in the right time as many countries are looking for alternative destinations to their healthcare organisations either due to cost escalation or due to a long waiting line for the procedures. However, it should be designed, regulated and monitored properly.

## Study Exercises

### MCQs

1. The concept of accreditation was started in which country? (a) USA (b) UK (c) Germany (d) France.
2. A Statement that defines the performance expectations and /or structure or processes that must be in place in order for an organization to provide safe, high quality care, treatment and services, is known as (a) Rationale (b) Element of performance (c) Vision (d) Standard.
3. The largest and oldest accrediting body of USA is (a) Accreditation Association for Ambulatory HealthCare (AAAHC) (b) American Medical Accreditation Program (AMAP) (c) National Committee for Quality Assurance (NCQA) (d) Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

4. The autonomous body set up jointly by Government of India and Industry to establish and operate accreditation structure in the country is (a) Bureau of Indian Standards (BIS) (b) Quality Council of India (QCI) (c) National Accreditation Authority (NAA) (d) Indian Confederation for Healthcare Accreditation (ICHA).
5. The cost of Accreditation process for a 500 bedded hospital is about (a) Rs. 10 Lakhs (b) Rs. 05 Lakhs (c) Rs. 07 Lakhs (d) Rs. 01 Lakh.

**Answers :** (1) a; (2) d; (3) d; (4) b; (5) c.

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## Further Suggested Reading

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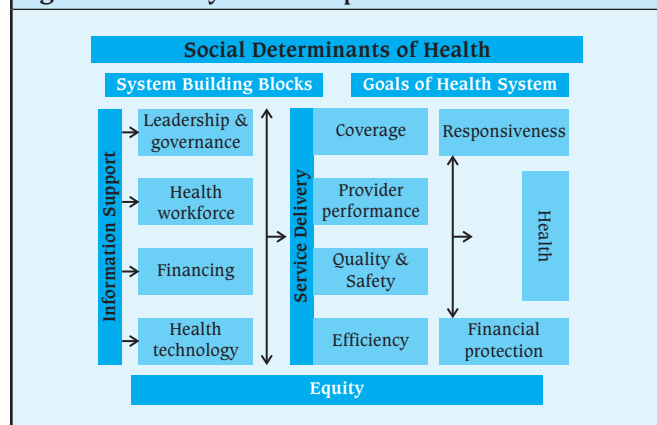
## 81 Health Care Financing

*Sunil Nandraj, N Devadasan, Alaka Singh*

Every health system has the responsibility not just to improve the health of the population, but also to protect them against the financial cost of illness and to treat them with dignity. The way a health system is financed is a key determinant of population health and well-being. In many of the poorest countries, the level of spending is still insufficient to ensure equitable access to basic and essential health services and interventions and therefore a major policy issue is how to ensure adequate and equitable resource mobilization for health. There is no single answer to the question of how to finance health systems. Not only do the specific challenges faced by countries differ, each country already has a system of health financing that has developed over a period of time.

Health policy and financing policy are inseparable because financing policy determines who has access to basic health care, how much is available, who controls the funds and how they are used; the technical, allocative and distributive efficiency of resource in use, social protection, what financial incentives are given to patients and providers and whether health care cost inflation can be controlled. Fig. - 1 shows conceptual framework of Health System.

**Fig. - 1: Health System conceptual framework**



Spending on health has been increasing world-wide. While cost-effective responses to preventable and communicable morbidity and mortality, there is a growing challenge from high-cost non-communicable and 'new' diseases. Advances in medical technology, higher population and providers' expectations, income growth, health system development are some determinants. Increased inequalities in health spending between and within countries. Health care financing is at the center of most health policy reforms. New medicines and other technological developments, rising expectations and aging populations fuel increased demand and hence put upward pressure on system costs. Concurrently, macroeconomic, demographic and fiscal constraints limit the extent to which governments can simply allocate more public revenues for health. The combination of upward pressure on costs and

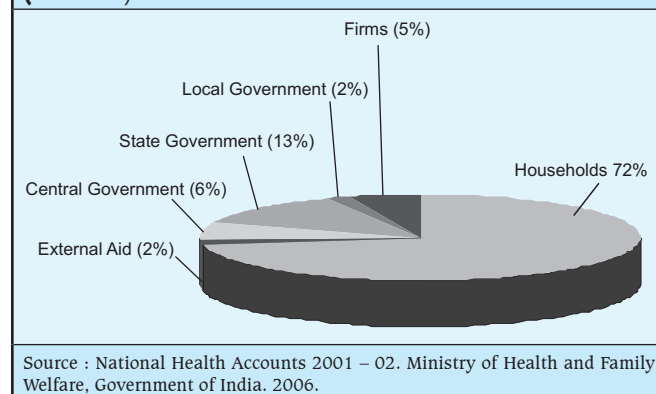
limitations on the ability of governments to increase spending forces countries to consider reforms to the way that their health systems are financed.

### Financing of Health Care in India

The current scenario in the health sector is plagued by high maternal and child mortality, dual burden of communicable & non-communicable diseases, poor health of majority, especially the poor. Inability of a large section of the population, especially from lower income to access good health care with spiraling health costs. Hospitalization for major illness is a cause of indebtedness for all income groups, especially those from the lower income. There is an increasing demand for health care services. The government is functioning under a resource crunch coupled with states facing financial crisis and unable to meet recurring expenditure of the health sector.

Like all countries in the world, India too faces difficult challenges and choices in financing its health systems. India has a mixed form of financing health care. The government is supposed to provide 'free' health care for all the citizens by raising funds from taxes. Unfortunately, the government's revenue is low, resulting in a small proportion being allocated for health care. Because of this chronic under funding, most government facilities are not able to provide health care to all its citizens. So, many patients go to the private sector institutions and pay for their health care which accounts for 72 percent from households (Chart 1). Thus, the Indian health service is financed by both tax based revenues and by out of pocket payments (OOP). Health insurance plays a very small part in financing health services in India. The total health expenditure in India for the year 2001-02 was Rs 1,057,341 million, which accounted for 4.6 percent of its GDP. Of the total expenditure, 20.3 percent was public / government expenditure, 77.4 percent was private expenditure and remaining 2.3 percent external support. (Table1) Over all, the per capita health expenditure for the year was Rs 1021 (about US\$ 25). Compare, this with amounts spent by high income countries (US\$ 3000 – 5,000).

**Chart - 1 : Health Expenditure by Financing Sources (2001-02)**



### Health Care Functions and Mechanisms

A health system has many actors and many functions. One of this is to finance health care. There are three basic functions of a health financing system :



**Revenue collection** : Financial contributions to the health system have to be collected equitably and efficiently;

**Pooling** : Contributions are pooled so that the costs of health care are shared by all and not borne by individuals at the time they fall ill. This requires a certain level of solidarity in the society.

**Purchasing** : The contributions are used to buy or provide appropriate and effective health interventions.

<b>Table - 1 : Health Care Expenditure in India (2001-02)</b>		
<b>Source of Funds</b>	<b>Exp. in Rs 000s</b>	<b>% Distribution</b>
<b>(a) Public funds</b>		
Central Government	67,198,262	6.3
State Government	132,709,065	12.5
Urban Local Bodies & PRI #	18,042,955	1.7
Total (a)	217,950,282	20.5
<b>(b) Private funds</b>		
Households	764,840,500	71.9
Firms \$	55,460,000	5.2
NGOs and Indian Funding Agencies	NA	
Total (b)	820,300,500	77.2
<b>(c) External Aid</b>		
Aid to Central Government (MOHFW Budget)	16,483,158	1.6
Material Aid to Central Government (MOHFW Budget)	825,937	0.1
Aid to State Government (State Budgets)	2,389,555	0.2
To NGOs	5,161,353	0.5
Total (c)	24,860,003	2.3
Total funds	1,063,110,785	100
# from National Commission on Macroeconomics and Health (2005); NA : not available		
Source : National Health Accounts 2001 – 02. Ministry of Health and Family Welfare, Government of India. 2006.		

Ideally a financing system should be able to generate revenue, pool the funds so that there is cross-subsidy between the rich and the poor and also between the healthy and the sick. Finally, the financing system should be able to purchase appropriate and efficient health care services from the provider on behalf of the patient. A health care financing is assessed on feasibility, equity, efficiency and sustainability.

Broadly, there are various options and mechanisms for financing the health care services :

- Out of Pocket Payment
- General Tax Revenue
- Insurance : Social Health Insurance; Private Health Insurance; Community Based Health Insurance
- External Finance

- Provider Payment

### **Out of Pocket Payments (OOP)**

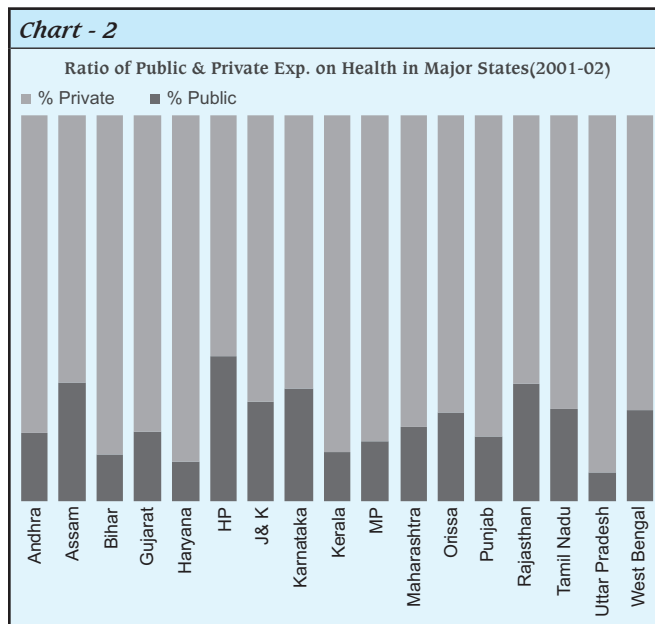
This is the simplest form of health care financing i.e. a patient goes to a provider and pays for the services received. In India, this is commonly followed when a patient visits a private practitioner. User fees paid in government hospitals are an example of “out of pocket payments”. In India, this is the most common form of financing health care. While the revenue collection function may be good, the pooling and purchasing mechanism is negligible. Individual patients have very little negotiation power and information to purchase effective and appropriate care.

The main financier of health services in India is the individual household. They meet 72% of the total health care costs by paying out of pocket at the time of service. Thus patients go to dispensaries, clinics and hospitals and receive health care. In turn they pay money for this health care from their own funds. Indian households have one of the least protection in terms of OOP payments. In most high income countries, only about 5-10% of households have to pay OOP payments and these are usually in the form of pre/co-payments to contributory financial protection schemes e.g. social health insurance. In middle income and low income countries, the proportion increases to about 25-50% of households. OOP have two adverse consequences, they lower access to health care by creating financing barriers. Some people hesitate to go to hospitals or dispensaries as they may not be able to afford the fees. NSSO studies have shown that 18% of households do not access even OP care, mainly because of financial barriers. Secondly, they impoverish the households because of high medical costs. Studies have shown that at least 40% of Indian households have had to borrow or to sell their assets to pay hospital bills. A quarter of hospitalised patients in India have been impoverished because of high medical costs. (NSSO 60th Round : Morbidity, Health care and condition of the aged). Further, it is seen from Chart - 2 that there are wide variations of ratio of public to private expenditure across the major states in India.

### **General Tax Revenue**

Governments collect revenue through taxes, both direct and indirect. This revenue is allocated to various sectors including the health sector. Equity and efficiency of government revenue-financed health systems ultimately depends on the overall tax collection structure. Financing health services through government is to raise sufficient and sustainable revenues in an efficient and equitable manner to provide individuals with both a basic package of essential services and financial protection against unpredictable catastrophic financial losses caused by illness and injury. The key issues in revenue collection are level of income, tax-base and fiscal space, tax incidence, transaction cost and size of informal sector. General revenues are considered to be the most equitable means for health financing. They may be considered a mechanism for sustainable risk pooling that allows financial protection based on political and societal choices – this may be subsidized primary care, public health interventions and / or services for targeted population groups. General revenues allow a broader

range of taxes for financing health while earmarked taxes could potentially safeguard funds for health – from competing demands on general revenues from other sectors as well as for flexibility in use. Earmarked taxes are the ‘boundary’ between tax-based health financing and social insurance.



Government health services are usually financed by general revenue sources e.g. in India, most of the government health services are financed from this budgetary allocation. This is the second most important mechanism of financing health care in India. Here the collection and pooling functions are the best, but purchasing function may be limited. This is seen very obviously in our country where the government financing is low. As seen from Table 1, out of the total expenditure, 20.3 percent was public / government expenditure. The break up of the public expenditure shows that one third of the government spending was from the central government, the rest two thirds was from state and local governments. Thus the state governments are the main funding of public health services.

Given this scenario, the Government in India in its National Health Policy 2002 had suggested that the allocation to health be raised to 2-3%. In the recent past, the National Rural Health Mission (NRHM) has been formed with a view to increasing the expenditure in the health sector from a current 0.9% of GDP to 2% over the next five years and to focus on Primary Health Care. The Mission has been made operational from April 1, 2005. The NRHM financing for the period 2005-2012 would be around Rs. 300, 000 million for non recurring expenditure and recurring expenditure of more than Rs. 400, 000 million. This financing is to be shared between the Centre and the states (increase the share of central and state from 20-80 to 40-60 sharing in the long run).

## Insurance

This is the most complex mechanism of financing health care. The revenue is generated either by individuals paying a premium or by employers contributing towards their employees

or even the government paying on behalf of the poor. This revenue (called premium) is pooled into an autonomous fund that is used specifically to finance health care. In this way, this mechanism is different from the tax based government funding as the taxes collected is not dedicated only to health care. The insurance fund subsequently purchases health services on behalf of the insured from providers – be it government or private. The objective is to manage the revenues to equitably and efficiently pool health risks allowing for subsidies from healthy to unhealthy, rich to poor and productive workers to dependents. Health insurance has a limited effectiveness in collecting revenue; it depends on the workforce in the formal sector and also the size of the better off population. However, it has the potential to pool the funds effectively, especially if funds are collected from both low income and high income individuals. And finally because it is autonomous, it has an enhanced ability to purchase health services.

Health insurance could be an alternative health financing mechanisms; however, factors on both demand side and supply side coupled with high administrative costs limit the smooth functioning of the market for insurance in health. Further, action to counter market failure requires mature financial systems and institutional capacity to enforce corrective measures.

**Demand side limitations** : Protection from the real cost of ill-health may make individuals less risk averse, causing them to neglect precautionary/preventative measures. Or, being covered, an individual may consume excessive amounts of health care. This change in health behaviour due to insurance is moral hazard. Further, given uncertainty and incomplete/asymmetric information regarding ill-health, each member of an insurance pool may have different individual expected losses from ill-health and where this is lower than that reflected in premium charged, members may drop out of the group, leaving only an ‘adverse selection’ of high expected losses in the pool.

**Supply side limitations** : With insurance, excess demand can be supplier - induced as well -- the provider has fuller information on health status than the patient and could have used this asymmetry in information to over-prescribe services covered under the insurance plan. Adverse selection on the supply side occurs when insurers ‘cream skim’ through risk selection by including only healthier individuals in the plan; or, conversely, skimp or exclude certain high cost disease or pre-existing conditions.

There are various types of health insurance namely, Indemnity insurance wherein the person spends first and gets it reimbursed from the insurer afterwards. Health Maintenance Organizations (HMO's), which is broadly managed care, a health plan providing a full range of health services against a fixed monthly premium.

Broadly there are three major types of health insurance:

- Social Health Insurance (SHI)
- Private Health Insurance
- Community Health Insurance

## Social Health Insurance

SHI is usually publicly mandated for specific groups, financed through payroll taxes, semi-autonomous administration, the care provided is through its own, public, or private facilities.

The law mandates employers to deduct a percentage of each employee's monthly wage for health to be paid to a "social insurance fund". This fund could be managed publicly or privately; they can be monopolies or competitive. The employer/employee deductions are earmarked for health and cannot be used for any other purpose. Usually, it is applicable largely to formal sector employers and employees. The main strengths of SHI are that they are an additional health revenue source, generally provides covered population with access to a broad package of services, can effectively redistribute between high and low risk and high and low income groups in covered population and often serves as the basis for the expansion to universal coverage. The major weaknesses are that the poor are often excluded unless subsidized by government, potential negative impact on employment, administrative cost can be high, can lead to cost escalation unless effective contracting mechanisms are in place, poor coverage for preventive services and often needs to be subsidized from general revenues. In India, there are two major SHI schemes namely the Employees State Insurance Scheme (ESIS) and the Central Government Health Services (CGHS).

**Employees State Insurance Scheme (ESIS) :** The ESIS is a social security system which provides both cash and medical benefits. The Employees State Insurance Corporation (ESIC) manages the scheme and is a corporate semi-government body headed by the Union Minister of Labour as Chairman and a Director General as the chief executive. The Act compulsorily covers : (a) all power using non-seasonal factories employing 10 or more persons; (b) all non-power using factories employing 20 or more employees and (c) service establishments like shops, hotels, restaurants, cinema, road transport and news papers are covered. Contributions are paid through a payroll tax levied on the employer and a contribution levied on the employee and contribution by state governments. The benefits are comprehensive cover, including OP, IP and rehabilitation. All workers and their dependent relatives are eligible for the benefits. These include comprehensive health care at ESIS facilities, cash compensation for illness, maternity benefits, disability benefits, survivorship and funeral expenses in the event of death of the worker. ESIS has its own dispensaries, hospitals and medical staff. It also empanels select private practitioners to provide medical care. Presently the scheme is spread over 677 centres in 25 states and Union territories across India covering 7.8 million employees and more than 25 million beneficiaries (17). In 1992, of a total expenditure of Rs 3.8 billion, Rs 2.2 billion was spent on health care. In 2001, the ESIC had surplus funds of Rs 67 billion, invested mostly in government securities.

While the ESIS has managed to cover the low paid workers in many organizations and provided them with a degree of comprehensive health security, various studies have been critical for the following reasons : Less than half the enrollees use the ESIS facilities because of the low quality of care. This is further compounded by the shortage of staff, inadequate drug and supplies and non-functional equipment. Many of the staff are not aware of the benefits. The employers also do not disseminate the information to their staff. Also, because of the salary limits on eligibility, some staff keep shifting in and

out of the ESIS and they may not be aware of their eligibility status. There is very little penetration in rural areas.

**Central Government Health Scheme (CGHS) :** The CGHS was introduced in 1954 as a contributory health scheme to provide comprehensive medical care to the central government employees and their families. The list of beneficiaries includes all categories of current as well as former central government employees, members of Parliament, Supreme Court and High Court Judges. In 1997, there were approximately 4.2 million beneficiaries. The staff contributes a nominal amount (ranging from Rs 15 to Rs 150 per month) from their salaries. The benefit package includes both outpatient care and hospitalisation. OP care is provided through its own dispensaries, 320 in 2002 in 17 major cities. It also uses the facilities of the Government and approved private hospitals to provide inpatient care and reimburses the expenses to the patient. The entire scheme is funded by the government of India and is administered by a separate directorate. Various evaluations have noted that while it has been effective in providing health security for more than 4 million people, there are certain problems in the scheme that need to be addressed. In terms of demand side, *moral hazard* – it is noted that 83% of the hospitalised patients are self-referred. It appears that most patients prefer to bypass the dispensaries and directly avail of specialist services. The number of annual visits per beneficiary was 3.5 (1994-95). *Poor quality care* – there are regular complaints about long waiting periods, inadequate supply of medicines and equipment and unhygienic conditions.

### Private Health Insurance

Private health insurance emerges from voluntary actions in a market where buyers are willing to pay premium to insurance companies that pool people with similar risks and insure them for health expenses. Commercially run for-profit private insurance companies usually base contributions on risk-rating i.e. adjusted according to the anticipated cost of use of services, care reimbursed in private and public facilities who provide treatment for members. Private health insurance is generally motivated by the prospect of earning a profit and companies compete for clients on the basis of "price" and quality. The major strengths are that as a prepayment and risk pooling mechanism it is generally preferable to out of pocket expenditure. It may increase financial protection and access to health services for those able to pay. When there is "strategic purchasing" function is present it may also encourage better quality and cost-efficiency of health care providers. The main weaknesses are : it is associated with high administrative costs and profit, it is generally inequitable. Applicability in LICs and MICs requires well developed financial markets and strong regulatory capacity.

Private health insurance in India is usually associated with the "Mediclaim" policy. Introduced in 1986, it is a voluntary health insurance scheme offered by private insurance companies. While initially only "non-life insurance companies" were allowed to market health insurance products, the Insurance Regulatory & Development Authority (IRDA) has recently permitted even life insurance companies to introduce health insurance products. Currently there are 14 general insurance companies and three life insurance companies providing health insurance products.



With the introduction of Third Party Administrators (TPAs), the reimbursement policy has changed into a 'cashless' policy, where the TPA reimburses the hospitals and the entire treatment is cashless for the patient. While initially only hospitalisation expenses were covered, today health insurance products cover a variety of risks, ranging from hospitalisation to outpatient care to ambulance expenses and also pre & post hospitalisation expenses. While earlier, there were only individual or group insurance products, recently family floater products have slowly gained popularity. While earlier a family of four had to pay the individual premiums (e.g. Rs 2000 X 4 = Rs 8000) and get a cover of Rs 2 lakhs each, today under a family floater product, the family needs to pay a much lower premium (e.g. Rs 5, 000) and get a family cover of Rs 5 lakhs. This means that anybody who is sick in the family can avail of hospitalisation expenses upto Rs 5 lakhs. This is a much more attractive product to cover families. Today many of the products also provide a daily cash benefit for each day of hospitalisation. This is to take care of non-medical expenses like transport, food, attendant expenses etc. Yet another innovation has been the introduction of 'critical illness' cover. Under this, an individual is insured for a particular period. During that period, if the individual contracts one of the listed critical ailments like stroke or cancer or myocardial infarction (MI) or end stage renal failure (CRF), then the patient is paid a lumpsum amount and the policy is terminated. The patient is free to use this lumpsum for whatever need required. There is no need to submit any bills and receipts, just a proof of diagnosis of the critical ailment. Initially the senior citizens had very little opportunity to insure themselves, but today many companies have developed products tailor made to the needs of senior citizens. Similarly, more and more products are reducing the list of exclusions and providing a more comprehensive cover. While earlier pre-existing diseases were not insurable in the Indian market, today many of the companies include them in the cover after a fixed claim free period (usually two years). Today there are many different products catering to people.

### Community Health Insurance

Community health insurance is mostly not-for-profit prepayment plans for health care, with community control and voluntary or compulsory membership, care is generally provided through NGO or private facilities. Members pre pay a set amount periodically for specified services. It is managed by community members and accountable back to members. Community based health insurance schemes have had some success in providing financial protection to the poor in the informal sector. These initiatives are based on the social insurance principle of solidarity, de-linking contributions from use and thus supporting equitable access to care. It promotes pre-payment and mobilizing additional resources, providing access and financial protection in LICs. Experience indicates that community health financing has been most successful where this has been associated with income generation activities. The major weakness are Community health initiative tends to be limited in scope by their capacity for financial risk pooling – while based on the principles of social insurance, they cannot establish similarly large pools. Also, such schemes rely on the existing network of public and private providers (rather their

own facilities). This has implications for the benefit package offered as well as long term sustainability. CHI can be a helpful complement but is not a substitute for SHI systems. CHI movement is slowly picking up momentum in India. Currently there are about 100+ CHIs in the country, many of which have begun operations in the past two to four years.

Unfortunately, in India, there is very little penetration of health insurance in the country. Estimates range from 3 to 8% (10, 11). This for a country of 1 billion is negligible. Most of those insured are in the formal sector and have security in terms of insurance policies as well as steady incomes. On the other hand, the rural populations are left at the mercy of ailments; and usually have to borrow and sell assets to meet even a small hospitalisation episode.

### External Finance

There are two main forms of external contributions for development : loans and grants. Loan, administered largely through the Bretton Woods Institution, are non-commercial long-term loans at substantially low rates of interest. Eligibility for such 'soft' loans is based on country economic status/progress. Usually negotiated between the loan agency and the concerned ministries for a specific programme and with funds flowing through the national budget (albeit earmarked for programme activities), such external assistance does, in theory, allow country 'ownership'. Donor assistance in the form of grants traditionally took the form earmarked project funding, restricted to specific activities and implemented by the donor alone or in collaboration with the government, depending on national procedures. More recently, two new options are being used by donors to promote aid harmonisation and alignment in support of the overall national health strategies. Basket funding is a joint funding mechanism that pools donor contributions and provides un-earmarked funds for implementing planned national health strategies (usually developed in consultation with donors). Through general budget support, donor funds for health are released to ministries of finance and allow them the ultimate decision vis-à-vis actual allocation. For health, this means such funding is not necessarily secure for health activities. For national budget and macroeconomic planning, given experiences with volatility in donor contributions particularly during global economic downturns, this brings in elements of unpredictability and instability. Overall, external assistance may be effective for filling short/medium term funding gaps. For sustainable financing for health, this must in the long run depend primarily on domestic resources.

Development assistance, including loans and grants, contribute a small percentage of India's expenditure on the health sector and has never been more than 1–3% of the total public health expenditure. The overall foreign assistance to India in 1999 was 0.4% of GDP and per capita Overseas Development Assistance (ODA) was US\$1.6 in 1998 as against an average of US\$ 9 for developing countries. Of this, the share of health in the total assistance was 6.7%. In India, at present, assistance from only a few countries is accepted to be channeled through the Government. Other donors are requested to direct their contributions through UN agencies and non-governmental organizations.



Recent years have also seen the emergence of funding agencies that are not governments or part of the UN system. Important among these are the Global Alliance for Vaccine Initiative (GAVI), Global Fund for AIDS, TB and Malaria (GFATM) and the Bill and Melinda Gates Foundation, among others. These agencies could be expected to further influence the development assistance scenario in the medium term.

### Provider Payments

The objectives in purchasing are to assure the purchase of health services is strategic and both allocatively and technically efficient (for whom to buy, what services to buy, from who to buy and how to pay). Provider payments may be made to individuals or at facility level and, these may be prospective or retrospective. The key issues are that purchasing is performance-based payments to promote quality and efficiency, equity and social protection, allocative efficiency. Provider payments mechanisms are the channels through which payments are transferred from the purchaser of care to the service provider. For health financing, they are an important part of the overall strategy to impact equity and efficiency. They have been used very successfully in Cambodia to increase access to hospital care for the poor (1). In India provider payment mechanism has been used under the Chiranjeevi scheme in Gujarat. For more details [http://gujhealth.gov.in/Chiranjeevi%20Yojana/M\\_index.htm](http://gujhealth.gov.in/Chiranjeevi%20Yojana/M_index.htm).

### Mapping Resource Flows in National Health Systems through National Health Accounts (NHA)

Major financing reforms in the health sector concern securing sustainable financing for health care. Regular updates of NHA provide useful insights to governments as to what their further options are, or as to the level of public and private expenditure, as well as to modifying the allocation of these expenditures.

NHA provides a systematic, consistent, comprehensive information for any given year all the resources that flow through the country's health system over time and across countries both in absolute and relative terms. Time series information permits the use of NHA as a standard management tool for situation analysis, planning, monitoring and evaluation purposes. NHA are designed to capture the full range of information contained in these resource flows and to reflect the main functions of health care financing : resource mobilisation and allocation, pooling and insurance, purchasing of care and the distribution of benefits. NHA enable stakeholders to identify policy concerns and to simulate the impact of solutions to the problems monitored. NHA address four basic sets of questions : where do resources come from, where do they go, what kinds of services and goods do they purchase and whom do they benefit ? In doing so, NHA captures total national health expenditure from all sources, public and private. NHA are a standard set of tables showing and describing the financial flows of health system. They are presented in two-way tables (matrix format) and the tables are interconnected. The tables provide key indicators to policymakers as well as researchers to diagnose the financial health of the health system. It shows the flow of financing from a source of funding to a particular use, to a user of that expenditure or to beneficiaries following a standard classification of health expenditure. Six dimensions

are considered :

**Financing sources** : Defined as resources for health goods and services, whether from tax-based, social security, other private entities such as firms, NGOs, households or other entities.

**Financing agents** : Defined as institutions receiving and managing funds from financing sources to pay for or purchase health goods and services, including social security schemes, ministries of health, medical private insurance, NGOs and firms.

**Providers** : Defined as entities that receive financial resources and use those resources to produce health goods and services, include public and private hospitals, clinics, nursing homes, community health centres, private practitioners etc.

**Functions** : Defined as the categories of goods and services consumed, include inpatient services, ambulatory services, public health interventions, etc. Health related functions, part of the total, refer to investment, training and R&D.

**Cost of Factors of Production (often referred to as "line items")** : Defined as the type of resources allocated to health care. It includes variables such as labour, drugs and pharmaceuticals, medical equipment etc.

**Beneficiaries** : Defined through distributional tables in which the value of goods and services produced are classified according to : geographic boundaries, demographic characteristics, economic strata and disease categories/interventions.

For more details a good reference is 'Guide to Producing National Health Accounts : With special applications to low and middle income countries, WB, WHO and USAID, 2003. Link- [http : // www. who. int/nha/docs/English\\_PG. pdf](http://www.who.int/nha/docs/English_PG.pdf).

In India the work on National Health Accounts is underway, The MOHFW, GOI in collaboration with WHO India Country office has brought out the NHA for 2001-02 which is available at link- [http : //mohfw. nic. in/NHA%202001-02. pdf](http://mohfw.nic.in/NHA%202001-02.pdf).

### Health Financing Issues in India

As seen from above public health financing is very low as a ratio to GDP, total health expenditure and per capita expenditure. Seventy percent of public spending is by the states where a major part of it is on salary and administration. Eighty percent of all health spending is from out-of-pocket at the point of service use. More than forty percent of the people hospitalized borrow money / sell assets to cover expenses. A quarter of those hospitalized fall below the poverty line because of high costs. Only around four to six percent of people in India have some form of health insurance coverage. Health financing policy questions broadly would be : Are we investing enough in health? Is there a minimum efficient level of spending? What would be "optimum" investment by public funding? Do external funds help? What amount and how to use? What are the opportunity costs of investing more for health? Is the financial risk protection feasible? If so, how? Can user charges play a useful role? Is there a role for community-based financing?

### Summary

The way a health system is financed is a key determinant of population health and well-being. There is no single answer to the question of how to finance health systems. Health policy

and financing policy are inseparable because financing policy determines who has access to basic health care, how much is available, who controls the funds and how they are used. While cost-effective responses to preventable and communicable morbidity and mortality, there is a growing challenge from high-cost non-communicable and 'new' diseases. The combination of upward pressure on costs and limitations on the ability of governments to increase spending forces countries to consider reforms to the way that their health systems are financed. Like all countries in the world, India too faces difficult challenges and choices in financing its health systems. India has a mixed form of financing health care. The total health expenditure in India for the year 2001-02 was Rs 1,057,341 million, which accounted for 4.6 percent of its GDP. Of the total expenditure, 20.3 percent was public / government expenditure, 77.4 percent was private expenditure and remaining 2.3 percent external support. There are three basic functions of a health financing system; Revenue collection, Pooling and Purchasing. Broadly, there are various options and mechanisms for financing the health care services. Out of Pocket Payments is the simplest form of health care financing. In India, this is the most common form of financing health care. The main financier of health services in India is the individual household. They meet 72% of the total health care costs by paying out of pocket at the time of service. In most high income countries, only about 5 – 10% of households have to pay OOP payments and these are usually in the form of pre/co-payments to contributory financial protection schemes e.g. social health insurance. In middle income and low income countries, the proportion increases to about 25 - 50% of households. Governments collect General Taxes, both direct and indirect, which is allocated to various sectors including the health sector. General revenues are considered to be the most equitable means for health financing. Government health services are usually financed general revenue sources e.g. in India, most of the government health services are financed from this budgetary allocation. The Government in India in its National Health Policy 2002 had suggested that the allocation to health be raised to 2-3%. Insurance is the most complex mechanism of financing health care. The revenue is generated either by individuals paying a premium or by employers contributing towards their employees or even the government paying on behalf of the poor. Health insurance could be an alternative health financing mechanisms, however, factors on both demand side and supply side coupled with high administrative costs limit the smooth functioning of the market for insurance in health. Protection from the real cost of ill-health may make individuals less risk averse, causing them to neglect precautionary/ preventative measures. With insurance, excess demand can be supplier- induced as well -- the provider has fuller information on health status than the patient and could use this asymmetry in information to over-prescribe services covered under the insurance plan. There are various types of health insurance namely, Indemnity insurance, Social Health Insurance (SHI), Private Health Insurance and Community Health Insurance. The Employees State Insurance Scheme (ESIS) is a social security system which provides both cash and medical benefits. All workers and their dependent relatives are eligible for the benefits. Central Government Health Scheme (CGHS) was introduced in 1954 as a contributory health scheme

to provide comprehensive medical care to the central government employees and their families. The benefit package includes both outpatient care and hospitalisation. Private health insurance emerges from voluntary actions in a market where buyers are willing to pay premium to insurance companies that; pools people with similar risks and insure them for health expenses. Private health insurance in India is usually associated with the "Mediclaime" policy. With the introduction of Third Party Administrators (TPAs), the reimbursement policy has changed into a 'cashless' policy, where the TPA reimburses the hospitals and the entire treatment is cashless for the patient. Community health insurance is mostly not-for-profit prepayment plans for health care, with community control and voluntary or compulsory membership, care is generally provided through NGO or private facilities. Experience indicates that community health financing has been most successful where this has been associated with income generation activities. In India, there is very little penetration of health insurance in the country. Most of those insured are in the formal sector and have security in terms of insurance policies as well as steady incomes. There are two main forms of external contributions for development: loans and grants. Loan, administered largely through the Bretton Woods Institution, are non-commercial long-term loans at substantially low rates of interest. Development assistance, including loans and grants, contribute a small percentage of India's expenditure on the health sector and has never been more than 1-3% of the total public health expenditure. Recent years have also seen the emergence of funding agencies that are not governments or part of the UN system. Regular updates of National Health Accounts (NHA) provide useful insights to governments as to what their further options are, or as to the level of public and private expenditure, as well as to modifying the allocation of these expenditures. NHA address four basic sets of questions : where do resources come from, where do they go, what kinds of services and goods do they purchase and whom do they benefit? The flow of financing from a source of funding to a particular use, to a user of that expenditure or to beneficiaries following a standard classification of health expenditure. Six dimensions are considered : Financing sources, Financing agents, Providers, Functions, Cost of Factors of Production and Beneficiaries. Health financing policy questions broadly would be like Are we investing enough in health and Is there a minimum efficient level of spending.

## Study Exercises

### MCQs

1. The most common form of financing health care in India is (a) Provider Payment (b) General Tax Revenue (c) Out of Pocket Payment (d) External Finance.
2. What percentage of hospitalised patients in India have been impoverished because of high medical costs (a) 25% (b) 10% (c) 50% (d) 35%.
3. The National Rural Health Mission (NRHM) has been formed with a view to increasing the expenditure in the health sector from a current 0.9% of GDP to \_\_\_\_ over the next five years (a) 1% (b) 2% (c) 3% (d) 4%.
4. The most complex mechanism of financing health care is (a) Provider Payment (b) General Tax Revenue (c) External Finance (d) Insurance.

5. Central Government Health Scheme was introduced in the year (a) 1952 (b) 1954 (c) 1955 (d) 1957.
6. Penetration of health insurance in India is in the range of (a) 3-8% (b) 9-15% (c) 16-20% (d) 25-40%.

**Answers :** (1) c; (2) a(3) b; (4) d; (5) b; (6) a.

### Further Suggested Reading

1. [http : //www. who. int/health\\_financing/mechanisms/en/](http://www.who.int/health_financing/mechanisms/en/)
2. Achieving universal health coverage : developing the health financing system [pdf 337kb, link-[http : //www. ho. int/health\\_financing/documents/pb\\_e\\_05\\_1-universal\\_coverage. pdf](http://www.who.int/health_financing/documents/pb_e_05_1-universal_coverage.pdf)

3. Health Financing Revisted : Gottret, Schieber George, The World Bank, 2006 Link-[http : //siteresources. worldbank. org/INTHSD/Resources/topics/Health-Financing/HFRFull. pdf](http://siteresources.worldbank.org/INTHSD/Resources/topics/Health-Financing/HFRFull.pdf)
4. Better Health Systems for India's Poor, Preker, Alexander S. ; Peters, David H.; Yazbeck, Abdo S. ; Sharma, Rashmi R. ; Ramana, G. N. V. ; Pritchett, Lant H.; Wagstaff, Adam
5. Report of the National Commission on Macroeconomics and Health, NCMH, MOHFW, 2005 link-[http : //mohfw. nic. in/reports\\_on\\_ncmh. htm](http://mohfw.nic.in/reports_on_ncmh.htm)
6. Bulletin of the World Health Organization, Special Theme : Health Financing, Volume, 86, Number, 11, November, 817-908 [http : //www. who. int/bulletin/volumes/86/11/en/index. html](http://www.who.int/bulletin/volumes/86/11/en/index.html)

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## Trade and Public Health

*Sunil Nandraj*

In the recent times the impact of trade on public health has come under sharp attention of governments, policy makers, academia and civil society. A few explanations can be given for this growing interest in trade and public health. During the last part of 20th century most countries shifted their development strategy from self-sufficiency to export oriented growth strategy. This was then complemented with the establishment of world Trade Organization (WTO) and a web of Free Trade Agreements (FTA) with developed countries. The underline rationale of this shift towards export oriented growth strategy was that growing trade would help countries to achieve over all development including alleviation of poverty. As a result most of the countries made a series of policy change to facilitate gains from international trade. However, these policy shifts were not accepted without criticism because much of these policy changes were aiming at increasing competing capacity of the manufacturers within a country. As a result, policy changes were introduced to many countries to liberalize labour markets and environmental regulations. These changes constituted vast changes in the public health scenario of many countries especially developing countries.

However, the most important issue with regard to trade and public health is the loss of policy space of developing country government related to public health. This erosion of policy space is the result of a set of international trade agreements regulating international trade and trade related subject matters.

### International Trade Regime

International trade regime is regulated through various institutions and international agreements. However, the most important institution and agreement relevant the discussion here is WTO and the agreement establishing WTO. Another set of relevant international trade agreements are FTA entered

between developed and developing countries. The first attempt to establish an international trade agreement was in 1948 to establish and international trade organization. However, the organization did not get establish mainly due to the internal resistance from the USA. However, an ad hoc arrangement known as General Agreement on Trade Tariff (GATT) was established and it continued to function till 1994. In 1995 GATT was replaced by WTO. The agreement establishing WTO contains a set of international agreements regulating specific aspects of trade. Two of these agreements deal with intellectual property protection and trade in services. These agreements reduces the policy space of countries with regard to access to medicines and access to health services. Since these agreements are part of the agreement establishing WTO, member countries cannot be members of WTO without accepting these agreements. Similarly, member countries are not allowed to make any reservation in the provisions of these agreements. As a result, all WTO members are to accept these agreements in its entirety. However, these agreements provide certain transition periods for developing countries and least developing countries to full comply with this agreements.

However, free trade agreements between developed and developing countries forces developing countries to undertake more commitments than WTO agreements in areas of intellectual property and trade in services. As a result, developing countries are on the verge of loosing the existing policy space in those areas. As mentioned earlier, the trade itself has the potential to impact the people life negatively as well as positively. However, the following paragraphs discuss the impact of intellectual property provisions and services on public health.

### Intellectual Property Rights

The term intellectual property rights generally refer to a set of exclusive rights granted to the owner of intellectual property. Generally speaking, intellectual property refers to the extension, of property rights to intangible assets including the intellectual efforts like invention. There are nearly seven types of intellectual property rights viz. patents, trademark, copyrights, industrial designs, plant varieties protection, trade secrets and geographical indications. International intellectual



property regime is governed through a series of international agreements regulating various procedural and substantial aspects of intellectual property rights. Till the conclusion of Agreement on trade related aspects of Intellectual Property Rights (TRIPS), these international agreements did not put minimum level of protection. In other words, these IP agreements gave member countries sufficient policy space to determine the level of intellectual property protection.

TRIPS is one of the most controversial agreements administered under the World Trade Organisation's (WTO) frame work because it took away the freedom of member countries to determine the level of intellectual property protection. It prescribes a universal minimum standard of protection to all types of intellectual properties irrespective of member countries developmental needs. This universal minimum standard put an end to hitherto freedom of determining the level of intellectual property protection in member countries. In other words, every member country is to offer a minimum level of all types of intellectual property. The most controversial provisions TRIPS are related to the patent protection. TRIPS patent regime resulted in the denial of access to medicine to the people in developing and least developing countries.

Often monopoly results in abuse of monopoly position and extracts high prices from the consumer. Patents especially product patents create a statutory monopoly for a limited number of years and increases the chance of abuse of patents. This statutory monopoly will have undesired consequence on vital sectors especially in the health sector because pharmaceutical industry rely heavily on the patents to market their product using the monopoly rights provided by the patents. For instance, till 2000 anti-retro viral (ARV) drugs for the treatment of HIV/AIDS were not affordable to people due to the exorbitant price charged by the multinational pharmaceutical companies. The price of first line ARV drugs used to be USD 10,000-12,000 per patient per year (PPY). In 2001, the Indian pharmaceutical companies using the advantage of absence of product patent protection in India at that time introduced the cheap generic version of first line ARV drugs to USD 350 PPY. This generated competition in the market and reduced the price of first line ARV drugs especially price of first line ARV drugs for bulk procurement. Currently various governments and international agencies are procuring first line ARV drugs at USD 132 PPY. After the introduction of product patent protection, Indian pharmaceutical companies cannot produce the generic version of new drugs because most of the new drugs are patent protected. Therefore, the product patent protection eliminates the possibility of availability of affordable generic drugs in the market. Hence, countries need to take utmost care while framing their patent laws to address the bad effects of patents especially to facilitate access to medicines.

### Nature of TRIPS Obligation

As mentioned above, TRIPS prescribes a universal minimum standard to different forms of intellectual property viz. Trademarks, designs, Copyrights, Geographical Indications, Topography of Integrated circuits, patents, plant varieties, trade secrets etc. Regarding patents it obligates member countries to provide the following : compulsory product patents for pharmaceuticals and agro-chemicals, 20 years duration of

protection, recognise importation as part of exclusive rights of the patent holder, reversal of burden of proof in the case of process patent infringement proceedings, certain procedural regulation on the granting of compulsory license and exclusive marketing rights during the transitional period. However, TRIPS provides a ten-year transitional period (1-1-1995-31-12-2004) for developing countries like India to fully comply with TRIPS patent regime. Further, TRIPS permits a three-stage time frame (1995, 2000 and 2005) for compliance. Patents especially product patents create monopoly and eradicate competition. Patent monopoly often abused by the patent holder and fixes a higher price for the patented medicines. Hence, patents on drugs compromise the accessibility and availability of medicines, two important components of right to health. Today, there is ample evidence to show how patents adversely affect the accessibility and availability of medicines. The main task before lawmakers during the implementation of TRIPS patent regime is to provide strong public interest provisions to curb the abuse of patent monopoly. Hence, the approach to the implementation of TRIPS is to place provisions to ensure accessibility of medicines and not to strengthen patent protection. In other words, the task is how can WTO member country implement TRIPS agreement without compromising the policy objective ensuring access to affordable medicines.

Question often asked is whether TRIPS permits use of public interest provisions to safeguard accessibility and availability of medicines in the product patent era. The answer is that TRIPS does recognise such approach. Even, though product patent *per se* creates barriers to access to affordable medicines the damage can be minimise to certain extent by incorporating the flexibility available within the TRIPS in the domestic legislation. The domestic legislation should incorporate the flexibilities to the maximum extent. The following paragraphs explain the nature of TRIPS obligation and the flexibility available within the TRIPS.

The Preamble of TRIPS states that measures and procedures to enforce intellectual property rights should not themselves become barriers to legitimate trade. Further, the Preamble recognises the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives. Hence, the implementation of TRIPS should not undermine the developmental and technological objectives including public health goals of the implementing country. In other words, it states that under TRIPS protection of intellectual property is not an end itself but a means to achieve developmental goals.

According to Article 1 of TRIPS, members "*shall not be obliged to, implement in their domestic law more extensive protection than required by this Agreement*". Thus, there is no obligation under TRIPS to provide extra protection to any intellectual property rights other than what is mentioned in the TRIPS Agreement. Further, TRIPS permits states to "determine the appropriate method" to implement the provisions of the TRIPS Agreement within their legal system. As a result, it is up to each state to decide the manner in which it should implement TRIPS Obligations. India along with other developing countries stated in their submission to TRIPS Council on 29 June 2001 (IP/C/W/296) states : " ... *more extensive protection in national*



legislation than is required by the TRIPS Agreement may result in limitations for the implementation of health policies. We consider that Members should be free to implement the TRIPS Agreement in ways that best accommodate the protection of health policies in national legislation” Hence, there is no need for India country to implement provisions which goes beyond TRIPS patent regime.

The objective of TRIPS mentioned in Article 7 states that “the protection and enforcement of intellectual property rights should contribute... to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare...”. On objectives, India’s submission states : “ ...patent rights should be exercised coherently with the objectives of mutual advantage of patent holders and the users of patented medicines, in a manner conducive to social and economic welfare and to balance of rights and obligations. Where confronted with specific situations where the patent rights over medicines are not exercised in a way that meets the objectives of Article 7, Members may take measures to ensure that they will be achieved...”. Thus, the submission put the question of access above the patent rights and assert the right to take measures to achieve the objectives of Article 7.

Further, principles of implementation under Article 8 states “members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development...”. According to the submission “any interpretation of the provisions of the Agreement should take into account the principles set forth in Article 8. The reading of such provision should confirm that nothing in the TRIPS Agreements will prevent Members from adopting measures to protect public health, as well as from pursuing the over-arching policies defined in Article 8”. Thus, the domestic legislation should strike a balance between public and private rights and the rights of patentee should not be at the cost of public health concerns.

In 2001, WTO Ministerial Conference in Doha endorsed the same approach for the implementation of TRIPS patent provisions at the domestic level by adopting the Doha Declaration Public Health and the TRIPS Agreement (Doha Declaration). According to Doha Declaration “...TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Member’s right to protect public health and, in particular, to promote the access to medicines for all”. Further, the Declaration reaffirms “the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”. Hence, India has a legal right to interpret and implement the TRIPS Agreement to promote access to drugs.

Further, Doha Declaration explicitly recognises the following flexibilities viz. using the customary rules of interpretations of public international law and the interpretation of TRIPS provisions in the light of objectives and principles, right to grant compulsory license and freedom to determine the grounds

of granting compulsory license, right to determine what circumstances constitute a national emergency, freedom to adopt suitable exhaustion regime. Further, there is a flexibility to determine the scope of patentability by providing suitable definitions three basic criteria viz. novelty, inventive step and industrial applications. Furthermore, flexibility also exists to define the subject matter of patents. For instance in the absence of a definition to microorganisms in TRIPS through a definition certain microorganisms can be excluded from patentability.

The general understanding on TRIPS is that obligations under TRIPS do not create any hierarchy of international obligations and therefore does not override obligations under other treaties. Therefore, TRIPS implementation should not compromise any of the rights guaranteed by any previous international treaty. India as a party to the International Covenant on Economic, Social and Cultural Rights (ICESCR), it cannot compromise the right to health (Article 12, ICESCR) and the right to enjoy the benefits of scientific progress and its applications (Article 15, ICESCR) while implementing TRIPS patent regime. The right to health also falls within Article 21 of the Indian Constitution (*Vincent Panikurlangara v Union of India 1987 (2) SCC 165*). The Supreme Court has recognised that Article 21 has to be interpreted in consonance with international treaties. Hence, the implementation of any provision in TRIPS should not result in the denial of any of the rights guaranteed under the ICESCR and the Constitution of India. In the absence of a contrary statute enforceability of ICESCR and the International Covenant on Civil and Political Rights (ICCPR) in India has been upheld by the Supreme Court through a number of judgements (*Vishaka v State of Rajasthan (1997) 6 SCC 241*).

Even though TRIPS per se is objectionable and need to be reviewed in the coming days to ensure accessibility and availability of drugs the flexibility within TRIPS provides some manoeuvring space to Members States to address the issue of access to drugs. According to Commission on Intellectual Property Rights (CIPR) “developing countries should adopt a pro-competitive strategy that, as one observer suggests, is tilted towards second comers rather than distant patentees. This is especially important in those areas of technology such as pharmaceuticals and agriculture where, as we have already considered, the cost of providing strong protection is likely to be greatest”.

Thus, the flexibilities available within the TRIPS offer some policy options for the developing countries to mitigate the adverse affects of product patent protection on the availability of affordable medicines. However, the intellectual property rights provisions within the FTAs between developed and developing countries eliminate the possibilities of TRIPS flexibilities. Most of the FTAs entered between USA with developing countries obligates developing countries to limit the scope of TRIPS flexibilities. For instance, US FTAs insists that patent protection should be extended to the new use of known substance. Further these FTAs limits the circumstances under which a country can use the compulsory licence or a government use of patented invention. These FTAs also insists for extension of patents beyond 20 years prescribed under TRIPS. Hence, IP provisions of FTAs goes beyond TRIPS patent regime and considerably restrict the policy space of developing countries.

## India and TRIPS Implementation

India, as a member of the WTO has an obligation under TRIPS to comply with its patent provisions. A TRIP provides three time frames for developing countries like India for its absolute compliance, with the patent regime in particular. The first dead line was in 1995 to introduce mail box protection and exclusive marketing rights (EMR). The second was in 2000 to comply with TRIPS provisions on duration of patent protection, compulsory license, extension of patent protection to micro organism etc. India amended its Patents Act in 1999 and 2002 (well beyond the dead line) to comply with these obligations. The third deadline was to introduce product patent protection for pharmaceuticals and agrochemicals by 1 January 2005. To meet the deadline, Government of India issued an Ordinance on 26 December, to amend Patents Act 1970. The Ordinance carried out 77 amendments to the Act. Later, the ordinance was replaced through an amendment Act passed by the parliament in March 2005.

Thus, countries like India gave importance to the question access to affordable medicines and survival of its generic industry over the protection of intellectual property while implementing the TRIPS Agreement. India has incorporated restricted approach to the scope of patentability. As a result, a known substance is not eligible for patent protection in India unless there is a significant improvement in India. Similarly, substance obtained from by a mere admixture resulting in the aggregation of properties is excluded from patent protection. Further, the Indian Patents Act provides strong provisions against abuse of patented invention. The Act contains compulsory license and government use provisions. For instance, a compulsory license can be granted if patented article is not available at an affordable price. Compulsory license allows a third party to use the patented without the authorisation of the patent holder. However, a compulsory license is issued by the patent office after examining the application for compulsory license. However, the critiques point out that compulsory licence provisions under the Patents Act, procedure wise, is cumbersome and therefore little use to curb the abuse of patents. Government use provisions allow government or its authorised agent to use the patent without the permission of patent holder. Patent Act also allows parallel importation, which allows third parties to import the patented article from any where in the world without the permission of the patent holder provided the product is introduced legally in that market. Patent Act contains the early working of patents in order to obtain the regulatory clearance. Hence, the generic companies can produce the patented drug during the life of the patent to obtain marketing approval. As a result, the generic companies can introduce the generic version immediately after the expiry of patent. Even though India implemented most of the TRIPS flexibilities in the Patents Act, it needs lot of fine tuning to use it as an effective tool to ensure access to affordable medicine under the product patent regime.

## Trade in Service

Traditionally, health services in most countries have been largely provided by the State. Healthcare services were seen as essentially public welfare services and were not regarded as commercial in nature. However, in many developing

countries, the public health system could not meet the demand for healthcare services. In this context, it was felt that private participation in health services might be the solution for meeting the demand for adequate healthcare services. The underlying assumption was that facilitating trade in healthcare services by liberalising healthcare services will not only increase the supply of healthcare services but will also provide a boost to the economic growth of the State, which in turn will lead to better standards of health in the country by enabling people to spend more on healthcare. A culmination of this logic was the push for liberalising health services. As a result, many developing countries started liberalising health services. Initially liberalisation of health services took place in two ways viz. autonomous liberalisation and liberalisation due to structural adjustment programmes under the instruction of the World Bank and the International Monetary Fund (IMF). Of late, countries entered into legally binding agreements to maintain the level of liberalisation through General Agreement in Trade and Service (GATS) and FTAs.

GATS attempts to establish a framework within the WTO for regulating international trade in services and it envisages the progressive liberalisation of all trade in services. To that end it locks in the level of liberalisation to which a State commits a particular service sector under the GATS. The current approach to GATS, negotiations involves a two-stage process wherein each Member makes specific requests on every sector to every other Member and every Member makes their offers on each sector. The GATS can be applied to all services including health services. In respect of liberalisation of health services under GATS, the WTO regards the current level of liberalisation as inadequate (1). Hence, liberalisation of health services within the framework of the GATS is a thrust area of current GATS negotiations.

However, there is a concern expressed by health policy analysts and the civil society as to the adverse implications of GATS disciplines on health services. The concern is that it may reduce the space available to governments to devise policies and regulations for the health sector, particularly with regard to access and affordability of health services (2). This is based on the belief that many public health measures may be deemed to be unnecessarily restrictive of trade in health services under GATS. This concern assumes significance in the light of the fact that the right to health is a human right.

## Trade in Health Services

Health services have not been considered traditionally as a commercially tradable service. However, the traditional notion of health as non-commercial services has undergone a paradigm change. The growing potential for trade in health services is driven by various factors such as

- Decline in public sector expenditure on health services and the rise of private sector participation in healthcare;
- Liberalisation of related sectors like insurance and telecommunications services;
- Increasing mobility of consumers and health service providers;
- Technological developments enabling cross-border delivery of health services (3).

While the ultimate delivery of a health service necessarily involves physical contact between the health professionals like doctors and nurses with the patient, owing to technological developments the extent to which physical contact is required can be reduced significantly. For instance, a team of doctors in one country may seek the opinion of some specialist in another country through electronic exchange of medical data in real time without having the patient to visit that specialist in a foreign country. Such services are called telemedicine services. Similarly, a hospital can reduce its expenses of maintaining medical records by outsourcing the same to firms in other countries where the records can be maintained at lesser costs while their transcripts can be communicated back in real time to the concerned hospital whenever needed. The health sector comprises various kinds of health services including medical and dental service, hospital services, diagnostic services, nursing and midwifery services, medical education services, veterinary services and medical data processing services. Hospital services comprises not only services that include treatment of patients, these also include services like hospital management services that facilitate the treatment of patients.

However, while health services comprise a host of health related services, countries do not follow a uniform system of classification of such services. Services are usually classified in the GATS in accordance with the Services Sectoral Classification List of the WTO, which closely follows the UN Central Products Classification system (UN CPC), which provides a more detailed breakdown of the services that fall within each service sector. In scheduling their GATS commitments, Members are free to follow either the Services Sectoral Classification List or the UN CPC or their own system of classification. Hence, every Member's commitment on a particular service sector has to be seen in the context of the system of classification that it follows. In terms of classification of services under GATS, nursing services and services of doctors are classified as professional services and not health services. Hence, many health related services do not fall within the health services. For instance, medical education services would be classified as education services and medical transcription services as data processing services under GATS. Trade in health services involves 4 modes of services delivery.

For example, services like telemedicine and teleradiology can be delivered through cross-border supply, health tourism can be facilitated through movement of patients, hospitals of one country may set up commercial presence in another and medical and paramedical professionals may move abroad to offer their services. Table - 1 illustrates the kinds of health and health related services that can be delivered in each mode.

It is necessary to examine the impact of trade in health services in each of the four modes on access of all to health services. A joint study by WHO and UNCTAD has examined this issue. The WHO has identified three policy objectives in terms of which the impact of liberalisation of health services may be measured viz. equitable access to health services, quality of health services and efficient allocation of resources for health services (4). Hence, the liberalisation of health services should not compromise any of the three policy objectives.

### Issues of Concern

In India the public sector provides health services through the central governments, state governments, municipal corporations and other local bodies. The private sector includes health services provided by charitable institutions, missions, trusts, non-governmental organisations (NGOs), etc. as well as clinics, nursing homes and hospitals providing such services for profit. The private sector has comprised the largest constituent of the country's healthcare delivery system ever since India's independence and has expanded rapidly since the 1980s even before the creation of the GATS. In 1990, 57.95 per cent of hospitals and 29.12 per cent hospital beds in India were in the private sector (5). According to the National Health Accounts India (2001-02), 77.4 per cent of the total health expenditure in India was private expenditure while only 20.3 per cent was government expenditure, while the total health expenditure accounted for only 4.6 per cent of the GDP. However, there is a strong concentration of bed occupancy in the public health sector at a ratio of about 62 per cent (6). While developed countries like USA, Germany, France, Canada and UK spent from about 7 to 14 per cent of their GDP on health, their government's share of this expenditure was in the range of 44 to 84 per cent (7). This clearly shows that even in developed countries, the government has a substantial share in the expenditure on

**Table - 1**

Mode of delivery of the Service	Kind of service delivered
Cross-border service (mode 1)	Shipment of samples, diagnosis, clinical consultation via traditional mail channels. Electronic delivery of health services like telemedicine, telesurgery, teleradiology services; medical back office services, medical transcription services and online medical education services.
Consumption abroad (mode 2)	Medical tourism for super specialty medical services and alternative systems of healthcare.
Commercial presence (mode 3)	Establishment of super specialty hospitals and clinics, diagnostic and treatment centres in collaboration between domestic and foreign health services providers, health insurance services and hospital management services.
Movement of natural persons (mode 4)	Services of doctors, surgeons, nurses and midwives in foreign countries.
Source : Rupa Chanda, 'Liberalizing Trade in Health Services : Issues and Concerns for India', presentation made at the National Workshop on Health Services Liberalisation under WTO / GATS - Whither and How?, organised by the Ministry of Health and Family Welfare and the WHO India Office, 15 Feb 2006.	



health sector and this factor certainly helps in maintaining equity in access to healthcare in this sector. Hence, a further liberalization without addressing equity in access to healthcare would worsen the situation.

There is evidence of a strong concentration of hospitals in India in economically developed areas including a strong concentration in economically developed urban areas (8). From 1991 to May 2001 there have been 62 cases of approval of foreign investments in hospitals or diagnostic centres in India. An overwhelming majority of these investments are concentrated in urban areas with the most investments being in Chennai, Delhi and Kolkata (9).

Noting the growing presence of super-specialty private hospitals in India established with foreign collaboration and India's emergence as a hub for medical tourism, the report of the National Commission on Macroeconomics and Health (NCMH) has observed that this '... will increase the overall cost of healthcare in the country and generate pressures for increased budgetary allocations for government hospitals to stay competitive.' On the basis of a survey of the health sector, the report draws the following conclusions :

- The resources in the health sector are distributed unevenly with 88 per cent concentration of resources in towns;
- 75 per cent of specialists and 85 per cent of technology is in the private sector;
- 49 per cent of beds are in the private sector with an occupancy ratio of 44 per cent while the public sector has an occupancy ratio of 62 per cent;
- There is an acute shortage of human resources in the health sector with an average of 0.49 doctors and 0.79 nurses per 1000 people while the global norm is 2.25 per 1000 people. This shortage is further compounded in rural areas with about two-thirds concentration of health professionals in urban centres;
- 75 per cent service delivery for dental health, mental health, orthopaedics, vascular and cancer diseases are provided by the private sector (10).

Thus, while there is a severe shortfall in the availability of doctors and nurses in proportion to the population, most of the human resource is concentrated in the private sector, which is primarily based in urban centres. On the other hand the understaffed public sector with less resource has a higher occupancy ratio than the private sector. Therefore, the growth of the private sector with foreign collaboration has not reduced the load on the public sector. Indeed while the economy was growing at about 8 per cent in 2005, the Infant Mortality Rate (IMR), considered, as the most important indicator of how the resources are distributed for health, in India was 60 per thousand live births (11). The NCMH report also shows that there is already a two-tier system with internal and external brain drain is exiting in India. The following discussion examines how far the existing regulatory mechanism addresses the concerns on health service liberalisation.

### **Trade and Health : Human Rights Implications**

The issue of impact of liberalisation on access to health services including access to health medicines should be seen from a human rights perspective. Multilateral trade agreements adopt

a commercial approach towards trade issues which reduces the policy making space for states. Rights based approach to trade liberalisation the promotion, protection and fulfilment of human rights as an integral and fundamental objective of trade liberalisation, which seeks to make the States primarily responsible under international human rights law for ensuring that human rights are not compromised in the process of trade liberalisation.

The human rights based approach to trade liberalisation regards certain goods and services that are essential for leading a life in dignity as entitlements, which must be accorded to all. In accordance with this approach, the international community has been examining the possible ways of ensuring the availability of these entitlements for all peoples through the process of trade liberalisation.

The UN Sub-Commission on the Promotion and Protection of Human Rights has examined the relationship between the liberalisation of trade in services and the enjoyment of human rights including the right to health. The right of everyone to the enjoyment of the highest attainable standard of physical and mental health is recognised in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). To achieve the full realisation of this right States have the responsibility to create conditions that would ensure to everyone medical service and medical attention in the event of sickness (12).

The content of the right to health has been explained in general comment no.14 of the Committee on Economic, Social and Cultural Rights (CESCR). Accordingly, the essential elements of the right to health are :

- The availability of a functioning public health system and health-care facilities including hospitals, clinics, trained medical professionals and essential drugs.
- Universal access to health services in both physical as well as economic terms. Thus, there should not be an over-promotion of investments in expensive curative health services instead of primary and preventive healthcare services which benefits a larger section of the population.
- The State must ensure the quality of health services (13).

Besides the UN, the right to health as a fundamental human right has also been recognised by the Alma-Ata Declaration of the International Conference on Primary Health Care. The Declaration had set the attainment by all people of the world a level of health suitable for leading a socially and economically productive life by the year 2000, as a main social target for governments, international organisations and the world community (14). Though it is evident that the timeline set by the Alma-Ata Declaration has been missed, the objectives set therein still remain valid and they should be observed in the process of liberalisation of health services.

Thus, in spite of TRIPS and GATS commitments on patent rights and liberalising health services or autonomous liberalisation of such services, all States are primarily responsible for creating and sustaining conditions that promote, protect and fulfill the access of all peoples to a functioning, affordable, accessible and high quality health service. This primary responsibility of States under international human rights law extends to the



trade liberalising commitments that they negotiate in the WTO and other regional trading arrangements.

## Summary

During the last part of 20th century most countries shifted their development strategy from self-sufficiency to export oriented growth strategy. Most important issue with regard to trade and public health is the loss of policy space of developing country government related to public health. The most important institution and agreement relevant the discussion here is WTO and the Agreement establishing WTO. The agreement establishing WTO contains a set of international agreements regulating specific aspects of trade. It reduces the policy space of countries with regard to access to medicines and access to health services. Developing countries are on the verge of losing the existing policy space in those areas. The term intellectual property rights generally refer to a set of exclusive rights granted to the owner of intellectual property.

TRIPS is one of the most controversial agreements administered under the World Trade Organisation's (WTO) frame work because it took away the freedom of member countries to determine the level of intellectual property protection. Patents especially product patents create a statutory monopoly for a limited number of years and increases the chance of abuse of patents. As mentioned above, TRIPS prescribes a universal minimum standard to different forms of intellectual property. Patent monopoly often abused by the patent holder and fixes a higher price for the patented medicines. Hence, patents on drugs compromise the accessibility and availability of medicines, two important components of right to health. The domestic legislation should incorporate the flexibilities to the maximum extent. The Preamble of TRIPS states that measures and procedures to enforce intellectual property rights should not themselves become barriers to legitimate trade. The domestic legislation should strike a balance between public and private rights and the rights of patentee should not be at the cost of public health concerns. India has a legal right to interpret and implement the TRIPS Agreement to promote access to drugs. TRIPS implementation should not compromise any of the rights guaranteed by any previous international treaty. Even though TRIPS *per se* is objectionable and need to be reviewed in the coming days to ensure accessibility and availability of drugs, the flexibility within TRIPS provides some manoeuvring space to Members States to address the issue of access to drugs. The flexibilities available within the TRIPS offer some policy options for the developing countries to mitigate the adverse affects of product patent protection on the availability of affordable medicines.

India, as a member of the WTO has an obligation under TRIPS to comply with its patent provisions. Countries like India gave importance to the question access to affordable medicines and survival of its generic industry over the protection of intellectual property while implementing the TRIPS Agreement. The generic companies can introduce the generic version immediately after the expiry of patent. In many developing countries, the public health system could not meet the demand for healthcare services. General Agreement in Trade and Service (GATS) attempts to establish a framework within

the WTO for regulating international trade in services and it envisages the progressive liberalisation of all trade in services. However, there is a concern expressed by health policy analysts and the civil society as to the adverse implications of GATS disciplines on health services. The traditional notion of health as non-commercial services has undergone a paradigm change. While the ultimate delivery of a health service necessarily involves physical contact between the health professionals like doctors and nurses with the patient, owing to technological developments the extent to which physical contact is required can be reduced significantly. Trade in health services involves 4 modes of services delivery. In India the public sector provides health services through the central governments, state governments, municipal corporations and other local bodies. Even in developed countries, the government has a substantial share in the expenditure on health sector. While there is a severe shortfall in the availability of doctors and nurses in proportion to the population, most of the human resource is concentrated in the private sector, which is primarily based in urban centres. The NCMH report also shows that there is already a two-tier system with internal and external brain drain existing in India. The following discussion examines how far the existing regulatory mechanism addresses the concerns on health service liberalisation. Multilateral trade agreements adopt a commercial approach towards trade issues which reduces the policy making space for states. The human rights based approach to trade liberalisation regards certain goods and services that are essential for leading a life in dignity as entitlements, which must be accorded to all. The content of the right to health has been explained in the Committee on Economic, Social and Cultural Rights (CESCR). In spite of TRIPS and GATS commitments on patent rights and liberalising health services or autonomous liberalisation of such services, all States are primarily responsible for creating and sustaining conditions that promote, protect and fulfill the access of all peoples to a functioning, affordable, accessible and high quality health service.

## Study Exercises

### MCQs

1. The most important institution and agreement regulating International trade regime at present is (a) Free Trade Agreements (FTA) (b) Doha Declaration (c) UN Central Products Classification system (UNCPC) (d) World Trade Organization (WTO)
2. The most controversial provisions TRIPS are related to (a) Patent protection (b) Trademark (c) Copyrights (d) Industrial designs
3. Members "shall not be obliged to, implement in their domestic law more extensive protection than required by this Agreement". This is enshrined in which article of TRIPS ? (a) 1 (b) 2 (c) 3 (d) 4.
4. In 2001, WTO Ministerial Conference endorsed the same approach for the implementation of TRIPS patent provisions at the domestic level in (a) Johannesburg (b) New Delhi (c) Doha (d) New York

Answers : (1) d; (2) a; (3) a; (4) c.

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The fact that the world is but a global village and health and disease can not be limited by the boundaries of the nations, was recognized long ago. Way back in 1377, the first recorded quarantine legislation was promulgated for prevention of transshipment of rodents to Venice from foreign ports. The International Sanitary Conference, convened in Paris in 1851, was the first step towards seeking international cooperation in prevention of communicable diseases with epidemic potentials. This conference, in spite of not succeeding in framing the uniform code for quarantine, gave rise to many such conferences in quick succession which in turn led to the establishment of *Office International d'Hygiene Publique* (OIHP) in 1907 – a precursor of League of Nations and World Health Organization (WHO).

The term "International Health" first appeared sometime in early twentieth century and became well known following the establishment of International Health Commission in 1913 in United States. The commission played a vital role in the opening of first school of public health in 1917 in the United States at John Hopkins University but it was only in 1960 that the international health division was established in the school. Since then the activities in the field of international health has increased by leaps and bounds and has involved many governmental, inter-governmental and non-governmental organizations.

### Definition of International Health

Simply said international health means public health with an international dimension. The predominant notion refers to the interactions taking place in the field of health at international level. This not only includes the risks and hazards to health

faced by individuals and populations owing to the mobility of health hazards and people but also includes various measures taken for the promotion, protection, prevention and restoration of health. It uses tools of public health, takes into account the information received from other disciplines and addresses questions that transcend the frontiers of a country. The term 'international health' has been defined as *a field of research and intervention embracing the international dimensions of health, disease process and care systems*.

While research refers to the analysis of health determinants and the health states of the individuals and populations, the intervention refers to the actions taken at economic, political and administrative levels. Broadly speaking, international health is *a systematic comparison of the factors that affect the health of all human populations*.

However, international health means differently to different people e.g. for a public health worker it means protection of population from illness, for an epidemiologist it means a study of distribution and control of diseases, for a clinician it means practice of medicine in a remote area, for an administrator it means organization and operation of health services, for an economist it means a study of health resource allocation and financing and for a politician it means controlling spheres of influences. The popular view, as shaped by media and perceived by masses, is that the international health deals with situations like tsunami, SARS or pandemic influenza, giving little importance to inequity in health sector globally or even the hard core issues of public health.

### Contents of International Health

International health is seen as a conglomeration of various aspects of public health, as follows :

- It uses principles of epidemiology while appreciating the root causes of ill health in the world in general and in defined populations in particular, with an aim of alleviating the global burden of diseases.

- It deals with psychosocial aspects while understanding the psychosocial effects of diseases or health related events on individuals, families and communities.
- Demographic aspects are important for understanding the composition of population segments in individual countries and of populations in different countries.
- Economic aspects come into play when it deals with public health expenditure and out of pocket expenditure on health, resource allocations and the cost of illness to individuals, families, communities and countries.
- It also dwells upon health system and governance while discussing the health systems of the countries, their health infrastructure and their governance and also of the health ministries and their interactions with other ministries which have a direct impact on the health.
- It also includes certain miscellaneous aspects like ethical issues, utilization of alternative medicine by various population segments, humanitarian response to disasters and emergencies and the participation of various governmental, non-governmental and private agencies.

### Organizations Involved in International Health

A number of governmental, inter-governmental and non-governmental organizations are actively involved in International health. They can be classified as government sponsored international agencies and non-governmental organizations further subdivided into private voluntary organizations and philanthropic organizations. Among government sponsored international agencies are included several United Nations (UN) organizations of which World Health Organization (WHO) is the most important. A brief about some of these organizations are given in succeeding paragraphs.

### World Health Organization (WHO)

Following World War II and creation of intergovernmental organizations like United Nations (UN), a need of having an international health agency was felt by many of the countries who experienced the devastating after effects and were still reeling under colonial rule. Brazilian and Chinese delegations submitted a joint declaration to United Nations for inclusion of health in the charter of UN and when diplomats met, one of the things they discussed was setting up a global health organization. As a result the landmark international health conference was held in New York in Jun – Jul 1946. At this conference, all the 61 members approved the constitution of World Health organization (WHO) on 22 Jul 1946. This constitution, after many deliberations and ratifications, came into force on 7 April 1948 – a date we now celebrate every year as World Health Day.

Thus WHO became the United Nations' specialized agency for Health with its headquarters in Geneva, Switzerland. It inherited the mandate and all the resources of its predecessor, the League of Nations and acts as a coordinating authority on international public health.

### Mission

Its objective, as set out in its Constitution, is the attainment by all peoples of the highest possible level of health. The Constitution defines health as a state of complete physical,

mental and social well-being and not merely the absence of disease or infirmity.

### Role in Public Health

WHO fulfils its objectives through its core functions, which are:

- (a) **Leadership** : Providing leadership on matters critical to health and engaging in partnerships where joint action is needed
- (b) **Setting standards** : Setting norms and standards and promoting and monitoring their implementation
- (c) **Policy formulation** : Articulating ethical and evidence-based policy options
- (d) **Capacity building** : Providing technical support, catalysing change and building sustainable institutional capacity;
- (e) **Monitoring** : Monitoring the health situation and assessing health trends
- (f) **Research** : Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge.

### Organisation

The WHO has its Headquarters comprising of the world health assembly and the executive board, at Geneva and its regional offices for six regions covering all the member states, at six different places.

The World Health Assembly is the supreme decision-making body for WHO. It deals with the administration, finances and international policies and programmes. It also elects the Director General of the WHO who is the chief technical and administrative officer of WHO. It meets each year in May in Geneva and is attended by delegations from all 193 Member States.

The Executive Board, which is like a cabinet, is composed of 34 members technically qualified in the field of health. Members are elected for three-year terms. The main Board meeting, at which the agenda for the forthcoming Health Assembly is agreed upon and resolutions are adopted for forwarding to the Health Assembly, is held in January, with a second shorter meeting in May, immediately after the Health Assembly, for more administrative matters. The main functions of the executive board is to give effect to the decisions and policies of world Health assembly and to facilitate its work.

In the year 1998, all the existing programmes were reduced to 35 departments grouped into nine clusters which are enumerated as follows :

- (a) Health system and community health
- (b) Communicable diseases
- (c) Non-communicable diseases
- (d) Sustainable development and healthy environments
- (e) Evidence and information for policy
- (f) Health technology and pharmaceuticals
- (g) External relations and governing bodies
- (h) Social change and mental health
- (i) General management

Each cluster was headed by an executive director who in turn had a high profile senior management and decision making



team called a Cabinet. These cabinets carried out and monitored the projects assigned to them.

**Regions :** The six different regions of WHO and their headquarters are as given in Table - 1 :

<b>Table - 1 : Regions of WHO</b>	
<b>Regions</b>	<b>Headquarters</b>
The Americas	Washington D. C. (U. S. A. )
Europe	Copenhagen (Denmark)
Eastern Mediterranean	Alexandria (Egypt)
Western Pacific	Manila (Philippines)
South East Asia	New Delhi (India)
Africa	Harare (Zimbabwe)

Each regional organization is headed by a regional director who is assisted by administrative officers and technical officers. Representatives of the member states form the regional committee which meets once a year to review the ongoing health projects, their continuation and further development in their respective countries.

#### **Activity Areas in India**

In India, WHO provides technical assistance and collaborates with the Government of India and major stakeholders in health development efforts. It assists notably in Policy Development; Capacity Building and Advocacy. Technical assistance to the Government is provided through the following Core Programme Clusters :

**(a) Health system and community health :** Reproductive Health and Research; Child and Adolescent Health; Gender and Women Health; Immunization; Nursing and Midwifery; Nutrition and AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy).

**(b) Communicable diseases :** Leprosy; Malaria; Filariasis; Tuberculosis; HIV/AIDS and International Health Regulations.

**(c) Non-communicable diseases :** Cardiovascular Diseases; Tobacco Control; Health Care for the Elderly; Prevention of Deafness; Prevention of Blindness; Health Promotion; Oral Health; Cancer; Non-Communicable Disease Risk Factors Surveillance and other Non-Communicable Diseases.

**(d) Sustainable development and healthy environments:** Chemical Safety; Emergency & Humanitarian Action; Food Safety; Health & Environment; Healthy Cities; Environmental Epidemiology and Water Sanitation.

**(e) Evidence and information for policy :** National Health Accounts; Policies; Medical Ethics; Information System; Burden of Diseases; World Health Survey.

**(f) Health technology and pharmaceuticals :** Essential Drugs and Medicines; Development of Vaccines.

**(g) Social change and mental health :** Mental Health and Substance Abuse; Disability, Injury Prevention and Rehabilitation.

**(h) General management :** Health Finance; Trade Agreements and Reform Issues.

#### **Special Programmes**

WHO has also facilitated some special health programmes like National Polio Surveillance Programme, Revised National Tuberculosis Control Programme, 3 by 5 for HIV / AIDS, Leprosy Elimination, Roll Back Malaria, Tobacco Free Initiative, Lymphatic Filariasis and Health networking. WHO, in the recent past, has assisted the government of India in emergency and humanitarian action in Gujarat and Rajasthan, in the aftermath of the tsunami and for epidemic outbreaks like the Japanese Encephalitis. WHO is also working with the Ministry of Health in the pandemic preparedness plans for the Avian Influenza.

#### **United Nations Children's Fund (UNICEF)**

United Nations International Children's Emergency Fund (UNICEF) was originally created to deal with the issue of child poverty in Europe after World War II. But it could gain official permanent status in the UN only in 1953, six years after its birth as United Nations Relief and Rehabilitation Agency (UNRRA). Over a period, it dropped the terms International and Emergency from its name, but because of the difficulty in pronunciation of UNCF it kept the acronym UNICEF. In 1961, UNICEF also included the rights of children to education and proper health care under the umbrella of its activity. Four years later, it was awarded the Nobel Peace Prize "for the promotion of brotherhood among nations. "

#### **Objectives**

"UNICEF identifies young child survival and development as the first right of the child. It advocates quality basic education for all children - girls and boys - with an emphasis on gender equality and eliminating disparities of all kinds.

Its priorities include promotion of breast feeding, immunization, growth monitoring, oral rehydration, education of girl child, child spacing and nutritional supplementation.

As the mandate of the organization is to protect a child's right to survival and to ensure that children are given the basic right to an education, needs are analyzed primarily at a local level, assisted regionally by UNICEF and ultimately funded and administrated by UNICEF international.

#### **Structure and Funding**

The administrative and organizational headquarter of UNICEF is at New York City. Eight regional offices and 125 external offices permit UNICEF to carry out its role efficiently and provide cover to almost all children of the world. It is governed by an Executive Board made up of 36 members. Each of these members is elected for a three-year term. The election system is based on rotation, so as to take all countries into account. The Executive Director of UNICEF is nominated by the Secretary General of the UN.

UNICEF is funded exclusively by voluntary contributions. This comes through contributions from corporations, civil society organizations and more than 6 million individual donors worldwide.

#### **UNICEF in India**

UNICEF has been working in India since 1949 and today, it has a network of 13 state offices in the country. These enable



the organization to focus attention on the poorest and most disadvantaged communities and to ensure that each child born in this vast and complex country gets the best start in life, thrives and develops to his or her full potential. It is currently implementing a \$400 million programme from 2003 to 2007.

The milestones in the history of UNICEF's work in India are as follows :

- (a) 1949 : UNICEF begins working in India.
- (b) 1967 : UNICEF's association with GOI's rural water programme provides emergency relief to tackle severe drought. Since then, the national water programme has expanded to provide access to protected sources of drinking water to 95% of India's villages.
- (c) 1975 : UNICEF supports piloting and launch of Integrated Child Development services (ICDS).
- (d) 1985-86 : UNICEF supports launch of GOI's Universal Immunization Programme (UIP).
- (e) 1986 : UNICEF works with GOI to launch Oral Rehydration Therapy Programme for treatment of diarrhoea.
- (f) 1996 : UNICEF supports launch of GOI's Reproductive and Child Health (RCH) programme.
- (g) 2000 : UNICEF partners with GOI to ensure eradication of guinea worm.
- (h) 2004 : UNICEF joins Government of India's (GOI) efforts to eradicate polio.

Besides this, UNICEF, within the context of National AIDS Control Plan III, also collaborates with the Government of India and other partners in four key areas which include primary prevention among young people, prevention of Parent-To-Child Transmission (PPTCT), paediatric HIV/AIDS and protection, care and support for affected children.

## United Nations Educational, Scientific and Cultural Organization (UNESCO)

UNESCO - the heir of the League of Nations' International Commission on Intellectual Cooperation - was founded on 16 November 1945. Today it has 193 Member States and 6 Associate Members. The organizational headquarter is at Paris. It has over 50 field offices and many specialized institutes and centres throughout the world. The organization aims at promotion of international co-operation among its Member States in the fields of education, science, culture and communication.

Through its strategies and activities, UNESCO is actively pursuing the Millennium Development Goals, especially those aiming to :

- (a) halve the proportion of people living in extreme poverty in developing countries by 2015
- (b) achieve universal primary education in all countries by 2015
- (c) eliminate gender disparity in primary and secondary education by 2005
- (d) help countries implement a national strategy for sustainable development by 2005 to reverse current trends in the loss of environmental resources by 2015.

## Mission

The mission of UNESCO is to contribute to sustainable human development and create the conditions for dialogue, based upon respect for commonly shared values and the dignity of each civilization and culture, through programmes and projects in UNESCO's fields of competence - education, the natural and social sciences, culture and communication and information.

## Structure

The day-to-day administration, governance, policy making and activities of UNESCO are carried out by the General Conference, the Executive Board and the Secretariat.

The General Conference consists of the representatives of member states. It meets every two years and is attended by representatives of member states, observers from non-member states, intergovernmental organizations and non-governmental organizations (NGOs). Each country has one vote, irrespective of its size or the extent of its contribution to the budget. The General Conference determines the policies and programmes and elects Members of the Executive Board. The working languages of the General Conference are Arabic, Chinese, English, French, Russian and Spanish.

The Executive Board, is responsible for the overall management of UNESCO. It meets twice a year and outlines the work of the General Conference and sees that its decisions are properly carried out. The functions and responsibilities of the Executive Board are derived primarily from the Constitution and from rules or directives laid down by the General Conference.

The Secretariat consists of the Director-General and his staff and is responsible for the day-to-day running of the organization. The Director-General is elected by the General Conference for a term of four-years. The Secretariat is divided into various administrative offices and five programme sectors viz. education, natural sciences, social and human sciences, culture and communication and information. These sectors reflect the organization's major areas of focus.

## UNESCO in India

India joined UNESCO on November 4, 1946. The Cluster Office in New Delhi covers Bangladesh, Bhutan, India, Maldives, Nepal and Sri Lanka and helps them to build their human and institutional capacities in diverse fields. It, as the Organization's contribution towards the six Millennium Development Goals, has identified six broad areas for providing assistance and directing its activities. These are :

- (a) Universal Primary Education
- (b) Promoting gender equity and equality
- (c) Implementation of the new commitment to science
- (d) Protecting world's cultural diversity
- (e) Equitable access to information and knowledge to all
- (f) Sustainable Development

Education is a top priority in India's cooperation with UNESCO. The fourth UNESCO Regional Conference in Support of Global Literacy was held on 29 and 30 November 2007 in New Delhi.

India also participates in a variety of UNESCO activities related to cultural heritage and to intercultural dialogue. The Maitreya Temples (Ladakh, India) received the Award of Excellence in

the 2007 UNESCO Asia-Pacific Heritage Awards for Culture Heritage Conservation.

The UNESCO project in Sikkim has been found to be successful. The project promotes community participation in developing tourism in the Central Asia/Himalayan region, by helping to generate employment for local people.

### Food and Agriculture Organization (FAO)

The FAO was founded in 1945. It is an intergovernmental organization with its headquarter at Rome. As of now, it has 174 Member Nations plus a member organization, the European Community. It is the largest specialized agency in the United Nations system and the lead agency for agriculture, forestry and rural development.

#### Activities

Its activities comprise four main areas:

**(a) Putting information within reach :** FAO serves as a knowledge network. It collects, analyses, interprets and disseminates information relating to nutrition, food, agriculture, forestry and fisheries. Through newsletters, reports and books, magazines and host dozens of electronic for a, it assists governments and planners to make rational decisions on planning, investment, marketing, research or training.

**(b) Sharing policy expertise :** FAO lends its years of experience to member countries in devising agricultural policy, supporting planning, drafting effective legislation and creating national strategies to achieve rural development and hunger alleviation goals.

**(c) Providing a meeting place for nations :** FAO provides a neutral forum where all nations - rich and poor, developing and developed - can meet to build a common understanding and to discuss and formulate policy on major food and agriculture issues.

**(d) Bringing knowledge to the field :** FAO provides the technical know-how and funds, only to a limited extent, for thousands of field projects throughout the world.

#### Mission

FAO aims at achieving food security for all. Its efforts are directed to make sure that all people of the world have regular access to enough high-quality food and lead an active, healthy lives. Its mandate is to raise levels of nutrition, improve agricultural productivity, better the lives of rural populations and contribute to the growth of the world economy.

#### Structure

FAO is governed by the Conference of Member Nations, which meets every two years to review the work carried out by the Organization. The Conference elects the Director-General and a Council of 49 Member Nations to act as an interim governing body. Members serve three-year on a rotation basis.

FAO currently has five regional offices, nine sub-regional offices, five liaison offices and 74 fully-fledged country offices in different parts of the world.

FAO is composed of eight departments viz. agriculture and consumer protection; economic and social department; fisheries and aquaculture; forestry; human, financial and physical resources; knowledge and communication; natural resource

management and environment and technical cooperation.

#### FAO in India

The FAO, with its regional office at Bangkok, provides regular support to India in the field of Food Security and Nutrition. Its current focus is mainly on plant production activities, forestry, fisheries, nutrition and food quality & safety. A special interests lies in the field of vulnerability mapping through the establishment of a Food Insecurity and Vulnerability Information and Mapping System (FIVIMS) and the preparation of a Nutrition Country Profile for India. In addition, under its Special Programme for Food Security, FAO supports the design of a large scale maize production scheme. Under its Technical Cooperation Programme (TCP), the various projects in India are as follows :

- (a) Transfer of technology for vegetative propagation of walnuts in Jammu & Kashmir
- (b) Development of integrated plant nutrition systems methodology
- (c) Training in sea safety development programmes
- (d) Greenhouse technology for floriculture
- (e) Food quality control

### International Labour Organization (ILO)

The ILO was founded in 1919 to improve the living and working conditions of the working population all over the world. In 1946, it became the first specialized agency of the UN. It has its headquarter at Geneva, Switzerland.

With 175 Members, ILO is unique in having a tripartite character i.e. at every level in the organization, governments with the two other social partners, namely the workers and employers jointly shape policies and programmes. This helps in setting minimum standards of basic labour rights : freedom of association, the right to organize, collective bargaining, abolition of forced labour, equality of opportunity and treatment and other standards addressing conditions across the entire spectrum of work-related issues. The overall purpose is to bring decent work and livelihoods, job-related security and better living standards to the people of both poor and rich countries.

#### Objectives

The objectives of ILO are :

- (a) To promote and realize standards and fundamental principles and rights at work.
- (b) To create greater opportunities for women and men to secure decent employment and income.
- (c) To enhance the coverage and effectiveness of social protection for all.
- (d) To strengthen tripartism and social dialogue.

#### Structure

The administration and functioning of ILO is carried out by its three organs :

- (a) International Labour Conference, which is the General Assembly of the ILO, meets every year in the month of June.
- (b) Governing Body, which is the executive council of the ILO, meets three times in a year in the months of March, June and November.
- (c) International Labour Office is the permanent secretariat.

## ILO in India

India is a founder member of ILO and has a branch office in New Delhi since 1929. The Branch Office became an Area Office of ILO in 1970. It coordinates and provides technical assistance to India and Bhutan in the field of rural labour, women workers, employment generation, occupational safety and health etc.

ILO's interest in child labour, young persons and their problems is well known. In India, within a framework of the Child Labour (Prohibition and Regulations) Act, 1986 and through the National Policy on Child Labour, ILO has funded the preparation of certain local and industry specific projects. In two Kanor projects, viz. Child Labour Action and Support Programmes (CLASP) and International Programme on Elimination of Child Labour (IPEC), the ILO is playing a vital role.

The implementation of IPEC programmes in India has created a very positive impact towards understanding the problem of child labour and in highlighting the need for elimination of child labour. A major contribution of the IPEC programme in India is that it has generated a critical consciousness among all the 3 social partners for taking corrective measures to eliminate child labour.

## United Nations Development Programme (UNDP)

Founded in 1965, the UNDP is an executive board within the United Nations General Assembly. Its Administrator is the third highest ranking member of the United Nations after the United Nations Secretary-General and Deputy Secretary-General. It has its headquarter in New York City and country offices in 166 countries where it works with governments and local communities to help find solutions to global and national development challenges.

UNDP provides expert advice, training and grant support to developing and least developing countries (a) to meet developmental challenges (b) to develop local capacity and (c) to accomplish MDGs. It focuses on developmental challenges. It encourages the protection of human rights and the empowerment of women in all of its programmes. It also publishes an annual Human Development Report which critically analyze and present the developmental progress made by the countries of the world.

### Functions

UNDP focuses primarily on five developmental challenges :

**(a) Democratic governance:** UNDP supports existing democratic institutions by increasing dialogue, enhancing national debate and facilitating consensus on national governance programs. It also supports the transition to democracy by providing policy advice, technical assistance, increasing awareness and capacity building.

**(b) Poverty reduction :** UNDP works with governments, NGOs and local leaders to provide opportunities to impoverished people and improve their predicament. It assists governments to evolve strategies to combat poverty by linking poverty alleviation programmes to major national programmes and to find ways and means for economic opportunities.

**(c) Crisis prevention and recovery :** During disasters and armed conflicts UNDP assists governments in early recovery.

Recovery programs include disarmament, demobilization and reintegration of ex-combatants, programs to reintegrate displaced persons and restoration of basic services for countries recovering from warfare.

**(d) Environment and Energy :** As the poor are disproportionately affected by environmental degradation and lack of access to clean, affordable energy services, UNDP seeks to address environmental issues in order to improve developing countries' abilities to develop sustainably.

**(e) HIV/AIDS :** UNDP works to help countries prevent further spreading of HIV/ AIDS and reduce its impact.

### UNDP in India

UNDP has been India's partner in development since 1951. Some of its success stories are as under :

- (a) In 1980s, it supported the institution building and technology transfer to apex scientific research institutions like the Council for Scientific and Industrial Research (CSIR) and the Indian Council for Agricultural Research (ICAR).
- (b) In 1990s, UNDP launched a project on social sector strategy to enhance the incomes of the poor and disadvantaged people employed in leather and jute industries. Subsequently the project was extended to other sectors like textiles, fibres and handicrafts that employed people from these groups.
- (c) In response to the Orissa cyclone and the Bhuj earthquake, UNDP launched a disaster mitigation and preparedness programme. The community-based disaster preparedness approach tried out by UNDP in Orissa following the 1999 super-cyclone has now been scaled up nationally in 169 multi-hazard prone districts in 17 states through the UNDP-Government of India Disaster Risk Management Programme.
- (d) The model of poverty alleviation developed and piloted under the UNDP South Asia Poverty Alleviation Programme (SAPAP) in Andhra Pradesh successfully demonstrated the value of women's unity and mobilisation for their social, economic and political empowerment.
- (e) In Maharashtra, under the Community-based Pro-poor Initiatives (CBPPI) Programme, UNDP supported the Swayam Shikshan Prayog (SSP), a local NGO, to build alliances between women's groups and panchayats (local elected bodies) to operationalise community monitoring of development programmes, particularly for identifying and measuring the barriers that restrict women's access to public services.

The current country programme document for India (2008 - 12) is in harmony with the eleventh five-year plan of the Government and is based on a comprehensive review of lessons from past cooperation.

## The United Nations Population Fund (UNFPA)

United Nations Fund for Population Activities (UNFPA) was founded under the administration of the United Nations Development Fund in 1969. In 1987, its name was changed to United Nations Population Fund but the acronym UNFPA was retained. It is the world's largest international source of



funding for population and reproductive health programs.

UNFPA is an international development agency that promotes the right of every woman, man and child to enjoy a life of health and equal opportunity. UNFPA supports countries in using population data for policies and programmes (a) to reduce poverty (b) to ensure that every pregnancy is wanted (c) to ensure that every birth is safe (d) to ensure that every young person is free of HIV/AIDS and (e) to ensure that every girl and woman is treated with dignity and respect.

The Fund works with governments and non-governmental organizations in over 140 countries with the support of the international community, supporting programs that help women, men and young people.

UNFPA is guided in its work by the Programme of Action adopted at the International Conference on Population and Development held at Cairo in 1994. At the conference, 179 countries agreed that meeting needs for education and health, including reproductive health, is a prerequisite for sustainable development over the long term. The main goals of Programme of Action, as refined in 1999, are :

- (a) Universal access to reproductive health services by 2015
- (b) Universal primary education and closing the gender gap in education by 2015
- (c) Reducing maternal mortality by 75 per cent by 2015
- (d) Reducing infant mortality
- (e) Increasing life expectancy
- (f) Reducing HIV infection rates

#### **UNFPA in India**

UNFPA has been providing assistance to India since 1974. Following the adoption of the Programme of Action, the approach has been to empower women and to expand access to education, health services and employment opportunities.

UNFPA supported Integrated Population and Development (IPD) Projects in approximately 40 districts in 6 states in India (Maharashtra, Gujarat, Madhya Pradesh, Kerala, Rajasthan and Orissa) are aimed to address the needs of individuals and couples to achieve their personal reproductive intentions, to help in eliminating discrimination against girls and to help in providing quality reproductive health services.

UNFPA supports the Government of India in the following key areas :

- Integrating population issues within a wider development context
- Implementing the draft national policy for the empowerment of women
- Developing special programmes to improve women's status and address gender disparities
- Strengthening the logistics system for distribution of contraceptives and broadening the choice of available contraceptive methods
- Enhancing advocacy efforts to promote the concept of reproductive health and gender equality

#### **Joint United Nations Programme on HIV / AIDS (UNAIDS)**

Established in 1994 by a resolution of the UN Economic and Social Council and launched in January 1996, UNAIDS is

the main advocate for global action on the HIV epidemic. It brings together ten UN agencies in a common effort to fight the epidemic. Cosponsors include UN High Commission for Refugees (UNHCR), UN Children's Fund (UNICEF), World Food Programme (WFP), UN Development Programme (UNDP), UN Population Fund (UNFPA), United Nations Office on Drugs and Crime (UNODC), International Labour Organization (ILO), UN Educational, Scientific and Cultural organization (UNESCO), World Health Organization (WHO) and the World Bank. It has its headquarter at Geneva, Switzerland. The Cosponsors and the UNAIDS Secretariat comprise the Committee of Cosponsoring Organizations, which meets annually.

#### **Mission**

UNAIDS' mission is to lead, strengthen and support an expanded response to HIV and AIDS that includes preventing transmission of HIV, providing care and support to those already living with the virus, reducing the vulnerability of individuals and communities to HIV and alleviating the impact of the epidemic.

#### **Role**

UNAIDS help mount and support an expanded response – one that engages the efforts of many sectors and partners from government and civil society. Its role can be summarized in five major components :

- (a) Leadership and advocacy for effective action on the epidemic
- (b) Strategic information and technical support to guide efforts against AIDS worldwide
- (c) Tracking, monitoring and evaluation of the epidemic and of responses to it
- (d) Civil society engagement and the development of strategic partnerships
- (e) Mobilization of resources to support an effective response

#### **UNAIDS – WHO HIV Vaccine Initiative**

UNAIDS and WHO, taking advantage of their complementary expertise – UNAIDS contributing with its expertise in social and behavioural research, ethical issues, political mobilization and its strong link with community and WHO bringing in its experiences in vaccine development, its administration and delivery for public health prevention programmes – joined forces to give a boost to the new HIV Vaccine Initiative (HVI). It is guided by a WHO-UNAIDS Vaccine Advisory Committee (VAC), which provides to scientists from different agencies and disciplines, a unique forum for exchange of information and a common ground for collaboration.

#### **UNAIDS in India**

UNAIDS works closely with the Government through the National AIDS Control Organization, government and private institutions, NGOs etc. In its fight against HIV/ AIDS it shares knowledge, skills and its worldwide experience. Specifically it supports the national response to HIV/ AIDS by promoting :

- (a) Strengthened leadership and resource mobilization
- (b) Improved planning, financing, technical assistance and coordination at all levels for a sustainable multi-sectoral response to the epidemic
- (c) Strengthened evidence base of the response through greater



availability and use of strategic information from better monitoring and evaluation, surveillance and resource tracking

- (d) Enhanced human resources and robust delivery system at all levels
- (e) Policies to reduce stigma and discrimination
- (f) Increased coverage and sustainability of programmes for injecting drug users, men having sex with men and sex workers
- (g) Increased coverage and sustainability of programmes to address the vulnerability of women and girls, young people, emergency-affected populations and uniformed personnel.

### United States Agency for International Development (USAID)

History of creation of USAID dates back to 1947 Marshall Plan – European Recovery Programme following World War II – and Foreign Assistance Act. But it was only in 1961 when USAID was created by an executive order for administering economic assistance programmes. It has its headquarter at Washington, D. C.

USAID is an independent federal government agency that extend assistance to countries recovering from disaster, trying to escape poverty and engaging in democratic reforms. It supports long-term and equitable economic growth and advances U. S. foreign policy objectives by supporting economic growth, agriculture and trade; global health; and democracy, conflict prevention and humanitarian assistance.

The strength of USAID is its field offices around the world where it works in close partnership with governments, private voluntary organizations, indigenous organizations and international agencies. It provides assistance in five regions of the world :

- (a) Sub-Saharan Africa
- (b) Asia
- (c) Latin America and the Caribbean
- (d) Europe and Eurasia
- (e) The Middle East

#### USAID in India

In India, USAID has been providing assistance in the following areas :

**(a) Economic Growth** : For the sustained economic growth of the country, USAID supports agricultural reforms, links small scale farmers to newer markets, strengthens financial institutions and provides know how for generating finances for urban services.

**(b) Health** : USAID has made considerable contribution for prevention of HIV/ AIDS and for improving maternal and child health. It is because of its efforts that the use of contraception in Uttar Pradesh increased from 27 percent in 1992–1993 to 44 percent in 2005–2006; the HIV prevalence rate in Tamil Nadu reduced from 1.13 percent in 2001 to 0.4 percent in 2005. In Muslim communities with persistent polio, USAID works with faith-based organizations to battle misconceptions about the polio vaccine, creating community support and ensuring that children are immunized.

**(c) Disaster Management** : Floods, droughts, landslides, cyclones and earthquakes are regular features in India. USAID collaborates with the Indian government and local communities to improve their capacity in disaster risk reduction to save lives and minimize threats from large-scale financial, infrastructure, crop and productivity losses. USAID is also providing scientists and engineers with state-of-the-art tools for better early warning, for providing architecture to government buildings in Delhi which can withstand earthquakes; and for training of Indian disaster management professionals.

**(d) Energy and Environment** : USAID provides assistance to increase viability in the power sector to meet consumer needs, conserve energy and water resources. By leveraging private funds along with government resources, USAID's urban program is promoting better city governance and improving water and sanitation services for over 18 million people by the end of 2008.

**(e) Opportunity and Equity** : USAID's education program works with Indian non-governmental organizations, state governments and private corporations to reach the vulnerable groups. USAID also supports activities that keep girls in school, improve the legal rights of women, address the problem of female feticide and combat human trafficking. Partnerships with the private sector provide disadvantaged youth with the skills they need to participate in India's growing economy.

### World Bank

The world bank was established as International bank for Reconstruction and Development (IBRD) in 1944 following United Nations Monetary and Financial Conference organized by the U. S. government. It was established to provide financial and technical assistance to developing countries around the world. But by mid- 1950s it became clear that many poor countries were unable to repay standard IBRD loans. This led to the establishment of International Development Association (IDA) in 1960. Today World bank is made up of two unique development institutions owned by 185 member countries - the IBRD and the IDA. The IBRD focuses on middle income and creditworthy poor countries, while IDA focuses on the poorest countries in the world. Together they provide low interest loan, interest-free credit and grants to developing countries for education, health, infrastructure, communications and many other purposes.

In addition to IBRD and IDA, three other institutions viz International Finance Corporation (IFC), Multilateral Investment Guarantee Agency (MIGA) and International Centre for Settlement of Investment Dispute (ICSID) are also closely associated with the world bank. Together these five make the World Bank Group.

#### Mission

The mission of the world bank is to help developing countries achieve Millennium Development goals by alleviating poverty and providing opportunities for sustained development.

#### Organization

The world bank is like a cooperative with 185 member countries. These countries are represented by Board of Governors who are the policy makers and usually meet once a year. The functioning

of the World Bank is carried out by its 24 executive Directors. The five largest shareholders i.e. US, France, Germany, Japan and United Kingdom contribute one director each. The other 19 come from the remaining countries on rotation basis. The headquarter of the world bank is at Washington, D. C. Its president is a US national and is nominated by the United States, the bank's largest shareholder.

### World Bank in India

India is one of the oldest members of the World Bank. The bank's New Delhi office, established in 1957, is the oldest continuously running country office. India is the bank's largest single borrower and receives half of its loans interest-free. The World Bank is the largest financiers of India's National AIDS Control Program (NACP) with a commitment of around US\$275 million in interest-free credits. Its four-year Country Strategy for 2005 - 2008 focuses on lending for infrastructure, human development and improving rural livelihoods. The Bank is increasingly focusing on providing analytical reports on the country's major development challenges and extending practical advice to policy makers by sharing good practices and experience from within the country and abroad.

### Ford Foundation

The Ford Foundation is a private foundation based in New York City. It was founded in 1936 by Henry Ford and Edsel Ford in Michigan with an aim "to receive and administer funds for scientific, educational and charitable purposes, all for the public welfare". Its grant making teams work in three broad program areas viz strengthen democratic values, reduce poverty and injustice, promote international cooperation and advance human achievement.

The foundation's first international field office opened in New Delhi, India in 1952. In 1976, the foundation helped to launch the *Grameen Bank*, which offers small loans to the rural poor of Bangladesh. In the late 1980s, the foundation began making grants to fight the AIDS epidemic, which included support for the establishment of a programme to improve AIDS education and treatment in communities around the country. In 2000, the foundation launched the International Fellowships Program (IFP) to provide fellowships to students from marginalized communities outside the U. S. to pursue graduate studies at universities anywhere in the world.

For many years, the foundation topped annual lists compiled by the Foundation Center of U. S. foundations with the most assets and the highest annual giving; but with the establishment of the Bill and Melinda Gates Foundation in 2000, the Ford Foundation fell far behind the Gates Foundation in terms of assets and 4th in terms of annual grant giving.

### Ford Foundation in India

Ford foundation has helped India in following projects :

- Establishment of National Institute of Health Administration (NIHAE) and education at Delhi for training of health administrators
- Establishment of training centres at Singur, Najafgarh and Poonamalle for training of medical and paramedical persons in the field of public health
- Research-cum-action projects for organization of rural

health services and use of hand-flushed sanitary latrines in rural areas

- Supporting research in reproductive biology and fellowship programmes in family planning
- Collaborating with other agencies for improving the water supply and drainage in the urban areas of Kolkata.

### Rockefeller Foundation (RF)

The Rockefeller Foundation (RF), based in New York City, is the most prominent philanthropic organization and private foundation in the field of International Health. Its central historical mission is to "promote the well-being" of humanity. The international health commission, set up within RF in 1913 and subsequently designated as International Health division (IHD) cooperated, in its early years, with 75 governments for the control of 21 separate diseases including tuberculosis, malaria, yaws, hookworm and yellow fever. The most prominent achievement being the development of 17D vaccine for yellow fever and ridding the southern United States of malaria and hookworm.

Besides its role in disease control, RF has also been closely associated with medical education. RF supported medical schools in Beirut, Bangkok, Brussels and elsewhere but the most famous being Peking Union Medical college (PUMC), China which was created and operated by RF. RF also financed and supported School of public Health at John Hopkins University. An interesting initiative of RF is the establishment of International Clinical Epidemiology Network (INCLEN) which is an independent non-profit organization with its headquarter at Philadelphia. The network includes clinical epidemiologists, biostatisticians, health economists and social scientists who are interested in health care research leading to development of preventive and treatment strategies. INCLEN supports the young researchers, provides training opportunities and a platform for international communications.

In India, RF began its activities in 1920 with a scheme for control of hookworm disease in Madras Presidency. Since then, RF is associated with many public health programmes and medical education. The establishment of All India Institute of Hygiene and Public Health in Kolkata is largely due to the cooperation of RF. Clinical Epidemiology Network - India (IndiaCLEN), a part of regional INCLEN, has 7 Clinical Epidemiology Units across the country and has played important role in the development of Integrated Disease surveillance Project (IDSP), NACP III and evaluation of Pulse polio immunization.

### International Red Cross and Red Crescent Movement

Henry Dunant, a Swiss businessman, in his book "A Memory of Solferino" gave a vivid description of his experiences with the wounded soldiers of Battle of Solferino in June 1859 and advocated the formation of national voluntary relief organizations to help and nurse wounded soldiers in the case of war. In addition, he called for the development of international treaties to guarantee the protection of neutral medics and field hospitals for soldiers wounded on the battlefield. It was because of his efforts that the first Geneva Convention "for the Amelioration of the Condition of the Wounded in Armies in the Field" was adopted on August 22, 1864 and "International

Committee of the Red Cross" (ICRC), which is still its official designation today, came into being. For his work, Henry Dunant was awarded the Nobel Prize for Peace in 1901.

The Red Crescent Movement is an international humanitarian movement with approximately 97 million volunteers worldwide. Its mission is to protect human life and health, to ensure respect for the human being and to prevent and alleviate human suffering, without any discrimination based on nationality, religious beliefs, or political opinions. The movement consists of several distinct organizations that are legally independent from each other, but are united within the Movement through common basic principles, objectives, symbols, statutes and governing organs. These include :

***The International Committee of the Red Cross (ICRC)*** : founded in 1863 in Geneva, Switzerland it has a unique authority under international humanitarian law to protect the life and dignity of the victims of international and internal armed conflicts.

***The International Federation of Red Cross and Red Crescent Societies (IFRC)*** : founded in 1919 and based in Geneva, Switzerland, it coordinates activities between the 186 National Red Cross and Red Crescent Societies within the Movement. On an international level, the Federation leads and organizes, in close cooperation with the National Societies, relief assistance missions responding to large-scale emergencies.

National Red Cross and Red Crescent Societies exist in nearly every country in the world. Currently 186 National Societies are recognized by the ICRC and admitted as full members of the Federation. Each entity works in its home country according to the principles of international humanitarian law and the statutes of the international Movement.

### **The Red Cross Symbol**

The Red Cross on white background was the original protection symbol declared at the 1864 Geneva Convention. It is, in terms of its color, a reversal of the Swiss national flag, a meaning which was adopted to honor Swiss founder Henry Dunant and his home country. According to an agreement within the Red Cross and Red Crescent Movement, the shape of the cross should be a cross composed of five squares. However, regardless of the shape, any Red Cross on white background should be valid and must be recognized as a protection symbol in conflict.

### **Red Cross in India**

In India, the red cross society was established in 1920. During peace time, while working with Military hospitals, it provides news papers and periodicals, musical instruments and indoor games to the indoor patients. While working outside the military hospitals, its role is diverse like running of blood banks, organizing voluntary blood donations, providing opportunities to young boys and girls for getting associated with activities like Pulse Polio Immunization on National immunization day (NID), village upliftment, first aid in the event of an emergency and building up of international friendliness. The Red Cross Home at Bangalore for disabled ex-servicemen is one of the pioneering institutions of its kind in Asia.

## **Swedish International Development Agency (SIDA)**

Swedish International Development Agency (SIDA) has been assisting India since 1964. The broad priority areas of assistance are (a) Poverty oriented projects in the primary health sector with special emphasis on reproductive health and rights of girls and women (b) Environment and urban development with focus on water and sanitation and waste management, air and noise pollution; and (c) Mutual exchange and research cooperation in the field of knowledge and technology. After 1976, Swedish bilateral development assistance has been in the form of grants and is available for mutually agreed projects. Since 1979, SIDA has been supporting the National Tuberculosis Control Programme of India. The grants given for this purpose is utilized for procuring supplies like microscopes, x-ray units and anti-tuberculosis drugs.

## **Danish International Development Assistance (DANIDA)**

Denmark's development co-operation with India started in 1959 and within a decade India became one of the three main recipients of bilateral Danish aid. The areas of activity included health (especially blindness control, polio, leprosy and tuberculosis), agriculture and water and sanitation mainly in the states of Tamil Nadu, Karnataka, Orissa and Madhya Pradesh.

In 1998, consequent to India's nuclear weapons policy, the Government of Denmark officially announced its intention to phase out Danish development assistance to the country. In 2003, however, it was mutually agreed between the two governments to complete the phasing out of the Indo-Danish bilateral official development cooperation by end 2005. During the 45 years of cooperation, Denmark has channelled around 6 billion Danish Kroner (about 1.1 billion US dollars) to the support of the development process in India.

## **Aga Khan Foundation (AKF)**

Founded in 1967 by Aga Khan IV, AKF is a non-governmental development network working to promote social development in the low income countries of Asia and Africa. It has its headquarters in Geneva and is currently active in Afghanistan, Bangladesh, Canada, India, Kenya, the Kyrgyz Republic, Mozambique, Pakistan, Portugal, Switzerland, Syria, Tajikistan, Tanzania, Uganda, the United Kingdom and the United States of America. With affiliates that are important national institutions in North America and Europe and grant-making offices in Africa as well as in South and Central Asia, the Foundation has genuine roots in both the developed and developing worlds. Experience and skills flow in both directions.

The foundation supports primary health care projects in several countries, including a large scale community based system that provides tetanus toxoid to mothers and iodinated oil to prevent goiter and cretinism in children in the rugged mountains of northern Pakistan. Besides, it also supports more than 200 educational and 166 health institutions.



## **Oxford Committee for Famine Relief (OXFAM)**

Originally founded in England in 1942 as the Oxford Committee for Famine Relief by a group of Quakers, social activists and Oxford academics; today OXFAM International is a confederation of 13 organizations working with over 3,000 partners in more than 100 countries to find lasting solutions to poverty and injustice.

Though OXFAM's initial concern was the provision of food to relieve famine, over the years OXFAM has developed strategies to combat the causes of famine. It has three main points of focus viz. (a) development work to lift communities out of poverty with long-term, sustainable solutions; (b) humanitarian work to assist those affected by conflict and natural disasters and (c) advocacy and popular campaigning, to affect policy decisions on the causes of conflict at local, national and international levels.

OXFAM's areas of activities also include works on HIV/AIDS, gender equality, natural disasters, democracy and human rights and climate change.

## **Programme for Appropriate Technology in Health (PATH)**

Based in Seattle, Washington, PATH is an international, nonprofit organization that by collaborating with diverse public- and private-sector partners and with the help of innovative ideas and appropriate technologies try to find sustainable, culturally relevant solutions, for communities worldwide to break long-standing cycles of poor health. Its mission is to improve the health of people around the world by advancing technologies, strengthening systems and encouraging healthy behaviors.

### **Activities**

With country offices in more than 70 countries, collaboration is always at the core of PATH's activities. It focuses on :

- Solutions for emerging and epidemic diseases, like AIDS, tuberculosis and malaria.
- Health technologies designed for low-resource settings, by the people who will use them.
- Safer childbirth and healthy children.
- Health equity for women, among the world's most vulnerable - and influential - populations.

## **Co-operative for Assistance and Relief Everywhere (CARE)**

Founded in North America following World War II, CARE, today, is a leading humanitarian organization with more than 14,500 employees worldwide, fighting global poverty. It is a non-political, private voluntary organization operating in more than 65 countries in Africa, Asia, Latin America, the Middle East and Eastern Europe. It is often one of the first to deliver emergency aid to survivors of natural disasters and war.

CARE's mission is to serve individuals and families in the poorest communities in the world. It works hand in hand with vulnerable families, especially women and girls to help them access their rights.

In India, CARE is operational since 1950. Its main area of focus

had been to provide food support to school children and to ICDS programme. Over the years it has spread its wings and is supporting many projects run by Central Government as well as by State Governments. Notable among these are Integrated Nutrition and Health Projects, Anaemia Control Project, Adolescent Girl's project, Improving Women's Reproductive health and Family Spacing Project. CARE is also conducting a social audit on infant and maternal mortality in Jharkhand to identify and classify all causes of maternal and infant deaths.

## **International Health Regulations (IHR)**

International Sanitary Regulations, first approved in 1892, was revised and adopted by WHO in 1951. It focused on the control of communicable diseases mainly cholera, plague, small pox, yellow fever and enteric fever. These regulations were further modified and adopted as International Health Regulation (IHR) in 1969. It required member states to report outbreaks of certain communicable diseases to WHO. With ever changing physical, social and biological environment, with increasing urbanization and decreasing distances, with mounting threats of natural and man-made disasters and with the risk of emerging and reemerging diseases, IHR required amendments in 1973 and 1981. Subsequent epidemiological evidences demonstrated the need for regulations for broader disease coverage and measures to stop their spread across borders. Accordingly, IHR was completely revised in 2005 to provide the legal framework for international cooperation. The stated purpose of IHR is to control and prevent the spread of disease, protect against it and evoke an international response commensurate with the existing public health practices without unnecessarily affecting the trade and the traffic.

### **IHR (2005) : The Objectives**

The IHR (2005) entered into force with effect from 15 June 2007 with its main objectives as follows :

- (a) The appropriate application of routine, preventive measures (e.g. at ports and airports) and the use by all countries of internationally approved documents (e.g. vaccination certificates).
- (b) The notification to WHO of all events that may constitute a public health emergency of international concern.
- (c) The implementation of any temporary recommendations should the WHO Director General have determined that such an emergency is occurring.

### **Scope and Notification**

IHR (2005) has radically changed the international notification requirements of States to WHO. Member states are no longer required to notify the occurrence of Cholera, plague and yellow fever. Notification is now based on the identification of an "event that may constitute a public health emergency of international concern" (PHEIC). PHEIC has been defined in the Regulations as an extraordinary public health event which constitutes a public health risk to other States through the international spread of disease and may require a coordinated international response.

This non-disease specific definition of notifiable events expands the scope of the IHR (2005) and include events (beyond communicable diseases) arising from any origin or



source. Such events are required to be reported, using decision instrument given in Annex II of the IHR (2005) to WHO (Fig. -1). If the event is identified as notifiable, it must be notified giving detailed public health information, number of cases and deaths and available lab results, to WHO immediately i.e. within 24 hours after having carried out the initial assessment.

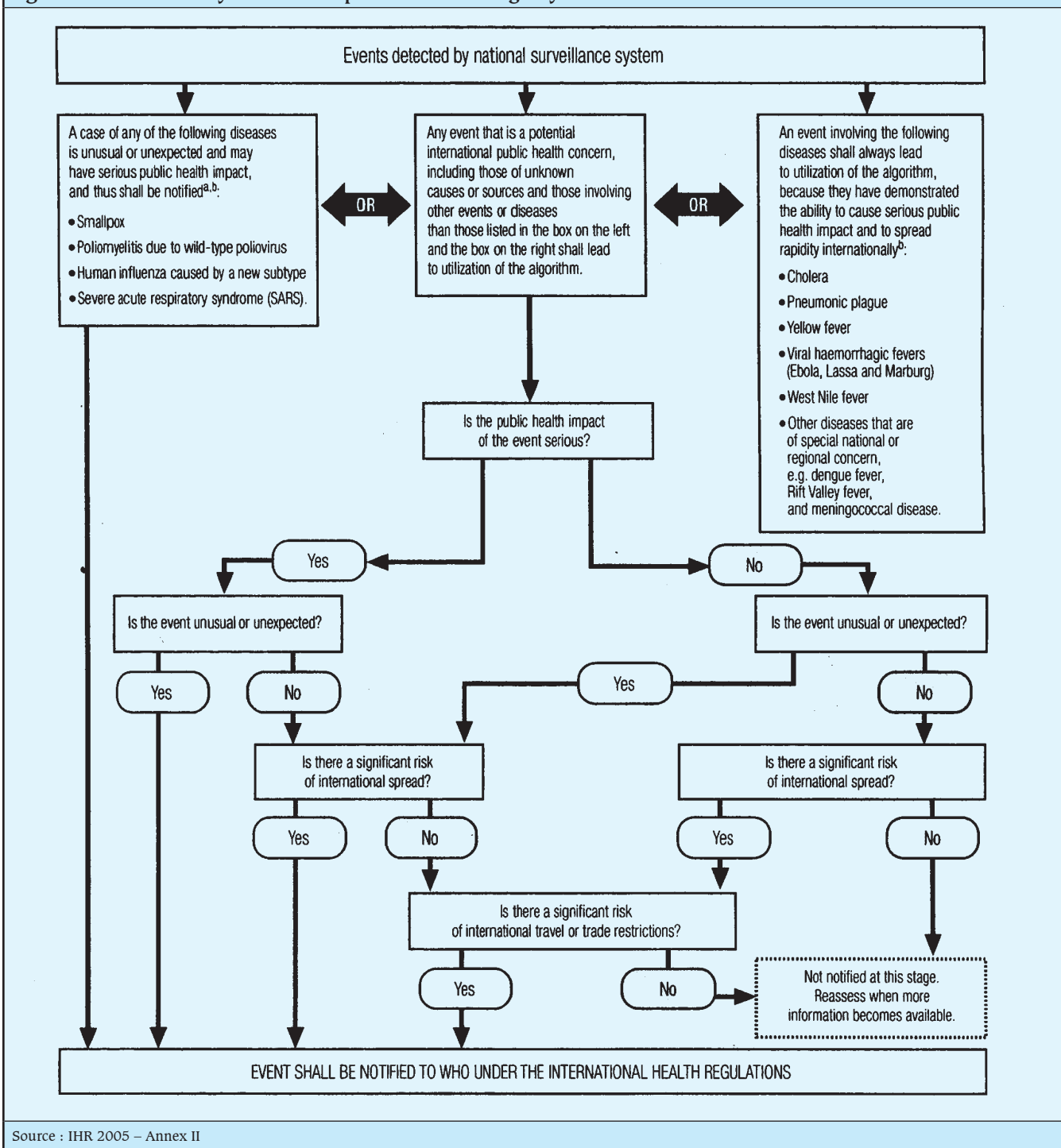
The four decision criteria to be used in the assessment of a

public health event are :

- The seriousness of the event's public health impact.
- The unusual or unexpected nature of the event.
- The risk of international disease spread.
- The risk that travel or trade restrictions will be imposed by other countries.

In essence, the events which must be assessed are those that

**Fig. - 1: Events that may constitute a public health emergency of international concern.**



may fulfil one or more of the four decision instrument criteria and the events which must be notified are those that meet at least any two of the criteria therein.

### **Mandatory notification**

While any urgent event can be assessed for notification, the decision instrument identifies two groups of diseases which raise particular concerns :

**(a) Group 1** : A single case of smallpox, poliomyelitis due to wild type poliovirus, human influenza caused by a new subtype and severe acute respiratory syndrome (SARS) must be immediately notified to WHO, irrespective of the context in which it occurs.

**(b) Group 2** : Events involving epidemic-prone diseases of special national or regional concern which “have demonstrated the ability to cause serious public health impact and to spread rapidly internationally” must always be assessed using the decision instrument but only notified when fulfilling the requirements of the algorithm.

### **Consultation**

IHR (2005) also provide for a “consultation” process between a State Party and WHO. This consultation process provides States Parties with the opportunity to keep WHO informed and to have, similarly to notification, a confidential dialogue with WHO on further event assessment and any appropriate investigative or health response measures.

### **Other Reporting Requirements**

In addition to notification and consultation, States Parties are required to inform WHO within 24 hours of receipt of evidence of public health risks occurring outside their territory that may cause international disease spread. The evidence may be manifest by imported or exported human cases, or the identification of infected or contaminated vectors or contaminated goods.

### **Points of Entry Provisions**

Points of entry provisions in the IHR (2005) are designed to minimize public health risks caused by the spread of diseases through international traffic. The IHR (2005) define a point of entry as “a passage for international entry or exit of travellers, baggage, cargo, containers, conveyances, goods and postal parcels, as well as agencies and areas providing services to them on entry or exit”. There are three types of points of entry: international airports, ports and ground crossings.

The two specific applications of IHR (2005) at point of entry include (a) the requirement of yellow fever vaccination of travelers as imposed by certain countries; and (b) the disinsection of aircrafts to prevent importation of disease vectors. These requirements are intended to help prevent the international spread of the diseases.

### **Roles for Competent Authorities and Conveyance Operators**

States Parties to the IHR (2005) are required to identify the competent authorities to carry out :

- (a) development of core capacities at designated points of entry;
- (b) implementation at points of entry of appropriate levels

of hygiene and sanitation as well as ensuring effective vector, rodent and environment control measures and procedures;

- (c) application of health measures at points of entry in affected areas.

### **Ship Sanitation Certificates**

Under the IHR (2005), the current Deratting and Deratting Exemption certificates have been replaced by Ship Sanitation Control and Ship Sanitation Control Exemption certificates which address a broader range of public health risks on sea going vessels.

### **Guidance on IHR (2005) Implementation at Points of Entry**

Guidance materials are being developed in the following areas:

- 1 Management of public health risks at points of entry
- 2 Provision of technical assistance in developing points of entry capacities
- 3 Maintenance of accessible data for designated points of entry, including capacity to issue Ship Sanitation Control Exemption and Ship Sanitation Control certificates
- 4 Inspection and WHO certification criteria for airports and ports
- 5 Recommended measures for affected travellers, conveyances, containers, cargo and goods
- 6 Ship sanitation and hygiene and sanitation in aviation
- 7 Application of health measures at ground crossings

### **Health Advice to Travellers**

Number of people who are undertaking international travels, is increasing with every passing year and with that, is increasing the travel related risks to their health. These health risks are due to sudden changes in altitude, climate and physical and biological environment.

### **Determinants of the Health Risks**

Determinants of the health risks to which travellers are exposed to are as follows :

**(a) Health state before undertaking the travel** : Underlying health condition of the traveller is the most important determinant of the health of traveller during the period of the travel e.g. a traveller with low immunity is more susceptible to the infectious diseases prevalent in developing countries.

**(b) Place of travel** : Destinations where accommodation, hygiene-sanitation, water quality and medical care are of high standard, pose little risk for the travellers.

**(c) Purpose of travel** : Travellers going on business trips, staying in hotels/ business centres and away from exposure to natural physical and biological environments have lesser risks compared to those who go on adventure trips or for field works and stay in resorts or temporary shelters.

**(d) Duration of travel** : Duration of the visit determines the nature of exposure to climatic conditions. A shorter duration of visit and inability to acclimatize to local conditions may adversely affect the health.

**(e) Behaviour of traveller** : Behaviour also plays an important role e.g. going out-doors in the evening in malaria endemic

areas without taking adequate precautions poses the risk of malaria infection to the traveller.

### **Actions to be Taken**

In order to protect the health, every traveller is required to be proactive and prepared. The travel must be planned well in advance and following actions must be taken :

#### **(a) Actions taken before the travel**

**(i) Learn about the destination** : Collect as much information about the place of travel as possible. Find out about the health risks in the area, altitude of the place, type of available accommodation, availability of health care facility etc.

**(ii) Have the medical consultation** : Visit a travel clinic at least six to eight weeks prior to travel to ensure enough time to get the necessary immunizations. Even the last minute medical consultation is better than no consultation. If you have an ongoing health concern, discuss your travel plans with your doctor. Ask your doctor for a letter stating your medical history and prescribed medications. Dental, ophthalmological and - for women - gynaecological check-ups are advisable before travel to developing countries.

**(iii) Health insurance** : Obtain special travellers' health insurance for destinations where health risks are significant and medical care is expensive or is not readily available.

**(iv) Medical kit** : Make or buy a first aid kit for common health concerns. Its contents should include :

- First-aid items like adhesive tape, antiseptic wound cleaner, bandage, emollient eye drops, insect repellent, nasal decongestant, oral rehydration salt, sterile dressing, scissors and safety pins, thermometer, simple analgesic and antipyretic
- Additional items according to destination and individual needs like anti-diarrhoeal medication, anti-malarial medication, condoms, anti-fungal cream, water disinfectant, medication for any pre-existing medical condition, sterile syringes and needles etc.

**(b) Actions taken during the travel** : The following action must be taken while travelling to the destination and during the period of stay :

**(i) While Travelling to Destination** : Travel can be tiring, hence get plenty of sleep before leaving. Wear loose and comfortable clothes; eat light meals, drink plenty of water and avoid alcohol and caffeine; when possible, walk around to improve circulation.

**(ii) Food and Water Safety** : Always wash your hands after going to the toilet and before handling food or eating. Eat fresh and well cooked food, avoid raw vegetables, salads, cut fruits or food kept in open. Do not eat undercooked or raw meat, fish or shellfish. Drink only boiled or bottled water and beverages made with boiled water. Use dairy products that are pasteurized and refrigerated. If in doubt, avoid them.

**(iii) Sun Protection** : To avoid skin and eye damage caused by the sun, wear clothing that covers your skin and eyes such as a hat with a wide brim and sunglasses with proper UV filter. Apply a sunscreen with a SPF 15 (sun protection factor) about 15 to 30 minutes before going out into the sun.

**(iv) Safe sex** : Always use a condom for sexual intercourse. Women who only use diaphragms should insist that their male partners use condoms as well.

**(v) Injury Prevention** : Wear closed-toe shoes to prevent cuts, wounds, insect or snake bites, or infection from parasites.

**(vi) Swimming** : Swim only in pools filled with clean, disinfected water. Do not swim in tropical waters, streams, canals or lakes, which may be infested with parasites. Try not to swallow water while swimming.

**(vii) Road safety** : Traffic accidents are the major cause of death among travellers. Whether you're driving or walking, always check the local traffic regulations. Be very careful when driving in a foreign country and on unfamiliar roads. Use your seat belts. Do not drink alcohol and drive. Be sure to use common sense and caution.

**(viii) Insect and animal bites** : Use an insect repellent and keep your arms and legs covered if there's a chance of being bitten. Animal bites can lead to serious – and even fatal – infections like rabies. Keep away from animals, even if they seem tame. If bitten, cleanse the wound with soap and clean water immediately. Consult local health authorities regarding the possible need for rabies treatment.

#### **(c) Actions taken after the travel.**

All travellers, after return, must undergo a medical examination if :

- (i) they spent more than three months in a developing country
- (ii) they suffer from a chronic disease or the existing disease condition has worsened
- (iii) they consider that they have been exposed to a serious infection during the travel
- (iv) they experience illnesses like fever, persistent diarrhoea, jaundice, skin or genital infections, in the weeks following their return

### **Checklist for the Traveller**

#### **(a) Obtain information on local conditions (the destination)**

- Risks related to the area (urban or rural)
- Type of accommodation available
- Length of stay
- Altitude
- Security problems in the area
- Availability of health care facility in the area of visit

#### **(b) Prevention**

- Vaccination requirement
- Malaria-risk of infection, preventive measures, prophylaxis
- Food hygiene
- Specific local diseases and the preventive measures for them

#### **(c) Accidents related to**

- Traffic (carry health card showing blood group)
- Animals (beware of snakes and rabid dog)
- Allergies – common allergens in the area and their prevention
- Sun – carry sunglasses and sunscreen

**(d) Get the following check-ups**

- Medical – medical kit and health card showing underlying health condition and prescription for medication
- Dental
- Ophthalmological – carry an extra pair of spectacles
- Checkup for specific conditions e.g. pregnancy

**(e) Subscribe to a medical insurance**

**Responsibilities of the Traveller**

By and large, travellers themselves are responsible for their health and well being while travelling. Responsibilities that they must accept as their own, are enumerated as under :

- Decision to travel
- Planning for travel
- Recognition and acceptance of the risk
- Seeking medical advice in time
- Compliance with the medical advice and recommended vaccination
- Carrying and understanding the use of medical kit
- Taking precautions before, during and after the journey
- Obtaining insurance cover
- Responsibility for the health and well being of the accompanying children

**Summary**

International Health has been defined as a field of research and intervention embracing the international dimensions of health disease process and care systems. While the research refers to the analysis of health determinants and the health state of the individuals and populations, the intervention refers to the actions taken at economic, political and administrative levels. Broadly speaking, international health is a systematic comparison of the factors that affect the health of all human populations. International health aims at promotion, maintenance, protection and prevention of health by an interdisciplinary approach. Dealing with problems of intersectoral nature, International cooperation for capacity building of countries, Strengthening technical cooperation among countries, Interaction – multidirectional, not unidirectional (i.e. not from developed countries to developing countries only) – among countries, Providing an instrument for diplomacy and solidarity and not a mechanism for domination. Content of international health covers a wide area like social, economic, behavioural cultural etc factors related to health. Its organization involves governmental and non governmental organization. Main international intergovernmental organizations include the World Health Organization (WHO), the International Labour Organization (ILO), the Food and Agriculture Organization (FAO), the UN Development Programme (UNDP), the UN Children's Fund (UNICEF), etc.

Regional office of WHO South East Asia is located in New Delhi in India. In India, WHO provides technical assistance and collaborates with the Government of India and major stakeholders in health development efforts. It assists notably in Policy Development; Capacity Building and Advocacy.

*International Health Regulation* was completely revised in 2005 to provide the legal framework for international cooperation in health. The purpose of IHR is to control and

prevent the spread of disease, protect against it and evoke an international response commensurate with the existing public health practices without unnecessarily affecting the trade and the traffic. Stated objective of IHR are the appropriate application of routine, preventive measures (e.g. at ports and airports) and the use by all countries of internationally approved documents (e.g. vaccination certificates), the notification to WHO of all events that may constitute a public health emergency of international concern, the implementation of any temporary recommendations should the WHO Director General have determined that such an emergency is occurring. Notification is now based on the identification of an “event that may constitute a public health emergency of international concern” (PHEIC).

“Public health emergency of international concern” means an extraordinary event which is determined, as provided in these Regulations : to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response.

The four decision criteria to be used in the assessment of a public health event are : the seriousness of the event's public health impact; the unusual or unexpected nature of the event; the risk of international disease spread; and the risk that travel or trade restrictions will be imposed by other countries.

*Health Advice To Travellers* : Travellers are exposed to health risks owing to sudden changes in altitude, climate and physical and biological environment. Determinants of the health risks to which travellers are exposed are health state of the traveller before undertaking the travel, place of travel and conditions prevailing therein, purpose of travel, duration of travel, behaviour of traveller.

In order to protect the health, every traveller is required to be proactive and prepared. The travel must be planned well in advance and following actions must be taken by traveller: learn about the destination not only about the ecological condition but also about the health facility, have the medical consultation, health insurance, medical kit - make or buy a first aid kit for common health concerns.

While travelling the traveller should take due precaution not to tire himself, maintain food and water hygiene, protection against physical condition prevailing in the destination, prevention of injuries and insect and animal bites, safe sex etc.

All travellers after travel must undergo medical examination if they spent more than three months in a developing country, they suffer from a chronic disease or the existing disease condition has worsened, they consider that they have been exposed to a serious infection during the travel, they experience illnesses like fever, persistent diarrhoea, jaundice, skin or genital infections, in the weeks following their return.

By and large, travellers themselves are responsible for their health and well being while travelling. Responsibilities that they must accept as their own, are decision to travel, planning for travel, recognition and acceptance of the risk, seeking medical advice in time, compliance with the medical advice and recommended vaccination, carrying and understanding the use of medical kit, taking precautions before, during and after the



journey, obtaining insurance cover, responsibility for the health and well being of the accompanying children.

## Study Exercises

**Short Notes :** (1) IHR 2005- New regulations (2) Health advice to travellers (3) WHO Activities in India (4) UNICEF Activities in India (5) Activities of Red cross in India.

### MCQs :

1. WHO came into force in (a) 1942 (b) 1948 (c) 1952 (d) 1945
2. World Health day is celebrated on (a) 24 Oct (b) 01 Dec (c) 07 April (d) 01 Jan.
3. The administrative and organizational headquarter of UNICEF is at (a) Geneva (b) New York (c) Rome (d) Paris.
4. The administrative and organizational headquarter of UNESCO is at (a) Geneva (b) New York (c) Rome (d) Paris.
5. The FAO was founded in (a) 1945 (b) 1942 (c) 1948 (d) 1950.
6. The administrative and organizational headquarter of ILO is at (a) Geneva (b) New York (c) Rome (d) Paris.
7. The organization which provides expert advice, training and grant support to accomplish MDGs is (a) UNICEF (b) UNDP (c) UNESCO (d) UNFPA.
8. The world's largest international source of funding for population and reproductive health programs is (a) UNICEF (b) UNDP (c) UNESCO (d) UNFPA.
9. The founder of International Red Cross and Red Crescent Movement is (a) Rockefeller (b) Philip Russel (c) Henry Dunant (d) None.
10. Agency which has been supporting the National Tuberculosis Control Programme of India is (a) IRCS (b) SIDA (c) DANIDA (d) UNICEF.
11. IHR was completely revised recently in (a) 2005 (b) 2007 (c) 2009 (d) 2004.

**Answers :** (1) b; (2) c; (3) b; (4) d; (5) a; (6) a; (7) b; (8) d; (9) c; (10) c; (11) a.

Leo S. Vaz

The Health Care Services Organization in the country extends from the national level to village level.

### Central level

The organization at the national level consists of the Union Ministry of Health and Family Welfare. The Ministry has three departments, viz. - Department of Health & Family Welfare, Department of Ayurveda, Yoga-Naturopathy, Unani, Sidha & Homeopathy (AYUSH) and Department of Health Research. Each of these departments is headed by respective secretaries to Govt of India. The department of Health & Family Welfare is supported by a technical wing, the Directorate General of Health Services, headed by Director General of Health Services (DGHS).

### State level

The organization at State level is under the State Department of Health and Family Welfare in each State headed by Minister and with a Secretariat under the charge of Secretary/Commissioner (Health and Family Welfare). The State Directorate of Health Services, as the technical wing, is an attached office of the State Department of Health and Family Welfare and is headed by a Director of Health Services. The area of medical education which is with the Directorate of Health Services at the State, is known as Directorate of Medical Education and Research. This Directorate is under the charge of Director of Medical Education, who is answerable directly to the Health Secretary/Commissioner of the State. Some states have created the posts of Director (Ayurveda) and Director (Homeopathy). These officers enjoy a larger autonomy, although sometimes they still fall under the Directorate of Health Services of the State.

### Regional level

In some states like Bihar, Madhya Pradesh, Uttar Pradesh, Andhra Pradesh, Karnataka and others, zonal or regional or divisional set-ups have been created between the State Directorate of Health Services and District Health Administration. Each regional/zonal set-up covers three to five districts and acts under authority delegated by the State Directorate of Health Services.

### District level

All health care programmes in a district are placed under a unified control. It is a link between the State/ regional structure on one side and the peripheral level structures such as PHC/ sub-centre on the other side. The district officer with the overall control is designated as the Chief Medical and Health Officer (CM & HO) or as the District Medical and Health Officer (DM & HO). These officers are popularly known as DMOs or CMOS, and are overall in-charge of the health and family welfare programmes in the district. These DMOs/CMOs are assisted by Dy. CMOs and programme officers.

## Community level

For a successful primary health care programme, effective referral support is to be provided. For this purpose one Community Health Centre (CHC) has been established for every 80, 000 to 1, 20, 000 population, and this centre provides the basic specialty services in general medicine, pediatrics, surgery, obstetrics and gynecology.

### Community Health Centres (CHCs)

CHCs are being established and maintained by the State Government. It is manned by four medical specialists i.e. Surgeon, Physician, Gynecologist and Pediatrician supported by 21 paramedical and other staff. It has 30 in-door beds with one OT, X-ray, Labour Room and Laboratory facilities. It serves as a referral centre for 4 PHCs and also provides facilities for obstetric care and specialist consultations. As on March, 2007, there are 4, 045 CHCs functioning in the country. The present staffing pattern of CHCs is as in Box - 1.

Box - 1 : Staffing Community Health Centre			
S. No	Staff For Community Health Centre	Existing	IPHS proposed
1	Medical Officer#	4	7
2	Nurse Mid-Wife (staff Nurse)	7	9
3	Dresser	1	1
4	Pharmacist/Compounder	1	1
5	Laboratory Technician	1	1
6	Radiographer	1	1
7	Ward Boys	2	2
8	Dhobi	1	-
9	Sweepers	3	3
10	Mali	1	-
11	Chowkidar	1	-
12	Aya	1	-
13	Peon	1	-
14	OPD Attendant		5*
15	Stat Asst. / Data Entry Operator		
16	OT attendant		
17	Registration clerk		
18	Ophthalmic Asst.		1
	Total :	25	31
# : Surgeon, Obstetrician, Physician, Pediatrician, Anaesthetist, Public health programme manager, Eye surgeon.			
* Sr No. 11, and 14 - 17 - total 5, flexibility rests with State for recruitment as per need			

### Primary Health Centre (PHC)

PHCs are the cornerstone of rural health services- a first port of call to a qualified doctor of the public sector in rural areas for the sick and those who directly report or referred from Sub-centres for curative, preventive and promotive health care. The Bhoré

Committee in 1946 gave the concept of a PHC as a basic health unit to provide as close to the people as possible, an integrated curative and preventive health care to the rural population with emphasis on preventive and promotive aspects of health care. The health planners in India have visualized the PHC and its Sub-Centres (SCs) as the proper infrastructure to provide health services to the rural population. The central Council of Health at its first meeting held in January 1953 had recommended the establishment of PHCs in Community Development Blocks. These centres were functioning as peripheral health service institutions with little or no community involvement. They were not able to provide adequate health coverage, partly, because they were poorly staffed and equipped and lacked basic amenities. The 6th Five year Plan (1983-88) proposed reorganization of PHCs on the basis of one PHC for every 30,000 rural population in the plains and one PHC for every 20,000 population in hilly, tribal and backward areas for more effective coverage.

PHC is the first contact point between village community and the Medical Officer. The PHCs were envisaged to provide an integrated curative and preventive health care to the rural population with emphasis on curative, preventive, Family Welfare Services and promotive aspects of health care. One Primary Health Centre covers about 30,000 (20,000 in hilly, desert and difficult terrains) or more population. Many rural dispensaries have been upgraded to create these PHCs. At present, a PHC is manned by a Medical Officer supported by 14 paramedical and other staff. It acts as a referral unit for 6 sub-centres and refer out cases to Community Health Centres (CHCs-30 bedded hospital)/sub-district/district hospitals. It has 4-6 indoor beds for patients. There are 22, 370 PHCs functioning as on March 2007 in the country. The staffing pattern of new primary health centre is shown in Box - 2.

<b>Box - 2 : Staffing Primary Health Centre</b>			
S. No.	Staff for New Primary Health Centre	Existing	IPHS proposed
1.	Medical Officer	1	2
2.	Pharmacist	1	1
3.	Nurse Mid-wife (Staff Nurse)	1	3
4.	Health Worker (Female)/ANM	1	1
5.	Health Educator	1	1
6.	Health Assistant (Male)	1	1
7.	Health Assistant Female)/LHV	1	1
8.	Upper Division Clerk	1	1
9.	Lower Division Clerk	1	1
10.	Laboratory Technician	1	1
11.	Driver (Subject to availability of Vehicle)	1	*
12.	Class IV	4	4
	<b>Total</b>	<b>15</b>	<b>17/18</b>
*Optional / vehicle may be outsourced			

## Sub-Centre

The Sub-Centre is the most peripheral and first contact point between the primary health care system and the community. Sub-Centres are assigned tasks relating to interpersonal communication in order to bring about behavioral change and provide services in relation to maternal and child health, family welfare, nutrition, immunization, diarrhoea control and control of communicable diseases programmes. The Sub-Centres are provided with basic drugs for minor ailments needed for taking care of essential health needs of men, women and children. There are 1,45,272 Sub Centres functioning in the country as on March 2007. Currently a Sub-centre is staffed by one Female Health Worker commonly known as Auxiliary Nurse Midwife (ANM) and one Male Health Worker commonly known as Multi Purpose Worker (Male). One Health Assistant (Female) commonly known as Lady Health Visitor (LHV) and one Health Assistant (Male) located at the PHC level are entrusted with the task of supervision of all the Sub-centres (generally six subcentres) under a PHC. The Ministry of Health & FW, GOI provides assistance to all the Sub-centres in the country since April 2002 in the form of salary of ANMs and LHVs, rent (if located in a rented building) and contingency, in addition to drugs and equipment kits. The salary of Male Health Worker is borne by the State Governments. The staffing pattern of sub-centre is depicted in Box - 3.

<b>Box - 3 : Staffing Sub centre</b>			
S. No	Staff For Sub-Centre	Existing	IPHS proposed
1.	Health Worker(Female)/ANM	1	2
2.	Health Worker (Male)	1	1
3.	Voluntary Worker (optional on honorarium)	1	1
	<b>Total</b>	<b>2/3</b>	<b>3/4</b>

*The shortfall in the rural health infrastructure, based on 2001 population census, has been depicted in Box - 4.*

<b>Box - 4 : Shortfall in Rural Health Infrastructure All India</b>				
As per 2001 Population	Required	Existing (as on 31 Mar 2007)	Shortfall	% Shortfall
Sub-Centres	158792	145272	20855	13. 13
PHCs	26022	22370	4833	18. 57
CHCs	6491	4045	2525	38. 90
Note : All India shortfall is derived by adding state-wise figures of shortfall ignoring the existing surplus in some of the states.				
Source : Bulletin of Rural Health Statistics in India, MOHFW (GOI), 2007.				

## Indian Public Health Standards (IPHS)

The overall objective of IPHS is to provide health care that is quality oriented and sensitive to the needs of the community. In order to provide optimal level of quality health care, a set of standards are being recommended for Community Health

Centre /Primary Health Centre/sub centre. The IPHS for Primary Health Centres has been prepared keeping in view the resources available with respect to functional requirement for Primary Health Centre with minimum standards such as building manpower, instruments, and equipments, drugs and other facilities etc. These standards would help monitor and improve the functioning of the PHCs. The objectives of IPHS for PHCs are :

- i. To provide comprehensive primary health care to the community through the Primary Health Centres.
- ii. To achieve and maintain an acceptable standard of quality of care.
- iii. To make the services more responsive and sensitive to the needs of the community.

#### **Minimum Requirements at the Primary Health Centre for meeting the IPHS :**

##### **1. Medical care :**

*(a) OPD services* : 4 hours in the morning and 2 hours in the afternoon / evening. Minimum OPD attendance should be 40 patients per doctor per day.

*(b) 24 hours emergency services* : Appropriate management of injuries and accident, First Aid, Dog bite/snake bite/scorpion bite cases, and other emergency conditions

*(c) Referral services*

*(d) In-patient services (6 beds)*

##### **2. Maternal and Child Health Care including family planning:**

*a) Antenatal care* : Early registration of all pregnancies and minimum 3 antenatal checkups with minimum laboratory investigations.

*b) Intra-natal care* : (24-hour delivery services both normal and assisted) Promotion of institutional deliveries, appropriate and prompt referral for cases needing specialist care.

*c) Postnatal Care* : Two postpartum home visits, first within 48 hours of delivery, 2nd within 7 days through Sub-centre staff, essential new born care, provision of facilities under *Janani Suraksha Yojana* (JSY).

*d) New Born care*

*e) Care of the child* : Emergency care of sick children including Integrated Management of Neonatal and Childhood Illness (IMNCI), full Immunization of all infants and children against vaccine preventable diseases, Vitamin A prophylaxis to the children.

*f) Family Planning* : Education, Motivation and counseling towards family planning, Provision of contraceptives.

##### **3. Medical Termination of Pregnancies using Manual Vacuum Aspiration (MVA) technique. (wherever trained personnel and facility exists)**

##### **4. Management of Reproductive Tract Infections / Sexually Transmitted Infections**

##### **5. Nutrition Services (coordinated with ICDS)**

**6. School Health** : Regular check ups, appropriate treatment including deworming, referral and follow-ups.

**7. Adolescent Health Care** : Life style education, counseling, treatment.

##### **8. Promotion of Safe Drinking Water and Basic Sanitation**

##### **9. Prevention and control of locally endemic diseases like malaria, Kalaazar, Japanese Encephalitis, etc.**

**10. Disease Surveillance and Control of Epidemics** : Disinfection of water sources and Promotion of sanitation.

##### **11. Collection and reporting of vital events**

##### **12. Education about health / Behaviour Change Communication (BCC)**

**13. National Health Programmes including Reproductive and Child Health Programme (RCH), HIV/AIDS control programme, Non communicable disease control programme, Revised National Tuberculosis Control Programme (RNTCP)**

**14. Referral Services** : Appropriate and prompt referral of cases needing specialist care.

**15. Training** : Training of Health workers and traditional birth attendants; Initial and periodic training of paramedics in treatment of minor ailments; Training of ASHAs. Periodic training of Doctors through Continuing Medical Education, Training of ANM and LHV in antenatal care and skilled birth attendance.

**16. Basic Laboratory Services** : Essential Laboratory services

**17. Monitoring and Supervision** : Monitoring and supervision of activities of sub-centre.

**18. AYUSH services as per local people's preference** : (Mainstreaming of AYUSH).

**19. Rehabilitation** : Disability prevention, early detection, intervention and referral.

**20. Selected Surgical Procedures** : The vasectomy, tubectomy (including laparoscopic tubectomy), MTP, hydrocelectomy and cataract surgeries as a camp/fixed day approach have to be carried out in a PHC having facilities of O.T.

##### **21. Record of Vital Events and Reporting**

**Charter of Patients' Rights for Primary Health Centres** : Primary Health Centres exist to provide health care to every citizen of India within the allocated resources and available facilities.

##### **1. The Charter seeks to provide a framework, which enables citizens to know**

- What services are available and users' charges if any.
- The quality of services they are entitled to.
- The means through which complaints regarding denial or poor qualities of services will be addressed.

##### **2. Objectives**

- To make available health care services and the related facilities for citizens.
- To provide appropriate advice, treatment, referral and support that would help to cure the ailment to the extent medically possible.
- To redress any grievances in this regard.

##### **3. Commitments of the Charter**

- To provide access to available facilities without discrimination.
- To provide emergency care, if needed on reaching the PHC.



- To provide adequate number of notice boards detailing the location of all the facilities and the schedule of field visits.
- To provide written information on diagnosis, treatment being administered.
- To record complaints and respond at an appointed time.

4. **Grievance redressal** : Grievances that citizens have will be recorded. Aggrieved user after his/her complaint recorded would be allowed to seek a second opinion at CHC.

5. **Responsibilities of the users** : Users of PHC would attempt to understand the commitments made in the charter and would not insist on service above the standard set in the charter because it could negatively affect the provision of the minimum acceptable level of service to another user. Instructions of the PHC personnel would be followed sincerely, and in case of grievances, the redressal mechanism machinery would be addressed by users without delay.

6. **Performance audit and review of the charter** : Performance audit may be conducted through a peer review every two or three years after covering the areas where the standards have been specified.

#### **Duties of Medical Officer, Primary Health Centre**

The Medical Officer of Primary Health Centre (PHC) is responsible for implementing all activities grouped under Health and Family Welfare delivery system in PHC area. He/she is responsible in his individual capacity, as well as over all in charge.

##### **I. Curative Work**

1. The Medical Officer will organize the dispensary, outpatient department and will allot duties to the ancillary staff to ensure smooth running of the OPD.
2. He/she will attend to cases referred to him/her.
3. He/she will screen cases needing specialized medical attention including dental care and nursing care and refer them to referral institutions.
4. He/she will provide guidance to the Health Assistants, Health Workers, Health Guides and School Teachers in the treatment of minor ailments.
5. He/she will visit each Sub-centre in his/her area at least once in a fortnight on a fixed day not only to check the work of the staff but also to provide curative services.
6. Organize and participate in the "health day" at Anganwadi Centre once in a month.

##### **II. Preventive and Promotive Work**

1. The Medical Officer will ensure that all the members of his/her Health Team are fully conversant with the various National Health & Family Welfare Programs including NRHM to be implemented in the area allotted to each Health functionary. He/she will further supervise their work periodically both in the clinics and in the community setting to give them the necessary guidance and direction.
2. He/she will keep close liaison with Block Development Officer and his/her staff, community leaders and various social welfare agencies in his/her area.
3. He/she will coordinate and facilitate the functioning of AYUSH doctor in the PHC.
4. He will plan and implement the Reproductive and Child Health Programme.

5. Universal Immunization Programme (UIP) : He/she will plan and implement UIP in line with the latest policy and ensure cent percent coverage of the target population in the PHC (i.e. pregnant mothers and new born infants).
6. National Vector Borne Disease Control Programme (NVBDCP) : He/she will be responsible for all NVBDCP operations for Malaria, Kala Azar and JE in his/her PHC area and will be responsible for all administrative and technical matters.
7. Control of Communicable Diseases : He/she will ensure that all the steps are being taken for the control of communicable diseases and for the proper maintenance of sanitation in the villages.
8. Leprosy : He/she will provide facilities for early detection of cases of Leprosy and confirmation of their diagnosis and treatment.
9. Tuberculosis : He/she will provide facilities for early detection of cases of Tuberculosis, confirmation of their diagnosis and treatment and also ensure functioning of Microscopic Centre (if the PHC is designated so) and provision of DOTS.
10. Sexually Transmitted Diseases (STD) : He/she will ensure that all cases of STD are diagnosed and properly treated and their contacts are traced for early detection.
11. School Health : He/she will visit schools in the PHC area at regular intervals and arrange for Medical Checkups, immunization and treatment with proper follow up of those students found to have defects.
12. National Programme for Prevention of Visual Impairment and Control of Blindness : He/she will make arrangements for rendering treatment for minor ailments and testing of vision.

**III. Training** : He/she will organize training programmes including continuing education for the staff of PHC and ASHA under the guidance of the district health authorities and Health & Family Welfare Training centres.

**IV. Administrative Work** : He/She will carry out all administrative activities required for smooth running of the PHC.

#### **Job Responsibilities of Health Educator**

The Health Educator will function under the technical supervision and guidance of the Block Extension Educator. However, he/she will be under the immediate administrative control of the PHC Medical Officer. He/she will be responsible for providing support to all health and family welfare programmes in the block. His duties and functions are :

- 1) He/she will have with him/her all information relevant to development activities in the block, particularly concerning health and family welfare, and will utilize the same for programme planning.
- 2) He/she will develop his/her work plan in consultation with the medical officer of his/her PHC and the concerned Block Extension Educator.
- 3) He/she will collect and interpret the data in respect of extension education work in his/her PHC area.
- 4) He/she will be responsible for regular maintenance of records of educational activities, tour programmes, daily dairies and other registers, and will ensure preparation and display of

relevant maps and charts in the PHC.

5) He/she will assist the Medical Officer, PHC in conducting training of health workers under the MPW and ASHA and other schemes under NRHM.

6) He/she will organize the celebration of health days and weeks and publicity programmes at local fairs, on market days, etc.

7) He/she will organize orientation training for health and family welfare workers, opinion leaders, local medical practitioners, school teachers, dais and other involved in health and family welfare work.

8) He/she will assist the organizing of mass communication programmes like film shows, exhibition, lecturers and dramas.

9) He/she will supervise the work of field workers in the area of education and motivation.

10) He/she will supply education material on health and family welfare to health workers in the block.

11) While on tour he/she will verify entries in the eligible couple register for every village and do random checking of family welfare acceptors.

12) While on tour he/she will check the available stock of conventional contraceptive with the depot holders and the kits with MPHWS and ASHAs.

13) He/she will help field workers in winning over resistant cases and drop-outs in the health and family welfare programmes.

14) He/she will maintain a complete set of educational aids on health and family welfare for his/her own use and for training purpose.

15) He/she will organize population education and health education sessions in schools and for out-of school youth.

16) He/she will maintain a list of prominent acceptors of family planning method and opinion leaders village wise and will try to involve them in the promotion of health and family welfare programmes.

17) He/she will prepare a monthly report on the progress of educational activities in the block and send it to the higher authority.

#### **Job Responsibilities of Health Assistant Female (LHV - Lady Health Visitor) (Female Supervisor)**

Under the Multipurpose Workers Scheme, a Health Assistant Female is expected to cover a population of 30,000 (20,000 in tribal and hilly areas) in which there are six Sub-centres, each with the health worker female. The health assistant female will carry out the following duties :

##### **1. Supervise and guide**

- Supervise and guide the Health Worker Female, Dais and guide ASHA in the delivery of health care service to the community.
- Visit each sub-centre at least once a week on a fixed day to observe and guide the Health Worker Female in her day to day activities under various National Health Programmes.

##### **2. Team Work**

- Assist the Medical Officer of the primary health centre in the organization of the different health services in the area.

- Participate as a member of the health team in mass camps and campaigns in health programmes.
- Help the health workers to work as part of the health team.

**3. Supplies, equipment and maintenance of Sub-centres :** In collaboration with the health assistant male, check at regular intervals the stores available at the sub-centre and help in the procurement of supplies and equipment.

##### **4. Records and Reports :**

- Scrutinize the maintenance of records by the Health Worker Female and guide her in their proper maintenance.
- She will carry with her the proper record forms, diary and guidelines for identifying suspected Kala-Azar and JE cases.
- She will be responsible along with Health Assistant Male for ensuring complete treatment of Kala-Azar and JE patients in his area.
- She will be responsible along with health assistant male for ensuring complete coverage during the spray activities and search operation.

##### **5. Training**

- Organize and conduct training for dais/ASHA with the assistance of the health worker female.
- Assist the medical officer of the primary health centre in conducting training programme for various categories of health personnel.

##### **6. Maternal and Child Health :**

- Conduct weekly MCH clinics at each Sub-centre with the assistance of the health worker female and dais.
- Conduct deliveries when required at PHC level and provide domiciliary and midwifery services.

##### **7. Family Planning and Medical Termination of Pregnancy**

- She will ensure that health worker female maintains up-to-date eligible couple registers all the times.
- Conduct weekly family planning clinics along with the MCH clinics at each Sub-centre with the assistance of the health worker female. Provide information on the availability of services for medical termination of pregnancy and refer suitable cases to the approved institutions.
- Personally motivate resistant case for family planning.

##### **8. Nutrition**

- Ensure that all cases of malnutrition among infants and young children (0-5 years) are given the necessary treatment and advice and refer serious cases to the primary health centre.
- Ensure that iron and folic acid, vitamin A are distributed to the beneficiaries as prescribed.

**9. Universal Immunization Programme :** Supervise the immunization of all pregnant women and children (0-5 years).

##### **10. Acute Respiratory Infection :**

- Ensure early diagnosis of pneumonia cases.
- Provide suitable treatment to mid/moderate cases of ARI.
- Ensure early referral in doubtful/severe cases.

**11. School Health :** Help medical officers in school health services.

**12. Primary Medical Care :** Ensure treatment for minor ailments provide ORS & first aid for accidents and emergencies

and refer cases beyond her competence to the primary health centre or nearest hospital.

**13. Health Education :** Carry out educational activities for MCH, Family Planning, Nutrition and Immunization, Control of blindness, Dental care and other National Health Programmes like leprosy and Tuberculosis with the assistance of the Health Worker Female.

#### **Job Responsibilities of Health Assistant Male (Supervisor)**

Under the Multipurpose workers scheme, a health assistant male is expected to cover a population of 30,000 (20,000 in tribal and hilly areas) in which there are six Sub-centres, each with the health worker male. The Health Assistant Male will carry out the following duties :

##### **1. Supervise and guide**

- Strengthen the knowledge and skills of the health worker male and supervise and guide him in the delivery of health care service to the community.
- Visit each Health Worker Male and at least once a week to observe and guide him in his day to day activities.
- Assess monthly the progress of work of the Health Worker Male.
- Carry out supervisory home visits in the area of the health worker male.

##### **2. Team Work**

- Help the health workers to work as part of the health team.
- Coordinate his activities with those of the Health Assistant Female and other health personnel including the dais and health guide.
- Coordinate the health activities in his area with the activities of workers of other departments and agencies and attend meeting at PHC level.
- Conduct staff meetings fortnightly with the health workers in coordination with the Health Assistant Female at one of the Sub-centres by rotation.
- Attend staff meetings at the Primary Health Centre.
- Assist the medical officer of the Primary Health Centre in the organization of the different health services and conducting training programmes for various categories of health personnel.
- Participate as a member of the health team in mass camps and campaigns in health programmes.

##### **3. Supplies, equipment and maintenance of Sub-centres**

- In collaboration with the Health Assistant Female, check at regular intervals the stores available at the Sub-centre and ensure timely placement of indent for and procure the supplies and equipment in good time.
- Check that the drugs at the Sub-centre are properly stored and that the equipment is well maintained.

**4. Records and Reports :** Scrutinize the maintenance of records by the Health Worker Male and guide him in their proper maintenance.

##### **5. Malaria**

- He will supervise the work of Health Worker Male. He should check minimum of 100 of the houses in a village to verify the work of the Health Worker Male.
- He will carry with him a kit for collection of blood smears

during his visit to the field and collect thick and thin smears from any fever case he comes across and he will administer presumptive treatment of prescribed dosage of Anti-malarial drugs.

- He will be responsible for prompt radical treatment to positive cases in his area.
- Supervise the spraying of insecticides during local spraying along with the Health Worker Male. Where Kala-Azar and JE is endemic he will supervise the work of Health Worker Female.
- He should verify that the Health Worker Male really visited those houses and identified suspected Kala-Azar and JE cases and ensured complete treatment has been done properly.
- He will carry with him the proper record forms, diary and guidelines for identifying suspected Kala-Azar and JE cases.
- He will be responsible for ensuring complete coverage treatment of Kala-Azar and JE patients in his area.
- He will be responsible for ensuring complete coverage during the spray activities and search operation.
- He will also undertake health education activities particularly through interpersonal communication, arranging group meetings with leaders and organizing and conducting training of community leaders with the assistance of health team.

##### **6. Communicable Disease**

- Be alert to the sudden outbreak of epidemics of diseases, such as diarrhoea/dysentery, fever with rash, jaundice, encephalitis, diphtheria, whooping cough or tetanus poliomyelitis, tetanus neonatorum, acute eye infections and take all possible remedial measures.
- Take the necessary control measures when any noticeable disease is reported to him.
- Carryout the destruction of stray dogs with the help of the Health Worker Male.

##### **7. Leprosy**

- In cases suspected of having leprosy take skin smears and send them for examination.
- Ensure that all case of leprosy take regular and complete treatment and inform the medical officer PHC about any defaulters to treatment.

##### **8. Tuberculosis**

- Check whether all cases under treatment for Tuberculosis are taking regular treatment, motivate defaulters to take regular treatment and bring them to the notice of the Medical Officer, PHC.
- Ensure that all cases of Tuberculosis take regular and complete treatment and inform the Medical Officer, PHC about any defaulters to treatment.

##### **9. Environmental Sanitation**

- Help the community sanitation for safe water sources, Soakage pits, Manure pits, Compost pits, Sanitary latrines, Smokeless chullas and supervise their construction.
- Supervise the chlorination of water sources including wells.

**10. Universal Immunization Programme :** Conduct immunization of all school going children with the help of the



Health Workers Female.

#### 11. Family Planning

- Personally motivate resistant case for family planning.
- Guide the Health Worker Male in establishing female depot holders.
- Assist M.O. PHC in organization of family planning camps and drives.
- Provide information on the availability of services for medical termination of pregnancy and refer suitable cases to the approved institutions.
- Ensure follow up of all cases of vasectomy, tubectomy, IUD and other family planning acceptors.

#### Job Responsibilities of Health Worker Female (ANM)

**1. Maternal and Child Health :** She will register and provide care to pregnant women throughout the period of pregnancy. She will ensure that every pregnant woman makes at least 3 (three) visits for ante natal check-up, estimate their haemoglobin level and test urine of these women for albumin and sugar. She will refer all pregnant women to PHC for RPR test for syphilis and refer cases of abnormal pregnancy and cases with medical and gynaecological problems to Health Assistant Female (LHV) or the Primary Health Centre. She will conduct deliveries in her area when called for and supervise deliveries conducted by Dais and assist them whenever called in. She will refer cases of difficult labour and newborns with abnormalities, help them to get institutional care and provide follow up to the patients referred to or discharged from hospital. She will identify the ultimate beneficiaries, complete necessary formalities and obtain necessary approvals of the competent authority before disbursement to the beneficiaries under *Janani Suraksha Yojana*. She will make at least two post-natal visits for each delivery in her areas and render advice regarding care of the mother and care and feed of the newborn. She will also assess the growth and development of the infant and take necessary action required to rectify the defect. She will educate mothers individually and in groups in better family health including maternal and child health, family planning, nutrition, immunization, control of communicable diseases, personal and environmental hygiene.

**2. Family Planning :** She will utilise the information from the eligible couple and child register for the family planning programme. She will be responsible for maintaining eligible couple registers and updating at all times. She will spread the message of family planning to the couples and motivate them for family planning individually and in groups. She will distribute conventional contraceptives and oral contraceptives to the couples, provide facilities and to help prospective acceptors in getting family planning services, if necessary, by accompanying them or arranging for the Dai/ASHA to accompany them to hospital. Provide follow-up services to female family planning acceptors, identify side effects, give treatment on the spot for side effects and minor complaints and refer those cases that need attention by the physician to the PHC/Hospital. She will establish female depot holders, help the Health Assistant Female in training them, and provide a continuous supply of conventional contraceptives to the depot holders.

**3. Medical Termination of Pregnancy :** She will identify the women requiring help for medical termination of pregnancy

and refer them to nearest approved institution. Educate the community of the consequences of septic abortion and inform them about the availability of services for medical termination of pregnancy.

**4. Nutrition :** She will identify cases of malnutrition among infants and young children (zero to five years) give the necessary treatment and advice and refer serious cases to the Primary Health Centre. She will distribute Iron and Folic Acid (IFA) tablets as prescribed to pregnant nursing mothers and administer Vitamin A solution to children. She will educate the community about nutritious diet for mothers and children in coordination with Anganwadi Workers.

**5. Universal Programme on Immunization (UIP) :** She will immunize pregnant women with tetanus toxoid, administer DPT, oral polio, measles and BCG vaccine to all infants and children, (Hepatitis-B in pilot areas) as per immunization schedule.

**6. Dai Training :** She will list Dais in her area and involve them in promoting Family Welfare and help the Health Assistant Female / LHV in the training programme of Dais.

**7. Communicable Diseases :** She will notify the Health Worker Male/MO PHC immediately about any abnormal increase in cases of diarrhoea/dysentery, fever with rigors, fever with rash, fever with jaundice or fever with unconsciousness which she comes across during her home visits, take the necessary measures to prevent their spread. If she comes across a case of fever during her home visits she will take blood smear, administer presumptive treatment and inform Health Worker male for further action. She will identify cases of skin patches, especially if accompanied by loss of sensation, which she comes across during her home visits and bring them to the notice of the Health Worker Male/MO (PHC). She will give oral rehydration solution to all cases of diarrhoea/dysentery/vomiting and identify and refer all cases of blindness including suspected cases of cataract to MO PHC.

**8. Vital Events :** She will record and report to the health authority of vital events including births and deaths, particularly of mothers and infants.

**9. Record Keeping :** She will register (a) pregnant women from three months of pregnancy onward (b) infants zero to one year of age; and (c) women aged 15 to 44 years. She will maintain the pre-natal and maternity records and child care records and prepare the eligible couple and child register. She will maintain the records as regards contraceptive distribution, IUD insertion, couples sterilized, clinics held at the sub-centre and supplies received and issued. While maintaining passive surveillance register for malaria cases, she will record : No. of fever cases, No. of blood slides prepared, No. of malaria positive cases reported, No. of cases given radical treatment.

**10. Treatment of minor ailments :** She will provide treatment for minor ailments, provide first-aid for accidents and emergencies and refer cases beyond her competence to the PHC/CHC/hospital.

**11. Team Activities :** She will attend and participate in staff meetings at PHC/Community Development Block or both. She will coordinate her activities with the Health Worker Male and other health workers including the Health volunteers/ASHA



and Dais.

**12. Role of ANM as a facilitator of ASHA :** Auxiliary Nurse Midwife (ANM) will guide ASHA in performing the following activities :

She will hold weekly / fortnightly meeting with ASHA and discuss the activities undertaken during the week/fortnight. She will guide her in case ASHA had encountered any problem during the performance of her activity. She will act as a resource person for the training of ASHA. She will take help of ASHA in updating eligible couple register of the village concerned. She will utilize ASHA in motivating the pregnant women for coming to subcentre for initial checkups and bringing married couples to sub centres for adopting family planning. She will guide ASHA in motivating pregnant women for taking full course of IFA Tablets and TT injections etc. ANMs will educate ASHA on danger signs of pregnancy and labour so that she can timely identify and help beneficiary in getting further treatment.

#### **Job Responsibilities of Health Worker (Male)**

The Health worker Male will make a visit to each family once a fortnight. He will record his visit on the main entrance to the house according to the instructions of the State/UT. His duties pertaining to different National Health Programme are :

**(A) Malaria and other diseases under NVBDCP :** From each family, he shall enquire about presence of any fever cases; whether there was any fever case in the family in between his fortnightly visits; whether any guest had come to the family and had fever ; whether any member of the family who had fever in between his fortnightly visit had left the village. He shall collect thick and thin blood smears on one glass slide from case having fever or giving history of fever. He shall begin presumptive treatment for Malaria after blood smear has been collected. He will follow the instructions given to him regarding administration of presumptive treatment under NVBDCP. He shall contact the ASHA, FTD during their fortnightly visit to the village and (i) collect blood smears already taken by the ASHA, FTD (ii) also collect details of each case in MF-2 (iii) replenish both drugs and glass-slides and Rapid Diagnostic Kits (RDKs) and look into the account of consumption of Anti malarial drugs and use of RDKs. He shall dispatch blood smears along with MF-2 collected from the ASHA, FTD, multipurpose worker female and those collected during their visit in his area to the PHC Laboratory twice a week. He shall see the results obtained by the use of RDKs and verify the radical treatment administered by the ASHA, FTD if any during his visit. He shall administer radical treatment to the positive cases as per drug schedule prescribed and as per instructions issued by the Medical Officer PHC and take laid down action if toxic manifestations are observed in a patient receiving radical treatment with primaquine. He shall contact the ASHA and FTD and inform him of the spray dates and assist the Health Supervisor Male in supervising spraying operations and training of field spraying staff.

**Where Kala-Azar / Japanese Encephalitis is endemic :** From each family he shall enquire about presence of any fever cases of more than 15 days duration or fever with encephalitic presentation. He will identify the fever cases detected by him during his visits and direct such a case to report to PHC for

confirmatory diagnosis. He will guide the suspected cases to the nearest diagnostic and treatment centre for diagnosis and treatment by the MO. He will keep a record of all such cases and shall verify from PHC about their diagnosis during the monthly meeting or through health supervisor during his visit. He will carry a list of all Kala-azar/JE cases in his area for follow up and will ensure administration of complete treatment. He will assist during the spray activities in his area. He will conduct all health education activities particularly through interpersonal communication by carrying proper charts etc. and also assist health supervisors and other functionaries in their education activities.

**(B) National Leprosy Eradication Programme :** He will identify cases of skin patches especially if accompanied by loss of sensation, refer the above cases to PHC Medical Officer for diagnosis. If Leprosy patients want to take MDT from sub-centre, he will provide treatment and maintain patient card.

**(C) National Blindness Control Programme :** He will identify and refer all cases of blindness including suspected cases of cataract to Medical Officer, PHC.

**(D) Revised National Tuberculosis Control Programme :** He will identify persons especially with fever for 15 days and above with prolonged cough or spitting blood and take sputum smears from these individuals and refer these cases to the M. O. PHC for further investigations. He will check whether all cases under treatment for Tuberculosis are taking regular treatment, motivate defaulters to take regular treatment and bring them to the notice of the medical officer PHC.

**(E) Universal Immunization Programme :** He will administer DPT, oral Polio, measles and BCG vaccine to all infants and children in his area in collaboration with health worker female and assist her in administration of tetanus toxoid to all pregnant women. He will assist the health supervisor male/ health supervisor female in the school health programme.

**(F) Reproductive and Child Health Programme :** He will utilize the information from the eligible couple and child register for the family planning programme. He will distribute conventional contraceptives and oral contraceptives to the couples and provide follow up services to male family planning acceptors, and refer those cases that need attention by the physician to PHC/Hospital. He will assist the health supervisor male in training the community and its leaders in family welfare. He will identify the women requiring help for medical termination of pregnancy, refer them to the nearest approved institution and inform the health worker female.

**(G) Other Communicable Diseases :** He will identify cases of diarrhoea/dysentery, fever with rash, jaundice encephalitis, diphtheria, whooping cough and tetanus, poliomyelitis, neonatal tetanus, acute eye infections and notify the health supervisor male and MO PHC immediately about these cases. He will carry out control measures until the arrival of the health supervisor male and assist him in carrying out these measures.

**(H) Environment Sanitation :** He will chlorinate the public water sources including wells at regular intervals. Educate the community on (a) The method of disposal of liquid wastes (b) The method of disposal of solid waste (c) Home sanitation

(d) Advantage and use of sanitary type of latrines  
(e) Construction and use of smokeless chulhas.

**(I) Primary Medical Care :** He will provide treatment for minor ailments provide first aid for accidents and emergencies and refer cases beyond his competence to the PHC/hospital.

**(J) Health Education :** He will educate the community about various health services.

**(K) Nutrition :** He will identify cases of malnutrition among infants and young children (0-5 years) in his area, give the necessary treatment and advice or refer them to the anganwadi for supplementary feeding and refer serious cases to the PHC. Educate the community about the nutrition diet for mothers and children from locally available food.

**(L) Vital Events :** He will Enquire about births and deaths occurring in his area, record them in the births and deaths register and report them to the Health Supervisor Male / ANM and educate the community on the importance of registration of births and deaths.

#### Accredited Social Health Activists (ASHA)

A trained female community health worker - ASHA - is being provided in each village in the ratio of one per 1000 population. For tribal, hilly, desert areas, the norm could be relaxed for one ASHA per habitation depending on the workload. ASHA must be a primary resident of the village with formal education upto Class VIII and preferably in the age group 25-45. She would be selected by the Gram Sabha following an intense community mobilization process. She would be fully accountable to Panchayat. Induction training of ASHA is to be of 23 days in all (five modules), spread over 12 months. On the job training would continue throughout the year.

Though she would not be paid any honorarium, she would be entitled for performance based compensation. It is expected that on an average an ASHA working with reasonable efficiency would be able to earn Rs. 1000 per month. Since as per the existing approval, the compensation for ASHA is not factored in the scheme, it is proposed to modify the programmes mentioned in the ASHA compensation package, wherever necessary, to enable the payment of compensation to her. The cost of training and drug kits to ASHAs would be supported by the Centre in the 18 high focus states. The other states would have the flexibility to have Health link workers to support it out of the RCH II flexible fund. As a special case, ASHAs could be supported in very remote backward regions in non-focus States.

ASHAs would reinforce community action for universal immunization, safe delivery, newborn care, prevention of water-borne and other communicable diseases, nutrition and sanitation. She will also help the villagers promote preventive health by converging activities of nutrition, education, drinking water, sanitation etc. In order that ASHAs work in close coordination with the AWW, she would be fully anchored in the Anganwadi system. ASHAs would also be provided with a 'drug kit' which would help her in providing immediate and easy access for the rural population to essential health supplies like ORS, contraceptives, a set of ten basic drugs. She would also have a health communication kit and other IEC materials developed for villages.

At present, Health Day's are organized every month at the Anganwadi level in each village in which immunization, ante/post natal check ups and services related to mother and child health care including nutrition are being provided. Space at each Anganwadi to serve as the hub of health activities in the village could be considered under other Rural Development Programmes. This space could also serve as depot for medicines and contraceptives.

A revolving fund would be set up at the village level for providing referral and transport facilities for emergency deliveries as well as immediate financial needs for hospitalization. The fund would be operated by the VHSC. Untied fund would also be made available to VHSC for various health activities including IEC, household survey, preparation of health register, organization of meetings at the village level etc. Since VHSC would be asked to play a leading role in the health matters of the village, its members would be given orientation training to equip them to provide leadership as well as plan and monitor the health activities at the village level.

For those villages which are far away from the Sub-Centre, a TBA with requisite educational qualifications would be identified for training and support. She would assist the ANM at the Sub Centre. ASHAs willing to play this role would be given preference. In places where even an ANM's services are not reaching and there is no accredited ASHA available, the RMPs would be identified for training so that they could upgrade their skills and get accredited. Efforts would also be made to regulate quacks and untrained dais. ASHA will assist the villagers in referral services for AYUSH/testing HIV/AIDs, STI, RTI, also preventive, promotive health already with AWW/SHGs etc. ASHA will provide them information on the treatments available under AYUSH.

#### Summary

The health care services' organization in the country extends from the national level to village level. At the national level it consists of the Union Ministry of Health and Family Welfare, which has three departments, viz. - Department of Health & Family Welfare, Department of AYUSH and Department of Health Research. Each of these departments is headed by respective secretaries to Govt of India. The department of Health & Family Welfare is supported by a technical wing, the Directorate General of Health Services, headed by Director General of Health Services (DGHS). At State level it is under the State Department of Health and Family Welfare in each State headed by Minister and with a Secretariat under the charge of Secretary/Commissioner (Health and Family Welfare). The State Directorate of Health Services, as the technical wing, is an attached office of the State Department of Health and Family Welfare and is headed by a Director of Health Services. At Regional level, in some states each regional/zonal set-up covers three to five districts and acts under authority delegated by the State Directorate of Health Services. At District level, all health care programmes are placed under a unified control and is a link between the State/ regional structure on one side and the peripheral level structures such as PHC/Sub-centre on the other side. The district officer with the overall control is designated as the Chief Medical and Health Officer (CM & HO)

or as the District Medical and Health Officer (DM & HO).

One Community Health Centre (CHC) has been established for every 80, 000 to 1, 20, 000 population, and this centre provides the basic specialty services in general medicine, pediatrics, surgery, obstetrics and gynecology. CHCs are being established and maintained by the State Government. It is manned by four medical specialists i.e. Surgeon, Physician, Gynecologist and Pediatrician supported by 21 paramedical and other staff. It has 30 in-door beds with one OT, Xray, Labour Room and Laboratory facilities. It serves as a referral centre for 4 PHCs.

PHCs are the cornerstone of rural health services- a first port of call to a qualified doctor of the public sector in rural areas for the sick and those who directly report or referred from Sub-centres for curative, preventive and promotive health care. One Primary Health Centre covers about 30, 000 (20, 000 in hilly, desert and difficult terrains) or more population. At present, a PHC is manned by a Medical Officer supported by 14 paramedical and other staff. It acts as a referral unit for 6 sub-centres and refer out cases to Community Health Centres (CHCs-30 bedded hospital)/sub-district/district hospitals. It has 4-6 indoor beds for patients.

The Sub-centre is the most peripheral and first contact point between the primary health care system and the community. Sub-centres are assigned tasks relating to interpersonal communication in order to bring about behavioral change and provide services in relation to maternal and child health, family welfare, nutrition, immunization, diarrhoea control and control of communicable diseases programmes. The Sub-centres are provided with basic drugs for minor ailments needed for taking care of essential health needs of men, women and children. Currently a Sub-centre is staffed by one Female Health Worker commonly known as Auxiliary Nurse Midwife (ANM) and one Male Health Worker commonly known as Multi Purpose Worker (Male). One Health Assistant (Female) commonly known as Lady Health Visitor (LHV) and one Health Assistant (Male) located at the PHC level are entrusted with the task of supervision of all the Sub-centres (generally six sub centres) under a PHC.

The overall objective of Indian Public Health Standards (IPHS) is to provide health care that is quality oriented and sensitive to the needs of the community. In order to provide optimal level of quality health care, a set of standards are being recommended for Community Health Centre /Primary Health Centre/Sub centre with reference to Infrastructure, Functioning and Staffing including responsibilities of each.

The Medical Officer of Primary Health Centre (PHC) is responsible for implementing all activities grouped under Health and Family Welfare delivery system in PHC area. He/she is responsible in his individual capacity, as well as over all in charge for his curative, preventive and promotive care of the patients. He will organize training programmes including continuing education for the staff and carry out all administrative activities required for smooth running of the PHC.

The health assistant female will supervise, guide and train the Health Worker Female, Dais and ASHAs; and also visit each Sub-centre at least once a week. The Health Assistant Male will strengthen the knowledge and skills of the health worker male and supervise and guide him in the delivery of health care

service to the community; and visit each Health Worker Male at least once a week. They maintain records and carry out a team work at PHC.

Health Worker Female (ANM) provides MCH care, Family planning, identify the women requiring help for MTP and identify cases of malnutrition among infants and young children and refer them. She will immunize pregnant women with tetanus toxoid, administer DPT, oral polio, measles and BCG vaccine to all infants and children, (Hepatitis-B in pilot areas) as per immunization schedule. Dai Training, identifying, notifying and referring various Communicable Diseases and recording the vital events are some of her important jobs. The Health worker Male will make a visit to each family once a fortnight and performs the prescribed duties pertaining to different National Health Programmes like NVBDCP, NLEP, RNTCP, UIP, National Blindness Control Programme and others. He will chlorinate the public water sources including wells at regular intervals and educate the community.

A trained female community health worker - ASHA - is being provided in each village in the ratio of one per 1000 population. She must be a primary resident of the village with formal education upto Class VIII and preferably in the age group 25-45. She would be selected by the Gram Sabha and would be fully accountable to Panchayat. Though she would not be paid any honorarium, she would be entitled for performance based compensation. ASHAs would reinforce community action for universal immunization, safe delivery, newborn care, prevention of water-borne and other communicable diseases, nutrition and sanitation.

## Study Exercises

**Long Questions :** (1) Describe the Health care organization in India. Explain how "Primary Health Care" is provided to all. (2) Describe the Staffing and functioning of PHC. (3) Describe the duties of Medical Officer at PHC.

**Short Notes :** (1) ASHA (2) Duties of Health worker Male (3) Duties of Health worker Female (ANM) (4) Duties of Health Assistant Female (5) Duties of Health Assistant Male. (6) Staffing pattern of PHC (7) Functioning of CHC (8) Functioning of Sub-centre

## MCQs

- (1) According to the national health policy, one sub-centre for the hilly areas covers a population of (a) 3000 (b) 5000 (c) 1000 (d) 4000
- (2) All are grass root workers except (a) Anganwadi workers (b) Traditional birth attendants (c) Village health guide (d) Health assistants.
- (3) A female multipurpose worker should be able to detect all of the following except (a) Anemia (b) Renal disease (c) Hydramnios (d) Malpresentation
- (4) Which is true about Community health centre : (a) It covers a population of one lakh (b) It has 60 beds with specialties in surgery, medicine and gynecology (c) Community health officer is selected with a minimum of 5 years of exposure (d) New medical post of community health officer is created
- (5) One PHC should be present in hilly areas for every



- (a) 10,000 people (b) 20,000 people (c) 30,000 people (d) 50,000 people
- (6) Guideline for selection of village health guide are all except  
 (a) They should be permanent resident of local community  
 (b) They should have minimum formal education at least upto 10th standard (c) Acceptable to all sections of society  
 (d) They should be able to spare at least 2-3 hrs daily for community health work
- (7) A dai is trained for (a) 30 working days (b) 90 working days (c) four months (d) six months
- (8) Govt trains a health guide from a village (a) every year (b) once in three years (c) once in five years (d) only once
- (9) Which is not a duty of a traditional birth attendant  
 (a) Aseptic delivery (b) Health education (c) Injection of Tetanus toxoid (d) Registration of birth
- (10) The minimum number of beds recommended for CHC by IPHS is (a) 30 (b) 35 (c) 40 (d) 60
- (11) Health Assistants visit Sub-centre / Health Workers once in every (a) week (b) 2 weeks (c) 3 weeks (d) month
- (12) One Health Assistant (Male) is entrusted with the task of supervision of \_\_\_\_ Sub centres (a) 2-3 (b) 5-6 (c) 7-8 (d) only 2
- (13) Which is false regarding ASHA : (a) Provided in each village in the ratio of one per 1000 population (b) A primary resident of the village with formal education upto Class IV (c) Preferably in the age group 25-45 (d) Selected by the Gram Sabha
- Answers :** (1) a; (2) d; (3) b; (4) a; (5) b; (6) b; (7) a; (8) b; (9) c; (10) a; (11) a; (12) b; (13) b.

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## Reports of Health Committees

*Sunil Agrawal*

In the pre-independence period, the British had started a number of Public Health initiatives. Quarantine act was passed in 1825. Commission of Public Health in 1859 had pointed out the need of safe water and environmental sanitation to prevent occurrence of epidemics. In 1864, Sanitary commissioners were appointed in all three provinces of Bombay, Madras and Bengal to study the health problems and initiate measures for improvement. Local self government act was passed in 1885. Decentralization of health administration had begun in 1919 with Montague-Chelmsford constitutional reforms. The colonial era was marked by the dichotomy which continues to operate in the country's health policy to date. They acknowledged the existence of the gaps in coverage of health services, proclaiming the responsibility for the same and recommending suitable action while simultaneously not providing resources for implementation. This trend was unfortunately perpetuated even in free India.

In 1940, the resolution adopted by the National Planning Committee based on the Sokheys Committee's recommendations recommended integration of preventive and curative functions and the training of a large number of health workers. Bhore committee constituted in 1943 laid the framework on which the health care was eventually built in the independent India. The health care in India has since moved from bureaucratic government based top down approach to decentralized community based bottom-up system after the Panchayati Raj came into being. This model was long ago propagated by the Father of the nation "Mahatma Gandhi".

## Bhore Committee (1943-1946)

During pre independence era, to improve the preventive, promotive and curative health services of country, a National Planning Commission was set up by the Indian National Congress in 1938. The rulers of that time, the British Empire realised the importance of Public Health and instituted the 'Health Survey and Development Committee,' in the year 1943 under the chairmanship of Sir Joseph Bhore. The committee was tasked to survey the then health conditions and health organisations in the country, and to make recommendations for future development. The committee submitted its report in 1946. The integration of preventive, promotive and curative health services and establishment of Primary Health Centres in rural areas were the major recommendations made by this committee (Box - 1).

### Box-1 : Important recommendations of the Bhore committee

- Integration of Preventive, Promotive and Curative services at all administrative levels.
- The development of Primary Health Centres for the delivery of comprehensive health services to the rural India. Each PHC should cater to a population of 40, 000 with a Secondary Health Centre (now called Community Health Centre) to serve as a supervisory, coordinating and referral institution.
- In the long term (3 million plan), the PHC would have a 75 bedded hospital for a population of 10,000 to 20,000.
- It also reviewed the system of medical education and research and included compulsory 3 months training in Community Medicine.
- Committee proposed the development of National Programmes of health services for the country.



This document laid the utmost emphasis on primary health care; it needs no emphasis that primary health care was later on recognised as the key strategy to achieve Health for All (HFA) by 2000 during Alma-Ata conference. The Bhore committee model was based on the allopathic system of medicine. The traditional health practices and indigenous system of medicine prevalent in rural India, which had great influence and were part of their socio-cultural milieu were not included in the model proposed by Bhore committee. The approach was not entirely decentralized but had a top down approach. However it provided a ready-made model at the time of independence and thus was adopted as a blueprint for both health policy and development of the country.

**Post Independence Era :** Since, the dawn of independence, rapid strides have been made in effecting improvements in the quality and out reach of health care services to the people. After Independence in 1947, the Indian Government constituted Planning Commission in 1950, and started Five year plan system for socioeconomic development of the country of which health was the important and integral part. Besides the planning commission the government also set up various committees to plan specific public health services or review existing health situations.

### Mudaliar committee (1962)

During second five year plan, Government decided to relook at the health needs and resources of the country to provide necessary guidelines to national health planning. Also to review the progress made since submission of Bhore committee report, Government appointed "*Health Survey and Planning Committee*" under the chairmanship of Dr A Lakshmanswami Mudaliar in 1959 to make future recommendations for development and expansion of health services. It admitted that the basic health facilities had not reached at least half the nation and there was gross mal distribution of hospitals and beds in favour of urban areas. The committee found that the quality of services provided by PHCs were grossly inadequate with poor functioning, lack of referral system, and gross under staffing due to insufficient resources. Important recommendations of the Mudaliar committee are depicted in Box - 2.

#### Box - 2 : Important recommendations of the Mudaliar committee

- Strengthening of existing PHCs and development of referral centres before new centres were established.
- Strengthening of subdivisional and district hospitals.
- Integration of medical and health services.
- It also suggested constitution of an All India Health Service in the pattern of Indian Administrative service.

### Chadah Committee (1963)

Dr MS Chadha, the then DGHS, was appointed to study the details of the necessary requirements related to PHCs and maintenance of National Malaria Eradication Program. Important recommendations of the Chadah committee are shown in Box - 3.

#### Box - 3 : Important recommendations of the Chadah committee

- Strict monitoring and vigilance of implementation of NMEP is responsibility of general health services at all levels i.e. health workers of PHC, CHC, ZP.
- One basic health worker (now called Multi Purpose worker) for every 10, 000 population was recommended.
- Basic health workers should visit house to house once in a month to implement malaria activities.
- Basic Health worker should take additional duties of collection of vital statistics, family planning etc.

### Mukerji Committee, 1965

By recommending basic health workers to take on additional responsibilities and work as multi purpose worker, both NMEP and family planning programme got a major set back. A committee under the chairmanship of Shri Mukerji, then Health Secretary to GOI was appointed to review the health system at different levels from the point of manpower and financial planning. Important recommendations of the Mukerji committee are in Box - 4.

#### Box - 4 : Important recommendations of the Mukerji committee

- Strengthening of the administrative set up at different levels from PHC to state health services.
- Separate staff was recommended for family planning program.
- Basic health worker to be utilised for all duties except for family planning.

### Jungalwalla Committee, 1967

In 1967, Central Council of Health appointed "*Committee on integration of Health Services*" headed by Dr N. Jungalwalla, then Director, National Institute of Health Administration and Education. Important recommendations of the Jungalwalla committee are represented in Box - 5.

#### Box - 5 : Important recommendations of the Jungalwalla committee

- Integrated health services with :
  - Unified cadre
  - Common seniority
  - Recognition of extra qualifications
  - Equal pay for equal work
  - No private practise
  - Special pay for specialised service
  - Improvement in their service conditions
- Medical care of the sick and conventional public health programmes functioning under single administrator.

### Kartar Singh Committee, 1973

The Committee headed by then additional secretary, MOH and Family planning, Shri Kartar Singh, was constituted to study and make recommendations on the structure for integrated health services at peripheral and supervisory levels. It was to

study the feasibility of bi purpose and multipurpose workers in the field. Important recommendations of the Kartar Singh committee are shown in Box - 6.

### Shrivastav Committee (1974-75)

This is known as “Group on Medical Education and Support Manpower” constituted in 1974 by the Government. The concept of community participation in the health sector originated which has given concept of “people’s health in people’s hand”. Convened under the chairmanship of Dr J B Shrivastav, Director General Health Services, this committee made the recommendations as in Box - 7.

#### Box - 6 : Important recommendations of the Kartar Singh committee

- It recommended “Female Health Worker” in place of ANM and “Male Health Worker” in place of malaria surveillance worker, vaccinators, health education assistants and family planning health assistants.
- The committee proposed a PHC per 50, 000 population with 16 subcentres, each covering a population of 3000-3500. (4)
- Each subcentre to have one male and one female health worker.
- There should be one male and one female health supervisor at PHC to monitor and supervise the activities of staffs of 3-4 sub centres.
- The MO i/c PHC will be the overall in charge of all peripheral staff.
- Training for all workers engaged in the field of health, family planning and nutrition should be integrated.

#### Box - 7 : Important recommendations of the Shrivastav committee

- Creation of Village Health Guide (VHG) or community health volunteers from the community itself like teachers, postmasters, gram sevaks who can provide comprehensive health services as paraprofessionals.
- Primary health care be provided within the community itself through specially trained workers so that the health of the people is placed in the hands of people themselves.
- Creation of MPW and Health Assistants (HA) in between the VHG and MO i/c PHC.

Based on these recommendations “Rural Health Scheme” was launched by the government in 1977-78. The programme of training of community health workers was initiated during 1977-78. The major steps initiated were :

- a) Involvement of medical colleges in health care of selected PHCs with the objective of reorienting medical education according to rural population called Re Orientation of Medical education (ROME). It led to teaching and training of undergraduate students and Interns at PHCs.
- b) Training of Village Health Guides and utilising their services in the general health service system.

### Shivaraman Committee health report

A Committee on Basic Rural Doctors was framed under the guidance of Shri Shivaraman, then member of planning commission. The committee recommended establishment of countrywide cadre of basic rural doctors consisting of trained paraprofessionals to extend comprehensive health care delivery to rural community.

### V Ramalingaswamy Committee Health Report

This committee under the chairmanship of Dr V Ramalingaswamy, then DGHS, recommended as in Box-8.

#### Box - 8 : Important recommendations of the Ramalingaswamy committee

- Involvement of community for health planning and health programme implementation
- 30 bedded hospital for every 1 lakh population
- Integration of health services at all levels
- Redefined the role of doctor in the community
- Recommended that PHC and District health centres should be under the control of three tier Panchayati Raj System.

### Bajaj Committee health report 1986

A expert committee for ‘health manpower planning, production and management’ was constituted under the chairmanship of Dr JS Bajaj, then member of planning commission, to tackle the problem of health manpower planning, production and management. Important recommendations of the Bajaj committee are in Box - 9.

#### Box-9 : Important recommendations of the Bajaj committee

- Recommended for Formulation of National Health Manpower planning based on realistic survey.
- Educational Commission for health sciences should be developed on the lines of UGC.
- Recommended for National and Medical education policy in which teachers are trained in health education science technology.
- Uniform standard of medical and health science education by establishing universities of health sciences in all states.
- Establishment of health manpower cells both at state and central level.
- Vocational courses in paramedical sciences to get more health manpower.

### Krishnan Committee Health Report 1992

The committee under the chairmanship of Dr Krishnan reviewed the achievements and progress of previous health committee reports and also made comments on shortfalls. The committee address the problems of urban health and devised the health post scheme for urban slum areas. The committee had recommended one voluntary health worker (VHW) per

2, 000 population with an honorarium of Rs 100. Its report specifically outlines which services have to be provided by the health post. These services have been divided into outreach, preventive, family planning, curative, support (referral) services and reporting and record keeping. Outreach services include population education, motivation for family planning, and health education. In the present context, very few outreach services are being provided to urban slums.

## Summary

Public Health initiatives like Quarantine act, safe water and environment sanitation, appointment of sanitary inspectors were started in the pre-independence era. Bhole committee laid the framework on which the Indian health care is built in independent India. The health care in India has since moved from top down approach to bottom- up approach. The 'Health Survey and Development Committee, ' was instituted in the year 1943 under the chairmanship of Sir Joseph Bhole. The committee submitted its report in 1946 with following important recommendations like the integration of preventive, promotive and curative health services and establishment of Primary Health Centres (for 40, 000 population) in rural areas. Later on it forms the key strategy to achieve Health for All (HFA) by 2000 during Alma-Ata conference. It was based on allopathic system. It provided a ready-made model adopted as a blueprint for both health policy and development of the country.

In post independent era planning commission and several committees were set up to plan specific public health services or review existing health situations. *Mudaliar committee* (1962) found that the quality of services provided by PHCs were grossly inadequate with poor functioning, lack of referral system, and gross under staffing due to insufficient resources and its major recommendations were strengthening of existing PHCs and development of referral centres, strengthening of subdivisional and district hospitals, integration of medical and health services, and suggested constitution of an All India Health Service in the pattern of Indian Administrative service etc. *Chadha committee* (1963) was appointed to study the details of the necessary requirements related to PHCs and maintenance of National Malaria Eradication Program. Main recommendations were basic health worker for every 10, 000 population who will supervise malaria activities along with additional duties of family planning. Due to set back in both malaria and family planning *Mukerji committee* (1965) was appointed. It recommended separate staff for family planning. In 1967, Central Council of Health appointed "*Committee on integration of Health Services*" headed by Dr N. Jungalwalla (1967) which recommended no private practice for govt doctors. The Committee (1973) headed by *Shri Kartar Singh*, was constituted to study and make recommendations on the structure for integrated health services at peripheral and supervisory levels. The committee proposed a PHC per 50, 000 population with 16 sub-centres, each covering a population of 3000-3500. Each sub-centre to have one male and one female health worker. There should be one male and one female health supervisor at PHC to monitor and supervise the activities of staffs of 3-4 sub centres, The MO i/c PHC will be the overall

in charge of all peripheral staff. *Srivastava committee* (1974) recommended Creation of Village Health Guide (VHG) or community health volunteers based on its recommendation rural health scheme was launched. It recommended establishment of countrywide cadre of basic rural doctors consisting of trained paraprofessionals to extend comprehensive health care delivery to rural community. Important recommendations of the *Ramalingaswamy committee* were 30 bedded hospital for every 1 lakh population, PHC and District health centres should be under the control of three tier Panchayati Raj System. A expert committee for 'health manpower planning, production and management' was constituted under the chairmanship of Dr JS Bajaj and recommended (1986) Formulation of National Health Manpower planning based on realistic survey etc. The committee under the chairmanship of Dr Krishnan (1992) reviewed the achievements and progress of previous health committee reports and also made comments on shortfalls.

## Study Exercises

**Long Question :** Describe various health committees in post-independent era.

**Short Notes :** (1) Recommendation of Bhole committee  
(2) Recommendation of Jungalwalla committee  
(3) Recommendation of Kartar Singh committee.

**MCQs :**

1. Quarantine act was passed in \_\_\_\_\_ (a) 1840 (b) 1825 (c) 1852 (d) 1882
2. Bhole committee was formed in \_\_\_\_\_ (a) 1943 (b) 1934 (c) 1948 (d) 1938
3. According to Bhole committee each PHC cater for \_\_\_\_\_ population (a) 20,000 (b) 40,000 (c) 25,000 (d) 30, 000
4. Which committee recommended a Basic Health worker per 10, 000 population (a) Bhole committee (b) Mudaliar committee (c) Chadha committee (d) Kartar Singh committee
5. Which committee recommended 'No private practise' for govt. Doctor (a) Mudaliar committee (b) Chadha committee, (c) Kartar Singh committee (d) Jungalwalla committee
6. Rural health scheme was based on recommendation of which committee (a) Srivastav committee (b) Chadha committee (c) Kartar Singh committee (d) Jungalwalla committee
7. Which committee proposed a PHC per 50,000 population with 16 subcentres, each covering a population of 3000-3500 (a) Mudaliar committee (b) Chadha committee (c) Kartar Singh committee (d) Jungalwalla committee
8. Which committee suggested constitution of an All India Health Service in the pattern of Indian Administrative Service (a) Mudaliar committee (b) Chadha committee (c) Kartar Singh committee (d) Jungalwalla committee
9. Which committee recommended establishment of countrywide cadre of basic rural doctors consisting of trained paraprofessionals to extend comprehensive health care delivery to rural community (a) Shivaraman committee (b) Chadha committee (c) Kartar Singh committee (d) Jungalwalla committee

10. Match the following

1. Bhore committee	a. 1963
2. Chadah committee	b. 1967
3. Mudaliar committee	c. 1943
4. Jungalwala committee	d. 1973
5. Kartar Singh committee	e. 1962

Answers : (1) b; (2) a (3) b; (4) c; (5) d; (6) a; (7) c; (8) a; (9) a; (10) 1-c; 2-a; 3-e; 4-b; 5-d.

### Further Suggested Reading

1. Govt. of India (1946). Report of the Health Survey and Development Committee, Govt of India Press, Simla.
2. Govt. of India (1962). Report of the Health Survey and Planning Committee, Ministry of Health, Delhi.
3. Govt of India (1973). Report of the Committee on Multipurpose Workers Under Health and Family Planning Programme, Department of Family Planning, Ministry of Health and Family Planning, New Delhi.
4. Govt of India (1976). Swasth Hind, 20, 233
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## Health Planning Process in India

*Sunil Agrawal*

Health of a nation is an essential component of development, vital to a nation's economic growth and internal stability. Assuring a minimal level of health care to the population is a critical constituent of the development process. Since Independence, India has built up a vast health infrastructure and health personnel at primary, secondary, and tertiary care in public, voluntary, and private sectors. For producing skilled human resources, a number of medical and paramedical institutions including Ayurveda, Yoga and Naturopathy, Unani, Siddha & Homeopathy (AYUSH) institutions have been set up.

The strong link between poverty and ill health needs to be recognized. The onset of a long and expensive illness can drive the non-poor into poverty. Ill health creates immense stress even among those who are financially secure. High health care costs can lead to entry into or exacerbation of poverty. The importance of public provisioning of quality health care to enable access to affordable and reliable health services cannot be underestimated. This is specially so, in the context of preventing the non-poor from entering into poverty or in terms of reducing the suffering of those who are already below poverty line. The country has to deal with rising costs of health care and growing expectations of the people. The challenge of quality health services in remote rural regions has to be urgently met. Given the magnitude of the problem, we need to transform public health care into an accountable, accessible, and affordable system of quality services. The role of scientific health planning at the national level, to achieve this goal, needs no highlighting.

Among socialist countries, India is the first and foremost country to show tradition of health planning. During British India, the National congress had a planning committee under the chairmanship of Pandit Jawaharlal Nehru. A committee was

appointed by the British, with Sir Joseph Bhore as Chairman, for survey and planning; their report is a major event in the history of Indian Health Planning.

As on today, India is the world's 12th largest economy and the third largest in Asia behind Japan and China, with total GDP of around 1 trillion ( \$1,000 billion). Nearly two-thirds of the population depends on agriculture for its livelihood. 700 million Indians live on Rs.42 per day or less, but there is a large and growing middle class of 325-350 million with disposable income for consumer goods. Real GDP growth for the fiscal year ending March 31, 2007 was 9.4% up from 9.0% growth in the previous year. Growth for the year ending March 31, 2008 is expected to be between 8.5-9.0%.

### The Planning Commission

After independence in 1950 the present Planning Commission was established, which launched first five year plan in 1951. The Planning Commission was set up to make an assessment of the material, capital and human resources of the country, and to draft developmental plans for the most effective utilisation of these resources addressing the needs of the community and country at large. It gives suggestions and recommendations to the cabinet on the various issues of the country's development in consultation with ministers of the state and central government. There are 29 divisions in the Planning Commission like agriculture, health, nutrition, education, environment, family welfare, housing, water supply, manpower, rural development, multilevel planning and monitoring, etc. In 1957, the Planning Commission was provided with a Perspective Planning Division which makes projections into the future over a period of 20-25 years.

The membership of the planning commission is highly distinguished and from the very beginning it is chaired by the Prime Minister of the country. The planning commission consists of Chairman, Deputy Chairman and 5 members. The Planning Commission works through 3 major divisions :

- Programme Advisors
- General Secretariat
- Technical Divisions



Planning Commission reviews, from time to time, the progress made in various directions and makes recommendations to Government on problems and policies relevant to rapid and balanced economic development.

### Health Sector Planning

The Planning Commission gave considerable importance to health programmes in overall development of the country. The health sector is divided into the following subsectors:

<i>Subsectors of Health in Planning Commission</i>
<ul style="list-style-type: none"> <li>• Water supply and sanitation</li> <li>• Communicable diseases</li> <li>• Medical education, training and research</li> <li>• Curative services i.e., Hospitals, PHCs, etc.</li> <li>• Public Health Services</li> <li>• Family Planning</li> <li>• Indigenous Systems of Medicine</li> </ul>

All the above subsectors receive due importance in five year plans, however the priority changes from plan to plan depending upon the felt needs of the community, technical considerations and the progresses made. A Bureau of Planning was constituted in 1965 in the Ministry of Health to have better coordination between Centre and State Governments. The working of the national plans is reviewed time to time by National Development Council (NDC), which decides the social and economic policy affecting national development.

### Health Finance Indicators

Health finance indicators include allocations under five year plans, expenditure on health, trends in public and private spending. It provides an understanding of patterns of investments, expenditure, sources of funding and proportion of allocation in the health sector, vis a vis other total allocations.

**Budgetary Allocations:** Health in India, like most social sectors, is a state subject and the contribution of the state governments to health spending is between 80 and 85 per cent. While in the recent years the Union government has substantially hiked its contribution to the health budget increasing at 30 per cent per annum, in itself this makes a very small impact on the overall health budget. Presently, the health budget of state and central governments combined is less than one percent of GDP.

In India there has been a growing analysis of health budgets and health expenditures. The economic reforms of the 90's have created a trajectory of public health spending that shows a downward trend both in terms of share of the government budget as well as a proportion of the Gross Domestic Product. Prior to economic reforms in the mid- 80s, public health expenditures had peaked 1.6 per cent of the GDP and was 3.95 per cent of government's budget. By 2001, these figures read a dismal 0.9 per cent and 2.7 per cent, respectively, and further down to 0.8 and 2.4 per cent in 2005. What was worse was the decline in new investments by the Ministry of Health as reflected in the decline in capital expenditures from a robust 12 per cent in 1986-87 to a mere four per cent in 2000-01 and only a slight improvement in 2004-05 at five per cent.

Government expenditure on health as percentage of total expenditure on health is 24.8% while that of Private Expenditure

is 75.2%. Public spending on health has increased from 0.22% of GDP in 1950-51 to 1.05% of GDP during the mid 1980s and stagnated at around 0.9% of GDP during the later years. India spent approx Rs 1,08,732 Crores on health and health related expenditure during 2001-02. This amounted to about 4.8% of the estimated GDP at market prices in 2001-02. National health expenditures, when taken as a proportion of GDP at factor cost, were 5.2%. Since 1995-96 household expenditure on health has been growing at the current rate of approx 14% overall. In 1995-96, households in India spends an estimated Rs 33,253 crores at nominal prices which is estimated to have increased to Rs 72,759 crores in 2001-02. With an overall growth rate of 14% household spending, it is likely to be close to Rs 1,00,000 crores in nominal terms during 2003-04.

<b>Table - 1 : Allocations for Selected Key Programs in the Union Health Budget (Rs Crores)</b>			
Programme	2004-05	2005-06	2006-07
Hospitals & Dispensaries	240.75	268.70	263.25
Medical edn & Research	912.82	1397.33	1436.64
AYUSH	225.73	405.98	447.89
NACO - HIV/AIDS	232.00	476.50	636.67
RCH	710.51	881.73	1765.83
Pulse Polio		832.00	1004.00
Routine Immunisation	1186.40	472.60	326.50
FW services & contraception	1948.71	2412.41	1942.61
Area Projects	123.01	501.26	205.57
NRH Mission Flexible Funds			1530.88
Source: Demand for Grants, respective Budget years, Ministry of Finance, GOI, New Delhi			

Table -1 looks at and summarises some of the key programmatic allocations in the Union Health Budget. Here we see that traditional sectors like hospitals, medical education and family planning services are now receiving a smaller chunk of the health budget in comparison to the "new" sectors like RCH, HIV/AIDS, immunization (especially pulse polio). From the 2005-06 budget onwards, NRHM has taken a large share of the RCH and Family Planning budgets giving a boost to rural health allocations.

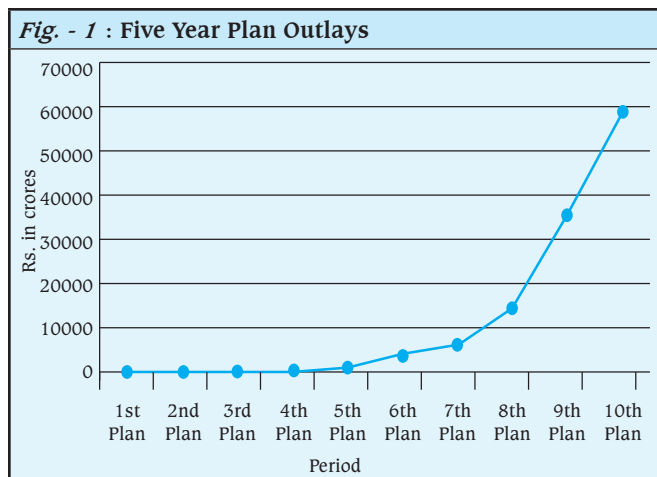
### Five Year Plans

The five year plans were conceived for organised development of the country by planning a long term road map focussing on sustained development instead of short term gains. It lays main emphasis on rebuilding rural India, industrial development, health for all and balanced development in all sectors. Planning Commission laid special emphasis on health programmes with the broad objectives of:

- Control and eradication of major communicable diseases of public health importance.
- Strengthening basic rural health services by establishing

- Sub-centres and Primary Health Centres.  
c) Population Control.  
d) Development of health manpower resources.

Health planning has been ensured of proper investment through successive five year plans, which is as under showing pattern of allocation since inception. The overall outlays during the various plan periods are shown in Fig. - 1 & Table-2 respectively.



### First plan (1951-1956)

The first Indian Prime Minister, Shri Jawaharlal Nehru presented the first five-year plan to the Parliament of India on December 8, 1951. The total plan budget of 206.8 billion INR (23.6 billion USD in the 1950 exchange rate) was allocated to seven broad areas: irrigation and energy (27.2 percent), agriculture

and community development (17.4 percent), transport and communications (24 percent), industry (8.4 percent), social services (16.64 percent), land rehabilitation (4.1 percent), and other (2.5 percent).

The target growth rate was 2.1 percent annual gross domestic product (GDP) growth; the achieved growth rate was 3.6 percent. During the first five-year plan the net domestic product went up by 15 percent. Lower increase of per capita income as compared to national income was due to rapid population growth. The World Health Organization, with the Indian government, addressed children's health and reduced infant mortality, contributing to population growth.

### Second plan (1956-1961)

The second five-year plan focused on industry, especially heavy industry. Domestic production of industrial products was encouraged, particularly in the development of the public sector.

### Third plan (1961-1966)

The third plan stressed on agriculture and improving production of rice, but the brief Sino-Indian War in 1962 exposed weaknesses in the economy and shifted the focus towards defence. In 1965-1966, the Green Revolution in India advanced agriculture. The war led to inflation and the priority was shifted to price stabilization.

In an effort to bring democracy to the grassroots level, Panchayat elections were started and the states were given more development responsibilities.

Gross Domestic Product rate during this duration was lower at 2.7% due to 1962 Sino-Indian War and Indo-Pakistani War of 1965.

**Table - 2 : Pattern of central Allocation (Rs in Crores) in Five Year Plans**

S No	Period	Total Investment	Health	Family Welfare	AYUSH	SubTotal
1	First Plan (1951-56)	1960.00	65.2 (3.3)	0.1(0.1)		65.3(3.4)
2	Second Plan (1956-61)	4672.00	140.8 (3.0)	5.0 (0.1)		145.8 (3.1)
3	Third Plan (1961-66)	8576.5	225.9 (2.6)	24.9 (0.3)		250.8 (2.9)
4	Annual Plans (1966-69)	6625.4	140.2 (2.1)	70.4 (1.1)		210.6 (3.2)
5	Fourth Plan (1969-74)	15778.8	335.5 (2.1)	278.0 (1.8)		613.5 (3.9)
6	Fifth Plan (1974-79)	39426.2	760.8 (1.9)	491.8 (1.2)		1252.6 (3.1)
7	Annual Plan (1979-80)	12176.5	223.1 (1.8)	118.5 (1.0)		341.6 (2.8)
8	Sixth Plan (1980-85)	109291.7	2025.2 (1.8)	1387.0 (1.3)		3412.2 (3.1)
9	Seventh Plan (1985-90)	218729.6	3688.6 (1.7)	3120.8 (1.4)		6809.4 (3.1)
10	Annual Plan (1990-91)	61518.1	960.9 (1.6)	784.9 (1.3)		1745.8 (2.9)
11	Annual Plan (1991-92)	65855.8	1042.2 (1.6)	856.6 (1.3)		1898.8 (2.9)
12	Eight Plan (1992-97)	434100.0	7494.2 (1.7)	6500.0 (1.5)	108.0 (0.02)	14102.2 (3.2)
13	Ninth Plan (1997-02)	859200.0	19818.4 (2.31)	15120.2 (1.76)	266.35 (0.03)	35204.95 (4.09)
14	Tenth Plan (2002-07)	1484131.3	31020.3 (2.09)	27125.0 (1.83)	775.0 (0.05)	58920.3 (3.97)
15	Eleventh Plan (2007-12)	2156571.0	136147.0 (6.3%)		3988.0 (0.18%)	140135.0 (6.5%)

Notes:- (a) Dept of ISM & H (now AYUSH) was created during 8th plan period (b) Figures in bracket indicate percentage to total plan investment outlay (c) Deptt of Health and Family Welfare were merged from 2005

#### Fourth plan (1969-1974)

At this time Smt Indira Gandhi was the Prime Minister. The Indira Gandhi government nationalized 19 major Indian banks. In addition, the situation in East Pakistan (now independent Bangladesh) was becoming dire as the Indo-Pakistani War of 1971 and Bangladesh Liberation War took place.

#### Fifth plan (1974-1979)

Stress was laid on employment, poverty alleviation, and justice. The plan also focused on self-reliance in agricultural production and defense. In 1978, the newly elected Morarji Desai government rejected the plan.

#### Sixth plan (1980-1985)

Called the Janata government plan, the sixth plan marked a reversal of the Nehruvian model. When Rajiv Gandhi was elected as the prime minister, the young prime minister aimed for rapid industrial development, especially in the area of information technology. Family planning was expanded in order to prevent overpopulation. In contrast to China's harshly-enforced one-child policy, Indian policy did not rely on the threat of force. More prosperous areas of India adopted family planning more rapidly than less prosperous areas, which continued to have a high birth rate.

#### Seventh plan (1985-1989)

The Seventh Plan marked the comeback of the Congress Party to power. The plan lay stress on improving the productivity level of industries by up gradation of technology.

#### Period between 1989-91

1989-91 was a period of political instability in India and hence no five year plan was implemented. Between 1990 and 1992, there were only Annual Plans. At that time Dr. Manmohan Singh (currently, Prime Minister of India) launched India's free market reforms that brought the economic stability in the country. It was the beginning of privatization and liberalization in India.

#### Eighth plan (1992-1997)

Modernization of industries was a major highlight of the Eighth Plan. This plan can be termed as Rao and Manmohan model of Economic development. The major objectives include Containing population growth, poverty reduction, employment generation, strengthening the infrastructure, institutional building, HUMAN RESOURCE DEVELOPMENT, Involvement of Panchayat raj, Nagarapalikas, NGOs and Decentralisation and people's participation.

#### Ninth plan (1997-2002)

During the Ninth Plan period, the growth rate was 5.35 per cent, a percentage point lower than the target GDP growth of 6.5 per cent.

#### Tenth plan (2002-2007)

The main objectives of the 10th Five-Year Plan were:

- Reduction of poverty ratio by 5 percentage points by 2007;
- Providing gainful and high-quality employment to the labour force;
- All children in India in school by 2003; all children to

complete 5 years of schooling by 2007;

- Reduction in gender gaps in literacy and wage rates by at least 50% by 2007;
- Reduction in the decadal rate of population growth between 2001 and 2011 to 16.2%;
- Increase in Literacy Rates to 75 per cent within the Tenth Plan period (2002-3 to 2006-7);
- Reduction of Infant mortality rate (IMR) to 45 per 1000 live births by 2007 and to 28 by 2012;
- Reduction of Maternal Mortality Ratio (MMR) to 2 per 1000 live births by 2007 and to 1 by 2012;
- All villages to have sustained access to potable drinking water within the Plan period.

Goals & Achievements during Tenth Plan are given in Table-3.

Table - 3 : Goals and Achievements during Tenth Plan		
Indicator	Goal for Tenth Plan	Achievements
Decadal Rate of Population Growth	16.2%	15.9% for 2001-11 (Projected) <sup>1</sup>
Infant Mortality Rate	45 per 1000 live births	58 per 1000 live births <sup>2</sup>
Maternal Mortality Ratio	2 per 1000 live births	3.01 per 1000 live births <sup>3</sup>
Source: 1. Technical Group on Population Projections set up by National Commission on Population (Dec 2006), RGI, GOI; 2. SRS 2005; 3. 2001-03 Special Survey of Deaths using RHIME (routine, resampled, household interview of mortality with medical evaluation), RGI (2006) GOI.		

**Review of Tenth Plan Schemes :** The Tenth Five-Year Plan (2002-07) indicated the dismal picture of the health services infrastructure and emphasized the need to invest more on building good primary-level care and referral services. To review the health services framework, design, and approach within which the policies were formulated the National Rural Health Mission was launched.

The original approved health and family welfare outlay for the Tenth Plan centrally sponsored and central sector schemes was Rs 36,378 crore. However, the sum of annual outlay increased to Rs 41,585 crore. Against this, the actual expenditure has been Rs 34,950.45 crore, that is, 84.05% of the sum of annual outlay. In 2005-06, all family welfare schemes and major disease control programmes were put under the umbrella of the National Rural Health Mission.

Review of the National Rural Health Mission at the end of the Tenth Plan reveals that in order to improve the public health delivery, the situation needs to change on a fast track mode at the grassroots.

The status as on 30 April, 2008 is as under:

- (a) State Health Missions have been constituted in all states.
- (b) ASHA training modules developed and revised.
- (c) Over 1500 management professionals (CA/MBA) appointed in Program Management Units (PMU) to support the programme management. This is being planed at the level of the block also.
- (d) RCH- II launched and under implementation.
- (e) IMNCI started in 142 districts.

- (f) Legal changes brought about to allow ANMs to dispense medication and MBBS doctors to dispense anesthesia.
- (g) At 1,611 PHCs AYUSH doctors have been co-located
- (h) 228413 Village Health & Sanitation Committees (VHSCs) have been constituted and operational by 30 April 2008.
- (j) Against the target of 5 lakh fully trained Accredited Social Health Activists (ASHAs) by 2008, the initial phase of training (first module) has been imparted to 5.36 lakh. ASHAs in position with drug kits are 224951 in number.
- (k) Out of the 145272 Sub-centres (SCs) expected to be functional with 2 Auxiliary Nurse Midwives (ANMs) by 2008, only 22471 had the same.
- (l) 22,370 Primary Health Centres (PHCs) are functional and out of which 3450 PHCs are functional with three staff nurses by 2008.
- (m) There has been a shortfall of 5,498 (>50%) specialists at the Community Health Centres (CHCs). Total CHCs functional are 4,045 out of which 2,966 have been selected to be upgraded to IPHS.
- (n) Number of Districts where annual integrated action plan under NRHM have been prepared for 2007-08 are 485.

#### **Eleventh plan (2007-2012)**

The Eleventh Five Year Plan provides an opportunity to restructure policies to achieve a New Vision based on faster, broad-based, and inclusive growth.

**Goal :** To achieve good health for people, especially the poor and the underprivileged.

#### **Strategies**

1. A comprehensive approach that encompasses individual health care, public health, sanitation, clean drinking water, access to food, and knowledge of hygiene and feeding practices.
2. To increase aggregate spending on health by the Centre and the states.
3. The contribution of the private sector in providing primary, secondary, and tertiary services.
4. Good governance, transparency, and accountability in the delivery of health services.
5. Health as a right for all citizens is the goal that the Plan will strive towards.

#### **Time-Bound Goals for the Eleventh Five Year Plan**

##### **1. Income & Poverty**

- Accelerate GDP growth from 8% to 10% and then maintain at 10% in the 12th Plan in order to double per capita income by 2016-17.

##### **2. Education**

- Reduce dropout rates of children from elementary school from 52.2% in 2003-04 to 20% by 2011-12
- Increase literacy rate for persons of age  $\geq 7$  years to 85%
- Lower gender gap in literacy to 10 percentage points
- Increase the percentage of each cohort going to higher education from the present 10% to 15% by the end of the plan

##### **3. Health**

- Reduce infant mortality rate to 28 and maternal mortality ratio to 1 per 1000 live births

- Reduce Total Fertility Rate to 2.1
- Provide clean drinking water for all by 2009 and ensure that there are no slip-backs
- Reduce malnutrition among children of age group 0-3 to half its present level
- Reduce anaemia among women and girls by 50% by the end of the plan

#### **4. Women and Children**

- Raise the sex ratio for age group 0-6 to 935 by 2011-12 and to 950 by 2016-17
- Ensure that all children enjoy a safe childhood, without any compulsion to work

#### **5. Infrastructure**

- Provide homestead sites to all by 2012 and step up the pace of house construction for rural poor to cover all the poor by 2016-17

#### **6. Environment**

- Attain WHO standards of air quality in all major cities by 2011-12
- Treat all urban waste water by 2011-12 to clean river waters

**Eleventh Five Year Plan Agenda in Health Sector :** Thrust areas to be pursued during the Eleventh Five Year Plan are summarized below:

##### **1. Improving Health Equity**

- i. National Rural Health Mission (NRHM)
- ii. National Urban Health Mission (NUHM)

##### **2. Adopting a system-centric approach rather than a disease-centric approach**

- i. Strengthening Health System through upgradation of infrastructure and public private partnership
- ii. Converging all programmes and not allowing vertical structures below district level under different programmes

##### **3. Increasing Survival**

- i. Reducing Maternal mortality and improving Child Sex ratio through Gender Responsive Health care
- ii. Reducing Infant and Child mortality through Home Based Neonatal Care (HBNC) and Integrated Management of Neonatal and Childhood Illnesses (IMNCI)

##### **4. Taking full advantage of local enterprise for solving local health problems**

- i. Integrating AYUSH in Health System
- ii. Increasing the role of Registered Medical Practitioners
- iii. Training the Traditional Birth Attendants (TBAs) to make them Skilled Birth Attendants (SBAs)
- iv. Propagating low cost and indigenous technology

##### **5. Preventing indebtedness due to expenditure on health/ protecting the poor from health expenditures**

- i. Creating mechanisms for Health Insurance
- ii. Health Insurance for the unorganized sector

##### **6. Decentralizing Governance**

- i. Increasing the role of PRIs, NGOs, and Civil Society
- ii. Creating and empowering Health committees at various levels



## 7. Establishing e-Health

- i. Adapting IT for governance
- ii. Establishing e-enabled Health Management Information System
- iii. Increasing role of telemedicine

## 8. Improving access to and utilization of essential and quality health care

- i. Implementing flexible norms for health care facilities (based on population, distance and terrain)
- ii. Reducing travel time to two hrs for emergency obstetric care
- iii. Implementing Indian Public Health Service Standards for health care institutions at all levels
- iv. Accrediting private health care facilities and providers
- v. Redeveloping hospitals/institutions
- vi. Mirroring of centres of excellence like AIIMS

## 9. Increasing focus on Health Human Resources

- i. Improving Medical, Paramedical, Nursing, and Dental education and availability
- ii. Reorienting AYUSH education and utilization
- iii. Reintroducing licentiate course in medicine
- iv. Making India a hub for health care and related tourism

## 10. Focusing on excluded/neglected areas

- i. Taking care of the Older persons
- ii. Reducing Disability and integrating disabled
- iii. Providing humane Mental Health services
- iv. Providing Oral health services

## 11. Enhancing efforts at disease reduction

- i. Reversing trend of major diseases
- ii. Launching new initiatives (Rabies, Fluorosis, Leptospirosis)

## 12. Providing focus to Health System and Bio-Medical research

- i. Focusing on conditions specific to our country
  - ii. Making research accountable
  - iii. Translating research into application for improving health
- Schemes and Outlays for Eleventh Five Year Plan :** To achieve the desired outcomes in the health sector, a substantially enhanced outlay for the Department of Health and Family Welfare has been earmarked during the Eleventh Five Year Plan (2007-12). The total projected GBS for the Eleventh Plan is Rs 1,20,374.00 crore (at 2006-07 prices) and Rs 1,36,147.00 crore (at current prices). This enhanced outlay is about four times the initial outlay for the Tenth Plan (Rs 36,378.00 crore). A large proportion of this amount i.e. Rs 89,478.00 crore (65.72 %) is for NRHM, the flagship of the Government of India. Another Rs 625 crore is to be contributed by the Dept. of AYUSH to make a total of Rs 90,103 crore for NRHM during the Eleventh Five Year Plan. For the other ongoing schemes, a total of Rs 23,995.05 crore has been earmarked. For the new initiatives it is Rs. 20,846.95 crore. Rs. 1,827.00 crore has also been earmarked for Oversight Committee.

## Summary

Since Independence, India has built up a vast health infrastructure and health personnel at primary, secondary, and tertiary care in public, voluntary, and private sectors.

The country has to deal with rising costs of health care and growing expectations of the people. The role of scientific health planning at the national level, to achieve this goal, needs no highlighting. Among socialist countries, India is the first and foremost country to show tradition of health planning. During British India, the National congress had a planning committee under the chairmanship of Pandit Jawaharlal Nehru. A committee was appointed by the British, with Sir Joseph Bore as Chairman, for survey and planning; their report is a major event in the history of Indian Health Planning. After independence in 1950 the present Planning Commission was established, which launched first five year plan in 1951. The Planning Commission was set up to make an assessment of the material, capital and human resources of the country, and to draft developmental plans for the most effective utilisation of these resources addressing the needs of the community and country at large. There are 29 divisions in the Planning Commission. In 1957, the Planning Commission was provided with a Perspective Planning Division which makes projections into the future over a period of 20-25 years. The membership of the planning commission is highly distinguished and from the very beginning it is chaired by the Prime Minister of the country. The planning commission consists of Chairman, Deputy Chairman and 5 members. The Planning Commission works through 3 major divisions: Programme Advisors; General Secretariat & Technical Divisions. The health sector is divided into the following subsectors: Water supply and sanitation, Communicable diseases, Medical education, training and research; Curative services i.e., Hospitals, PHCs, etc, Public Health Services, Family Planning & Indigenous Systems of Medicine. A Bureau of Planning was constituted in 1965 in the Ministry of Health to have better coordination between Centre and State Governments. The working of the national plans is reviewed time to time by National Development Council (NDC), which decides the social and economic policy affecting national development. The five year plans were conceived for organised development of the country by planning a long term road map focusing on sustained development instead of short term gains. It lays main emphasis on rebuilding rural India, industrial development, health for all and balanced development in all sectors. Planning Commission laid special emphasis on health programmes with the broad objectives of: a) Control and eradication of major communicable diseases of public health importance, b) Strengthening basic rural health services by establishing Subcentres and Primary Health Centres, c) Population Control, d) Development of health manpower resources. Health planning has been ensured of proper investment through successive five year plans, which is as under showing pattern of allocation since inception.

## Study Exercises

**Long Question :** Discuss the strategies, time bound goals & schemes of 11th five yr plan.

**Short Notes :** (1) Planning commission (2) Health sector planning (3) Achievements of 10 five yr plan.

### MCQs:

1. The 3 major divisions of Planning Commission are all except: (a) Programme Advisors (b) General Secretariat

- (c) Technical Divisions (d) Executive Division
2. All are the sub-sectors of health in planning commission except (a) Water supply and sanitation (b) Medical education, training and research (c) Indigenous Systems of Medicine (d) Agriculture
  3. Broad objectives of Five year plan are: (a) Control and eradication of major communicable diseases of public health importance (b) Strengthening basic rural health services by establishing Sub-centres and Primary Health Centres (c) Population Control (d) All
  4. One of the following is not the strategies of 11th plan: (a) To increase aggregate spending on health by the Centre and the states (b) The contribution of the private sector in providing primary, secondary, and tertiary services (c) To establish medical colleges in rural sectors of country (d) Health as a right for all citizens is the goal.
  5. 11<sup>th</sup> Plan will strive towards: (a) Accelerate GDP growth from 8% to 10% and then maintain at 10% in the 12<sup>th</sup> Plan in order to double per capita income by 2016-17 (b) Raise the sex ratio for age group 0-6 to 935 by 2011-12 and to 950 by 2016-17 (c) Attain WHO standards of air quality in all major cities by 2011-12 (d) All
  6. India is the world's 10th largest economy and the third largest in Asia behind Japan and China, with total GDP of around 1 trillion. True / False
  7. Growth for the year ending March 31, 2008 is expected to be between 8.5-9.0%. True / False
  8. There are 22 divisions in the Planning Commission. True / False
  9. A Bureau of Planning was constituted in 1965 in the Ministry of Health to have better coordination between Centre and State Governments. True / False
  10. The working of the national plans is reviewed time to time by National Development Council (NDC), which decides the social and economic policy affecting national development. True / False
  11. Contribution of the state governments to health spending is between 80 and 85 per cent. True / False
  12. Presently, the health budget of state and central governments combined is less than one percent of GDP. True / False
  13. Traditional sectors like hospitals, medical education and family planning services are now receiving a greater chunk of the health budget in comparison to the "new" sectors like RCH, HIV/AIDS, immunization (especially pulse polio). True / False
  14. From the 2005-06 budget onwards, NRHM has taken a large share of the RCH and Family Planning budgets giving a boost to rural health allocations. True / False
  15. Government expenditure on health as percentage of total expenditure on health is 24.8% while that of Private Expenditure is 75.2%. True / False
  16. Public spending on health has increased from 0.22% of GDP in 1950-51 and stagnated at around 10% of GDP during the later years. True / False
  17. Planning Commission was provided with a Perspective Planning Division which makes projections into the future over a period of 20-25 years. True / False
- Answers :** (1) d; (2) d; (3) d; (4) c; (5) d; (6) False; (7) True; (8) False; (9) True; (10) True; (11) True; (12) True; (13) False; (14) True; (15) True; (16) False; (17) True.

### Further Suggested Reading

1. India's Five Year Plans. Complete Documents, Academic Foundation, New Delhi.
2. Govt of India (2006), Annual Report 2005-06, Ministry of Health and Family Welfare, New Delhi.
3. League of Nations Health Organisation, European Conference on Rural Hygiene (1931), Recommendations on the principles governing the organization of Medical Assistance, the Public Health Services and Sanitation in Rural Districts, Geneva.

Sunil Agrawal

**National Health Policy (NHP) - 2002**

Policies are “courses” or “principles” of action adopted or proposed by a Government. In the developing countries like India, resources often fall short of requirements, the Government policies then guide us to set priorities and allocate resources to achieve our objectives. Health policies are intended to achieve a level of health status for most of the persons in the community. The policies enacted by various Government bodies have formal framework with legal backup. Health policy aims at the improvement of the conditions under which people live, including housing, education, nutrition, child care, reproductive health, transportation, information and communication.

**Background**

In 1977, the World Health Assembly at Alma Ata decided to launch an ambitious movement known as, “*Health for All (HFA) by 2000 AD*”. This broadly means attainment of level of health that will permit all people to lead economically and socially productive life. As a signatory to HFA strategy, the Government of India was committed to frame its own policy and implement to attain Health For All by 2000 AD. In pursuance of this objective, two important committees were framed to study this strategy in detail keeping in view local percept. These were, firstly, the Report of the study Group on ‘Health for All - an alternative strategy’, Sponsored by ICSSR and ICMR, and,

secondly, Report of the working group on ‘Health For All by 2000 AD’ sponsored by Ministry of Health and Family Welfare (MOHFW), Government Of India. These reports formed the basis of the National Health Policy formulated by MOHFW, GOI in 1983.

Since, the inception of National Health Policy there have been marked changes in the determinants of health. Some of the policy initiatives outlined in the NHP-1983 yielded results, while in several other areas, the outcome was not as expected. These include remarkable successes like eradication of Guinea Worm. Polio is on the verge of being eradicated. Leprosy, Kala Azar, and Filariasis can be expected to be eliminated in the foreseeable future. There has been a substantial drop in the total fertility rate and infant mortality rate. The success of the initiatives taken in the public health field is reflected in the progressive improvements of many demographic, epidemiological and infrastructural indicators over the period 1951 to 2007 (Box - 1).

Improvement of these health indicators were the outcome of several complementary initiatives of development sector covering rural development, agriculture, food production, animal husbandry, drinking water, sanitation, education etc. Despite the impressive public health gains, the morbidity and mortality levels in the country were high as compared to developed countries. Over the years the incidence of some of the communicable diseases like Malaria, Tuberculosis, HIV/AIDS, hepatitis and non communicable diseases like Cancers, life style diseases, diabetes etc were on the rise and much more dedicated efforts were required to achieve goal of, “Health For All by 2000 AD”. After the passage of year 2000, it was the time to take stock of situation and progress ahead with extra zeal to achieve ultimate goal of Health For All. Accordingly, the NHP -

**Box - 1**

Indicator	1951	1981	2000	2006
Life Expectancy	36.7	54	61 (M), 62.7 (F)	62.3 (M), 63.9 (F)
Crude Birth Rate per 1000	40.8	33.9(SRS)	26.1(99 SRS)	23.5
Crude Death Rate per 1000	25	12.5(SRS)	8.7(99 SRS)	7.5
IMR per 1000 live births	146	110	70 (99 SRS)	57
Total Fertility Rate	6	-	3.8	2.9
Malaria (cases in million)	75	2.7	2.2	1.78
Leprosy cases per 10,000 population	38.1	57.3	3.74	0.72
Small Pox (no of cases)	>44,887	Eradicated		
Guineaworm ( no. of cases)		>39,792	Eradicated	
Polio		29709	265	116
SC/PHC/CHC	725	57,363	1,63,181	1,71,567
Dispensaries & Hospitals	9209	23,555	43,322 (95-96-CBHI)	
Beds (Pvt & Public)	117,198	569,495	8,70,161	
Doctors (Allopathy)	61,800	2,68,700	5,03,900	6,96,747
Nursing Personnel	18,054	1,43,887	7,37,000	15,09,196

(Sources : 1 - 3)

1983 was revised and a new, extensive NHP was enunciated by the Govt of India in 2002.

### Objective of National Health Policy (NHP) 2002

The main objective of this policy is to achieve an acceptable standard of good health amongst the general population of the country. The noteworthy initiatives are presented in Box - 2

#### Box - 2 : Noteworthy initiatives under the National Health Policy 2002

- Comprehensive primary health care services
- Health volunteers
- Well worked out referral system
- Integrated network of evenly spread speciality and super speciality services

### Strategies

The revised strategies adopted by GOI to achieve above objective are :

- (a) Increase access to the decentralized public health system by establishing new infrastructure in deficient areas, and by upgrading the infrastructure in the existing institutions.
- (b) Ensuring a more equitable access to health services across the social and geographical expanse of the country.
- (c) Increasing the aggregate public health investment through a substantially increased contribution by the Central Government. It is expected that this initiative will strengthen the capacity of the public health administration at the state level to render effective service delivery.
- (d) The contribution of the private sector in providing health

services would be much enhanced.

- (e) Primacy to preventive and first-line curative initiative at the primary health level.
- (f) Emphasis will be laid on rational use of drugs within the allopathic system.
- (g) Increased access to tried and tested systems of traditional medicine.

The endeavour of NHP-2002 is to achieve the time-bound goals mentioned in Box - 3, within the framework of strategies mentioned above.

On a short term basis, within the context of the NHP, the Important health related targets for the eleventh five year plan (2007 - 2012) are :

- Reducing Maternal Mortality Ratio (MMR) to 1 per 1,000 live births.
- Reducing Infant Mortality Rate (IMR) to 28 per 1,000 live births.
- Reducing Total Fertility Rate to 2.1.
- Providing clean drinking water for all by 2009 and ensuring no slip-backs.
- Reducing malnutrition among children of age group 0-3 to half its present level.
- Reducing anaemia among women and girls by 50%.
- Raising the sex ratio for age group 0-6 to 935 by 2011-12 and 950 by 2016-17.

### Major Strategies of NHP-2002

(a) **Financial Resources** : It is concerning that Public Health expenditure has declined from 1.5% of GDP in 1990 to 0.9% of GDP in 1999. Given the difficult fiscal position of the State Governments, the Central Government will have to play a key

#### Box - 3 : Goals to be achieved by 2000 - 2015

Goals for which the target year is already over	Target Year	Result
Eradicate Polio	2005	Not achieved
Eradicate Yaws	2005	Achieved
Eliminate Leprosy	2005	Achieved
Achieve Zero level growth of HIV/AIDS	2007	Not achieved
Establish an integrated system of surveillance, National Health Accounts and Health Statistics.	2005	IDSP has been launched
Increase State Sector Health spending from 5.5% to 7% of the total budget	2005	Not achieved
Goals for which time is available	Target Year	
Eliminate Kala Azar	2010	
Reduce Mortality by 50% on account of TB, Malaria and Other Vector and Water Borne diseases	2010	
Reduce Prevalence of Blindness to 0.5%	2010	
Reduce IMR to 30/1000 and MMR to 100/Lakh	2010	
Increase utilization of public health facilities from current Level of <20 to >75%	2010	
Increase health expenditure by Government from the existing 0.9 % to 2.0% of GDP	2010	
Increase share of Central grants to Constitute at least 25% of total health expenditure	2010	
Increase State Sector Health spending from 5.5% to 7% of the budget and further increase to 8%	2010	
Eliminate Lymphatic Filariasis	2015	



role in augmenting public investments. It is planned, under the policy, to increase health sector expenditure by both central and state government as stated in Box 3 above. However, the higher public health investment should also be gainfully utilised by the public health administration for upliftment of health status of the community.

**(b) Equitable distribution** : To meet the objective of reducing various types of inequities and imbalances, i.e., interregional; across the rural - urban divide; and between economic classes - the most cost-effective method would be to increase the sectoral outlay in the primary health sector. Such outlets afford access to a number of individuals, and also facilitate preventive and early stage curative initiative. NHP-2002 sets out an increased allocation of 55 percent of the public health investment for the primary health sector, the secondary and tertiary health sectors being targeted for 35 percent and 10 percent respectively, for strengthening existing facilities and opening additional public service outlets.

**(c) Delivery of National Public Health Programmes** : The policy envisages a key role for the Central Government in designing national programmes with the active participation of the State Governments. Also, the policy ensures the provisioning of financial resources, in addition to technical support, monitoring and evaluation at the national level by the Centre. However, to optimize the utilization of the public health infrastructure at the primary level, NHP-2002 envisages the gradual convergence of all health programmes under a single field administration. Vertical programmes for control of major diseases like TB, Malaria, HIV/AIDS, as also the RCH and Universal Immunization programmes, would need to be continued till these diseases are no more a public health threat. The major change in programme implementation is through autonomous bodies at State and district levels whereas the role of district and state health departments will be limited to overall monitoring of achievements of programme targets and technical aspects. This will give better planning and operational flexibility and public health projects will be more suited to the local needs.

**(d) The State of Public Health Infrastructure** : The NHP 2002 envisages kick-starting the revival of the Primary Health System by providing some essential drugs under Central Government funding. This policy recognizes the need for more frequent in service training of public health medical personnel, at the level of medical officers as well as paramedics. Further, it also recognizes the practical need for levying reasonable user-charges for certain secondary and tertiary public health care services for those who can afford to pay.

**(e) Extending Public Health Services** : For better availability and distribution of medical personnel in their jurisdiction, State Governments will expand the pool of medical practitioners to include a cadre of licentiates of medical practice, practitioners of Indian Systems of Medicine and Homoeopathy. Simple services/procedures can be provided by such practitioners even outside their disciplines, as part of the basic primary health services in under-served areas after adequate training and subject to the monitoring of their performance through professional councils. The scope of expanding services of paramedical personnel from existing usage will be examined on lines of services rendered

by nurse practitioners in several developed countries.

**(f) Role of Local Self-Government Institutions** : NHP-2002 lays great emphasis upon the implementation of public health programmes through local self government institutions. The financial incentives will be provided by Central Government.

**(g) Norms for Health Care Personnel** : Minimal statutory norms for the development of doctors and nurses in medical institutions need to be introduced urgently under the provisions of the respective MCI and INC acts.

**(h) Education of Health Care Professionals** : Keeping in view the uneven distribution of colleges in the country, the policy envisages the setting up of a *Medical Grants Commission* for funding new Government Medical and Dental Colleges and upgradation of existing colleges in different parts of the country. The existing curriculum can be modified to a more need-based, realistic, skill oriented syllabus, at undergraduate level with a more significant component of practical training. This would make fresh doctors contribute effectively to providing of primary health services immediately after graduation. The policy recommends periodic skill updating through Continuing Medical Education (CME) programmes on important health issues.

**(j) Need for Specialists In Public Health and Family Medicine** : In order to alleviate the acute shortage of medical personnel in public health, the policy envisages to raise the proportion of postgraduate seats in the field of 'Public Health' and 'Family Medicine' progressively to reach a stage wherein 1/4th of the seats are earmarked for these disciplines. Since the public health discipline has an interface with many other developmental sectors, specialization in public health may be encouraged not only for medical doctors, but also for non-medical graduates from the allied fields of public health engineering, microbiology and other natural sciences.

**(k) Nursing Personnel** : In the interest of patient care, the policy emphasises the need for an improvement in the ratio of nurses vis-à-vis doctors/beds and an increase in degree holding nurses vis-a-vis diploma holding nurses and training of super speciality nurses.

**(l) Use of Generic Drugs and Vaccines** : NHP emphasizes the need for basing treatment regimens on generic drugs rather than proprietary drugs, except in special circumstances. This is a pre-requisite for cost effective public health care and production and sale of irrational combination of drugs would be prohibited through the drug standard statute. The UIP should be assured of uninterrupted supply of vaccines mainly from public sector institutions so that they are available at an affordable price.

**(m) Urban Health** : NHP-2002 envisages the setting up of an organized urban primary health care structure based on appropriate population norms. The structure conceived under NHP-2002 is a two-tiered one; the Primary centre covering a population of one lakh, with a dispensary providing an OPD facility and essential drugs, to enable access to all the national health programmes, and a second-tier of the urban health organization at the level of the Government general hospital, where referral is made from the primary centre. The funding of UHC will be jointly borne by state and centre. The policy

also recommends establishment of fully equipped trauma care networks to reduce accidental mortality and morbidity.

**(n) Mental Health** : NHP-2002 envisages a network of decentralized mental health services and the diagnosis of common disorders, and the prescription of common therapeutic drugs by general duty medical staff. Central Government has also committed to upgrade physical infrastructure of mental health institutions for indoor treatment of patients.

**(o) Information, Education And Communication (IEC)** : NHP-2002 envisages an IEC policy, which maximizes the dissemination of information to those population groups which cannot be effectively approached by using only the mass media. The focus would therefore be on the interpersonal communication of information and on folk and other traditional media to bring about behavioral change. Dispelling of myths and misconceptions about religious and ethical issues by the community leaders, particularly religious leaders is an effective way for behavioural change in the community. NHP 2002 also gives priority to school health programmes which aim at preventive health education, providing regular health check ups and promotion of health seeking behaviour amongst children.

**(p) Health Research** : The policy envisages an increase in Government funded health research to a level of 2 percent by 2010. Domestic medical research would be focused on new therapeutic drugs and vaccines for tropical diseases, such as TB and Malaria, as also on the sub-types of HIV / AIDS prevalent in the country. Private entrepreneurship will be encouraged in the field of medical research.

**(q) Role of The Private Sector** : In principle, this policy welcomes the participation of the private sector in all areas of health activities - primary, secondary or tertiary. It envisages the enactment of suitable legislation for regulating minimum infrastructure and quality standards in private clinical establishments / medical institutions along with statutory guidelines for the conduct of clinical practise. The NHP envisages the co-operation of private practitioners and NGOs in the national disease control programmes.

**(r) The Role of the Civil Society** : The policy emphasizes the need to simplify procedures for government - civil society interfacing in order to enhance the involvement of civil society in public health programmes.

**(s) National Disease Surveillance Network** : This Policy envisages the setting up of an integrated disease control network from the lowest rung of public health administration to the Central Government. This public health surveillance network will also encompass information from private health care institutions and practitioners. It is expected that real-time information will greatly strengthen the capacity of the public health system to counter local outbreaks of seasonal diseases.

**(t) Health Statistics** : The policy envisages the compilation of baseline estimates for the incidence of the common diseases. The policy proposes to enable the periodic updating of these baseline estimates through representative sampling, under an appropriate statistical methodology, so that the public health system would move closer to the objective of evidence-based policy-making.

**(u) Women's Health** : The policy envisages the increased access of women and underprivileged groups to basic health care of primary health sector and gives highest priority to the identified programmes relating to women's health.

**(v) Regulation of standards of Para Medical Disciplines and Medical Ethics** : The NHP 2002 recognises the need for the establishment of statutory professional councils for paramedical disciplines to register paramedic practitioners, maintain standards of training, and monitor performance. The policy also recommends that a contemporary code of ethics be notified and rigorously implemented by the Medical Council of India as well as the need to watch newer areas like gene manipulation, and stem cell research.

**(w) Enforcement of Quality Standards for Food and Drugs** : The NHP-2002 envisages that the food and drug administration will be progressively strengthened, in terms of both laboratory facilities and technical expertise. Food standards will be similar to Codex specifications and drug standards will be at par with the most rigorous ones adopted elsewhere.

**(x) Environmental and Occupational Health** : The policies and programmes of the environment related sectors be smoothly interfaced with the policies and the programmes of the health sector.

**(y) Providing Medical Facilities to Users from Overseas** : The policy strongly encourages the provision of secondary and tertiary health services on a payment basis to service seekers from overseas (Medical Tourism), due to comparatively cheaper cost.

**(z) Impact of Globalisation on the Health Sector** : The policy envisages a national patent regime for the future, which avails of all opportunities to secure for the country under its patent laws, affordable access to the latest medical and therapeutic discoveries.

## National Population Policy (NPP) - 2000

In 1952, India became the first country in the world to launch a national program, emphasizing family planning to the extent necessary for reducing birth rates "to stabilize the population at a level consistent with the requirement of national economy". The evolution of the national family planning programme is presented in Box - 4.

The National Health Policy, 1983, stated that replacement levels of fertility rate (TFR) should be achieved by the year 2000. On 11 May 2000, India had 1 billion (100 crore) people, i.e., 16 percent of the world's population on 2.4 percent of the globe's land area. If current trends continue, India may overtake China in 2045, to become the most populated country in the world. While global population has increased threefold during 20th century, from 2 billion to approximately 6 billion, the population of India has increased nearly five times from 238 million (23 crores) to 1 billion in the same period. India's current yearly increase in population of 15.5 million is enough to neutralize efforts to conserve our efforts towards resource endowment and environment.

The National Population Policy (NPP) 2000 provides a policy framework for advancing goals and prioritizing strategies during the next decade, to meet the reproductive and child

**Box - 4: Evolution of Family Planning Programme in India**

Year	Remarks
1925	Prof Raghunath Dhondo Karve opened the first birth control clinic in Mumbai
1938	National Planning Committee of the Indian National Congress set up in 1938 strongly supported Family Planning as a state policy
First five-year plan (1951-56)	India was the first country to have officially launched a well-defined family planning programme in 1951
Third five year plan (1961-66)	Extension wing was added to the existing programme, introduction of intrauterine device, integrated approach was adopted in 1966 and family planning formed an integral part of maternal and child health and nutritional services.
1968	Social marketing for condoms was introduced under which condoms or Nirodh were made available at highly subsidized price. And at this stage Lippies loop was introduced.
Fourth five year plan (1969-74)	Family planning services were integrated with Primary health care at this stage. 1970-All India Hospital Post Partum Programme (AIHHP) was launched. 1971-liberalisation of abortions by the govt. by passing MTP act.
Fifth five-year plan (1974-79)	The programme took the recourse in this time period with Mass Vasectomy Camp Approach leading to national emergency in 1975. The programme was renamed at this stage as Family Welfare Programme. Family welfare basket was filled with nutrition and child health programmes. 1975-Integrated Child Development Scheme. 1978-Child Marriage Restraint Act. India became signatory of Alma Ata declaration in 1978.
Sixth five-year plan (1980-85)	The national health policy diluted family planning and it became a part of concept of positive health and one of the means to achieve Health for All by 2000.
Seventh five-year plan (1986-90)	There was strengthening of Mother and child (MCH) services along with family welfare services. Other programmes as Oral Rehydration Therapy (ORT), control of respiratory group of infections and universal immunization programme were also included.
Eighth five-year plan (1992-97)	The programme was renamed again as Child survival and Safe Motherhood programme (CSSM) in 1992(7).
Ninth five-year plan (1997-2002)	Reproductive and Child Health programme was launched in 1997 comprising of Child Survival and Safe Motherhood (CSSM), Sexually transmitted infections (STI) and other components.
Tenth five year plan (2002-2007)	RCH II was launched with few modifications after evaluating RCH I

health needs of the people in India, and to achieve net replacement levels (TFR) by 2010. It is based upon the need to simultaneously address issues of child survival, maternal health and contraception, while increasing outreach and coverage of a comprehensive package of reproductive and child health service by government, industry and voluntary non-government sector, working in partnership. The NPP affirms the commitment of government towards voluntary and informed choice and consent of citizens while availing reproductive health care services, and continuation of the target free approach in administering family planning services. The objectives of NPP - 2000 are shown in Box - 5.

The major differences between the earlier approach and the newer approach, based on NPP - 2000 and RCH-II programme are shown in Box - 6.

**National Socio Demographic Goals**

In pursuance of these objectives, the following National Socio-Demographic Goals to be achieved by 2010 are formulated:

(a) Address the unmet needs for basic reproductive and child

health services, supplies and infrastructure.

- (b) Make school education up to age 14 free and compulsory, and reduce drop outs at primary and secondary school levels to below 20 percent for both boys and girls.
- (c) Reduce infant mortality rate to below 30 per 1000 live births.
- (d) Reduce maternal mortality ratio to below 100 per 100,000 live births.
- (e) Achieve universal immunization of children against all vaccine preventable diseases.
- (f) Promote delayed marriage for girls, not earlier than age 18 and preferably after 20 years of age.
- (g) Achieve 80 percent institutional deliveries and 100 percent deliveries by trained persons.
- (h) Achieve universal access to information / counselling, and services for fertility regulation and contraception with a wide basket of choices.
- (j) Achieve 100 percent registration of births, deaths, marriages and pregnancies.
- (k) Prevent and control communicable diseases.

**Box - 5 : Objectives of NPP - 2000**

Immediate objective	<ul style="list-style-type: none"> <li>To address the unmet needs for contraception</li> <li>Strengthen health care infrastructure, and health personnel</li> <li>Provide integrated service delivery for basic reproductive and child health care.</li> </ul>
Medium-term objective	<ul style="list-style-type: none"> <li>To bring the TFR to replacement levels by 2010</li> <li>Vigorous implementation of inter-sectoral operational strategies.</li> </ul>
Long-term objective	<ul style="list-style-type: none"> <li>To achieve a stable population by 2045, at a level consistent with the requirements of sustainable economic growth, social development, and environmental protection</li> </ul>

**Box - 6 : Differences between older and newer approach (8).**

Old Approach (Family Planning)	New Approach (Reproductive and Child Health)
Population-Centered	People-centered
Over-emphasis on sterilization	Informed Choice of contraceptives
Quantitative targets	Qualitative targets
Family Planning in a separate basket	FP merged with Health: One package for Health, MCH & FP
Focus on 30 + women with 3 or 4 children	Focus on new operation, in particular, adolescents (15-25 years)
Insensitive to gender issues	Focus on gender issues and concern for gender equity and elimination of discrimination against women
No linkage with basic needs of the poor	Priority for fulfilling the Minimum Needs Programme
No consultation with people at the grassroot level	Decentralised programme run through panchayats & nagarpalikas
Family Welfare Department- the sole custodian of population matters	Abolish the Department and establish a Population and Social Development Commission and Fund

- (l) Integrate Indian System of Medicine (ISM) in the provision of RCH services, and in reaching out to households.
- (m) Promote vigorously the small family norm to achieve replacement level of TFR.
- (n) Contain the spread of Acquired Immuno Deficiency Syndrome (AIDS), and promote greater integration between the management of RTI and STI.
- (o) Bring about convergence in implementation of related social sector programmes so that family welfare becomes a people centered programme.

**Targets set by NPP 2000 and Current Scenario**

These are shown in Box - 7 and 8.

If the NPP - 2000 is fully implemented, we anticipate a population of 1107 million (110 crores) in 2010, instead of 1162 million (116 crores) projected by Technical Group on population Projections.

**Causes of High Population Growth in India**

Population growth in India continues to be high on account of following -

- (a) Large size of population in the reproductive age group (estimated contribution 58 percent).
- (b) Higher fertility due to unmet needs of contraception. (estimated contribution 20 percent).
- (c) High desire for fertility due to high Infant Mortality Rate (estimated contribution about 20 percent).
- (d) Approximately 50 percent of girls marry below the age of 18, resulting in a typical reproductive pattern of 'too early

- too frequent- too many'.

- (e) Preference of male child.
- (f) More children are preferred by poor parents as more work force.

**Major Strategies in NPP - 2000**

There are 12 strategic themes in order to achieve the socio demographic goals by 2010. These are enumerated below:

- (a) Decentralized Planning and Program Implementation.
- (b) Convergence of Service Delivery at Village Levels.
- (c) Empowering Women for Improved Health and Nutrition.
- (d) Meeting the Unmet Needs for Family Welfare Services.
- (e) Focus on Under-Served Population Groups.
  - Urban Slums
  - Tribal communities, hill areas, displaced/migrant populations
  - Adolescents
- (f) Involvement of men in planned parenthood
- (g) Action through diverse Health Care Providers.
- (h) Collaboration with and Commitments from Non-Government Organizations and the Private Sector.
- (i) Mainstreaming Indian System of Medicine and Homeopathy.
- (j) Contraceptive Technology and Research on Reproductive and Child Health.
- (k) Providing for the Older Population.
- (l) Information, Education and Communication.

**Operational Strategies**

These include the following :



<b>Box - 7 : Targets set by NPP - 2000 and current scenario.</b>		
Indicators	Target by 2010	Current status (2007)
Population	1107 Million	1103 Million (2005)
Reduce drop outs at primary and secondary school levels	< 20 percent for both boys and girls	School attendance: <ul style="list-style-type: none"> <li>• 6-10 yrs - 83%</li> <li>• 11-14 yrs - 75%</li> <li>• 15-17 yrs - 41% (NFHS-3)</li> </ul>
Infant mortality rate	<30 per 1000 live births	57 per 1000 live births
Maternal Mortality Rate	<100 per 100,000 live births	301 per 100,000 live births (2001-2003)
Marriage for girls, not earlier than age 18	Promote delayed marriage	Marriage : <ul style="list-style-type: none"> <li>• Girls (Before 18yrs) - 46%</li> <li>• Boys (before 21 yrs) - 27% (NFHS-3)</li> </ul>
Achieve universal immunization of children.		44% of children fully vaccinated (NFHS-3)
Deliveries by trained persons.	100%	48%
CBR	21	23.5
TFR	2.1	2.9

<b>Box - 8 : Targets under various plans.</b>				
Indicator	Tenth Plan Goals (2002-2007)	RCH II Goals (2005-2010)	National Population Policy 2000 Goals (By 2010)	Millennium Development Goals
Infant Mortality Rate	<45/1000	<30/1000	<30/1000	-
Under Five Mortality Rate	-	-	-	Reduce by 2/3 from 1990 levels by 2015
Maternal Mortality Ratio	200/100000	<100/100000	<100/100000	Reduce by 3/4 from 1990 levels by 2015
Total Fertility Ratio	2.3	2.1	2.1	-
Couple Protection Ratio	65%	65%	100%	-

- (a) Utilize village self help groups to organize and provide basic services for reproductive and child health care, combined with the ongoing ICDS scheme.
- (b) Implement, at village levels, a one-stop integrated and coordinated service delivery package for basic health care, family planning and maternal and child health related services, provided by the community and for the community.
- (c) Wherever these village self-help groups have not developed for any reason, community midwives, practitioners of ISM, retired school teachers and ex-defence personnel may be organized to perform similar functions.
- (d) At village levels, the Anganwadi centre may become the pivot of basic health care activities, contraceptive counselling and supply, nutrition education and supplementation, as well as preschool activities. The Anganwadi centres can also function as depots for ORS/basic medicines and contraceptives.
- (e) A maternity hut should be established in each village to be used as the village delivery room with storage space for supplies and medicines. It should be adequately equipped with kits for midwifery, ante-natal care, and delivery; basic medication for obstetric emergency aid; contraceptives, drugs and medicines for common ailments.
- (f) Trained birth attendants as well as the vast pool of traditional dais should be trained and made familiar with emergency and referral procedures.
- (g) Provide wider basket of choices in contraception, through innovative social marketing schemes to reach household levels.
- (h) Improve district, sub-district and panchayat-level health management with coordination and collaboration between district health officer, sub-district health officer and the panchayat for planning and implementation activities.
- (j) Strengthen Community Health Centres (CHCs) and PHCs to provide comprehensive essential and emergency obstetric and neo-natal care.
- (k) Strengthening skills of health personnel and health providers through classroom and on-the-job training.
- (l) Focus attention on men in the information and education campaigns to promote the small family norm.
- (m) Sensitize, train and equip rural and urban health centres and hospitals towards providing geriatric health care.

## Promotional and Motivational Steps for Adopting Small Family Norm in NPP

- (a) Rewards for Panchayats and Zila Parishads for exemplary performance.
- (b) *Balika Samridhi Yojana* - A cash incentive of Rs 500 is awarded at the birth of the girl child of birth order 1 or 2 to promote survival and care of girl child.
- (c) *Maternity Benefit Scheme* - A cash incentive of Rs 500 is awarded to mothers who have their first child after 19 years of age for the birth of first or second child only.
- (d) *Family Welfare* - linked Health Insurance Plan.
- (e) Couples below the poverty line, who marry and produce two children after age of 21 are rewarded.
- (f) Opening/Establishing creches and child care centres in rural areas and urban slums, to promote participation of women in paid employment.
- (g) Provision of wider and affordable choices of contraceptives.
- (h) Strengthening and expansion of safe abortion facilities.
- (j) Increased vocational training schemes for girls leading to self-employment.
- (k) Villagers will be provided soft loans and encouraged to run ambulance services for referrals.
- (l) Village level self help groups will be set up.

## National Nutrition Policy

The adoption of National Nutrition Policy (NNP) by the Government under the aegis of the Deptt. of Women & Child Development in 1993 has been one of the significant achievements on Nutrition scene in the country. The Nutrition Policy recognized that “*Nutrition affects development as much as development affects nutrition*”. The Policy advocates a series of actions in different spheres like food production, food distribution, education, health and family welfare, people with special needs and nutritional surveillance. The direct and indirect instruments of Nutrition Policy were recommended to be institutionalized through inter-sectoral co-ordination mechanism at Central and State levels. It gives an integrated approach between broad sectors of agriculture, food and nutrition, Environment, animal husbandry etc and thereby improving the nutritional status of the society.

The major nutrition problems of India can be classified as follows :

- (1) Under-nutrition resulting in:
  - (a) Protein Energy Malnutrition (PEM);
  - (b) Iron deficiency;
  - (c) Iodine deficiency
  - (d) Vitamin A deficiency and other hypovitaminoses.
  - (e) Low Birth Weight children
- (2) Seasonal dimensions of Nutrition;
- (3) Natural calamities & the landless.
- (4) Market Distortion and Disinformation;
- (5) Urbanisation.
- (6) Special Nutritional Problems of Hill People, Industrial Workers, Migrant Workers, and other special categories;
- (7) Problems of over nutrition, overweight and obesity for a small section of urban population.

## Goals

The National Nutrition Policy had following goals :

1. Reduction in the incidence of malnutrition and stunted growth among children.
2. Reduction in the incidence of low birth weight to less than 10 percent.
3. Elimination of blindness due to Vit A deficiency.
4. Reduction in the iron deficiency anemia among pregnant women to 25 percent.
5. Universal iodisation of salt for reduction of iodine deficiency disorders to below endemic level.
6. Special emphasis to geriatric nutrition.
7. Annual production of 250 million tonnes of food grain.
8. Improving household food security through poverty alleviation programme.
9. Promoting appropriate diets and healthy life style.

## The Strategy

Nutrition is a multi-sectoral issue and needs to be tackled at various levels. It is important to tackle the problem of nutrition both through direct nutrition intervention for specially vulnerable groups as well as through various development policy instruments which will create conditions for improved nutrition.

### A. Direct Short Term Interventions

(i) *This envisages Nutrition Intervention for specially vulnerable groups:*

- (a) Expanding the Safety Net through the Universal immunization Programme, oral rehydration therapy and the Integrated Child Development Services (ICDS)
- (b) With the objective of reducing the incidence of severe and moderate malnutrition by half by the year 2000 A.D.
- (c) Reaching the Adolescent Girls : The Government's recent initiative of including the adolescent girl within 'the ambit of' ICDS should be intensified so that they are made ready for a safe motherhood.
- (d) Ensuring better coverage of expectant women in order to achieve a target of 10% incidence of low birth weight by 2000 A.D.

(ii) *Fortification of Essential Foods* : Essential food items shall be fortified with appropriate nutrients. e.g. salt with iodine and/or iron.

(iii) *Popularisation of Low Cost Nutritious Food* : Efforts to produce and popularise low cost nutritious foods from indigenous and locally available raw material shall be intensified.

(iv) *Control of Micro-Nutrient Deficiency amongst vulnerable Groups* : Deficiencies of Vitamin A, iron and folic acid and iodine among children, pregnant women and nursing mothers shall be controlled through intensified programmes.

**B. Indirect Policy Instruments** : Long Term Institutional & Structural Changes :

(i) *Food Security*: In order to ensure aggregate food security a per capita availability of 215 kg/person/year of foodgrains needs to be attained.

**(ii) Improvement of Dietary pattern through Production and Demonstration**

**(iii) Policies for Effecting Income transfers so as to improve the entitlement package of the rural and urban poor.**

(a) **Improving the purchasing power:** Poverty alleviation programmes, like the Integrated Rural Development Programme (IRDP) and employment generation schemes like Jawahar Rozgar Yojana, Nehru Rozgar Yojana and DWCRA are to be re-oriented and restructured to make a forceful dent on the purchasing power of the lowest economic segments of the population.

(b) **Public Distribution System:** Ensuring an equitable food distribution, through the expansion of the public-distribution system.

(iv) **Land Reforms:** Implementing land reform measures so that the vulnerability of the landless and the landed poor could be reduced.

(v) **Health & Family Welfare:** The health and family welfare programmes are an inseparable part of the strategy through "Health for All by 2000AD".

(vi) **Basic Health and Nutrition Knowledge:** Basic health and nutrition knowledge. With special focus on wholesome infant feeding practices, shall be imparted to the people extensively and effectively.

(vii) **Prevention of Food Adulteration:** Prevention of food adulteration must be strengthened by gearing up the enforcement machinery.

(viii) **Nutrition Surveillance:** Nutritional surveillance is another weak area requiring immediate attention.

(ix) **Monitoring of Nutrition Programmes:** Monitoring of Nutrition Programmes (viz ICDS), and of Nutrition Education and Demonstration by the Food & Nutrition Board, through all its 67 centres & field units, should be continued.

(x) **Research:** Research into various aspects of nutrition, both on the consumption side as well as the supply side, is another essential aspect

(xi) **Equal Remuneration:** Special efforts should be made to improve the effectiveness of programmes related to women.

(xii) **Communication:** Communication through established media is one of the most important strategies to be adopted for the effective implementation of the Nutrition Policy.

(xiii) **Minimum Wage Administration:** Closely related to the market, is the need to ensure an effective minimum wage administration to ensure its strict enforcement and timely revision and linking it with price rise through a suitable nutrition formula.

(xiv) **Community Participation:** The active involvement of the community is essential not only in terms of being aware of the services available to the community but also for deriving the maximum benefit from such services by giving timely feedback necessary at all levels.

(xv) **Education and Literacy:** It has been shown that Education & Literacy particularly that of women, is a key determinant for better nutritional status.

(xvi) **Improvement of the Status of Women :** The most effective way to implement Nutrition with mainstream activities in Agriculture, Health, Education and Rural Development is to focus on improving the status of women, particularly the economic status.

### **Administration and Monitoring**

The policy have been implemented and administered by several ministries and departments of Government of India and NGOs. The administration and monitoring of the programme is as under:

#### **1. Implementation of National Nutrition Policy**

(a) The measures enumerated above have to be administered by several ministries/departments of the Government of India and various governmental and non-governmental organisations. There should be a close collaboration between the Food Policy, the Agricultural Policy the Health Policy, the Education Policy, the Rural Development Programme and the Nutrition Policy as each complements the other.

(b) An Inter-Ministerial Co-ordination Committee will function in the Ministry of Human Resource Development under the Chairmanship of Secretary, Department of Women and Child Development, to oversee and review the implementation of nutrition intervention measures.

(c) A National Nutrition Council will be constituted in the Planning Commission, with Prime Minister as chairperson.

**2. Monitoring of Nutrition situation :** Nutritional surveillance of the country's population especially children and mothers, shall be the responsibility of the National Institute of Nutrition.

**3. Role of State Governments :** In a federal polity like ours, the cutting edge of governmental interventions commences from the state level. Full implementation of various special programmes being run for upliftment of nutritional status of country, will go a long way in ensuring success of the nutritional policy. The programmes have been discussed in detail in the section on nutrition in this book and include ICDS, Special Nutrition Programme, Balwadi Nutrition Programme, Wheat Based Supplementary Nutrition Programme, Tamil Nadu Integrated Nutrition Programme, Mid Day Meals Programme, Nutritional Anaemia Prophylaxis Programme, Goitre Control Programme and Programme for Prevention of Nutritional Blindness due to Vitamin A Deficiency.

### **Functions of the Food & Nutrition Board**

The Food & Nutrition Board', as reconstituted on 26 July 1990, advises Government, coordinates and reviews the activities in regard to food and nutrition extension/education; development, production & popularisation of nutritious Foods and Beverages; measures required to combat deficiency diseases; and 'Conservation and efficient utilisation as well as augmentation of food resources by way of food preservation and processing.

National Nutrition Mission (NNM) was set up in 2002 with overall responsibility of reducing both macro and micro nutritional deficiency in the country. As part of NNM, a new programme for adolescent girls and expectant and nursing

mothers is being launched by Department of Women and Child Development during 2002-03. Under this programme food grains are supplied free of cost through targeted public distribution system (PDS) directly to identified families.

## National Blood Policy

A well organised Blood Transfusion Service (BTS) is a vital component of any health care delivery system. An integrated strategy for Blood Safety is required for elimination of transfusion transmitted infections and for provision of safe and adequate blood transfusion services to the people. The main component of an integrated strategy include collection of blood only from voluntary, non-remunerated blood donors, screening for all transfusion transmitted infections and reduction of unnecessary transfusion.

The Blood Transfusion Service in our country is quite decentralised and lacks resources and good management. In spite of hospital based system, many large hospitals and nursing homes do not have their own blood banks and this has led to proliferation of stand-alone private blood banks. The blood component production/availability and utilisation is extremely limited. There is shortage of trained health-care professionals in the field of transfusion medicine and the requirements of good manufacturing practices and implementation of quality system management.

Thus, a need for modification and change in the blood transfusion service has necessitated formulation of a National Blood Policy and development of a National Blood Programme which will also ensure implementation of the directives of Supreme Court of India in 1996. Hon'able Supreme court directed to phase out unlicensed blood banks by May 2007 and professionals blood donors by December 1997.

**Mission Statement :** The policy aims to ensure easily accessible and adequate supply of safe and quality blood and blood components and transfusion under supervision of trained personnel for all who need it through comprehensive, efficient and a total quality management approach. The broad objectives and strategies to achieve as given in National Blood Policy are as under :

**Objective - 1 :** To reiterate firmly the Govt. commitment to provide safe and adequate quantity of blood, blood components and blood products.

### Strategy

1. A National Blood Transfusion Programme (NBTP) shall be developed to ensure establishment of non-profit integrated National and State Blood Transfusion Services in the country.
2. National Blood Transfusion Council (NBTC) shall be the policy formulating apex body in relation to all matters pertaining to operation of blood centres. National AIDS Control Organisation (NACO) shall allocate a budget to NBTC for strengthening Blood Transfusion Service.
3. State/UT Blood Transfusion Councils shall be responsible for implementation of the Blood Programme at State/UT level.
4. The enforcement of the blood and blood products standards shall be the responsibility of Drugs Controller General India.

5. Trading in blood i.e. Sale & purchase of blood shall be prohibited.
6. The practice of replacement donors shall be gradually phased out in a time bound programme to achieve 100% voluntary non-remunerated blood donation programme.
7. State Blood Transfusion Councils shall organise the blood transfusion service through the network of Regional Blood Centres and Satellite Centres and other Government, Indian Red Cross Society & NGO run blood centres and monitor their functioning.
8. The Regional Centres shall be autonomous for their day to day functioning and shall act as a referral centre for the region assigned to it.
9. Due to the special requirement of Armed Forces in remote border areas, necessary amendments shall be made in the Drugs & Cosmetics Act/Rules to provide special licences to small garrison units. These units shall also be responsible for the civilian blood needs of the region.

**Objective - 2 :** To make available adequate resources to develop and re-organise the blood transfusion service in the entire country.

### Strategy

1. National & State/UT Blood Transfusion Councils shall be supported/ strengthened financially.
2. Efforts shall be directed to make the blood transfusion service viable through non-profit recovery system.
3. Efforts shall be made to raise funds for the blood transfusion service for making it self-sufficient.
4. The mechanism shall be introduced in government sector to route the amounts received through cost recovery of blood/blood components to the blood banks for improving their services.

**Objective - 3 :** To make latest technology available for operating the blood transfusion services and ensure its functioning in an updated manner.

### Strategy

1. Minimum standards for testing, processing and storage shall be set and ensured.
2. All mandatory tests as laid down under provisions of Drugs & Cosmetics Act/Rules shall be enforced.
3. Inspectorate of Drugs Controller of India and State FDA shall be strengthened to ensure effective monitoring and a vigilance cell shall be created under Central/State Licensing Authorities.
4. Quality Assurance Manager shall be designated at each Regional Blood Centre/any blood centre collecting more than 15,000 units per year.
5. An External Quality Assessment Scheme (EQAS) through the referral laboratories approved by the National Blood Transfusion Council shall be introduced to assist participating centres in achieving higher standards and uniformity.
6. NBTC shall identify a centre of national repute for quality control of indigenous as well as imported consumables, reagents and plasma products.
7. Each blood centre shall develop its own Standard Operating Procedures on various aspects of Blood Banking.



8. All blood centres shall adhere to bio-safety guidelines as provided in the Ministry of Health & Family Welfare manual "Hospital-acquired Infections : Guidelines for Control" and disposal of bio-hazardous waste as per the provisions of the existing Biomedical Wastes(Management & Handling) Rules - 1996 under the Environmental Protection Act - 1986.

**Objective - 4 :** To launch extensive awareness programmes for blood banking services including donor motivation, so as to ensure adequate availability of safe blood.

**Strategy**

1. Efforts shall be directed towards recruitment and retention of voluntary, non-remunerated blood donors through education and awareness programmes.
2. Activities of NGOs shall be encouraged to increase awareness about blood donation amongst masses.
3. All blood banks shall have donor recruitment officer/donor organizer and shall create and update a blood donor's directory which shall be kept confidential.
4. Enrolment of safe donors shall be ensured.
5. A Counsellor in each blood centre shall be appointed for pre and post donation counselling.
6. State/UT Blood Transfusion Councils shall recognise the services of regular voluntary non-remunerated blood donors and donor organisers appropriately.
7. National/State/UT Blood Transfusion Councils shall develop and launch an IEC campaign using all channels of communication including mass-media for promotion of voluntary blood donation and generation of awareness regarding dangers of blood from paid donors and procurement of blood from unauthorised blood banks/laboratories.

**Objective - 5:** To encourage appropriate clinical use of blood and blood products.

**Strategy**

1. Blood shall be used only when necessary. Blood and blood products shall be transfused only to treat conditions leading to significant morbidity and mortality that cannot be prevented or treated effectively by other means.
2. National Guidelines on "*Clinical use of Blood*" shall be made available and updated as required from time to time.
3. State/UT Governments shall ensure that the Hospital Transfusion Committees are established in all hospitals to guide, monitor and audit clinical use of blood.
4. Medical Council of India shall be requested to take following initiatives:
  - a) To introduce Transfusion Medicine as a subject at undergraduate and all post graduate medical courses.
  - b) To introduce posting for at least 15 days in the department of transfusion medicine during internship.
  - c) Blood and its components shall be prescribed only by a medical practitioner registered as per the provisions of Medical Council Act - 1956.
5. Adequate facilities for transporting blood and blood products including proper cold-chain maintenance shall be made available to ensure appropriate management of blood supply.

**Objective - 6 :** To strengthen the manpower through Human Resource Development.

**Strategy**

1. Transfusion Medicine shall be treated as a speciality.
2. A separate Department of Transfusion Medicine shall be established in Medical Colleges.
3. Medical Colleges/Universities in all States shall be encouraged to start PG degree (MD in transfusion medicine) and diploma courses in Transfusion Medicine.
4. In all the existing courses for nurses, technicians and pharmacists, Transfusion Medicine shall be incorporated as one of the subjects.
5. In-service training programmes shall be organised for all categories of personnel working in blood centres as well as drug inspectors and other officers from regulatory agencies.
6. Short orientation training cum advocacy programmes on donor motivation and recruitment shall be organised for Community Based Organisations(CBOs)/NGOs who wish to participate in Voluntary Blood Donor Recruitment Programme.
7. States/UTs shall create a separate cadre and opportunities for promotions for suitably trained medical and para medical personnel working in blood transfusion services.

**Objective - 7:** To encourage Research & Development in the field of Transfusion Medicine and related technology.

**Strategy**

1. A corpus of funds shall be made available to NBTC/SBTCs to facilitate research in transfusion medicine and technology related to blood banking.
2. A technical resource core group at national level shall be created to co-ordinate research and development in the country.

**Objective - 8:** To take adequate legislative and educational steps to eliminate profiteering in blood banks.

**Strategy**

1. For grant/renewal of blood bank licenses including plan of a blood bank, a committee, comprising of members from State/UT Blood Transfusion Councils including Transfusion Medicine expert, Central & State/UT FDAs shall be constituted which will scrutinise all applications as per the guidelines provided by Drugs Controller General India.
2. Fresh licenses to stand-alone blood banks in private sector shall not be granted.
3. Approved regional blood centres/government blood centres/ Indian reduction cross blood centres shall be permitted to supply blood and blood products to satellite centres which are approved by the committee. The Regional Centre shall be responsible for transportation, storage, cross-matching and distribution of blood and blood products through satellite centres.
4. A separate blood bank cell shall be created under a senior officer not below the rank of DDC(I) in the office of the DC(I) at the headquarter. State/UT Drugs Control Department shall create such similar cells with the trained officers including inspectors for proper inspection and enforcement.

5. The existing provisions of drugs & Cosmetics Rules will be periodically reviewed to introduce stringent penalties for unauthorised/irregular practices in blood banking system.

## Summary

In 1978, the World Health Assembly at Alma Ata launched an ambitious movement known as, "Health for All (HFA) by 2000 AD". As a signatory to HFA strategy, the Government of India was committed to frame its own policy and implement to attain Health For All by 2000 AD. This formed the basis of the National Health Policy formulated by MOHFW, GOI in 1983. Since its inception, there have been marked changes in the determinants of health. Improvement of these health indicators were the outcome of several complementary initiatives of development sector covering rural development, agriculture, food production, animal husbandry, drinking water, sanitation, education etc. Despite the impressive public health gains, the morbidity and mortality levels in the country were high. In the year 2000, it was the time to take stock of situation and progress ahead with extra zeal to achieve ultimate goal of Health For All. Accordingly, the NHP - 1983 was revised and a new, extensive NHP was enunciated by the Govt of India in 2002. The main objective of this policy is to achieve an acceptable standard of good health amongst the general population of the country. The revised strategies adopted by GOI to achieve above objective are : (a) Increase access to the decentralized public health system. (b) Ensuring a more equitable access to health services across the country. (c) Increasing the aggregate public health investment through a substantially increased contribution by the Central Government. (d) The contribution of the private sector in providing health services would be much enhanced. (e) Primacy to preventive and first-line curative initiative at the primary health level. (f) Emphasis will laid on rational use of drugs within the allopathic system. (g) Increased access to tried and tested systems of traditional medicine.

On a short term basis, within the context of the NHP, the important health related targets for the eleventh five year plan (2007 - 2012) are: Reducing Maternal Mortality Ratio (MMR) to 1 per 1,000 live births; Reducing Infant Mortality Rate (IMR) to 28 per 1,000 live births; Reducing Total Fertility Rate to 2.1; Providing clean drinking water for all by 2009 and ensuring no slip-backs; Reducing malnutrition among children of age group 0-3 to half its present level; Reducing anaemia among women and girls by 50% ; and Raising the sex ratio for age group 0-6 to 935 by 2011-12 and 950 by 2016-17.

In 1952, India became the first country in the world to launch a national program, emphasizing family planning to the extent necessary for reducing birth rates. The National Health Policy, 1983, stated that replacement levels of fertility rate (TFR) should be achieved by the year 2000. The National population Policy (NPP) 2000 provides a policy framework for advancing goals and prioritizing strategies during the next decade, to meet the reproductive and child health needs of the people in India, and to achieve net replacement levels (TFR) by 2010. The NPP affirms the commitment of government towards voluntary and informed choice and consent of citizens while availing reproductive health care services, and continuation of the target free approach in administering family planning

services. In pursuance of these objectives, the National Socio-Demographic Goals to be achieved by 2010 are formulated. If the NPP - 2000 is fully implemented, we anticipate a population of 1107 million (110 crores) in 2010, instead of 1162 million (116 crores) projected by Technical Group on population Projections.

## Study Exercises

**Long Question:** Discuss the objectives and strategies adopted in National Health Policy 2000

**Short Notes :** National Socio Demographic Goals to be achieved by 2010.

### MCQs

1. World Health Assembly at Alma Ata launched movement known as, "Health for All (HFA) by 2000 AD" in the year (a) 1988 (b) 1998 (c) 1978 (d) 1983.
2. The remarkable success of NHP 1983 includes elimination of : (a) Leprosy (b) Kala Azar (c) Filariasis (d) All.
3. Noteworthy initiatives under the National Health Policy 2002 includes all except : (a) Comprehensive primary health care services (b) Non involvement of health volunteers (c) Well worked out referral system (d) Integrated network of evenly spread speciality and super speciality services.
4. Important health related targets for the eleventh five year plan (2007 - 2012) are: (a) Reducing Maternal Mortality Ratio (MMR) to 1 per 1,000 live births (b) Reducing Infant Mortality Rate (IMR) to 28 per 1,000 live births (c) Reducing Total Fertility Rate to 2.1 (d) All.
5. The immediate/ short term objectives of NPP 2000 are: (a) To address the unmet needs for contraception (b) Strengthen health care infrastructure, and health personnel (c) Provide integrated service delivery for basic reproductive and child health care (d) All.
6. The major strategies under NPP 2000 include all except: (a) Empowering Women for Improved Health and Nutrition (b) Meeting the Unmet Needs for Family Welfare Services (c) Providing Medical Facilities to Users from Overseas (d) Focus on Under-Served Population Groups.

### Fill in the blanks

1. NHP - 1983 was revised and a new, extensive NHP was enunciated by the Govt of India in \_\_\_\_\_.
2. In 2006 nation's CBR was at \_\_\_\_\_ & CDR was \_\_\_\_\_.
3. One of the targets for the eleventh five year plan (2007 - 2012) is to raise the sex ratio for age group 0-6 to \_\_\_\_\_ by 2011-12 and \_\_\_\_\_ by 2016-17.
4. NHP 2002 envisages to raise the proportion of postgraduate seats in the field of 'Public Health' and 'Family Medicine' wherein \_\_\_\_\_ of the seats are earmarked for these disciplines.
5. By 2010 the NHP 2002 envisages an increase in Government funded health research to a level of \_\_\_\_\_ percent.
6. India's current yearly increase in population is \_\_\_\_\_ million.
7. NPP 2000 aims at Promote delayed marriage for girls, not earlier than age \_\_\_\_\_ and preferably after 20 years of age.

8. A cash incentive of Rs 500 is awarded at the birth of the girl child of birth order 1 or 2 to promote survival and care of girl child. Name the yojna \_\_\_\_\_.

**Answers : MCQs :** (1) c; (2) d; (3) b; (4) d; (5) d; (6) c ; **Fill in the blanks:** (1) 2002; (2) 23.5, 7.5; (3) 935, 950; (4) one-fourth; (5) 2; (6) 15.5; (7) 18; (8) Balika Samridhi Yojna.

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## National Rural Health Mission (NRHM)

Sunil Agrawal

Recognizing the importance of Health in the process of economic and social development and improving the quality of life of our citizens, the Government of India has resolved to launch the National Rural Health Mission to carry out necessary architectural correction in the basic health care delivery system. The Goal of the Mission is to improve the availability of, and access to, quality health care by people, especially for those residing in rural areas, the poor, women and children. Under the Common Minimum Programme, health care system of the country was given prime importance in which the UPA government had pledged to increase public spending on health to at least 2 - 3 % of the Gross Domestic Product (GDP) over the next five years of its term with a focus on primary health care.

The National Rural Health Mission was launched by the Hon'ble Prime Minister on 12th April 2005, to provide accessible, affordable and accountable quality health services even to the poorest households in the remotest rural regions. The difficult areas with unsatisfactory health indicators were classified as special focus states to ensure greatest attention where needed. The thrust of the Mission was on establishing a fully functional, community owned, decentralized health delivery system with inter sectoral convergence at all levels, to ensure simultaneous action on a wide range of determinants of health like water, sanitation, education, nutrition, social and gender equality.

It also aims at mainstreaming the Indian systems of medicine to facilitate health care. The Plan of Action includes increasing public expenditure on health, reducing regional imbalance in health infrastructure, pooling resources, integration of

organizational structures, optimization of health manpower, decentralization and district management of health programmes, community participation and ownership of assets, induction of management and financial personnel into district health system, and operationalizing community health centers into functional hospitals meeting Indian Public Health Standards in each Block of the Country.

### National Rural Health Mission (NRHM) : Will It Make A Difference?

Since independence, our country has created a vast public health infrastructure of Sub - centres, Public Health Centres (PHCs) and Community Health Centres (CHCs). There is also a large cadre of health care providers (Auxiliary Nurse Midwives, Male Health workers, Lady Health Visitors and Health Assistant Male). Yet, this vast infrastructure is able to cater to only 20% of the population, while 80% of health care needs are still being provided by the private sector. Rural India is suffering from a long - standing health care problem. Studies have shown that only one trained health care provider including a doctor with any degree is available per every 16 villages. Although, more than 70% of its population lives in rural areas, but only 20% of the total hospital beds are located there. Most of the health problems that people suffer in the rural community and in urban slums are preventable and easily treatable. In view of the above issues, the National Rural Health Mission (NRHM) has been launched by Government of India (GOI).

### What is NRHM ?

The National Rural Health Mission (2005 - 12) was launched in April 2005 to provide effective health care to rural population throughout the country with special focus on 18 states, which have weak public health indicators and/or weak infrastructure. These states are Arunachal Pradesh, Assam, Bihar, Chhattisgarh, Himachal Pradesh, Jharkhand, Jammu and Kashmir, Manipur, Mizoram, Meghalaya, Madhya Pradesh, Nagaland, Orissa,



Rajasthan, Sikkim, Tripura, Uttarakhand and Uttar Pradesh.

### Principles

The NRHM is conceived within the following set of guiding principles :

1. Promote equity, access, efficiency, quality and accountability in Public Health System.
2. Enhance people oriented and community based approaches.
3. Decentralize and involve local bodies.
4. Ensure Public Health Focus.
5. Recognized value of traditional knowledge base of communities.
6. Promote new innovations, method and process development.

The NRHM will cover all the villages in these 18 states through approximately 2.5 lakh village - based "Accredited Social Health Activists" (ASHA) who would act as a link between the health centers and the villagers. One ASHA will be raised from every village, who would be trained to advise village populations about Sanitation, Hygiene, Contraception, and Immunization to provide Primary Medical Care for Diarrhoea, Minor Injuries, and Fevers; and to escort patients to Medical Centers. They would also be expected to deliver direct observed short course therapy for tuberculosis and oral rehydration, to give folic acid tablets and chloroquine to patients and to alert authorities to unusual outbreaks. ASHA will receive performance - based compensation for promoting universal immunization, referral and escort services for RCH, construction of house - hold toilets, and other health care delivery programs (See Box - 1).

#### Box - 1 : Key Components of NRHM

- Provision of health activist in each village
- Village health plan to be prepared by village panchayat
- Strengthening of rural hospitals
- Integration of vertical health and family welfare programs at district level
- Strengthening delivery of Primary Health Care

### Goals - The major goals of NRHM are :

- (a) Reduction in Infant Mortality Rate (IMR) and Maternal Mortality Ratio (MMR).
- (b) Universal access to public health services such as women's health, child health, water, sanitation & hygiene, immunization, and nutrition.
- (c) Prevention and control of communicable and non - communicable diseases, including locally endemic diseases.
- (d) Access to integrated comprehensive primary health care.
- (e) Population stabilization, gender and demographic balance.
- (f) Revitalize local health traditions and mainstream AYUSH.
- (g) Promotion of healthy life styles.

### Specific Targets

The expected outcomes of NRHM are listed below :

- IMR - to be reduced to 30/1,000 live births by 2012.
- Maternal Mortality - to be reduced to 100/100,000 live births by 2012.

- TFR - to be reduced to 2.1 by 2012.
- Malaria Mortality - 50% reduction by 2010, additional 10% by 2012.
- Kala Azar Mortality Reduction - 100% by 2010 and sustaining elimination until 2012.
- Filaria/Microfilaria Reduction - 70% by 2010, 80% by 2012, and elimination by 2015.
- Dengue Mortality Reduction - 50% by 2010 and sustaining at that level until 2012.
- Cataract operations - increasing to 46 lakh until 2012.
- Leprosy Prevalence Rate - reduce from 1.8 per 10,000 in 2005 to less than 1 per 10,000 thereafter.
- Tuberculosis DOTS - maintain 85% cure rate through entire Mission Period and also sustain planned case detection rate.
- Upgrading all health establishments in the districts to Indian Public Health Standards (IPHS).
- Increase utilization of First Referral units from bed occupancy by referred cases of less than 20% to over 75%.
- Over 5 lakh ASHAs, one for every 1,000 population/large habitation, in 18 Special Focus States and in tribal pockets of all states by 2008.
- All Sub - centres (nearly 1.75 lakh) functional with two ANMs by 2010.
- All Primary Health Centres (nearly 30,000) with three staff nurses to provide 24x7 services by 2010.
- 6,500 Community Health Centres strengthened/established with seven specialists and nine staff nurses by 2012.
- 1,800 Taluka/Sub Divisional Hospitals and 600 District Hospitals strengthened to provide quality health services by 2012.
- Mobile Medical Units for each District by 2009.
- Functional Hospital Development Committees in all CHCs, Sub Divisional Hospitals, and District Hospitals by 2009.
- Untied grants and annual maintenance grants to every SC, PHC, and CHC released regularly and utilized for local health action by 2008.
- All District Health Action Plans completed by 2008.

### Objectives

- a) Train and enhance the capacity of Panchayati Raj Institutions (PRIs) to own, control and manage public health services
- b) Preparation of Health plan for each village through Village Health Committee of the Panchayat
- c) Strengthening sub - centers through an untied fund to enable local planning and action (each sub - center will have an Untied Fund of Rs. 10,000 per annum). This Fund will be deposited in a joint Bank Account of the ANM and Sarpanch and operated by the ANM, in consultation with the Village Health Committee.
- d) Provision of 24 hour service in 50% PHCs by addressing shortage of doctors, especially in high focus States, through mainstreaming AYUSH manpower.
- e) Preparation and implementation of an intersectoral District Health Plan prepared by the District Health Mission, including drinking water, sanitation and hygiene and nutrition;
- f) Integrating vertical Health and Family Welfare programs at National, State, Block, & District levels.



## Duration of NRHM

The duration of NRHM will be from 2005 to 2012. The total allocation for the Departments of Health and Family Welfare has been hiked from Rs. 8,420 crores to Rs. 90,103 crores in the budget proposals for the year 2007 - 08.

## Core Strategies

The main focus in NRHM would be on the following issues :

- Decentralized village and district level health planning.
- Appointment of *Accredited Social Health Activist (ASHA)*: The selection criteria would be "women, resident of the concerned village, married / widow / divorced, 25 - 45 years age, formal education up to 8th, to be selected out of a panel by village health and action committee of Gram Sabha". Norm would be 1 per 1000 population, but this norm may be changed for different areas. There would be NO pay or honorarium but she will be given compensation for various health and sanitation services provided. They will be given a kit of suitable drugs. They would be guided by Anganwadi Workers (AWW) and ANM. In 4 years, 2.5 lakh ASHAs will be deployed.
- Strengthening the public health service delivery system, particularly at village, primary and secondary level, by developing and implementing the Indian Public Health Standards; Developing CHCs as the First Referral Units (FRUs) by providing special care in the specialties of Medicine, Surgery, Obs & Gyn, and Pediatrics. Presently minimum standards of Indian Public Health for CHCs have been developed; later they will be developed for PHCs & subcentres also.
- Mainstreaming of AYUSH (Indian Systems of Medicine).
- Improved management capacity to organise health systems and services in public health.
- Emphasizing evidence based planning and implementation.

- Prompting non - profit factor to increase social participation, promoting health behaviors and improving intersectoral convergence.

## Supplementary Strategies

- Regulation of private sector to improve equity and reduce "out of pocket" expenses.
- Foster Public Private Partnership (PPP) to meet national public health goals.
- Re - Orientation of Medical Education (ROME).
- Raising health security / insurance for the poor.

## Organisational Structure

Organisational structure of NRHM from the apex till district level is shown in Box - 2.

To support the District Health Mission, every district will have an integrated District Health Society (DHS) and all the existing societies as vertical support structures for different national and state health programmes will be merged in the DHS. The DHS will be responsible for planning and managing all health and family welfare programmes in the district, both in the rural as well as urban areas.

## The Delivery System

A generic public health delivery system envisioned under NRHM from the village to block level is illustrated in Figure - 1

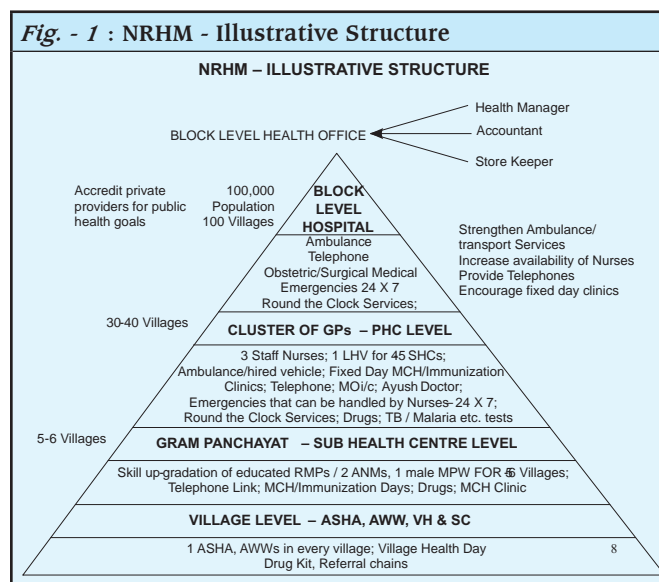
## Progress Under NRHM

The status as on 30 April, 2008 is as under :

- State Health Missions have been constituted in all states.
- ASHA training modules developed and revised.
- Over 1500 management professionals (CA/MBA) appointed in program management units (PMU) to support the programme management. This is being planned at the level of the block also.
- RCH - II launched and under implementation.
- IMNCI started in 142 districts.

Box - 2 : Organisational structure of NRHM	
Level	Organisation
Central level	<i>Mission Steering Group (MSG)</i> headed by the Union Minister for Health & Family Welfare and an Empowered Programme Committee (EPC) headed by the Union Secretary for Health & FW.
State level	<p><i>State Health Mission and State Health Society</i></p> <p>State Health Mission headed by the Chief Minister of the State. The functions under the Mission would be carried out through the State Health &amp; Family Welfare Society</p> <p><i>Composition</i></p> <ul style="list-style-type: none"> <li>Chairperson : Chief Minister</li> <li>Co - Chairperson : Minister of Health and Family Welfare, State Government</li> <li>Convener : Principal Secretary/ Secretary (Family Welfare)</li> <li>Nominated non - official members (5 to 8 members) such as health experts, representatives of medical associations, NGOs and Representatives of Development Partners</li> </ul> <p><i>Frequency of meetings : At least once in every six months</i></p>
District level	<p><i>District Health Mission</i></p> <p>Chairperson : Chairman, Zilla Parishad</p> <p>Co - Chairperson : District Collector/DM</p> <p>Vice Chairperson : CEO Zilla Parishad</p> <p>Mission Director : Chief Medical Officer/ CMHO/ Civil Surgeon</p>

**Fig. - 1 : NRHM - Illustrative Structure**



- Legal changes brought about to allow ANMs to dispense medication and MBBS doctors to dispense anaesthesia.
- At 1,611 PHCs, AYUSH doctors have been co - located.
- 2,28,413 Village Health & Sanitation Committees (VHSCs) have been constituted and operational by 30 April 2008.
- Against the target of 5 lakh fully trained Accredited Social Health Activists (ASHAs) by 2008, the initial phase of training (first module) has been imparted to 5.36 lakh. ASHAs in position with drug kits are 224951 in number.
- Out of the 145272 Sub - centres (SCs) expected to be functional with 2 Auxiliary Nurse Midwives (ANMs) by 2008, only 22471 had the same.
- 22,370 Primary Health Centres (PHCs) are functional and out of which 3450 PHCs are functional with three staff nurses by 2008.
- There has been a shortfall of 5,498 (>50%) specialists at the Community Health Centres (CHCs). Total CHCs functional are 4,045 out of which 2,966 have been selected to be upgraded to IPHS.
- Number of Districts where annual integrated action plan under NRHM have been prepared for 2007 - 08 are 485.

#### Janani Suraksha Yojana

To change the behaviour of the community towards institutional delivery, the Government of India, under NRHM in 2005, modified the National Maternity Benefit Scheme (NMBS) from that of a nutrition - improving initiative to the *Janani Suraksha Yojana* (JSY). The Yojana has identified the Accredited Social Health Activist (ASHA) as an effective link between the Government and the poor pregnant women.

The scheme has the dual objectives of reducing maternal and infant mortality by promoting institutional deliveries. Though the JSY is implemented in all states and UTs, its focus is on 10 low performing states having low institutional delivery rate. The scheme is 100% centrally sponsored and integrates cash assistance with maternal care. It is funded through the flexi - pool mechanism. Under the NRHM, out of 184.25 lakh institutional deliveries in the country (as on 1 April 2007), JSY beneficiaries were 28.74 lakh. The eligibility criteria are shown

in Box - 3.

Box - 3 : Eligibility criteria for JSY	
Category of states & cash assistance	Beneficiaries
<b>Low Performing States (LPS)</b> (Cash assistance in rural areas is Rs 1400 and Rs 600 for the mother & ASHA respectively; in urban areas it is Rs. 1000 and Rs 200 respectively).	All pregnant women / All SC/ST Women delivering in SC/PHC/CHC/ FRU/ Distt or state hospital or accredited private hospital
<b>High Performing States (HPS)</b> (Cash assistance for the mother in rural areas is Rs 700 and in urban areas it is Rs. 600).	BPL pregnant women aged 19 yrs and above/ All SC/ ST Women delivering in SC/PHC/CHC/FRU/ Distt or state hospital or accredited private hospital

#### National Urban Health Mission (NUHM)

The National Urban Health Mission (NUHM) will meet health needs of the urban poor, particularly the slum dwellers by making available to them essential primary health care services. This will be done by investing in high - caliber health professionals, appropriate technology through public - private partnership, and health insurance for urban poor. Recognizing the seriousness of the problem, urban health will be taken up as a thrust area for the Eleventh Five Year Plan. NUHM will be launched with focus on slums and other urban poor. The Eleventh Five Year Plan will aim for inclusive growth by introducing National Urban Health Mission (NUHM), which along with NRHM, will form *Sarva Swasthya Abhiyan*. The organisation would be :

**At the state level :** Besides the State Health Mission and State Health Society and Directorate, there would be a State Urban Health Programme Committee.

**At the district level :** There would be a District Urban Health Committee

**At the city level :** A Health and Sanitation Planning Committee.

**At the ward slum level :** There will be a Slum Cluster Health, Water and Sanitation Committee.

For promoting public health and cleanliness in urban slums, the Eleventh Five Year Plan will also encompass experiences of civil society organizations working in urban slum clusters. It will seek to build a bridge of NGO - GO partnership and develop community level monitoring of resources and their rightful use. NUHM would ensure the following :

- Resources for addressing the health problems in urban areas, especially among urban poor.
- Need based city specific urban health care system to meet the diverse health needs of the urban poor and other vulnerable sections.
- Partnership with community for a more proactive involvement in planning, implementation, and monitoring of health activities.

- Institutional mechanism and management systems to meet the health - related challenges of a rapidly growing urban population.
- Framework for partnerships with NGOs, charitable hospitals, and other stakeholders.
- Two - tier system of risk pooling : (a) Women's Mahila Arogya Samiti to fulfil urgent hard - cash needs for treatments; (b) A Health Insurance Scheme for enabling urban poor to meet medical treatment needs.

NUHM would cover all cities with a population of more than 100,000. It would cover slum dwellers and other marginalized urban dwellers like rickshaw pullers, street vendors, railway and bus station coolies, homeless people, street children, construction site workers, who may be in slums or on sites.

The existing Urban Health Posts (UHPs) and Urban Family Welfare Centres (UFWCs) would continue under NUHM. They will be marked on a map and classified as the Urban Health Centres on the basis of their current population coverage. All the existing human resources will then be suitably reorganized and rationalized. These centres will also be considered for upgradation. Intersectoral coordination mechanism and convergence will be planned between the Jawaharlal Nehru National Urban Renewal Mission (JNNURM) and the National Urban Health Mission.

#### **The Challenges before NRHM and its key approaches: A Critique**

It is clearly a gigantic task to bring about major changes in outcomes by simultaneous action on a wide range of determinants of health. NRHM has identified communitization, flexible financing, innovations in human resource management, monitoring against IPH Standards, and building capacities at all levels as the principal approaches to ensure quality service delivery, efficient utilization of scarce resources, and most of all, to ensure service guarantees to local households.

Health is a state subject and the NRHM will build partnership with the States to ensure meaningful reforms with more resources. Ultimately, the success of NRHM will depend on the ability of the Mission interventions to galvanize State Governments into action, pursuing innovations and flexibility in all spheres of public health action. Ensuring availability of fully trained and equipped resident health functionaries at all levels and large scale financing under initiatives like the *Janani Suraksha Yojana* for institutional deliveries are a few priorities for action. Partnerships with non governmental providers to strengthen public health delivery are also an important need given the distribution of Specialist doctors in India. While we have 30,000 MBBS graduates coming out of our Colleges every year, the entire rural health system for more than 750 million people never has more than 26000 doctors.

There is need to shift to decentralization of functions to hospital units/health centres and local bodies. The States need to move away from the narrow focus on the implementation of budgeted programmes and vertical schemes. They need to develop systems that comprehensively address the health needs of all citizens. Thus, in order to improve the health care services in the country, the Eleventh Five Year Plan will insist on Integrated District Health Plans and Block Specific Health

Plans, mandate involvement of all health related sectors and emphasize partnership with PRIs, local bodies, communities, NGOs, Voluntary and Civil Society Organizations.

#### **Summary**

The National Rural Health Mission was launched by the Hon'ble Prime Minister on 12th April 2005, to provide accessible, affordable and accountable quality health services even to the poorest households in the remotest rural regions. NRHM will give special focus to 18 states, which have weak public health indicators and/or weak infrastructure. The duration of NRHM will be from 2005 to 2012. The total allocation for the Departments of Health and Family Welfare has been hiked from Rs. 8,420 crores to Rs. 90,103 crores in the budget proposals for the year 2007 - 08.

Key component of NRHM are provision of health activist in each village, village health plan to be prepared by village panchayat, strengthening of rural hospitals, integration of vertical health and family welfare programs at district level, strengthening delivery of Primary Health Care.

The major goals of NRHM are (a) Reduction in Infant Mortality Rate (IMR) and Maternal Mortality Ratio (MMR), (b) Universal access to public health services, (c) Prevention and control of communicable and non - communicable diseases, including locally endemic diseases, (d) Access to integrated comprehensive primary health care (e) Population stabilization, gender and demographic balance (f) Revitalize local health traditions and mainstream AYUSH (g) Promotion of healthy life styles.

The expected outcomes of NRHM are by 2012 reduction in IMR and MMR to 30/1000 live births and 100/100,000 live birth respectively, reduction of TFR to 2.1 by 2012, Malaria Mortality - 50% reduction by 2010, additional 10% by 2012. Kala Azar Mortality Reduction - 100% by 2010 and sustaining elimination until 2012, Filaria / Microfilaria Reduction - 70% by 2010, 80% by 2012, and elimination by 2015, Dengue Mortality Reduction - 50% by 2010 and sustaining at that level until 2012, Cataract operations - increasing to 46 lakh until 2012, Leprosy Prevalence Rate - reduce from 1.8 per 10,000 in 2005 to less than 1 per 10,000 thereafter, Tuberculosis DOTS - maintain 85% cure rate through entire Mission Period and also sustain planned case detection rate, Upgrading all health establishments in the district to Indian Public Health Standards (IPHS), Increase utilization of First Referral units from bed occupancy by referred cases of less than 20% to over 75%, Over 5 lakh ASHAs, one for every 1,000 population/large habitation, in 18 Special Focus States and in tribal pockets of all states by 2008, All Sub - centres (nearly 1.75 lakh) functional with two ANMs by 2010, All Primary Health Centres (nearly 30,000) with three staff nurses to provide 24x7 services by 2010, 6,500 Community Health Centres strengthened/established with seven specialists and nine staff nurses by 2012, 1,800 Taluka/Sub Divisional Hospitals and 600 District Hospitals strengthened to provide quality health services by 2012, Mobile Medical Units for each District by 2009, Functional Hospital Development Committees in all CHCs, Sub Divisional Hospitals, and District Hospitals by 2009, Untied grants and annual maintenance grants to every SC, PHC, and CHC released regularly and utilized for local health action by 2008, All District Health Action Plans

completed by 2008.

The main focus in NRHM would be on (a) Decentralized village and district level health planning, (b) Appointment of Accredited Social Health Activist (ASHA) - "women, resident of the concerned village, married / widow / divorced, 25 - 45 years age, formal education up to 8th, to be selected out of a panel by village health and action committee of Gram Sabha". Norm would be 1 per 1000 population, (c) Strengthening the public health service delivery system, particularly at village, primary and secondary level, (d) Mainstreaming of AYUSH (Indian Systems of Medicine), (e) Improved management capacity in health systems, (f) Emphasizing evidence based planning and implementation, (g) Prompting non - profit factor to increase social participation, promoting health behaviors and improving intersectoral convergence. Supplementary Strategies are (a) Regulation of private sector to improve equity and reduce "out of pocket" expenses, (b) Foster Public - Private Partnership (PPP) to meet national public health goals, (c) Re - orientation Of Medical Education (ROME), (d) Raising health security / insurance for the poor.

At centre level there will be Mission Steering Group (MSG) headed by the Union Minister for Health & Family Welfare and an Empowered Programme Committee (EPC) headed by the Union Secretary for Health & FW. At state level State Health Mission headed by the Chief Minister of the State and will have minister of health and family welfare, state government and principal secretary (Family Welfare) plus 5 - 8 non - official members. At district level, district health mission with Chairman Zilla Parishad, District Collector / DM, CEO Zilla Parishad and Chief Medical Officer/ CMHO/ Civil Surgeon as its members. The delivery system is through strengthening health system.

*Janani Suraksha Yojana* is 100% centrally sponsored and integrates cash assistance with maternal care. It is funded through the flexi - pool mechanism. *Low Performing States* (LPS) beneficiaries are all pregnant women; cash assistance in rural areas is Rs 1400 and Rs 600 for the mother & ASHA respectively; in urban areas it is Rs. 1000 & Rs 200 respectively. *High Performing States* (HPS) : cash assistance for the mother in rural areas is Rs 700 and in urban areas it is Rs. 600. Beneficiaries are all pregnant ladies below poverty line.

The National Urban Health Mission (NUHM) will meet health needs of the urban poor, particularly the slum dwellers, by making available to them essential primary health care services. The organisation would be At the state level : the State Health Mission, State Health Society and Directorate; and

State and Urban Health Programme Committee. At the district level - District Urban Health Committee At the city level - A Health and Sanitation Planning Committee. At the ward slum level - Slum Cluster Health, Water and Sanitation Committee.

NUHM would ensure Resources for addressing the health problems in urban areas, especially among urban poor, need based city specific urban health care system to meet the diverse health needs of the urban poor and other vulnerable sections, Partnership with community for a more proactive involvement in planning, implementation, and monitoring of health activities, Institutional mechanism and management systems to meet the health - related challenges of a rapidly growing urban population, Framework for partnerships with NGOs, charitable hospitals and other stakeholders, Two - tier system of risk pooling : (i) women's Mahila Arogya Samiti to fulfil urgent hard - cash needs for treatments; (ii) a Health Insurance Scheme for enabling urban poor to meet medical treatment needs.

## Study Exercises

**Long Question :** How does NRHM envisage to achieve goals of NHP - 2002 ?

**Short Notes :** (1) Key components of NRHM (2) Specific targets of NRHM (3) JSY (4) Functions of ASHA.

### MCQs

1. NRHM was launched in (a) Apr 2005 (b) Mar 2006 (c) Nov 2003 (d) Dec 2004
2. According to NRHM IMR should be less than \_\_\_\_ per 1000 live births by 2012 (a) 30 (b) 28 (c) 32 (d) 35
3. According to NRHM MMR should be less than \_\_\_\_ per 1000 live births by 2012 (a) 1 (b) 2 (c) 1.5 (d) 3
4. According to NRHM Dengue mortality should be reduced by \_\_\_\_ by 2010 (a) 40% (b) 50% (c) 75% (d) 60%
5. According to NRHM target for cataract operation by the year 2012 (a) 40 lakh (b) 46 lakh (c) 51 lakh (d) 55 lakh
6. One ASHA is for \_\_\_\_\_ population in plain areas (a) 700 (b) 1000 (c) 300 (d) 1500

**Answers :** (1)a; (2)a; (3)a; (4)b; (5)b; (6)b.

## References & Further Suggested reading

1. Indian Journal of Public Health, 2007.
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The International Conference of Population and Development (ICPD) at Cairo in 1994 was the basis for the launch of RCH programme in our country in 1997. The RCH Programme is an umbrella programme to provide need based, client centered, demand driven, high quality services the beneficiaries with a view to enhancing the quality of reproductive life of the population and enabling country to achieve the population stabilization. The vision is to bring about outcomes as envisioned in the Millennium Development Goals, the National Population Policy 2000 (NPP 2000), the Tenth Plan document, the National Health Policy 2002 and Vision 2020 India, minimizing the regional variations in the areas of reproductive and child health and population stabilization through an integrated, focused, participatory program, meeting the unmet demands of the target population and provision of assured, equitable, responsive quality services. The programme now intends to gradually make a shift to address the entire gamut of women's health issues. The program will pay substantially more attention on the 8 states, (Empowered Action Group: EAG states) lagging behind in population stabilisation efforts viz. Bihar, Chattisgarh, Jharkhand, Madhya Pradesh, Orissa, Rajasthan, Uttar Pradesh & Uttaranchal. The programme also focuses on universalisation of immunization, ante-natal care, skilled attendance during delivery and other features of common childhood care.

### Definition

World Health Organization (WHO) has defined reproductive health as follows:

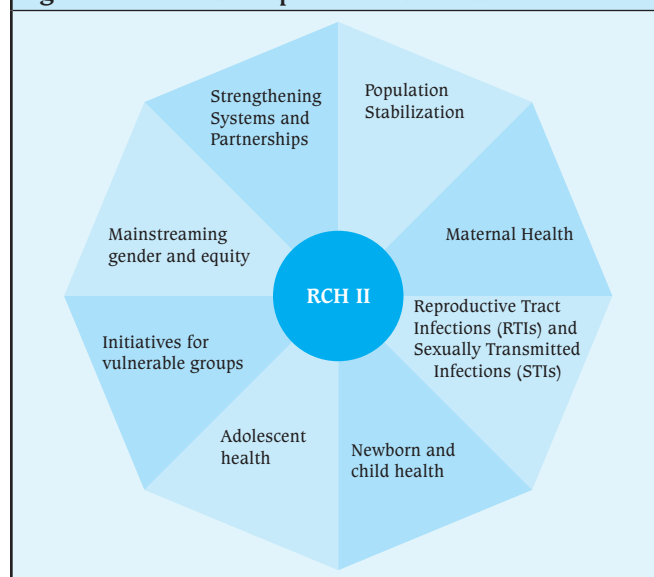
Within the framework of WHO's definition of health as a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity; reproductive health addresses the reproductive processes, functions and systems at all stages of life. Reproductive health therefore implies that people are able to have a responsible, satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide, if when, and how often to do so(1). This definition focuses on right of men and women to be informed of and to have access to safe, effective, affordable, and acceptable methods of fertility regulation of their choice, and the right to access to appropriate health care services that will enable women to go safely through pregnancy and childbirth and provide couples with the best chance of having a healthy infant.

Accordingly, RCH - I was launched in 1997 as a part of 9th plan, while RCH - II was launched in 2002 as a part of 10th five year plan. Many lessons have been learned from RCH Phase I. The design of RCH Phase II specifically seeks to address the lessons learnt from RCH Phase I to effectively reach the national long-term goals through flexible, cohesive and strategic planning.

## Essential Components of RCH-II Programme

The essential components of RCH - II programme (8) are illustrated in Fig. - 1. The individual components are discussed in detail herewith (See Table - 1).

**Fig. - 1 : Essential Components of RCH - II**



### Population Stabilization

The details of national family planning programme have been given in another chapter, in this book, on national health policy and national population policy (1-6) and you are advised to refer to the same.

Unmet need for family planning, 'which refers to the condition of wanting to avoid or postpone childbearing but not using any method of contraception' has been a core concept in international population for more than three decades(10). Unmet need for contraception arises from several reasons, such as weak motivation, low female autonomy, perceived health risks, and moral objection to the use of contraception. On a nationwide basis the family planning program currently offers five modern contraceptive options. The methods currently available for spacing are - oral contraceptive pills, condoms and intra-uterine devices. Male and female sterilization is often used for limiting family size.

### Expanding contraceptive choices in RCH Phase II :

International evidence shows that increasing the availability of method choice increases acceptance rates. It is estimated that every additional method increases the contraceptive prevalence rate by 12%. A wider contraceptive choice, including natural methods, helps meet the changing needs of couples during their lives. Multiple methods make switching easier, reduce method-specific discontinuation, and improve user satisfaction. Contraceptive choice can be expanded both by adding new methods to the existing range as well as increasing access to the services providing the choice. The details of contraceptives are dealt with in an exclusive chapter in the section on family health.

<b>Table- 1: RCH Phase II - Improvements over RCH Phase I (9)</b>	
<b>Lessons learnt from RCH I</b>	<b>Corrective Measures in RCH II</b>
Limited involvement of states and limited ownership by states of RCH Phase	States will prepare plans linked to clear outcomes after assessing their own priorities, allowing a needs-based state-specific plan to be developed.
Pace of implementation slow	Bottlenecks to fund flows will be removed by simplifying processes.
Low utilization of public health facilities	This has been diagnosed as being due to users' perceptions of low quality, frequent service unavailability and low acceptability of some services. This will be addressed through preservice and in-service training, with a particular focus on provider attitudes and making services more users friendly.
Infrastructure to be completed within the project time frame	Outsourcing will be undertaken with agreed institutional mechanisms to manage infrastructure and to ensure accountability and delivery of reliable and quality services. The processes of managing and construction of infrastructure will be simplified.
Limited management capacity	There will be a lateral infusion of skilled personnel to improve the management capacity structure at the national, state and district levels, with clearly defined functional responsibilities and roles.
Need to incorporate the system of smooth flow of funds	Financial management systems will be built into the program management structure.
RCH Phase I was implemented as a project; there was a need to incorporate well-defined outcome indicators	RCH is visualized as a long-term program, oriented towards achieving ambitious, but realistic health outcomes and improvements
RCH Phase I had a "one size fits all" design	States will have different requirements, levels of performance and capacities and will be able to take these into account when designing their state PIPs. Such a differential approach may be extended to the district level depending upon the performance of districts.
Need to move away from "stand alone" public health approach	RCH Phase II will adopt a program approach, bringing in key elements of sector management and reform and strengthening of systems.
RCH Phase I focused almost exclusively on the supply side	Whilst RCH Phase II necessarily includes supply side strategies, these will be complemented by an integrated and robust strategy to stimulate demand for services.
RCH Phase I was centrally designed with little consultation	RCH Phase II has been designed after wider consultation.

### Strategies to expand contraceptive choice in RCH Phase II

- 1. Expanding the range of FP services:** Each CHC and PHC having an OT (operation theatre) facility will have at least one Medical Officer trained in one method of sterilization.
- 2. Improving and integrating RCH services in PHCs and sub-centers:** The capacity of Lady Health Visitors (LHVs) and Auxiliary Nurse Midwives (ANMs) will be built through skill-based clinical training for spacing methods including IUCD insertion and removal, lactational amenorrhea method (LAM), standard days method (SDM) and emergency contraception (EC). They will also be trained in infection prevention, counseling and follow-up for different family planning methods.
- 3. Training of District Hospital/CHC/PHC staff to offer an expanded choice of services:** Training providers to offer LAM, SDM, EC and injectables will help to increase the range of choice and ensure quality services and follow-up for clients.
- 4. Forging linkages with the ICDS division of women and child development department.**
- 5. Engaging the private sector to provide quality family planning services.**
- 6. Stimulating demand for quality family planning services**

by increasing compensation and by using media.

### 7. Involving Panchayati Raj Institutions, Urban Local Bodies and NGOs.

#### Maternal Health

The programme envisages a holistic strategy for bringing about a total intersectoral coordination at the grass root level and involving the NGOs, Civil Societies, Panchayati Raj Institutions and Womens' group in bringing down maternal mortality rate. The National Population Policy 2000 and National Health Policy 2002 have set the goal of reducing MMR to less than 10 per 100,000 live births by the year 2010(11). The maternal mortality rate in India is 301 per 100,000 live births (SRS, RGI 2001-03 Maternal Mortality Report). Various schemes under the programme are as under:

**Essential Obstetric Care :** The complete package of essential obstetric care includes antenatal care, institutional/ safe delivery services & postnatal care. It has been seen that a total of three antenatal checkups to be conducted where all components of essential obstetric care can be provided.

**Provision of 24 hrs Delivery Services at PHC :** Under RCH II all the CHCs and 50% of the proposed PHCs will be providing

round the clock delivery services.

**Postnatal care for mother and new born:** To ensure postnatal care within 24 hours of delivery and subsequent home visits on day 3 and 7 are the important components for identification and management of emergencies occurring during post natal period. The ANMs, LHVs and the staff nurses are being made aware of and also oriented for tackling these emergencies identified during these visits.

**Skilled Attendance at Birth:** To manage and handle some common obstetric emergencies at the time of birth the staff has been trained to give certain injections and perform certain interventions in emergency to save life.

**Provision of Emergency Obstetric and Neonatal Care at First Referral Unit (FRU) :** There are three critical elements of a facility being declared as FRU. They are availability of surgical interventions, newborn care and blood storage facility on a 24 hr basis.

**Referral Services at both Community and Institutional level:** Establishing referral linkages between the community and FRUs is an essential component for utilization of services particularly during emergencies. Since emergencies during the process of birth can not be predicted, it is essential to place effective referral linkages which can be accessed by all pregnant women in case of emergency.

**Setting of Blood Storage Centers at FRUs :** Timely treatment of complications associated with pregnancy is sometimes hampered due to non availability of Blood Transfusion services at FRUs. The drugs and cosmetics act has been amended to facilitate establishment of Blood Storage Centers at such FRUs.

**Training of MBBS Doctors in Life Saving Anesthetics Skills for Emergency Obstetric Care :** Provision of adequate and timely Emergency obstetric care has been recognized globally as the most important intervention for saving lives of pregnant women who may develop complications during pregnancy and child birth. It has not been possible till now due to lack of specialist man power gynecologist and anesthetist particularly at the district and subdistrict level. In view of above, a 18 weeks programme for training MBBS doctors in anesthetic skills has been started by govt. but at the same time it will not be a replacement of specialist.

**Obstetric Management skills :** GOI has also introduced training of MBBS doctors in obstetric management skills and has prepared a 16 weeks training programme in obstetric management skills including cesarean section operation.

**Safe Abortion Services/ Medical Termination of Pregnancy (MTP) :** Two thirds of all abortions take place outside the authorized health services by unauthorized often unskilled providers. Eight percent of all maternal deaths are due to complicated abortions. This is a preventable tragedy and an indication of unmet need for abortion. Provision of 24x7 MTP services at PHCs, CHCs and FRUs are being strengthened by training of medical manpower in techniques of MTP by the states. Following Strategies are being implemented:

#### Community Level

- Spread awareness regarding safe MTP in the community and the availability of services thereof

- Enhance access to confidential counseling for safe MTP, train ANMs, AWWs and link workers/ ASHA and AWWs while maintain confidentiality

#### Facility Level

- Provide quality Manual Vacuum Aspiration ) facilities at all CHCs and at least 50% of PHCs that are being strengthened for 24 hrs deliveries
- Provide comprehensive and high quality MTP services at all FRUs
- Encourage private and NGO sectors to establish quality MTP services

#### Other interventions for improving maternal health

**National Nutritional Anemia Prophylaxis Program (Now under RCH) :** As per NFHS III, 56.1% of ever married women aged 15-49 yrs are anemic. The problem is more severe during pregnancy with 57.8% being anemic. A program for prophylaxis and treatment of nutritional anemia has been under implementation in the country since 1997-98. Under this programme all pregnant and lactating women are provided with one tablet (containing 100 mg of elemental iron and 0.5mg Folic acid) for 100 days. Those who have severe anemia are provided with double dose of these tablets; and health education apart from other services.

**Village Health and Nutrition Day :** Organizing village health and nutrition day at Anganwadi center at least once a month to provide antenatal / postpartum care for pregnant women, promote institutional delivery and health education apart from other services.

**Janani Suraksha Yojana (JSY) :** It is a safe motherhood intervention under NRHM being implemented with the objective of reducing maternal and neonatal mortality by promoting institutional delivery among the poor pregnant women. It was launched on 12 April 2005 and is being implemented in all states and is a 100 % centrally sponsored scheme. The main element in the *yojana* is ASHA who will act as a link between govt and the poor pregnant woman. She is to facilitate pregnant women to avail services of maternal care and to arrange for transport services. Cash assistance will be given both to the mother and ASHA worker on getting an institutional delivery.

#### Reproductive Tract Infections (RTIs) and Sexually Transmitted Diseases (STDs)

RTIs and STDs were not recognized as a public health problem till recently. The spread of HIV infection and the role that RTI / STD play in the transmission of HIV have brought urgency to the problem. Strategies under RCH II are :

1. The prevention, early detection and effective management of common lower reproductive tract infections have been included as a component of essential care through the existing primary health care infrastructure.
2. Convergence with National AIDS Control Programme is envisaged in provision of these services, in terms of utilization of these services for case management, laboratory services, counseling services, drugs, equipment, blood safety etc.
3. Under RCH II programme there is a commitment for implementing the RTI/STI services at the sub district level i.e. in 50% of the PHCs and all FRUs, including drugs,

training, disposable equipment and provision of laboratory technicians.

4. National Guidelines for management of RTIs and STDs have been developed and disseminated to the states.

### Newborn and Child Health

Under RCH II, the activities being undertaken to achieve the NRHM goals under newborn and child health are:

1. Integrated Management of newborn and childhood illnesses
2. Home Based Newborn Care(HBNC)
3. Promotion of breastfeeding and complementary feeding
4. Control of deaths due to ARI
5. Control of Deaths due to Diarrhoeal Diseases
6. Supplementation with micronutrients
7. Universal Immunization Programme

**Integrated Management of newborn and childhood illnesses:** India is faced with an unparalleled challenge in the area of child survival and health. The country contributes 2.4 million of the global burden of 10.8 million under-five child deaths, which is the highest for any nation in the world. Nearly 26 million infants are born each year, of whom 1.2 million die before completing the first four weeks of life and 1.7 million die before reaching the first birthday.

**Why integrated approach?** Many well-known prevention and treatment strategies have already proven effective for saving young lives like Childhood vaccinations, Oral rehydration therapy, Effective antibiotics for pneumonia, Prompt treatment of malaria, breastfeeding practices etc have reduced childhood deaths. While each of these interventions has been successful, accumulating evidence suggests that an integrated approach is needed to manage sick children to achieve better outcomes. Because many children present with overlapping signs and symptoms of diseases, a single diagnosis can be difficult, and may not be feasible or appropriate. This is especially true for first-level health facilities where examinations involve few instruments, negligible laboratory tests, and no X-ray.

**History :** During the mid-1990s, the World Health Organization (WHO), in collaboration with UNICEF developed a strategy known as the Integrated Management of Childhood Illness (IMCI). This strategy has been expanded in India to include all neonates and renamed as 'Integrated Management of Neonatal and Childhood Illness (IMNCI)'. India has included care of new born and has modified generic IMCI and named it as IMNCI.

The differences are given in Table-2.

#### Components:

1. Improvements in the case-management skills of health staff through the provision of locally-adapted guidelines on Integrated Management of Neonatal and Childhood Illness and activities to promote their use;
2. Improvements in the overall health system required for effective management of neonatal and childhood illness;
3. Improvements in family and community health care practices.

(Details of IMNCI are discussed in a chapter exclusively in the section on family health)

**Home Based New Born Care :** The Govt of India has approved the implementation of home based new born care where ASHAs will be trained in identified aspects of new born care during the second year training. The underlying principle of effective care at birth is that wherever an infant is born, home or facility, he/ she is provided clean care, warmth, resuscitation, and exclusive breastfeeding. He/she is weighed and examined, and if the clinical needs are not manageable at the place of delivery, he/she is referred and managed at an appropriate facility. A large proportion of deliveries would continue to occur at homes by the TBAs for some more years to come, especially in the EAG states. It is therefore, considered desirable to continue to impart newborn care skills to TBAs in areas with high rates of home deliveries. They will also be provided clean delivery kits. At the same time, the overall effort would be to promote childbirth by skilled birth attendants and in institutions, both in the public and private sector. Interventions for newborn have been summarized in Table-3.

**Promotion of Breast Feeding and Complementary Feeding:** Revival of the Baby Friendly Hospital initiative (BFHI) has been approved and implementation shall be initiated.

**Control of Deaths due to Acute Respiratory Infections (ARI):** Acute respiratory infections (ARI) in children can involve the upper respiratory tract (nose, throat) or the lower respiratory tract (bronchi, lungs). The lower respiratory tract infections (broadly termed as pneumonias) are a major cause of deaths of infants and children in India accounting for about 30% of under-five deaths. The actual deaths are much higher as many children die at home (12). Timely treatment based on well-researched algorithms can save most children with ARI. The ARI control program was initiated as a pilot project in

Table 2 : Differences in generic IMCI and IMNCI		
Features	Generic IMCI	India IMNCI
Coverage of 0-6 days (early new born period)	No	Yes
Basic health worker module	No	Yes
Home visit module by provider for care of newborn and young infant	No	Yes
Sequence of training	Child first then young infant	New born/Young infant first then child
Home-based training	No	Yes
Duration of training on Newborn/young infant	2 to 11 days	4 to 8 days
Sequence of training	Child first then young infant	New born/Young infant first then child



<b>Table-3: Interventions for newborn care</b>		
<b>Level</b>	<b>Interventions</b>	<b>Key Players</b>
<b>Home and Community level</b>	<b>ANC</b> : Focus to be on enhancing coverage among the poor and marginalized women, improving quality and promoting institutional deliveries, birth preparedness and care seeking for danger signs.	ANMs, AWWs
	<b>Skilled care at birth</b> : Institutional deliveries to be promoted through <i>Janani Suraksha Yojana</i> involving TBA; deliveries by ANMs to be encouraged ; piloting Community Skilled Birth Attendant (C-SBA) program to be completed; in populations where access to skilled birth attendants or institutional deliveries not available, clean deliveries by trained TBAs to be accepted.	ANMs, C-SBAs TBAs
	<b>Home - based newborn and post-partum care</b> : Using IMNCI protocol, AWWs to provide home-based care neonates with emphasis on warmth, breastfeeding, prevention of infection, extra care of LBW infants, early detection of sickness; at least three contacts in the first week of life stipulated starting with the first day, extra contracts for LBW and sick neonates ; maternal post-partum care also provided healthy family practices; TBAs to reach neonates and mothers and promote healthy family practices; ANMs to supervise, especially the care of LBW and sick babies and mothers.	AWWs supervised by ANMs ; TBAs
	<b>Community - based management of sick neonates</b> : Using IMNCI protocols, ANMs to assess neonates with sickness and manage mild/moderate sickness.	ANMs
	<b>Referral of sick mothers and neonates</b> : Funds for referral transport to be made available at village level, communities to be encouraged to map facilities and development mechanisms, AWWs and TBAs to facilitate referrals.	Families communities, AWWs, TBAs
	<b>Behaviour Change Communication (BCC)</b> : BCC strategy to aim at promoting early and complete ANC, institutional deliveries birth preparedness recognition and early care-seeking for maternal and neonatal danger signs, healthy newborn and maternal care practices.	Community, media, ANMs, AWWs, TBAs
<b>Facility level</b>	<b>PHCs/CHCs</b> <ul style="list-style-type: none"> <li>50% of PHCs (1000) and all CHCs ( 600) to be upgraded to provide ; 24 hour basic emergency obstetric care (EmOC) and inpatient care to inborn and outborn sick neonates and children; outpatient IMNCI to be implemented, neonatal, antenatal and post-partum care to be strengthened.</li> <li>Rest of the PHCs to provide antenatal care ANC, outpatient IMNCI and post-partum care.</li> </ul>	Nurse, ANMs LHVs, MOs

14 districts in the country in 1990. In 1992, the ARI control strategy became a part of CSSM program, which continued into the RCH Phase I project in 1997. Co-trimoxazole tablets are being provided at subcenters and above. ANMs are being trained to treat children with ARI.

**Control of Deaths due to Diarrhoeal Diseases** : Diarrhoeal diseases account for 17 percent of under five mortality in post neonatal period, and 3 percent of neonatal deaths(13). The Oral Rehydration Therapy (ORT) program was started in 1986-1987. The main objective of the program was to prevent deaths due to dehydration caused by diarrhoeal disease. Health education aimed at rapid recognition and appropriate management of diarrhoea has been a major component of the CSSM and RCH Phase I project. ORS packets are provided at sub-centers as part of the drug kit-A, under the RCH program. The use of home available fluids and ORS has resulted in a substantial decline in the mortality associated with diarrhoea from an estimated 1.0 -1.5 million children every year prior to 1985 to six to seven lakh deaths in 1996. In addition, social marketing and supply of ORS through the public distribution system is being done in some states.

**Supplementation with micronutrients** : National Programme for Prophylaxis against Blindness in Children caused due to Vitamin A deficiency is being implemented through RCH programme (See Box - 1). The objectives are to decrease the prevalence of Vit A deficiency to 0.3%.

**Anemia among Children** : Iron deficiency anaemia is widely prevalent in young children. NFHS II (1998-99) revealed that 74.3% children under the age of three years are anemic. *Under the National Nutritional Anemia Prophylaxis Program* (now part of RCH) Iron & Folic acid tablet containing 20 mg of elemental Iron and 0.1mg of Folic acid are provided at sub center level. 100 tablets are given to children who are clinically anemic. As per the revised policy, infants between 6-12months of age are also included in the program as a significant proportion of these infants are anemic. For children aged 6-60 months, Ferrous sulphate and Folic acid is to be provided in a liquid formulation. For safety sake liquid formulation should be dispensed in bottles so designed that only 1ml can be dispensed each time. School children 6-10yrs of age are also included in the programme. Children 6-10 yrs are to be provided 30 mg of elemental Iron 250mcg and Folic acid per child per day for 100

<b>Box - 1 : Strategy for National Programme for Prophylaxis against Blindness in Children due to Vit 'A' deficiency</b>		
<b>Infancy</b>	<b>Childhood</b>	<b>Sick Children</b>
Health and nutrition education is being taken up to encourage colostrums feeding, exclusive breastfeeding for the first six months and the introduction of complimentary feeding thereafter 1,00,000IU of Vitamin A is being given at nine months	<ul style="list-style-type: none"> <li>Health education efforts to ensure adequate intake of vitamin A rich food throughout childhood</li> <li>Early detection and prompt treatment of infections</li> <li>Vitamin A dose of 1,00,000IU at nine months and 2,00,000IU thereafter at six monthly intervals up to three years of age</li> </ul>	<ul style="list-style-type: none"> <li>All children with xerophthalmia to be treated at health facilities</li> <li>All children suffering from measles to be given one dose of vitamin A if they have not received it in the previous one month</li> <li>All cases of severe malnutrition to be given one additional dose of vitamin A</li> </ul>

days. Adolescents are to be supplemented in the same dosage and duration as adults.

**Universal Immunization Programme** : National Immunization schedule is given in Table - 4. The impact of the UIP is measured in terms of Vaccine Preventable Diseases (VPD) burden. Over the last 15 years there has also been a general decline in the reported number of cases of the six main VPD. Despite the improvement indicated above, the stated goals were not fully achieved, thus there is an urgent need to address the immunization system deficiencies and emphasize the need for strengthening the system and vigilant monitoring and surveillance.

<b>Table - 4 : National Immunization schedule</b>	
<b>Age</b>	<b>Vaccines</b>
Birth	BCG, OPV
6 Weeks	DPT, OPV, Hepatitis B
10 Weeks	DPT, OPV, Hepatitis B
14 Weeks	DPT, OPV, Hepatitis B
9 months	Measles
16-24 months	DPT (1 st Booster), OPV
5 years	DPT (2nd Booster)
10 years	TT
Pregnant unimmunized	2 doses of TT with one month interval
Pregnant immunized	One booster dose of TT

**Urban Measles Campaign** : A special campaign was stated for slum areas in 1998 with assistance from UNICEF. In 1999-2000, 50 cities were covered. The emphasis is on covering all unprotected children up to age of 3 years with single dose of measles vaccine.

**Neonatal Tetanus elimination** : All women in reproductive age group should be covered with three doses of tetanus toxoid vaccine through a campaign approach. Such campaigns have been implemented in Rajasthan and Madhya Pradesh to achieve early elimination of neonatal tetanus.

### Adolescent Health

Adolescents (10-19 years) in India represent almost one-third of the population. A large number of them are out of school, get married early, work in vulnerable situations, are sexually active, and are exposed to peer pressure. Some of the public health challenges for adolescents include pregnancy, excess

risk of maternal and infant mortality, sexually transmitted infections and reproductive tract infections in adolescence, and the rapidly rising incidence of HIV in this age group. In context of the RCH program goals, with special reference to reduction in IMR, MMR and TFR, addressing adolescents in the program framework will yield dividends in terms of delaying the age at marriage, reducing the incidence of teenage pregnancy, the prevention and management of obstetric complications including safe abortion services and the reduction of unsafe sex.

**Strategy for addressing Adolescent Reproductive and Sexual Health (ARSH) in RCH Phase II** : It is proposed to provide adolescent health services through the existing subcenters/PHCs and CHCs (See Table-5).

### Initiatives for vulnerable groups

Vulnerable communities include those groups who are underserved due to problems of geographical access, (even in better off states) and those who suffer from social and economic disadvantages such as Scheduled Castes/Scheduled Tribes (SCs/STs) and the urban poor. Scheduled caste people (166.6 million) and scheduled tribe people (84.3 million) in India are considered to be socially and economically the most disadvantaged group. The SCs constitute 16.2% and STs 8.2% of the country's population (as per the 2001 Census). The RCH indicators for these groups of people are worse than the urban average due to following reasons:

1. Poor connectivity to health centers because of distance, topography, and lack of public transport
2. Lack of flexibility and reduced responsiveness to local diversity and needs
3. Lack of appropriate Human Resource Development (HRD) policy to encourage/motivate the service providers to work in remote and tribal areas

**Goals** : To improve the health status of the vulnerable population by ensuring accessibility and availability of quality primary health care and family welfare services to them.

**Objectives** : The objectives of the Vulnerable Plan are :

- (i) To improve accessibility, availability and acceptability of health services including RCH services by strengthening infrastructure including training and skill development of service providers, improving the supply of equipment, drugs etc. in an integrated and participatory manner
- (ii) To bring them at par in this respect with the rest of the population, and thus improving the aggregate indicators towards achieving the expected results set under RCH Phase II by the end of 2010.

**Table - 5: Services to adolescents under RCH II**

Level of Care	Service Provider	Target Group	Services
Sub center	HW (F)	Unmarried & Married Females and males	<ul style="list-style-type: none"> <li>• Enroll newly married couples</li> <li>• Provision of spacing methods</li> <li>• ANC care &amp; institutional delivery</li> <li>• STIs/HIV prevention</li> <li>• Anemia prevention</li> </ul>
PHC/CHC	Health Assistant (F)/ LHV/ MO	Unmarried & Married Females and males	<ul style="list-style-type: none"> <li>• Contraceptives</li> <li>• Management of menstrual disorders</li> <li>• RTIs education and management</li> <li>• Nutritional counseling and management of anemia</li> <li>• Counseling and services for MTP</li> </ul>

For tribal population and urban poor, separate health plans addressing specific needs of these groups have been made.

### Mainstreaming Gender and Equity in RCH Phase II

In India there is significant disparity in health care utilization and health status between women and men. Poor women consume less health care resources and suffer worse health than men and a large and increasing share of health expenditure by poor people is taking place outside of the public sector. The aim of mainstreaming gender is to correct imbalances between the position of men and women in terms of access to resources and benefits as well as to understand the differences in terms of health status and health determinants. The RCH Phase II equity objective is to reduce the health inequities both between geographical areas and between social groups, and to respond to the needs of vulnerable populations.

### Funds Flow Arrangement for RCH Program and Management of Funds

There are two routes through which the MoH&FW, GoI transfers funds to the state/Union Territory governments for implementation of the RCH program. Funds mainly for salary and grants-in-aid to institutions and purchase of contraceptives for social marketing are routed through state treasuries, while funds for other activities and a few selective components are provided through the State Committee on Voluntary Action (SCOVA) / state RCH /FW/Health Society, most of the funds for the day-to-day running and implementation of the RCH program are passed on to these societies directly by the MoH&FW, GoI.

### Monitoring and Evaluation

A comprehensive integrated Health management information system will be functional in RCH - II. Community Need Assessment and Monitoring Approach (CNAMA) will be used. The work plans for a particular year will originate from the sub center level under each PHC and are subsequently aggregate with appropriate additions at the CHC and district levels. Based on district action plans, aggregated state action plans are prepared at the state headquarters with appropriate additions. A similar reporting system will be followed for the monthly progress reports.

### Strengths

RCH II is an integrated and vast programme to address the

challenges of maternal and child health. The umbrella of RCH covers family planning, ORT, RTI, STD and CSSM. It has a participatory approach of all communities including ISM practitioners, Dais, opinion leaders, NGOs apart from intersectoral coordination of Govt. The programme lays great emphasis on training, IEC and research and development activities related to RCH. Procurement procedures and audit arrangements have been streamlined to ensure uniformity in accounting. The modern system of Management Information and evaluation will ensure accountability, especially at district level. Lessons learnt from RCH I have

been tackled well in RCH II. There is a scope for a separate plan for each state. The services are client-centered, demand driven and based on the needs of the community. Up gradations of level of facilities will contribute in reducing maternal and child mortality. Successful implementation will also provide out reach services to the vulnerable groups of population such as urban slums, tribal population and adolescents. Due to overlapping of expenditures there will be a reduction in costs inputs.

### Critical appraisal

The goals set up in RCH II to be met by 2010 seem difficult to be met. It is well known that socioeconomic development is the biggest contraceptive. There has been no mention of socioeconomic development in population stabilization. Implementation of such a vast program on ground seems difficult. The contraceptive basket has very little to offer for the males. The appropriate technology of seven cleans during delivery has lost its importance. There is actually physical shortage of manpower in health institutions at the periphery. To add to this there is also shortage of kits, drugs, vaccines and contraceptives. Referral system and feedback are not smooth when real time implementation on ground takes place. With the launch of National Rural Health Mission (NRHM) the govt desires that RCH II to be implemented under NRHM which has created lot of confusion in the minds of middle level managers.. The algorithm for implementing IMNCI is very exhaustive and it will be difficult to be implemented by the grass root level worker.

### Summary

India was the first country to have launched a Family Planning Programme in 1951 and again it is the first one to have converted the guidelines of International Conference of Population Development at Cairo in 1994 in the form of Reproductive and Child Health Programme (RCH) in 1997. RCH finished its Phase I and entered Phase II in 2002. The goals of RCH II are to reduce Infant Mortality rate to < 30/1000 and Maternal Mortality Ratio to <100/100,000 and attain a Total Fertility Ratio of 2.1. The immediate objective is to meet the unmet need of contraception, health care infrastructure and health personnel; medium term objective of attaining a Total Fertility Ratio of replacement level by 2010 : long term objective



of achieving population stabilization by 2045.

RCH II has been planned on the basis of lessons learnt from RCH I. Components of RCH II are Population Stabilization, Maternal Health, Reproductive Tract Infections (RTIs) and Sexually Transmitted Infections (STIs), Newborn and child health, Adolescent health, Initiatives for vulnerable groups, Mainstreaming gender and equity, Strengthening Systems and Partnerships.

To attain population stabilisation RCH II offers Expanding contraceptive choices in the form of injectables, non steroidal oral contraceptive, female condoms, Lactational amenorrhoea, safe days method and Non scalpel Vasectomy.

For improving maternal health, various schemes as Essential Obstetric care, Provision of Emergency Obstetric and Neonatal Care at First Referral Unit (FRU), Safe Abortion Services/ Medical Termination of Pregnancy (MTP) and *Janani Suraksha Yojana* (JSY) have been started.

Prevention, early detection and effective management of common lower reproductive tract infections have been included. Guidelines for same have been made. Under RCH II, the activities being undertaken to achieve the NRHM goals under newborn and child health are : Integrated Management of newborn and childhood illnesses, Home Based Newborn Care (HBNC), Promotion of breast feeding and complementary feeding, Control of deaths due to ARI, Control of Deaths due to Diarrhoeal Diseases, Supplementation with micronutrients, Universal Immunization Programme. Integrated Management of newborn and childhood illnesses aims at training the health staff to refer/treat patient at out patient facility/ home based care, of neonates and children up to five years of age. Co-trimoxazole tablets are being provided at subcenters to control deaths due to Acute Respiratory Infections (ARI) and ORS packets are being provided to Control Deaths due to Diarrhoeal Diseases.

National Programme for Prophylaxis against Blindness in Children caused due to Vitamin A deficiency is being implemented through RCH programme. The objectives are to decrease the prevalence of Vit A deficiency to 0.3%. National Nutritional Anemia Prophylaxis Program is also now part of RCH. Iron and Folic acid tablets are being distributed to Children, adolescents and pregnant ladies. Under this programme all pregnant and lactating women are provided with one tablet (containing 100 mg of elemental iron and 0.5mg Folic acid) for 100 days. Those who have severe anemia are provided with double dose of these tablets health education apart from other services. For children Iron and Folic acid tablet containing 20 mg of elemental iron and 0.1mg of Folic acid are provided at sub center level. 100 tablets are given to children who are clinically anemic. As per the revised policy, infants between 6-12 months of age are also included in the program as a significant proportion of these infants are anemic. For children 6-60 months, ferrous sulphate and Folic acid is to be provided in a liquid formulation. For safety sake liquid formulation should be dispensed in bottles so designed that only 1ml can be dispensed each time.

School children aged 6-10 yrs of age are also included in the programme. Children aged 6-10 yrs are to be provided 30 mg of elemental Iron and 250 mcg Folic acid per child per day for 100 days. Adolescents are to be supplemented in the same dosage and duration as adults.

Universal immunization programme is also being implemented through RCH and targets 6 vaccine preventable diseases. Recently Hepatitis B vaccination has been included and supply of auto disabled syringes is being ensured for immunisation. Adolescents have been included and are being provided services as dividends in terms of delaying the age at marriage, reducing the incidence of teenage pregnancy, the prevention and management of obstetric complications including access to early and safe abortion services and the reduction of unsafe sexual behavior.

Vulnerable communities include those groups who are under-served due to problems of geographical access, (even in better off states) and those who suffer from social and economic disadvantages such as Scheduled Castes/Scheduled Tribes (SCs/STs) and the urban poor. These have been included in RCH with specific goals and objectives to plans addressing specific needs of these groups. The RCH Phase II equity objective is to reduce the health inequities both between geographical areas and between social groups, and to respond to the needs of vulnerable populations. RCH II is an integrated and vast programme to address the challenges of maternal and child health.

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*In India today, two deaths occur every three minutes from tuberculosis (TB). But these deaths can be prevented. With proper care and treatment, TB patients can be cured and the battle against TB can be won.*

**Evolution of Tuberculosis Control in India** : See Table - 1

### RNTCP : Launch, Expansion and Coverage

National Tuberculosis Control Programme launched in 1962, suffered from weakness in the form of poor managerial control, inadequate funding, over-reliance on x-ray, non-standard treatment regimens, low rates of treatment completion, and lack of systematic information on treatment outcomes (Evolution of Tuberculosis Control in India is given in Table-1) (1). Program reviews showed that only 30% of estimated tuberculosis patients were diagnosed and only 30% of those were treated successfully. The Revised National Tuberculosis Control Programme (RNTCP), based on the DOTS strategy, took its roots in India in 1993 by pilot testing as Phase I project covering a population of about 18 million and was launched as a national Programme in 1997. The expansion began in late 1998 and at end of 2000, 30% of the country's population was covered, and by the end of 2002, 50% of the country's population was covered under the RNTCP (2). By the end of 2003, 778 million and at the end of year 2004, 997 million population was covered. By December 2005, around 97% (about 1080 million) of the population had been covered, and the entire country was covered under Directly Observed Treatment Short course (DOTS) by 24th March 2006(3). In the first phase of RNTCP (1998-2005), the programme's focus was on ensuring expansion of quality DOTS services to the entire country. The RNTCP has now entered its second phase in which the programme aims to firstly consolidate the gains made to date, to widen services both in terms of activities and access, and to sustain the achievements for decades to come in order to achieve ultimate objective of TB control in the country. Phase II of the RNTCP is a step towards achieving the TB-related Millennium Development Goal (MDG) targets. Directly Observed Treatment Short Course - 'DOTS' - remains the core strategy.

### The Goal and Objectives of the RNTCP

**Goal** : The goal of TB Control Programme is to decrease mortality and morbidity due to TB and cut transmission of infection until TB ceases to be a major public health problem in India.

#### Objectives :

- To achieve at least 85 percent cure rate of the newly diagnosed sputum smear-positive TB patients; and
- To detect at least 70 percent of new sputum smear-positive patients after the first goal is met.

**Strategy** : DOTS is a systematic strategy which has five components (See Box - 1).

'DOTS' - remains the core strategy; however all components of new *Stop TB Strategy* are incorporated in the second phase of RNTCP. These are:

1. *Pursue quality DOTS expansion and enhancement*, by improving the case finding and cure through an effective patient-centered approach to reach all patients, especially the poor.
2. *Address TB-HIV, MDR-TB and other challenges* by scaling up TB-HIV joint activities, DOTS Plus and other relevant approaches. The guidelines for management of MDR-TB under DOTS-Plus strategy have been developed.
3. *Contribute to health system strengthening*, by collaborating with other health programmes and general services.
4. *Involve all health care providers*, public, nongovernmental and private, by scaling up approaches based on a public-private mix (PPM), to ensure adherence to the International Standards of TB care.
5. *Engage people with TB, and affected communities* to demand, and contribute to effective care. This will involve scaling-up of community TB care; creating demand through context-specific advocacy, communication and social mobilization.
6. *Enable and promote research* for the development of new drugs, diagnostics and vaccines. Operational Research will also be needed to improve programme performance.

### RNTCP Structure and Service Delivery Mechanisms

**At the center** : The Central TB Division (CTD) is responsible for developing technical policies, procuring drugs, preparing training modules, programme and financial monitoring, quality assurance, advocacy, operational research priorities and mobilising funds.

**Table 1: Evolution of Tuberculosis Control in India**

Year	Remarks
1962	The National TB Control Programme (NTCP) launched. The strategy was based on early detection and treatment thereby converting infectious cases to noninfectious and preventing noninfectious cases from becoming infectious with treatment, Diagnosis through radiology and sputum microscopy, Free Domiciliary treatment through Primary Health Care Services, Establishing District Tuberculosis Centre in every district, Extend coverage under Short Course Chemotherapy (SCC), Strengthen state TB training and demonstration centers
1992	Government of India, together with the WHO and SIDA, reviewed the national programme and concluded that it suffered from various managerial and operational weaknesses. As a result, a Revised National Tuberculosis Control Programme (RNTCP) was designed
1993 -2005	Era of Directly Observed Treatment Short course(DOTS), RNTCP launched
2006-2010	RNTCP Phase II

**Box - 1 : Components of DOTS**

1	<i>Political and administrative commitment</i> : It warrants the topmost priority, which it has been accorded by the Government of India. This priority must be continued and expanded at the state, district and local levels.
2	<i>Good quality diagnosis</i> : Good quality microscopy allows health workers to see the tubercle bacilli and is essential to identify the infectious patients who need treatment the most.
3	<i>Good quality drugs and an uninterrupted supply of good quality anti TB drugs</i> : In the RNTCP, a box of medications for the entire treatment is earmarked for every patient registered, ensuring the availability of the full course of treatment the moment the patient is initiated on treatment.
4	<i>Supervise treatment to ensure right treatment</i> : The heart of the DOTS programme is “directly observed treatment” in which a health worker, or another trained person who is not a family member, watches as the patient swallows the anti-TB medicines in their presence.
5	<i>Systematic monitoring and accountability</i> : The programme is accountable for the outcome of every patient treated. This is done using standard recording and reporting system, and the technique of ‘cohort analysis’. The cure rate and other key indicators are monitored at every level of the health system, and if any area is not meeting expectations, supervision is intensified. The RNTCP shifts the responsibility for cure from the patient to the health system.

**At the State** : The RNTCP is integrated with the general health care delivery systems in the states. At the State level, the State Tuberculosis Officer (STO) is responsible for planning, training, supervising and monitoring the programme in their respective states as per the guidelines of the State TB Control Society or its equivalent (STCS or its equivalent). The STO based at the State TB Cell is administratively answerable to the State Government and technically follows the instructions of the CTD, and coordinates with CTD and the districts for executing the duties mentioned above. The State TB Cell (STC) is responsible for the supervision and monitoring of the programme throughout the state.

**At the District** : District TB Centre (DTC) is the key organisational unit responsible for the implementation of the programme in the respective districts. The district is the key level for the management of primary health care services. The district level (or municipal corporation level) performs functions similar to those of the state level in its respective area. The Chief District Health Officer (CDHO) / Chief District Medical Officer (CDMO) or an equivalent functionary in the district is responsible for all medical and public health activities including control of TB. The District Tuberculosis Centre (DTC) is the nodal point for TB control activities in the district. In RNTCP, the primary role of the DTC has shifted from a clinical one to a managerial one. The District TB Officer (DTO) at the DTC has the overall responsibility of management of RNTCP at the district level as per the programme guidelines. The DTO is also responsible for involvement of other sectors in RNTCP and is assisted by an MO, Statistical Assistant and other paramedical staff. For each district, there should be a full-time DTO, who is trained in RNTCP at a central level institution.

The DTC is supported by sub-district TB Units (TUs) established for every 5, 00,000 population to serve as a link between the district level and the periphery. The TU is the lowest reporting unit under the RNTCP. At the TUs, a special cadre of dedicated TB supervisory staff, the Senior Treatment Supervisor (STS) and the Senior Tuberculosis Laboratory Supervisor (STLS), have been appointed on a contractual basis for carrying out supervisory work in the field under the charge of a Medical Officer-TB Control. To further decentralise the diagnostic and

treatment services, RNTCP Designated Microscopy Centres (DMCs) have been established for every 1, 00,000 population. Norms for the establishments of TUs and DMCs are relaxed to 2, 50,000 and 50,000 population respectively in hilly/difficult and tribal areas. In addition, a vast network of DOT centres (treatment centres), all with trained DOT providers, have been established in all RNTCP areas so that patients can have easy access to TB treatment. In addition, there are 17 State TB Training and Demonstration Centres (STDCs) which act as technical support units to the respective STC. Responsibilities of the STDCs include assisting the STC in training, supervision and monitoring of the programme, quality assurance of the RNTCP sputum microscopy services, advocacy and IEC, and operational research. The level of involvement of the STDCs, however, varies from state to state. Release of programme funds from the centre to the state and districts is channeled via the state and district TB control societies. State and district societies make decisions on budget formulation according to guidelines from the centre, hire contractual staff, purchase necessary items, oversee programme planning, implementation and monitoring, and perform other functions which greatly facilitate programme implementation.

**Tuberculosis unit** : A major organizational change in RNTCP is the creation of a sub-district level Tuberculosis Unit. The Tuberculosis unit (TU) consists of a designated Medical Officer-Tuberculosis Control (MO-TC) who does tuberculosis work in addition to his/her other responsibilities, as well as two full-time supervisory staff for tuberculosis work-a Senior Treatment Supervisor (STS) and a Senior Tuberculosis Laboratory Supervisor (STLS). TUs are generally based in a Community Health Centre (CHC), Taluk Hospital (TH) or Block Primary Health Centre (BPHC). The team of STS and STLS at the Tuberculosis Unit level (TU level) are under the administrative supervision of the DTO / MO-TC. The TU covers a population of approximately 500,000 (250,000 in tribal, desert, remote and hilly regions). The TU will have one Microscopy Centre for every 100,000 population (50,000 in tribal, desert, remote and hilly regions) referred to as the Designated Microscopy Centre (DMC). DMCs are also provided in Medical Colleges, Corporate hospitals, ESI, Railways, NGOs, private hospitals,

etc, depending upon requirements. The TU is responsible for accurate maintenance of the Tuberculosis Register and timely submission of quarterly reports to the district level. The TU is the nodal point for TB control activities in the sub-district.

### Definitions - Types of Disease

**Pulmonary Tuberculosis, Smear-Positive** : TB in a patient with at least 2 initial sputum smear examinations (direct smear microscopy) positive for AFB or TB in a patient with one sputum smear examination positive for AFB and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO or TB in a patient with one sputum smear specimen positive for AFB and culture positive for *M.tuberculosis*.

**Pulmonary tuberculosis, Smear-negative** : TB in a patient with symptoms suggestive of TB with at least 3 sputum smear examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO followed by a decision to treat the patient with a full course of anti-tuberculosis therapy or Diagnosis based on positive culture but negative AFB sputum smear examinations.

**Extra Pulmonary tuberculosis** : TB of any organ other than the lungs, such as the pleura (TB pleurisy), lymph nodes, intestines, genitourinary tract, skin, joints and bones, meninges of the brain, etc. Diagnosis should be based on culture-positive specimen from the extra-pulmonary site, histological, radiological, or strong clinical evidence consistent with active extra pulmonary TB followed by decision of the treating MO to treat with a full course of anti-TB therapy. Pleurisy is classified as extra pulmonary TB. A patient diagnosed with both sputum smear positive pulmonary and extra pulmonary TB should be classified as pulmonary TB.

### Definitions : Types of cases

**New**: A case who has never had treatment for tuberculosis or has taken anti-tuberculosis drugs for less than one month.

**Relapse**: A TB patient who was declared cured or treatment completed by a physician, but who reports back to the health service and is now found to be sputum smear positive.

**Transferred in** : A TB patient who has been received for treatment into a Tuberculosis Unit, after starting treatment in another unit where s/he has been registered.

**Treatment after default** : A TB patient who received anti-tuberculosis treatment for one month or more from any source and returns to treatment after having defaulted, i.e., not taken anti-TB drugs consecutively for two months or more, and is found to be sputum smear positive.

**Failure** : Any TB patient who is smear positive at 5 months or more after starting treatment. Failure also includes a patient who was treated with Category III regimen but who becomes smear positive during treatment.

**Chronic** : A TB patient who remains smear positive after completing a re-treatment regimen.

**Others** : TB patients who do not fit into the above mentioned types. Reasons for putting a patient in this type must be specified.

### Definitions : Treatment Outcomes

**Cured** : Initially sputum smear-positive patient who has completed treatment and had negative sputum smears, on two occasions, one of which was at the end of treatment.

**Treatment completed** : Sputum smear-positive patient who has completed treatment, with negative smears at the end of the intensive phase but none at the end of treatment or Sputum smear-negative TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment or Extra-pulmonary TB patient who has received a full course of treatment and has not become smear positive during or at the end of treatment.

**Died** : Patient who died during the course of treatment regardless of cause.

**Failure** : Any TB patient who is smear positive at 5 months or more after starting treatment. Failure also includes a patient who was treated with Category III regimen but who becomes smear positive during treatment.

**Defaulted** : A patient who has not taken anti-TB drugs for 2 months or more consecutively after starting treatment.

**Transferred out** : A patient who has been transferred to another Tuberculosis Unit/District and his/her treatment result (outcome) is not known.

**Tuberculous infection** : It is the presence of viable but not multiplying virulent tubercular bacilli within the cells of the human being without any manifestation of clinical symptoms.

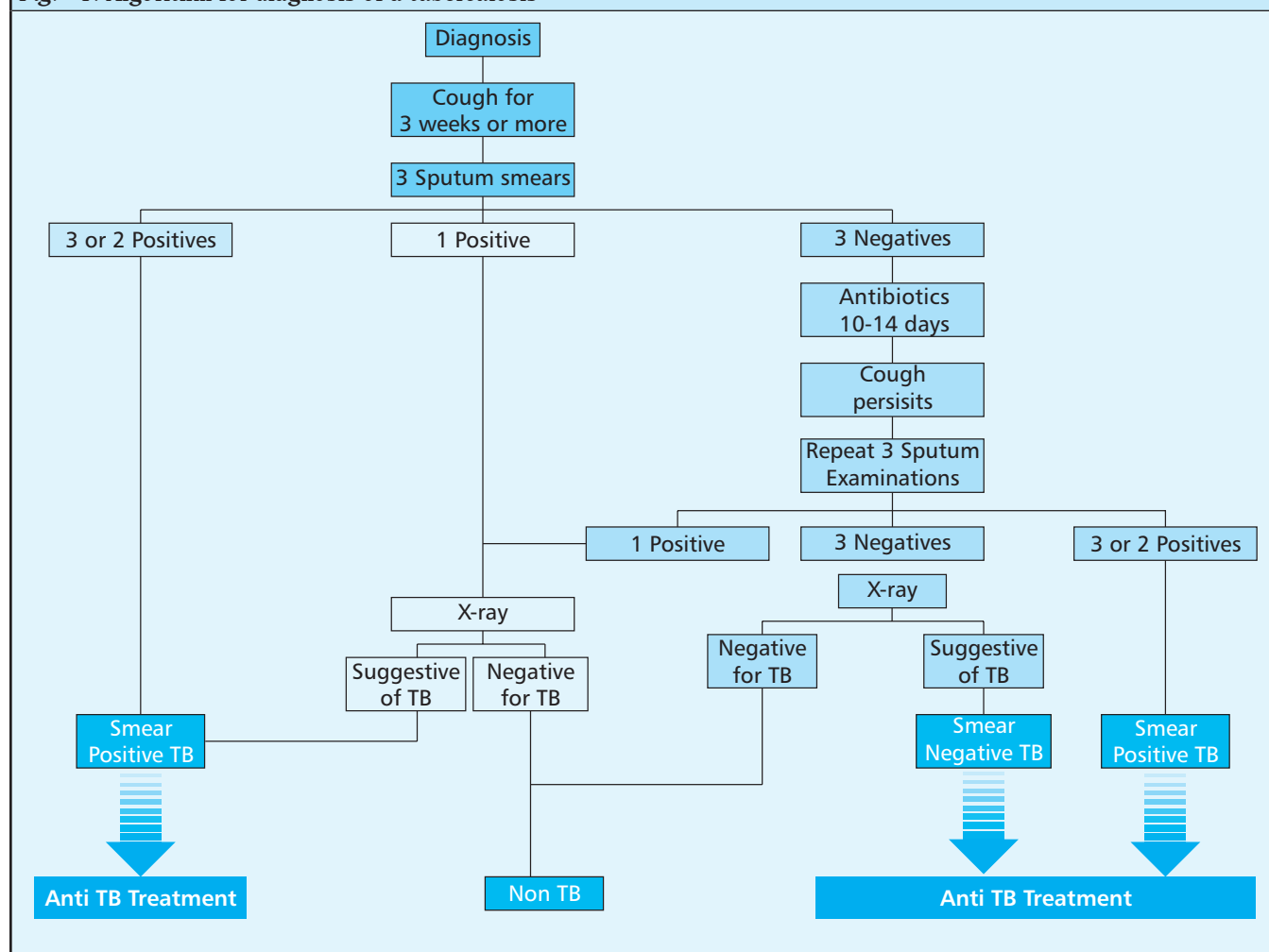
**Tuberculous disease** : It is the presence of viable, multiplying, virulent tubercular bacilli within the cells or tissues, with the presence of clinical symptoms.

### Diagnosis

Three samples of sputum are collected on two days [spot (I day), overnight/early morning (II Day), spot (II Day)] and are examined under microscope. Results of sputum microscopy are given in Table - 2. Algorithm for diagnosis and treatment is given as Fig. -1.

Table - 2 : Results of sputum microscopy			
If the slide has	Result	Grading	No of fields to be examined
More than 10 AFB per oil immersion field	Pos	3+	20
1-10 AFB per oil immersion field	Pos	2+	50
10-00 AFB per 100 oil immersion field	Pos	1+	100
1-9 AFB per 100 oil immersion fields	Pos	Scanty - B *	100
No AFB in 100 oil immersion fields	Neg		100
* Record actual number of bacilli seen in 100 fields - e.g " Scanty 4"			

**Fig. - 1: Algorithm for diagnosis of a tuberculosis**



Fluorescent microscopes have been provided to the state designated Intermediate Reference Laboratories (IRLs) under RNTCP and at present, the use of fluorescence microscopy is linked to the culture and Drug Sensitivity Testing (DST) activities of the IRLs. The most important advantage of the fluorescence technique is that slides can be examined at a lower magnification, thus allowing the examination of a much larger area per unit of time.

#### Treatment under RNTCP

Treatment in RNTCP is under two phases : Intensive and continuation phase. Categorization of patients is given in Table - 3. Duration of treatment alongwith phases is given for each category in Table - 4. Duration of treatment if patient is still sputum positive at end of intensive phase (IP) is given in Table - 5, while details of anti-tubercular drugs are given in Table - 6 and 7. Treatment categories and their relation to sputum examination schedule is given in Table - 8.

**Management of patients who interrupt treatment :** The details are given in Table - 9 and 10.

**Table - 3 : Classification of categories, types of patients, regimens adopted under RNTCP**

Cat	Type of patient	Regimens	Duration in months
I	New sputum smear +ve	2(HRZE) <sub>3</sub> 4(HR) <sub>3</sub>	6
	Seriously ill sputum -ve		
	Seriously ill sputum extra-pulmonary		
II	Sputum +ve relapse	2(HRZE) <sub>3</sub>	8
	Sputum +ve failure	1(HRZE) <sub>3</sub>	
	Sputum +ve treatment after default	5(HRE) <sub>3</sub>	
III	Sputum -ve Extra pulmonary not seriously ill	2(HRZ) <sub>3</sub> 4(HR) <sub>3</sub>	6
IV	MDR TB	4(KOCZEEt) 12-18(OCEEt)	18-24



Table - 4: Phase and duration of treatment			
Cat	Duration (number of doses)		Total
	Intensive Phase (IP)	Continuation Phase (CP)	
I	8 weeks (24 doses)	18 weeks (54 doses)	26 weeks (78 doses)
II	12 weeks (36 doses)	22 weeks (66 doses)	34 weeks (102 doses)
III	8 weeks (24 doses)	18 weeks (54 doses)	26 weeks (78 doses)

Table 5 : Duration if sputum is +ve at end of Intensive Phase*			
Cat	Duration (number of doses)		Total
	Intensive Phase (IP)	Continuation Phase (CP)	
I	12 weeks (36 doses)	18 weeks (54 doses)	26 weeks (90 doses)
II	16 weeks (48 doses)	22 weeks (66 doses)	34 weeks (144 doses)
* Cat I - at the end of 2 months; Cat II - at the end of 3 months			

Table - 6: Dosages of Anti tubercular drugs				
Medication	Drug Action	Dose (thrice a week) ***	Dose in children (mg/Kg)	Number of pills in combipack
Isoniazid	Bactericidal	600mg	10-15	2
Rifampicin	Bactericidal	450mg*	10	1
Pyrazinamide	Bactericidal	1500mg	25	2
Ethambutol	Bacteriostatic	1200mg	15	2
Streptomycin	Bactericidal	0.75g**	15	-
* Patients who weigh 60 kg or more at the start of treatment are given an extra 150mg dose of rifampicin. ** Patients over 50 years of age & those who weigh <30 kg are given 0.5g of streptomycin. *** Adult patients weighing <30kg receive drugs in patients-wise from the weight band suggested for pediatric patients.				

Table - 7 : Side effects of Anti tubercular drugs	
Drug	Side Effects
Isoniazid	Hepatitis, peripheral neuropathy, pellagra, like syndrome, skin rash, drowsiness, fatigue
Rifampicin	Hepatitis, flu-like syndrome, skin rash, gastritis, respiratory and hemolytic syndromes, orange discoloration of urine, sweat, saliva
Pyrazinamide	Hepatitis, joint pains like gout due to hyperuricemia
Ethambutol	Ocular toxicity, decreased visual acuity, blurring and red green colour blindness, gastrointestinal toxicity and peripheral neuropathy, not recommended in children less than 6 yrs of age.
Streptomycin	Vestibular damage leading to nystagmus, unsteadiness of gait, reduces hearing, hypersensitivity reaction, impairment in excretory functions of kidney. Contraindicated in pregnancy. Use of unsterile needles can transmit Hepatitis B and HIV.
Ofloxacin / Ciprofloxacin	GI symptoms like nausea, vomiting, anorexia, anxiety, dizziness, headache, convulsion, rupture of Achilles tendon
Kanamycin	Vestibular and auditory symptoms, cutaneous hypersensitivity
Ethionamide	GI symptoms like diarrhoea, abdominal pain, hepatotoxicity, convulsion, mental symptoms, impotency, gynecomastia

### Chemoprophylaxis for Children

Household contacts of smear-positive TB cases, especially those below 6 years of age, must be screened for symptoms of tuberculosis. In case of symptoms being present, the diagnostic algorithm for pediatric TB should be followed and the child should be given a full course of anti TB treatment if he is diagnosed as a TB case. For asymptomatic children and those who are not found to be suffering from TB, chemoprophylaxis with Isoniazid (5 mg per kg body wt) should be administered daily for a period of six months. This is regardless of the BCG vaccination status.

### Hospitalization of TB patients

Some TB patients may need hospitalization during their illness. All indoor patients are to be treated with RNTCP regimens. The treatment is given using prolongation pouches which will be supplied by District TB Officer through the STS of that TU. On discharge, patients may be given a maximum of three doses (1 week drug supply) to cover the intervening period prior to their continuation of treatment at their respective DOT Centre, which may/not be in the same district, hence ensuring no interruption in treatment. All indoor patients treated under RNTCP, should be registered under the local TU in which the hospital is located.

Table - 8 : Treatment categories and sputum examination schedule						
Treatment Regimen			Sputum Examination For Pulmonary Tb			
Cat	Type of patient	Regimen*	Pre-Treatment sputum	Test at month (end IP)	If result is	Then
I	New Sputum smear-positive	2H <sub>3</sub> R <sub>3</sub> Z <sub>3</sub> E <sub>3</sub> + 4H <sub>3</sub> R <sub>3</sub>	+	2	-	Start continuation phase, test sputum again at 2 month in CP ( 4 months) and at the end of treatment (6 months)
					+	Continue intensive phase for one more month, test sputum again at end of extended IP (3 months), end then at 2 months in CP (5 months) and at the end of treatment (7 months) #
	Seriously ill ** Sputum smear-negative Seriously ill ** extra pulmonary		-	2	-	Start continuation phase, test sputum again at the end of treatment (6 months)
					+	Continue intensive phase for one more month, test sputum again at end of extended IP ( 3 months), and then at 2 months in CP (5 months) and at the end of treatment ( 7 months) #
II	Sputum smear-positive Relapse Sputum smear-positive Failure Sputum smear - positive Treatment after default Others***	2H <sub>3</sub> R <sub>3</sub> Z <sub>3</sub> E <sub>3</sub> S <sub>3</sub> + 1H <sub>3</sub> R <sub>3</sub> Z <sub>3</sub> + 4H <sub>3</sub> R <sub>3</sub> E <sub>3</sub>	+	3	-	Start continuation phase, test sputum again at 2 month in CP and at the end of treatment (8 months)
					+	Continue intensive phase for one more month, test sputum again at end of extended IP (3 months), end then at 2 months in CP (6 months) at the end of treatment ( 9 months)
III	New Sputum smear-negative, not seriously ill	2H <sub>3</sub> R <sub>3</sub> Z <sub>3</sub> + 4H <sub>3</sub> R <sub>3</sub>	-	2	-	Start continuation phase, test sputum again at the end of treatment (6 months)
	New extra-pulmonary, not seriously ill				+	Re-register the patient and begin Category II treatment #

\* The number before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week. The dosage strengths are as follows: H : Isoniazid (600mg), R: Rifampicin (450mg), Z : Pyrazinamide (1500mg), E: Ethambutol (1200mg), S : Streptomycin (750mg), Patients who weigh 60 kg or more receive additional rifampicin 150 mg. Patients who are more than 50 years old receive streptomycin 500mg. Patients who weigh less than 30 kg, receive drugs as per body weight. Patients in Categories I and II who have a positive sputum smear at the end of the initial intensive phase receive an additional month of intensive phase treatment.

\*\* Seriously ill also includes, any patient, pulmonary or extra pulmonary who is HIV positive and declares his sero-status to the categorizing/treating medical officer. For the purpose of categorization, HIV testing should not be done.

\*\*\* In rare and exceptional cases, patients who are sputum smear-negative or who have extra-pulmonary disease can have Relapse or Failure. This diagnosis in all such cases should always be made by a MO and should be supported by culture or histological evidence of current, active TB. In these cases, the patient should be categorized as 'others' and given Category II treatment.

# Any patient treated with Category I who has a positive smear at 5 months or later should be considered a Failure and started on Category II treatment afresh. Any patient on Category III who has a positive smear anytime during the treatment is also considered as Failure and started on Category II treatment.

## DOTS plus

DOTS-Plus is an integral component of RNTCP to manage MDR-TB and is being implemented through programme infrastructure (4). The first WHO endorsed DOTS-Plus programmes began in 2000. At that time, the Green Light Committee (GLC) was established to promote access to high quality second-line drugs for appropriate use in TB control programmes. DOTS-Plus pilot projects have demonstrated the feasibility and effectiveness of MDR-TB treatment in less affluent countries. In 2002, the Global Fund to fight AIDS, TB, and Malaria (GFATM) started financing TB control programmes, including MDR-TB, greatly reducing the economic barrier to MDR-TB control. Based on data and experience from these projects, practices and further scientific

evidence have emerged regarding services for MDR-TB. DOTS-Plus programmes can and should strengthen the basic DOTS strategy. XDR TB (extensive drug resistant tuberculosis) is defined as MDR TB with further resistance to 3 of 6 classes of second line drugs. DOTS plus which is handling MDR Tb has a serious threat from XDR TB.

## Involvement of Private Practitioners in RNTCP

Private Practitioners (PPs) are generally the first point of contact for significant proportion of patients with tuberculosis (5). All PPs can support and encourage effective tuberculosis control by:

- Ensuring prompt referral of patients with cough for 3

Table - 9 : Management of patients who were smear -negative at diagnosis and who interrupt treatment						
Treatment received before interruption	Length of interruption	DO a sputum Smear examination	Result of sputum Smear examination	Outcome	Re-registration	Treatment
Less than 1 month	Less than 2 months	No	-	-	-	Resume Treatment and Complete All doses
	2 months or more	Yes	Neg	-	-	Resume Treatment
			Pos	Default	New	Begin CAT I afresh
	Less than 2 month	No	-	-	-	Resume Treatment and Complete All does
More than 1 month	More than 2 months	Yes	Neg	-	-	Resume Treatment and Complete All doses
			Pos	Default	Treatment After Default	Begin CAT II Treatment afresh

Table - 10 : Management of New smear-positive cases who interrupt treatment (Category I)						
Treatment received before interruption	Length of interruption	DO a sputum Smear examination	Result of sputum Smear examination	Outcome	Re-registration	Treatment
Less than 1 month	Less than 2 Weeks	No	-	-	-	Continue CAT I *
	2-7 Weeks	No	-	-	-	Start again on CAT I *
	8 Weeks or more	Yes	Positive	Default	New	Start again on CAT I **
			Negative	-	-	Continue CAT I *
1-2 Months	Less than 2 weeks	No	-	-	-	Continue CAT I *
More than 2 months	2-7 Weeks	Yes	Positive	-	-	1 extra month of intensive phase of CAT I *
	8 Weeks or more	Yes	Negative	-	-	Continue CAT I *
			Positive	Default	Treatment after Default	Start on CAT II*
	2-7 Weeks	Yes	Positive	Default ***	Other	Start on CAT II*
			Negative	-	-	Continue CAT I *
	8 Weeks or more	Yes	Positive	Default	Treatment After Default	Start on CAT II*
			Negative	-	-	Continue CAT I *

\* A patient must complete all 24 doses of the initial intensive phase. For example, if a patient has to continue his previous treatment and he took 1 month of treatment and he took 1 month of treatment (12 doses) before interrupting. He will have to take 1 more month (12 doses) of the intensive treatment. The patient will then start the continuation phase of treatment.

\*\* A patient who must start again will restart treatment from the beginning.

\*\*\* Although this patient does not strictly fit the definition of default. Default most closely describes the outcome of this patient, although at re-registration the patient should be categorized as 'Other'.

\* Patients with extra-pulmonary TB should receive Category III treatment unless they are seriously ill, in which case they should receive Category I treatment.

\*\* Examples of seriously ill patients are those suffering from meningitis, disseminated TB, tuberculous pericarditis, peritonitis, bilateral or extensive pleurisy, spinal TB with neurological complications, smearnegative pulmonary TB with extensive parenchymal involvement, intestinal, genito-urinary TB and co-infection with HIV. All forms of pediatric smear negative TB except primary complex and pediatric extrapulmonary lymph node TB and unilateral pleural effusion.

- weeks or more for sputum smears.
- Providing reassurance that tuberculosis can be cured.
- Giving only RNTCP recommended drug regimens.
- Starting treatment with rifampicin-containing regimens only if it can be ensured that treatment can be completed under observation.

### **Involvement of NGOs in RNTCP**

Involvement of Non-Governmental Organizations (NGOs) in RNTCP is of vital importance. NGOs have an active role in health promotion in the community and many patients seek treatment from/through them. Depending on the capacity of the NGOs, their possible areas of involvement can be health education, service delivery, planning, programming, implementation, training and evaluation(6).

### **Quality Assurance in RNTCP**

Sputum examination is the mainstay for diagnosis of Tuberculosis under RNTCP. Poor quality microscopy services have serious implications for the programme, including the failure to detect persons with infectious TB who will continue to spread infection in the community, or leading to unnecessary treatment for “non-cases.” The quality assurance activities take place at the National reference laboratories, intermediate level reference laboratories and TB unit.

In addition, Internal Quality Assurance includes all means by which the laboratory personnel performing TB smear microscopy control the process, including checking of instrument, new lots of staining solutions smear preparation, grading etc. It is a systematic internal monitoring of working practices, technical procedures, equipment, and materials, including quality of stains.

### **RNTCP Tribal Action plan**

Tribal constitute 8.08% of the country's population, which makes India the second largest concentration of tribal communities in the world (8). There are 635 tribes in India located in five major tribal belts across the country. The RNTCP Tribal Action Plan has the following objectives (9) :

1. Encourage tribal populations to report early in the course of illness for diagnosis.
2. Enhance treatment outcomes amongst tribal populations
3. Promote closer supervision of tribal areas by RNTCP staff

### **IEC in RNTCP**

Advocacy and communication is a central and integral part of the Phase II RNTCP (10). Communication plans are directed towards scaling up the current level of communication activities through good mass media campaigns to creating a supportive and enabling environment for grassroot level participatory processes and community empowerment.

### **TB and HIV**

As per NACO sentinel surveillance report of 2006, the prevalence of HIV infection is estimated to be 0.36 % of the population, which translates to 2.5 million people living with HIV/AIDS in India. Tuberculosis (TB) continues to be a public health challenge in India and it is estimated that 1.8 million cases of TB occur in India annually. Active TB disease is the commonest opportunistic infection amongst HIV-infected individuals. A low cost and high quality cure for TB is provided

under RNTCP which is implementing the DOTS strategy of diagnosis and treatment for TB nationwide (11).In 2007-08, TB-HIV collaborative activities are to be extended to the entire country and have been included as an integral part of NACP III and RNTCP II.

The goal of the National framework is to further enhance collaboration between RNTCP and NACP, and reducing the burden of TB and HIV in India. The objectives are-

1. To establish mechanisms for coordination between RNTCP and NACP at National, State and District levels.
2. To decrease morbidity and mortality due to tuberculosis among persons living with HIV/AIDS.
3. To decrease the impact of HIV in tuberculosis patients and provide access to HIV related care and support to HIV-infected TB patients.

### **Conclusion**

RNTCP is the second largest programme of the country and has strengthened the existing NTP structure and created TB unit at the sub district level. RNTCP has expanded in a systematic way covering the whole of country by March 2006. There has been intensified Public private mix in scaling up the initiatives to strengthen case detection and treatment. Political commitment is one of the main components of DOTS. DOTS have been made responsible for carrying out defaulter retrieval activity about the patients put on treatment. This ensures completion of treatment by the patients. Various NGOs are also playing useful role by providing man power or financial assistance (13).

### **Critical appraisal**

There has been poor coverage due to gaps in primary health care infrastructure and manpower in difficult to assess areas. Quality of sputum examination is not up to the mark. The private practitioners at many places use non standard treatment regimens. The problem of drug resistant TB is emerging very fast which is virtually untreatable and spreading all over the world including India (12). Given the problems of number of drugs to be used, their cost, adverse effect, the duration of therapy and accessibility of treatment, this group is going to pose a big problem for the RNTCP in particular and the community at large. Direct supervision is the corner stone for the success of RNTCP but in our country, lot of stigma is still attached to TB. As a result, many patients, especially young females, who want to hide their ailment, do not go to DOTS-provider thrice or even once a week. Such patients often resort to influence the DOTS-provider and get medicines in bulk. In this process, direct supervision is lost.

### **Summary**

National Tuberculosis Control Programme was launched in 1962 and suffered from weakness in the form of poor managerial control, inadequate funding, over-reliance on x-ray, non-standard treatment regimens, low rates of treatment completion, and lack of systematic information on treatment outcomes. The Revised National Tuberculosis Control Programme (RNTCP), based on the DOTS strategy, took its roots in India in 1993 with the goal of decreasing mortality and morbidity due to TB and cut transmission of infection until TB ceases to be a major public health problem in India. It progressed in a phased



manner and by 24th March 2006 entire country was covered by it and entered its second phase (2006-2010).

The objectives of the RNTCP are to achieve at least 85 percent cure rate of the newly diagnosed sputum smear-positive TB patients and to detect at least 70 percent of new sputum smear-positive patients after the first goal is met. Directly Observed Treatment Short course (DOTS) strategy has five components: Political and administrative commitment, Good quality drugs & an uninterrupted supply of good quality anti-TB drugs, Good quality diagnosis using sputum microscopy, Systematic monitoring and accountability and supervised treatment to ensure the right treatment. DOTS remain the core strategy of RNTCP II however few additional components in the form of DOTS expansion and enhancement, addressing TB-HIV, collaboration with other health programmes and general services and involvement of private practitioners have been emphasized.

The structure of RNTCP has The Central TB Division (CTD) at the top, State TB Cell (STC) at the state and District TB Centre (DTC) at the district level. The TB Units (TUs) at the subdistrict level is the lowest reporting unit under the RNTCP. The Tuberculosis unit (TU) consist of a designated Medical Officer-Tuberculosis Control (MO-TC) who does tuberculosis work in addition to his/her other responsibilities, as well as two full-time supervisory staff for tuberculosis work - a Senior Treatment Supervisor (STS) and a Senior Tuberculosis Laboratory Supervisor (STLS). The TU covers a population of approximately 500,000 (250,000 in tribal, desert, remote and hilly regions). The TU will have one Microscopy Centre for every 100,000 population (50,000 in tribal, desert, remote and hilly regions) referred to as the Designated Microscopy Centre (DMC).

Diagnosis of a case is based on sputum microscopy where three samples over two days are taken and ZN method of staining is used. For treatment the patient is classified into a category based on the definitions given in the programme and treatment of that particular category is started for the patient. The treatment is divided into two phases intensive phase and continuation phase. Antitubercular drugs being used in RNTCP are H : Isoniazid R : Rifampicin, Z : Pyrazinamide E : Ethambutol, S : Streptomycin. Household contacts of smear-positive TB cases, especially those below 6 years of age, must be screened for symptoms of tuberculosis. For asymptomatic children and those who are not found to be suffering from TB, chemoprophylaxis with isoniazid (5 mg per kg body wt) should be administered daily for a period of six months.

DOTS-Plus is an integral component of RNTCP to manage MDR-TB and is being implemented through programme infrastructure. XDR TB (extensive drug resistant tuberculosis) is defined as MDR TB with further resistance to 3 of 6 classes of second line drugs.

Another important aspect for success of RNTCP is involvement of private practitioners and NGOs in the programme. RNTCP also has a tribal action plan to Encourage tribal populations to report early in the course of illness for diagnosis, Enhance treatment outcomes amongst tribal populations, and Promote closer supervision of tribal areas by RNTCP staff. Tuberculosis is the commonest opportunistic infection in HIV cases. There is a strong collaboration between RNTCP and National AIDS Control Programme to decrease morbidity and mortality due to tuberculosis among persons living with HIV/AIDS and to decrease the impact of HIV in tuberculosis patients and provide access to HIV related care and support to HIV-infected TB patients.

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*Puja Dudeja & Ashok K. Jindal*

NVBDCP is an umbrella programme for prevention and control of major vector borne diseases of public health importance namely Malaria, Filariasis, Japanese encephalitis (JE), Kala azar and Dengue/Dengue Hemorrhagic Fever (DHF) (1). The programme lays special focus on the vulnerable groups of the society namely, children, women, Scheduled Castes (SC) and Scheduled Tribes (ST). Under the programme, it is ensured that the disadvantaged and marginalized sections benefit from the delivery of services so that the desired National Health Policy and National Rural Health Mission (NRHM) goals are achieved.

Before 2003, various centrally sponsored schemes namely National Anti Malaria Programme, National Filariasis Control Programme and Kala Azar Control Programme were fighting with menace of malaria, filariasis and kala azar respectively on a cost sharing basis between center and state (2). There was no centrally sponsored programme for JE, dengue, chikungunya. The states were managing these with their own resources without any financial and technical assistance. From the year 2003-2004, Government of India decided to fight the peril of all vector borne diseases on a common platform as NVBDCP.

#### **Mission Statement**

Integrated accelerated action towards reducing mortality on account of malaria, dengue, Japanese Encephalitis by half and elimination of Kala-azar by year 2010 and elimination of Lymphatic Filariasis by 2015 (3).

#### **Strategy**

During the Tenth Plan (2002-2007), NVBDCP was planned to be implemented through the existing health care infrastructure and was planned to focus on improved training of health care workers, reporting and monitoring of VBDs, insecticide and drug resistance, involvement of Panchayati Raj Institutions (PRIs), improved IEC and community acceptance and availability of ITBNs (4). During the eleventh five year plan (2007-2012) the existing strategies of vector borne diseases would be further continued and further strengthened with special emphasis on surveillance, human resource development, behavior change communication, supervision and monitoring, quality assurance and quality control of diagnostics & drugs and operational research (5).

#### **Implementation**

The programme runs under the Union Ministry of Health and Family Welfare. The execution of the programme at various levels is given in Table 1.

There is also a strong link up between NVBDCP and NRHM (6). NRHM will focus on all diseases of NVBDCP. ASHA is envisaged to play a key role in the grass-root level implementation of NVBDCP. Actions to be taken under the NRHM are:

- ASHA and Village Health Team to be oriented to community based vector control strategies. Convergence with Water and Sanitation Mission will facilitate this process.
- ASHA to be able to give presumptive treatment for malaria
- Enhanced surveillance capacity (human resources and infrastructure) at PHC and CHC levels
- Enhancing laboratory capacity at CHC and PHC

#### **Malaria**

Malaria is major public health trepidation in our country. At the

**Table - 1 : Organisational structure of NVBDCP**

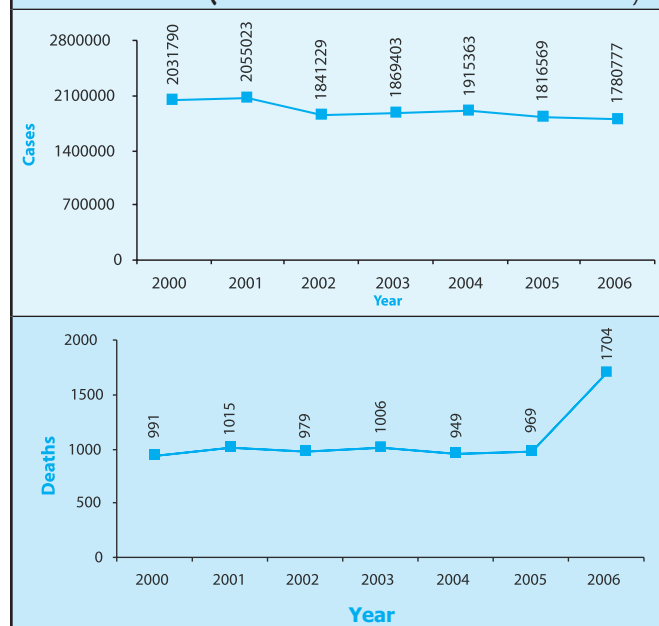
Level	Agency	Action
National	Directorate of National Vector Borne Diseases Control Programme	Framing technical guidelines & policies as to guide the states for implementation of Programme
		Budgeting and planning the logistics pertaining to central sector
		Monitoring of implementation through regular reports and returns
		Evaluation of Programme implementation
State	Regional Offices for Health and Family Welfare (ROH & FW) located at state HQ	Conduct the entomological studies in collaboration with zonal entomological setup of the state
		Drug resistance studies
		Cross checking of blood slides for quality control
		Capacity building of the states
	Directorate of Health Services	Responsible for implementation of Programme strategies and monitoring in accordance to Programme guidelines
		Development of infrastructure
		Coordination between the state and centre for effective implementation and monitoring
District	District Malaria Offices	Key unit for planning and monitoring of Programme under a technical officer
Village	Primary Health Centres	Passive surveillance for malaria

time of independence of the country, there were an estimated 75 million malaria cases and 0.8 million deaths annually. High malaria burden had adverse effects on agriculture, industrial development and national economy. Use of insecticides for malaria control became available in fifties and global experience in malaria control indicated then that malaria could be controlled or even eradicated within a short period, if available measures were implemented effectively.

### Magnitude of the problem

Trend of Malaria Cases and Deaths Due to Malaria in India is depicted in Fig - 1a & 1b respectively.

**Fig. - 1a & 1b : Trend of Malaria Cases and Deaths Due to Malaria in India (Source : National Health Profile 2007)**



As per the data from National Health Profile 2007, there were 1.78 million cases of malaria and 1704 deaths in the year 2006. The largest numbers of cases in the country were reported by Orissa, followed by Jharkhand, West Bengal, Assam, Chhattisgarh, Rajasthan, Gujarat & Uttar Pradesh and the largest numbers of deaths were reported by Assam followed by Orissa, West Bengal, Arunachal Pradesh, Meghalaya, Maharashtra, Mizoram, Gujarat and Karnataka.

### Evolution of the Programme

The National Malaria Control Program (NMCP) was launched in 1953 and was redesignated as Eradication Program (NMEP) in 1958. The NMEP made an excellent progress till 1965, bringing down the malaria incidence to almost nil. However, thereafter setbacks started due to various operational, administrative and technical reasons. Against this background, in 1977, the Modified Plan of Operations (MPO) was started. The evolution is presented in Table - 2.

In 1995 the Malaria Action Plan (MAP) was launched. It envisaged decentralized planning (akin to RCH), covering a total of 199 million (20.6%) population living in high risk areas. The criteria for defining a high risk area are as follows:

#### (A) Rural / Tribal areas

1. Death due to malaria (Pf) - last 3 years
2. Doubling SPR in last 3 years
3. No doubling but average SPR in 3 years > 4%
4. *P. falciparum* > 30 % with SPR > 3 % in 3 years
5. Chloroquine resistant Pf.
6. Aggregation of labor in project areas.
7. New settlement in endemic/receptive and vulnerable area.

#### (B) Urban Areas

1. SPR > 10% during any of last 3 years
2. Population > 50000 & 5% with ration malaria: fever cases > 1/3

In 1997 the Enhanced Malaria Control Project (EMCP) was

**Table - 2 : Evolution of National Malaria Control / Eradication Programme**

S. No	Year	Programme	Remarks
1	1953	National Malaria Control Programme	Strategy - Residual insecticide spray; 75 million cases
2	1958	National Malaria Eradication Programme	Residual Spray+ Active search of cases & Radical Treatment following reduction of cases to 2 million
			Brought down annual malaria incidence to 0.1 million cases by 1965
			Could not sustain for various technical, administrative and financial constraints
3	1965-66 1970's	Minimum no of cases 0.1million with no deaths. Resurgence of malaria with 6.47m cases in 1976	
4	1971	Urban Malaria Scheme (UMS)	Passive treatment of malaria cases, antilarval measures, minor engineering methods like closing ditches, biological control and awareness camps.
5	1977	Modified Plan of Operation (MPO) (also included <i>P. falciparum</i> containment programme)	The programme was integrated with primary health care delivery system in rural areas.
			Successfully brought down the annual incidence of malaria substantially, viz., reduction to a level of 2 million cases per annum by 1984
			Strategies were selective insecticide spray API>2, Active Surveillance-Fortnightly visits- blood smear collection, antilarval operations in urban areas.

launched covering a total of 1045 PHCs in 100 districts of AP, Jharkhand, Gujarat, MP, Maharashtra, Orissa and Rajasthan through World Bank assistance. The components were Early detection and prompt treatment through a Link worker for every 2000 population and selective vector control using Temephos (Abate) for anti-larval and DDT / malathion for residual applications.

In 1998, World Health Organization and other partners initiated the "Roll Back Malaria" (RBM) plan. The key interventions were Vector Control through Insecticide Treated Nets (ITN) and Indoor Residual Spray (IRS); Intermittent Preventive Therapy during pregnancy (IPT); and prompt and effective case management, in particular Artemisinin based combination therapy.

In 2003, the NVBDCP was launched, integrating the various components of control strategies for common vector borne diseases. In 2005, the programme was made a important strategic part of NRHM.

### Malaria control strategies in NVBDCP

#### 1. Early case Detection and Prompt Treatment (EDPT)

- EDPT is the main strategy of malaria control - radical treatment is necessary for all the cases of malaria to prevent transmission of malaria.
- Chloroquine is the main anti-malaria drug for uncomplicated malaria.
- Drug Distribution Centres (DDCs) and Fever Treatment Depots (FTDs) have been established in the rural areas for providing easy access to anti-malarial drugs to the community.
- Alternative drugs for chloroquine resistant malaria are recommended as per the drug policy of malaria. NVBDCP drug policy recommends the use of combination therapy i.e Artesunate plus Sulfadoxine Pyrimethamine as a second line of treatment for *P. falciparum* cases in chloroquine resistant areas.
- All fever cases should preferably be investigated for malaria by microscopy or Rapid Diagnostic Kit (RDK). RDK is a immunochromatographic test. It detects *Plasmodium falciparum* histidine rich protein in blood.

#### 2. Vector Control

##### (i) Chemical Control

- Use of Indoor Residual Spray (IRS) with insecticides recommended under the programme.
- Use of chemical larvicides like Abate in potable water
- Aerosol space spray during day time
- Malathion fogging during outbreaks

##### (ii) Biological Control

- Use of larvivorous fish in ornamental tanks, fountains etc.
- Use of biocides.

#### 3. Personal Prophylactic Measures that individuals/communities can take up

- Use of mosquito repellent creams, liquids, coils, mats etc.
- Screening of the houses with wire mesh
- Use of bednets treated with insecticide
- Wearing clothes that cover maximum surface area of the body

#### 4. Community Participation

- Sensitizing and involving the community for detection of Anopheles breeding places and their elimination
- NGO schemes involving them in programme strategies
- Collaboration with CII/ASSOCHAM/FICCI
- Observance of anti malaria month in June and intensify activities

#### 5. Environmental Management & Source Reduction Methods

- Source reduction i.e. filling of the breeding places
- Proper covering of stored water
- Channelization of breeding source

#### 6. Monitoring and Evaluation of the programme

- Monthly Computerized Management Information System (CMIS)
- Field visits by state by State National Programme Officers
- Field visits by Malaria Research Centres and other ICMR Institutes
- Feedback to states on field observations for corrective actions.

### National Antimalaria Drug Policy

National antimalaria drug policy essentially provides a framework for the safe and effective treatment of uncomplicated and severe malaria as well as prevention of malaria in vulnerable groups, such as pregnant women and young children. The policy is as follows :

**Presumptive Treatment (PT) - Low Risk Areas** : PT comprises of a single dose of chloroquine phosphate 10 mg/kg. body weight to all fever / suspected malaria cases (Table - 3).

Table - 3		
Age in Years	Chloroquine Phosphate	
	mg. Base	No. of Tablets (150 mg)
< 1	75	½
1-4	150	1
5-8	300	2
9-14	450	3
15 & above	600	4

**Presumptive Treatment (PT) - High Risk Areas** : As per revised policy of NVBDCP presumptive treatment of all suspected malaria cases, up to sub-centre level only, in "high risk areas" is as shown in Table - 4.

Table - 4		
Chloroquine Base	Day 1	10 mg/kg (600 mg adult)
Primaquine	Day 1	0.75 mg/kg (45 mg adult)
Chloroquine base	Day 2	10 mg/ kg (600 mg adult)
Chloroquine base	Day 3	5 mg/kg (300 mg adult)



## Radical Treatment - Low Risk Areas

For *Plasmodium vivax* (Table - 5)

Table - 5				
Age in year	Chloroquine Phosphate 150 mg base Single dose		Primaquine 2.5 mg base Daily dose for 5 days	
	mg base	No. of tablets	mg base	No. of tablets
< 1	75	1/2	Nil	Nil
1 - 4	150	1	2.5	1
5 - 8	300	2	5.0	2
9 - 14	450	3	10.0	4
15 & above	600	4	15.0	6

For *Plasmodium falciparum* : In “Low Risk Areas” where presumptive treatment with 600 mg chloroquine alone (adult dose) has been given and later blood smear is found positive for Pf, the complete radical treatment should be given with a single dose of tablet chloroquine 10 mg/kg bw combined with 0.75 mg/kg bw of primaquine.

## Radical Treatment - High Risk Areas

For *Plasmodium vivax* : In high risk areas where presumptive treatment with 1500 mg chloroquine base spread over three days and 45 mg primaquine (adult dose) has been given, chloroquine need not be administered again, but primaquine must be given for 5 days (Table - 6).

Table - 6		
Age in year	Tablets Primaquine 2.5 mg base Daily dose for 5 days	
	mg base	No. of tablets
<1	Nil	Nil
1-4	2.5	1
5-8	5.0	2
9-14	10.0	4
15 & above	15.0	6

For *Plasmodium falciparum* : In “High Risk Areas”, fever cases are given presumptive treatment with 1500 mg Chloroquine (over 3 days) and 45 mg Primaquine (adult single dose). Therefore radical treatment with primaquine is not required if they are found positive for Pf microscopically.

**Chloroquine resistant *P. falciparum* cases** : The radical treatment of Pf cases in chloroquine resistant areas, which are under alternate drug schedule, and in specific cases not responding to chloroquine, is by second line of treatment. Resistance should be suspected if in spite of full treatment and no history of vomiting, diarrhoea, patient does not respond within 72 hours parasitologically or deteriorate clinically. National Anti Malaria Drug Policy has recently recommended Artesunate + sulfadoxine/ sulfalene combination therapy (SP

-ACT) in confirmed chloroquine resistant cases. This must be followed with Primaquine (45 mg). The age-wise dosage is as shown in Table - 7.

Table - 7				
Age in year	Artesunate (AS) Sulfadoxine+ pyrimethamine (SP)	I day (no. of tablets)	II day (no. of tablets)	III day (no. of tablets)
< 1	AS	½	½	½
	SP	¼	Nil	Nil
1-4	AS	1	1	1
	SP	1	Nil	Nil
5-8	AS	2	2	2
	SP	1 ½	Nil	Nil
9-14	AS	3	3	3
	SP	2	Nil	Nil
15 & above	AS	4	4	4
	SP	3	Nil	Nil

- Dose of Artesunate is 4 mg /kg body weight for 3 days. Strength of the tablet is 50 mg.
- Dose of SP is 25 mg /kg body weight of sulfadoxine plus 1.25 mg /kg body weight of pyrimethamine single dose. The strength of SP tablet is 500 mg sulfadoxine and 25 mg of pyrimethamine.

**Note:** Sulfalene/ Sulphadoxine and Pyrimethamine combination does not take care of *P. vivax* cases. Where SP - ACT is not available, SP alone should be given.

**Chemoprophylaxis** : In chloroquine sensitive areas chloroquine is to be given. In chloroquine resistant areas it is to be supplemented by proguanil.

## Regimen

- Chemoprophylaxis is to be started a week before arriving at malarious area for visitors.
- For pregnant women in high risk area prophylaxis should be initiated from second trimester.
- Start with loading dose of 10 mg/kg bw and followed by a weekly dose of 5 mg/kg bw. This is to continue till 1 month after delivery in case of pregnancy and in travelers till one month after return from endemic area. The terminating dose should be 10 mg/kg bw along with 0.25 mg/kg bw of primaquine for five days.
- Chemoprophylaxis with chloroquine is not recommended beyond 3 years because of its cumulative toxicity.
- In chloroquine resistant areas chemoprophylaxis is recommended with chloroquine 5 mg/kg bw weekly and proguanil 100mg daily.

## Vector control

In our country, control of vectors is actually control of *An. culicifacies* as 60-70% of new cases of malaria are due to it and rest 15-20% by *An. fluviatilis*. Approx 70% of the allotted budget is spent for control of malaria in those areas where *An. culicifacies* is the vector species for malaria transmission.

Except for *An. stephensi* all other malaria vectors exist as species complexes comprising several sibling species that result in considerable impact on the transmission of malaria including susceptibility to commonly used insecticides in public health programme.

**Insecticides** : Wettable Powder (WP) formulations are used for indoor residual sprays and Emulsifiable Concentrate (EC) formulations are used for larval control. For Indoor Residual Spray (IRS) insecticides in use are DDT 50% WP, malathion 25% WP and synthetic Pyrethroid (WP). Synthetic Pyrethroids include deltamethrin 2.5% WP, Cyfluthrin 10% WP, lambda cyhalothrin 10% WP, alphacypermethrin 5% WP, Etofenprox 10% WP and Bifenthrin 10% WP. Synthetic pyrethroid insecticides are also used for impregnation of bed nets.

**Change of Insecticide** : The change of insecticide is warranted after production of data on vector resistance studies and field observations on epidemiological impact of spray in respect of insecticide in use by State Govt. The change of insecticide will always be decided in mutual consultation between State Programme Officer for NVBDCP, ROH&FW and the Dte. of NVBDCP with concurrences of State and Central Govts.

**Insecticide formulations used under NVBDCP** : The formulations/compounds used under the NVBDCP for control of malaria are DDT; Malathion 25% WP (used under the programme in areas with DDT resistance); and, Synthetic Pyrethroids. As regards synthetic pyrethroids, the cost of these insecticides is much higher than the cost of DDT and Malathion. Currently there are five insecticides of this group registered with Central Insecticide Board for use in the programme. These are (i) Deltamethrin 2.5% WP, (ii) Cyfluthrin 10% WP, (iii) Alphacypermethrin 5% WP (iv) Lambda cyhalothrin 10% WP and (v) Bifenthrin 10% WP.

**Insecticide Resistance in Malaria vectors** : Malaria vectors in India are resistant to DDT alone or double resistant to HCH or triple resistant to DDT, HCH, malathion and quadruple resistant to DDT, HCH, malathion and Deltamethrin (synthetic pyrethroid). HCH has been phased out in 1997. In the years to come development of resistance to synthetic pyrethroid warrants a caution of impending possibility of wide spread resistance to other compounds of this group that are introduced in public health programme for indoor residual spray as well as insecticide treated bed nets. Strategies for delaying / avoiding the onset of resistance include:

- Avoid indiscriminate use of insecticides
- Avoid use of insecticides that simultaneously select resistance to other chemically related insecticides.
- Avoid use of insecticides that induce development of more than one type of resistance mechanism of broad spectrum of resistance.
- Avoid use of the same insecticide for both against adults and larvae.
- Use of non chemical control methods, e.g. biopesticides, larvivorous fish.
- Use of synergist with insecticides to reduce physiological resistance.

#### Malaria Surveillance Under NVBDCP

The aim of surveillance is to detect changes in trends or distribution in malaria and other vector borne diseases in order to initiate investigative or control measures. Malaria surveillance presumes that every malaria case will present itself with symptoms of fever at some point of time during the course of infection. Surveillance activities are summarized in Table - 8.

**Table - 8 : Surveillance activities under NVBDCP**

S.No	Component	Remarks
1	Fortnightly Domiciliary visits	Active case detection (ACD) is carried out by multipurpose health workers (male) under Primary Health Care System. He carries out search for a fever case or who had fever in between the visits of MPW, collects blood smear from such cases, administers appropriate anti-malarial(s). The rationale is that the "incubation interval" i.e., the full life cycle of malaria for the development of the parasite in the mosquito and that in the human being in case of <i>P. vivax</i> is approximately 22 days while for <i>P. falciparum</i> it is 35 days. Thus, surveillance cycle of less than one incubation interval will catch most of the secondary cases before the commencement of next cycle. Through this activity, the malaria surveillance can be measured.
2	Fever Treatment Depots (FTDs)	To avoid delay in detection of cases which occur in between visits of MPW, establishment of Fever Treatment Depots in villages especially in areas which are remote/ inaccessible and have low population density collection of blood smears, administration of presumptive treatment, impregnation of bed nets, promotion of larvivorous fish etc,
3	Passive Case Detection (PCD)	By Allopathic, Ayurvedic, Homeopathic, Siddha medicine dispensaries in the health sector, local residents or voluntary agencies operating locally, Anganwadi workers, private practitioners etc.
4	Rapid Fever Survey	In case of an epidemic outbreak, the suspected epidemic zone is covered in a short duration and all fever cases are screened by taking blood smears
5	Mass survey	Mass survey of the entire population may be carried out in the suspected epidemic zone. Here all the population irrespective of age, sex or fever status is screened by taking blood smear. Specially children must be included in survey.
6	Drug Distribution Centre (DDC)	The functions of DDCs are the same as those of FTDs, except that the DDCs do not take blood slides but administer drugs to fever cases.

**Rationale behind surveillance :** Malaria surveillance presumes that every malaria case will present itself with symptoms of fever at some point of time during the course of infection. Therefore, if all fever cases occurring in the community are kept under surveillance over a period of time and their blood smears are examined for malaria parasite, the total malaria parasite load can be examined. For accurate estimates of malaria endemicity, the blood smear examination rate specially the Monthly Blood Examination Rate (MBER) should be equal to fever rate of the month in the community. Therefore it is necessary to ensure that all persons having fever during malaria transmission months are included in the total blood slides examined during the year. The MBER norms of 0.8 percent during non-transmission season and 1.2 to 1.8 percent during transmission season (or approximately 1% per month) were laid down in the Malaria Eradication Programme. MBER should be monitored MPW-wise by the medical officer-in-charge during monthly meeting at the PHC in order to assess the surveillance operation in the PHC area. In both the cases i.e. ABER and MBER the denominator is common because the entire population is covered during each fortnightly domiciliary visit by MPW (male). ABER is the cumulative sum of monthly rates during the year. ABER/ MBER is an index of operational efficacy of the programme. The Annual Parasite Incidence (API) depends upon the ABER. A sufficient number of blood slides should be systematically obtained and examined for malaria parasite to work out accurate API.

As a rough guide, MBER should be 1% and ABER should be at least 10%. If it is less than this figure it indicates a poor surveillance coverage and in this situation, API may not remain a good index of malaria incidence. In such situations, SPR, rather than API should be considered. While collecting ABER or MBER, blood slides collected by all agencies are taken into account, i.e blood smears collected through ACD, PCD, FTD or any other voluntary agency during the same period. However, number of blood smears collected and examined during a mass survey and their results should not be included while calculating ABER or MBER.

$$\text{ABER} = \frac{\text{No. of blood smears collected during the year}}{\text{Population covered under surveillance}} \times 100$$

$$\text{MBER} = \frac{\text{No. of blood smears collected during the month}}{\text{Population covered under surveillance}} \times 100$$

$$\text{API} = \frac{\text{No. of blood smears found +ve during the Year}}{\text{Population covered under surveillance}} \times 1000$$

The *Slide Positivity Rate (SPR)* among the blood smears collected through both active and passive surveillance gives more accurate information on distribution of malaria infection in the community over a period of time. Monthly SPR can be calculated to find out the seasonal rise and fall in malaria prevalence in the community. SPR among children 2-9 years of age can be utilized for comparison with pre-control Child Parasite Rates to assess the impact of control measures on local malaria endemicity and transmission. SPR in the age group of less than one year (Infant Parasite Rate) can be

utilized for assessment of the impact of control operations. The SPR of blood slides collected from cases currently having fever will be higher than the SPR of the slides collected from cases with history of fever. Therefore, higher positivity rates are obtained in blood smears collected at the PCD. Trends in SPR can be utilized for predicting epidemic situations in the area. If monthly SPR exceeds by 2½ times of the standard deviation observed in SPR of the preceding 3 years or preceding 3 months of the same year, an epidemic build up in the area can be suspected. Monthly or yearly trends of SPR are utilized to study the impact of control operations.

SPR is measured as follows:

$$\text{SPR} = \frac{\text{No. of blood smears found +ve for MP}}{\text{No. of blood smears examined}} \times 100$$

### Accelerated Urban Malaria Control Project

To address the malaria problem in urban areas, an Urban Malaria Scheme (UMS) was launched in 1971 with the objective to control malaria by reducing the vector population by way of recurrent anti-larval measures and detection and treatment of cases through the existing health services of the State/Urban Local Bodies. In this context, an “*Accelerated Urban Malaria Control Project*” is proposed in high endemic 28 towns/cities with GFATM support. The proposed project will be implemented by the Urban Local Self Govt, viz., Municipalities in collaboration with the local NGOs. The project goal is to reduce malaria morbidity and mortality in the project population (in 28 towns in 12 states) by 50% by 2015.

**Project Objectives :** Increasing the access to diagnosis and treatment in project areas, with particular focus on slums, construction sites/industrial estates/market areas with floating population. Majority of the population at risk at focused sites are poor and marginalized families, living below poverty line.

1. Malaria Transmission Risk Reduction through Integrated Vector Management mode (IVM).
2. Enhancing awareness towards behavioural impact about malaria prevention and control and promoting community, NGO and private sector participation.

### Kala-azar

Kala-azar, a disease transmitted by sand fly vector is a cause of high morbidity and mortality in the 4 states of Bihar, Jharkhand, Uttar Pradesh and West Bengal, with 165.4 million population living in these endemic areas (7). A total of 48 districts are endemic, with sporadic cases being reported from few other districts. The burden of disease since 2004 is given in Table - 9.

S.No	Year	Cases	Deaths
1	2004	24340	156
2	2005	31217	157
3	2006	39178	187
4	2007(Provisional)	22751	101

**Kala-azar Elimination Initiative** : The National Health Policy (2002) has set the goal for elimination of Kala-azar by year 2010. Elimination Programme is 100 per cent Centrally Supported (except regular staff of State governments & infrastructure). In addition to kala-azar medicines and insecticides, cash assistance is being provided to endemic states since December 2003 to facilitate effective strategy implementation by states.

#### Strategy

- Interruption of transmission through vector control by undertaking residual indoor insecticide spraying in affected areas, with DDT up to 6 feet height from the ground twice annually.
- Early diagnosis and complete treatment (Table - 10).
- IEC and community mobilization.

**Table - 10 : Treatment guidelines for Kala-azar**

Name of the Drug		Dosages
Injection SSG	Ist line drug for treatment	20 mg per kg. body weight daily for 20 days Maximum 8.5 ml per day
Injection Amphotericin-B	II nd line drug	1 mg. per kg. body weight alternate days 15 injections
Tablet Miltefosine		50 mg. bd below 12 years
		100 mg. bd above 12 years
		2.5 mg/kg body weight bd (56 tablets) for 28 days (adult Dose)

## Filariasis

Filariasis has been a major public health problem in India next only to malaria. India accounts for about 40% of the 120 million estimated cases globally with either disease or infection (Microfilaria cases). Cases of filariasis have been recorded from Andhra Pradesh, Assam, Bihar, Chattisgarh, Goa, Jharkhand, Karnataka, Gujarat, Kerala, Madhya Pradesh, Maharashtra, Orissa, Tamil Nadu, Uttar Pradesh, West Bengal, Pondicherry, Andaman & Nicobar Islands, Daman & Diu, Dadra & Nagar Haveli and Lakshadweep. It is a disabling & disfiguring disease and causes immense personalized trauma of the affected persons, even though it is not fatal. In 1955, the national filarial control programme was launched. The main control measures were mass DEC administration, antilarval measures in urban areas and indoor residual spray in rural areas.

The subsequent land marks in filarial control are given in Table - 11.

**Strategy for Elimination of Lymphatic Filariasis** : The strategy for achieving the goal of elimination is by annual mass drug administration of DEC for 5 years or more to the population excluding children below two years, pregnant women and seriously ill persons in affected areas to interrupt transmission of disease(8). Under the programme, Mass Drug Administration (MDA) campaign is organized and an annual single dose of Diethylcarbamazine citrate (DEC) tablets is administered to the eligible population in the affected areas on a single day designated as National Filaria Day. The drug distribution is made by door-to-door campaign. In addition, booths are established at health facilities, both in public and private sectors. Co-administration of DEC and Albendazole free of cost to be implemented in all the endemic districts by 2008 in a phased manner ( Albendazole kills intestinal helminthic infections also).

The transmission of infection can be stopped by treating the entire eligible population living in filarial endemic areas with Mass Drug Administration (MDA) with DEC given once a year for 5-7 years i.e. during the life span of adult filarial worm which gives birth to millions of microfilariae. With every treatment there will be a heavy reduction in the circulating microfilariae. This will markedly reduce or stop the transmission of the infection by the mosquitoes to other healthy persons.

DEC is available as 50 mg or 100mg tablets. The drug has been in use in India for more than five decades. It is a safe drug at the recommended doses. The dose of DEC is 6 mg/kg body weight. The dose schedule which was being followed is shown in Table - 12.

**Table - 12 : Conventional Drug Schedule**

Age (in year)	Dose of DEC
<2	Nil
2-3	50 mg
4-5	100 mg
6 - 11	150 mg
12 - 17	200 mg
> 18	300 mg

However, a simplified dose schedule was administered in Tamil Nadu for the mass drug administration campaigns. This was monitored by the state government and the Vector

**Table - 11**

S. No	Year	Activity	Remarks
1.	1996-97	Annual Mass Drug Admini-stration	Covered 41m population, extended to 77m population in 2002 and 400m in 2004 Strategy is to be continued for 5 years or more to the population excluding children below two years, pregnant women and seriously ill persons in affected areas to interrupt transmission of disease.
2.	2002	National Health Policy	Elimination of Lymphatic Filariasis (ELF) by the year 2015
3.	2003	NVBDCP	Convergence with other vector borne diseases



Control Research Centre (VCRC), ICMR and found to be safe and effective. The results were discussed by the National Task Force on Lymphatic Filariasis and the following simplified schedule has been recommended for MDA in the country (Table - 13).

Table - 13		
Age (in year)	DEC Dose	DEC (Tablet of 100 mg)
<2	Nil	Nil
2-5	100mg	1 tablet
6-14	200mg	2 tablets
15 & above	300mg	3 tablets

**Side effects of DEC :** DEC at the above doses is safe. Person with high mf density may experience general side effects in the form of headache, body ache, nausea and vomiting which result from the death of the Microfilariae. The side effects are temporary and subside in a day or two after symptomatic treatment. Rarely, localized reactions in the form swelling and tenderness of lymph nodes may occur. Temporary side effects that may occur in 1 to 10% of the population who may be carriers of microfilariae.

**Contraindications of DEC :** DEC is safe. However, as a matter of precaution, it should not be given to children under two years and to pregnant women. Severely ill patients may also avoid taking the drug.

The disease has been targeted for global elimination by 2020. Transmission control and disability alleviation are two pillars of the Global Elimination Strategy for Lymphatic Filariasis (GELF). Interruption of transmission can be achieved by mass annual drug administration of Diethylcarbamazine Citrate (DEC) to entire communities at risk of infection when community drug consumption rates are adequate. This is expected to result in reduction of transmission of lymphatic Filariasis to low levels and ultimately in the elimination of Filariasis, preventing new infections from occurring and protecting future generations from the disease.

## Dengue

Dengue Fever (DF) is an acute viral infection with the potential of causing large outbreaks. Death can occur in dengue haemorrhagic fever (DHF), which is a severe form of the disease. The National Health Policy (2002) has set the goal of reduction of mortality on account of Dengue by 50% by year 2010.

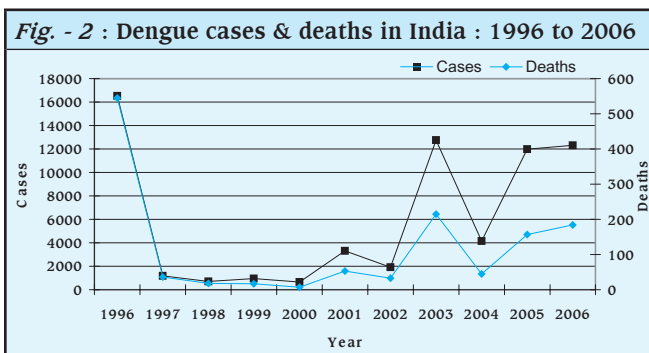
### Magnitude of the Problem

This is shown in the Fig. - 2.

Until June 2007 there were 256 cases and 2 deaths (9).

### Strategy for Control

- Disease and vector surveillance
- Vector management through source reduction with community participation
- Case management
- IEC initiatives
- Epidemic preparedness and early response.



### Guidelines for Integrated Vector Management for Control of Dengue / Dengue Haemorrhagic Fever under NVBDCP (10)

The key to control DF/DHF is adoption of a comprehensive approach by way of regular vector surveillance and integrated management of the Aedes mosquitoes through biological and chemical control that are safe, cost effective; and environmental management, legislations as well as action at household and community levels.

#### Vector Surveillance

Both larval and adult surveys to be carried out.

Larval surveys	Adult Surveys
i) House Index (HI)	i) Landing/biting collection
ii) Container Index (CI)	ii) Resting collection
iii) Breteau Index (BI)	iii) Oviposition traps
iv) Pupae Index (PI)	

**Environmental Management :** The major environmental management methods used for control of immature stages of dengue vector are:

(i) **Environmental modification:** Long lasting physical transformation of vector habitats. For example, improved water supply, mosquito proofing of overhead tanks, cisterns or underground reservoirs.

(ii) **Environmental manipulation:** Temporary changes to vector habitats that involve the management of essential and non-essential containers and management of or removal of natural breeding sites.

(iii) **Changes in human habitations:** Efforts are made to reduce man-virus contact by mosquito proofing of houses with screens on doors/windows.

**Personal Protection :** Insecticide treated mosquito nets have limited utility in dengue control, since the vector species bite during the day time. However, insecticide treated bed nets can be effectively used to protect infants and night workers while sleeping in daytime.

#### Biological Control

- Larvivorous fish are recommended for control of *Ae. aegypti* in large water bodies or large water containers.

- (ii) Endotoxin-producing bacteria, *Bacillus thuringiensis* serotype H-14 (Bt H-14) has been found to be an effective mosquito control agent.

**Chemical Control** : Chemical control measures (larvicides, adulticides) are recommended in permanent big water containers where water has to be conserved or stored because of scarcity of water or irregular and unreliable water supply.

**Larvicide** : Since *Ae. aegypti* breeds in clean water, which is stored and used for household purposes, as such all the larvicides, which are safe, without any odour or colour, have residual effect with low mammalian toxicity and do not pose any health hazard should be used. Temephos, an organophosphate compound meets all the above mentioned requirements and this insecticide is being used under the public health programme. The recommended dose for application of Temephos (50 EC) is 1 ppm (1 mg per liter of water).

**Adulticide** : The following methods are recommended for the control of adult *Ae. aegypti* mosquitoes:

- Pyrethrum spray
- Malathion fogging or Ultra Low Volume (ULV) spray

#### Legislative Measures

**Model civic byelaws** : Under this act, fine/punishment is imparted, if breeding is detected. These measures are being strictly enforced by Mumbai, Navi Mumbai, Chandigarh and Delhi Municipal Corporations.

**Building Construction Regulation Act** : Building byelaws should be made for appropriate overhead / under ground tanks, mosquito proof buildings, designs of sunshades, porticos, etc for not allowing stagnation of water vis-à-vis breeding of mosquitoes. In Mumbai, prior to any construction activity, the owners/builders deposit a fee for controlling mosquitogenic conditions at site by the Municipal Corporation

**Environmental Health Act** : Suitable byelaws should be made for the proper disposal/storage of junk, discarded tins, old tyres and other debris, which can withhold rain water.

**Behavior Change Communication (BCC) campaign** : The community needs to be educated to prevent breeding of mosquitoes.

### Chikungunya

Chikungunya is a relatively rare form of viral fever caused by an alpha virus that is spread by bite of *Aedes aegypti* mosquito. The name is derived from the Swahili word meaning 'that which bends up' in reference to the stopped posture developed as a result of the arthritic symptoms of the disease.

The preventive and control strategies are same as for dengue fever. Surveillance of fever cases with joint pains should be emphasized.

### Japanese Encephalitis

Directorate of National Vector Borne Disease Control Programme (NVBDCP) is a nodal agency for control and prevention of Japanese Encephalitis (JE) in the country (12). Reduction of mortality on account of Japanese Encephalitis by 50% by year 2010 has been envisaged under the National Health Policy (2002).

### Strategy

**Early case detection and treatment** : Early diagnosis & proper management of JE cases is of prime importance to reduce case fatality through strengthening of diagnostic and clinical management of JE cases, at PHCs/CHCs and District Hospitals. JE burden can be estimated satisfactorily if the facilities for JE confirmation are made available at least in referral hospitals. Considering the merits and demerits of each diagnostic test and the patients representing different clinical phases of infection, establishment of two diagnostic tests, one for detection of JE Reverse Transcriptase - Polymer Chain Reaction (RTPCR) and one for detection of virus antigen/virus genome is necessary.

#### Vector Control

**Chemical control** : Vector control is a serious challenge for JE control because of exophilic and exophagic behaviour of JE vectors, which limits effectiveness of conventional insecticides. *IRS is not recommended* for prevention and control for JE. However, in areas where vector is endophilic like *Mansonia annulifera*, IRS may be considered for vector control in high risk pockets. *Fogging is a very cost intensive vector control tool but with limited effect and therefore, not recommended as a routine vector control measure.* In case of JE outbreaks, since the vectors are mainly outdoor resting and outdoor feeding, peri-domestic fogging could be resorted to very carefully for containment of outbreaks. It has been suggested that most of the states *may resort to fogging whenever there is any JE outbreak* so that they can make their efforts visible in the community besides its impact on adult population of vector mosquitoes. Personnel protection methods and anti larval operations should also be taken.

**Reduction of breeding sources for larvae** : Two feasible methodologies have been demonstrated to control breeding of mosquitoes in rice fields. They are (i) water management system with intermittent irrigation system and (ii) incorporation of neem products in rice field. The water management is nothing but a strategy of alternate drying and wetting water management system in the rice fields. By using neem products as fertiliser in rice fields, they not only enhance the grain production but also suppress the breeding of culicine vector of JE.

**Larvivorous fish** : Introduction of composite fish culture for mosquito control in rice fields has been evaluated and proved to be successful. In other large and small water bodies release of larvivorous fish will prevent the JE vectors breeding.

**Biolarvicides** : Biocides like *Bacillus thuringiensis var. israelensis* and *Bacillus sphaericus* were promoted and anticipated to have great implications as biological larvicides against different mosquito species. Lack of suitable delivery system and short duration of larvicide effect restricted its use in vector control strategy.

**Reduction in man-vector contact** : Pyrethroid-impregnated bed nets and curtains have shown to reduce man-mosquito contact. However people may not prefer to use bed nets due to high temperature and humidity. In such areas, people do accept impregnated curtains instead of bednets. The limitation with this technology is the repeated impregnation of the curtains once in 6 to 9 months and periodic assessment of vectors for development of insecticide resistance to this product

**Control of Pigs** : Pigs constitute the amplifying host of JE and mosquitoes when bite pigs get infected that later infect humans. In JE endemic areas, pigs are found associated with human habitations. Control methods can include immunizing, slaughtering pigs, use of mosquito proof piggeries, etc. Segregating pigs at least 4-5 km away from human habitations can be used wherever it is possible by implementing some by-laws by local administration. Several studies conducted in Japan showed that pig immunization was effective in eliminating disease in pigs, which may reduce animal transmission and possibly lower human incidence. But it has not been used at the national level because pig immunization requires large number of newborn pigs to be immunized each year and because the period of vaccine effectiveness is limited.

**Behaviour Change Communication (BCC) or (Information Education Communication)** : Health Education should be imparted through all probable approaches on personal prophylaxis against vector, segregation of amplifier hosts by mosquito proofing and for early reporting of cases. Each endemic state should conduct a media advocacy and health education workshop a month prior to the expected season to educate media about the upcoming JE season and enlist their support in dissemination of messages on self protection methods and early case reporting at nearest medical facilities, etc., thereby avoiding any uninformed, adverse publicity.

**Immunization against JE** : There are three types of JE vaccine in widespread production and in worldwide use for control of JE. These are (i) inactivated mouse brain derived vaccine; (ii) inactivated primary hamster kidney cell-derived vaccine, and (iii) live attenuated vaccine. Under immunization protocol, immunization of pigs is to be considered which may reduce viral transmission by limiting or preventing viraemia in pigs. JE vaccines for pigs and equines have been used in various areas of China.

JE vaccine used in India is a formalin-inactivated product prepared from mouse brains infected with Nakayama JE virus manufactured at Central Research Institute, Kasauli, and Himachal Pradesh. The virus is purified with protamine sulphate treatment and ultra centrifugation. The final vaccine is supplied in a freeze dried form and reconstituted in 5.4 ml of sterile pyrogen free distilled water supplied by the laboratory. Pilot projects for JE vaccination have already started in few states in the country.

### Critical Appraisal of NVBDCP

**Technical manpower** : There is shortage of MPWs in all the states. In some states the shortage may be as high as 60% or more of the sanctioned strength. For the timely and regular surveillance these field level functionaries are crucial.

**Examination of blood smears** : The blood smears collected by ACD & PCD are to be examined expeditiously. Under the current situation, in most of the places, there is considerable time lag between collection and examination of blood smears due to inadequate facilities. The laboratory for malaria microscopy should be decentralized and brought as near to the community as possible. All efforts should be made to reduce the time lag between blood smear collection and examination by utilizing

existing facilities available both in public & private sectors.

**Urban Malaria** : It is perceived as a major threat; no structured health care delivery system like the primary health care system as in rural areas has been established. Funds are also allocated for larvicides / adulticides only and the operational costs of malaria control activities are met by the State/Urban Local Bodies. The coverage by anti larval measures however, limited and do not extend to the entire towns/city limits. The source reduction drives in domestic areas are hampered by denial of entry to public health personnel on security reasons, limited community mobilization and multi-sectoral collaboration and absence of appropriate civic legislations.

**Monitoring & Evaluation** : Enactment and enforcement of legislatures to prevent mosquito breeding in domestic and peri-domestic areas or work places, government/commercial buildings, construction sites, etc. are the responsibility of multiple authorities and often not implemented in a coordinated manner. No proper resource allocation is also made for most of these components, even though these are extremely critical to achieve the desired health objectives of health and well-being in urban areas.

**Use of insecticides for vector control** : Using insecticides in improper dosage and schedule promotes vector resistance. There is shortage of insecticides due to which incorrect chemical is used as an alternative or the same is diluted to meet the requirement.

**Community participation** : It is inadequate.

**Non Uniformity in treatment** : No uniformity in medical practitioners regarding treatment of vector borne diseases.

### Summary

NVBDCP is an umbrella programme for prevention and control of major vector borne diseases of public health importance namely Malaria, Filariasis, Japanese encephalitis (JE), Kala azar and Dengue / Dengue Hemorrhagic Fever (DHF). It came into existence in 2003.

The Mission is to have Integrated accelerated action towards reducing mortality on account of malaria, dengue, Japanese Encephalitis by half and elimination of Kala-azar by year 2010 and elimination of Lymphatic Filariasis by 2015. The strategy lays emphasis on Training of health personnel in the diagnosis of vector-borne diseases and appropriate treatment including referral, Improved reporting, recording and monitoring of vector-borne diseases, Monitoring drug and insecticide resistance, Use of standardised protocol for the diagnosis and management of these diseases, Involvement of PRIs and research studies in vector borne diseases. The implementation at the national level is by Directorate of National Vector Borne Diseases Control Programme, at the state level by Regional Offices for Health and Family Welfare (ROH & FW) located at state HQ, district level by District Malaria Offices and Primary Health Centres at the village level. National Rural Health Mission will focus on all the diseases covered under NVBDCP.

The strategies for malaria control under the programme has been Early case Detection and Prompt Treatment (EDPT), Vector control (Chemical, Biological Control methods), Personal Prophylactic



Measures, Community Participation and Environmental Management & Source Reduction Methods. National antimalaria drug policy essentially provides a framework for the safe and effective treatment of uncomplicated and severe malaria as well as prevention of malaria in vulnerable groups, such as pregnant women and young children. All fever cases should preferably be investigated for malaria by microscopy or Rapid Diagnostic Kit (RDK). RDK is a immunochromatographic test. It detects *Plasmodium falciparum* histidine rich protein in blood. The first line of treatment is Chloroquine and the second line for *P. falciparum* is Artesunate combination therapy (ACT) consisting of Artesunate+ Sulphadoxine/Sulphalene+Pyrimethamine. In case of resistance to these formulations quinine would be the drug of choice. ACT is not to be used against treatment of *P. vivax* cases as it is not effective against it. Chemoprophylaxis for malaria: In chloroquine sensitive areas chloroquine is to be given and in Chloroquine resistant areas it is to be supplemented by proguanil.

Insecticides under NVBDCP for malaria control are DDT, Organophosphorous compounds (Malathion), Synthetic Pyrethroids (i) Deltamethrin 2.5% WP, (ii) Cyfluthrin 10% WP, (iii) Alphacypermethrin 5% WP (iv) Lambda cyhalothrin 10% WP and (v) Bifenthrin 10 WP Wettable powder (WP) formulations are used for indoor residual sprays and emulsion concentrate (EC) formulations are used for larval control. Malaria vectors in India are resistant to DDT alone or double resistant to HCH or triple resistant to DDT, HCH, malathion and quadruple resistant to DDT, HCH, malathion and Deltamethrin (synthetic pyrethroid), however HCH has been phased out in 1997.

Malaria surveillance under NVBDCP is done through Fortnightly Domiciliary visits by MPW (male), Fever Treatment Depots (FTDs), Passive Case Detection (PCD), Rapid Fever Survey, Mass survey and Drug Distribution Centre (DDC). The National Health Policy (2002) has set the goal for elimination of Kala-azar by year 2010. Strategy under NVBDCP includes Interruption of transmission through vector control by undertaking residual indoor insecticide spraying in affected areas, with DDT up to 6 feet height from the ground twice annually, Early diagnosis & complete treatment and IEC & community mobilization.

The National Health Policy (2002) has set the goal for elimination of Lymphatic Filariasis (ELF) by the year 2015. The strategy for achieving the goal of elimination is by Annual Mass Drug Administration of DEC for 5 years or more to the population excluding children below two years, pregnant women and seriously ill persons in affected areas to interrupt transmission

of disease. The National Health Policy (2002) has set the goal of reduction of mortality on account of Dengue by 50% by year 2010. Strategy for dengue control comprise of Disease and Vector Surveillance, Vector management through source reduction with community participation, Case management, IEC initiatives and epidemic preparedness and early response.

Reduction of mortality on account of Japanese Encephalitis by 50% by year 2010 has been envisaged under the National Health Policy (2002). The strategy includes Early case detection and treatment, Vector Control (Reduction of breeding sources for larvae, use of Larvivorous fish, Biolavicides), Reduction in man-vector contact and control of Pigs. JE vaccine used in India is a formalin-inactivated product prepared from mouse brains infected with Nakayama JE virus manufactured at Central Research Institute, Kasauli, and Himachal Pradesh.

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## Further Suggested Reading

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Puja Dudeja &amp; Ashok K. Jindal

*"Leprosy work is not merely medical relief, it is transforming frustration in life into the joy of dedication, personal ambition into selfless service." Mahatma Gandhi*



The NLEP Emblem symbolizes beauty and purity in lotus. The Emblem captures the spirit of hope positive action in the eradication of Leprosy.

### Evolution of Leprosy control in India

The details are given in Table - 1

The National Leprosy Control Programme (NLCP) was launched in 1954 (3). The strategy of NLEP was based on controlling the disease through reduction in the quantum of infection in the population, and reduction in infective source, thus breaking the chain of disease transmission. The program, therefore, had been planned on the following basic activities :

1. Survey and case detection.
2. Registration of cases for treatment.
3. Provision of continuous treatment with Dapsone to all cases, as close to their homes as possible.
4. Education of patients, their families and community at

large about leprosy.

5. Correction of deformities through deformity care programme.

Treatment with MDT was introduced under NLEP in phased manner in the year 1983 and programme was renamed as National Leprosy Eradication Programme. At the 44th World Health Assembly held in 1991, WHO and its Member States committed themselves to eliminate leprosy as a public health problem by the year 2000, elimination being defined as prevalence below one case per 10,000 population. The Government of India was also a signatory to this commitment. To enhance the process of elimination, the first World Bank supported project on NLEP was started in the year 1993-94 and MDT made available to all the registered cases. The Second World Bank supported National Leprosy Elimination Project was started for a period of 3 years and was implemented with the following objectives.

### Objectives of NLEP II (2001 onwards)

**1. To decentralize the NLEP responsibilities to the states/UT:** State level societies will be formed in 24 states and funding to the districts will be done by state societies. State societies will not be needed in the 8 smaller states/ Union Territories since the district societies there are adequate for channeling funds.

**2. Integration of Leprosy Control Activities with the general health services :** To accomplish integration of leprosy services with general health care system in 27 low endemic states and proceed with integration as rapidly as possible in the 27 low endemic states. In the 27 low endemic states/ UTs integration will be affected in all districts during the first project year

**Table 1: Evolution of leprosy control in India**

Year	Remarks
Pre independence	Initially Leprosy patients were isolated and segregated. Several statutory acts and laws were also enacted during this time against them. In India 'The Lepers Act 1898' was enacted, which discriminated against the Leprosy patients and segregated them socially. This act has since been repealed by Union Government & all the States & UTs.
1955	Government of India launched National Leprosy Control Programme with the objective of controlling leprosy with Dapsone.
1983	Launched National Leprosy Eradication Programme(NLEP) and introduced MDT for treatment
1991	WHO declaration to eliminate leprosy at global level by 2000
1993 - 2000	World Bank supported NLEP - I
1998 to 2003	After integration of leprosy services with GHC system in 2002-03, leprosy diagnosis and treatment services are available free of cost at all the Primary Health Centres (PHCs) in all the districts in India.
2002	National Health Policy had set the goal of elimination of leprosy (i.e., to reduce the number of cases to < 1/10,000 population) by the year 2005
2001 - 2004	World Bank supported NLEP - II
2005	National programme continues with GOI funds
2005	India achieved elimination of leprosy at National Level in December' 05, when the recorded Prevalence Rate (PR) in the country was 0.95/10,000 (<1/10,000) population.(1,2). By March 2007, the prevalence rate of leprosy in the country had declined to 0.72 per 10,000 population and 28 states/UTs have achieved the goal of leprosy elimination. The remaining 7 States/UTs viz. Bihar, Chhattisgarh, Jharkhand, West Bengal, Chandigarh, D&N Haveli and Delhi are having PR of > 1 per 10,000 population and are progressing towards elimination. Out of 611 districts, 487 (79.71%) districts have achieved the elimination status

itself. In the 8 high endemic states a mixed approach has been followed from the first year onward with the general health service staff offering leprosy services that included case finding and treatment. The vertical staff is focusing on covering previously un-reached areas as well as providing support to general health service.

### 3. To achieve elimination at national level

#### Strategies

**1. Special Action Project for Elimination of Leprosy (SAPEL) for rural and Leprosy Elimination campaigns for urban areas:** It is an initiative aimed at providing MDT services in difficult to reach areas.

**2. Modified Leprosy Elimination Campaign (MLEC):** It is organizing camps which include a package of teaching, training, intensified IEC, case detection and prompt MDT. Wide publicity is given prior to camp. Five such nation wide campaigns have been carried out.

#### Activities

1. Early detection through active surveillance by the trained health workers
2. Regular treatment of cases by providing Multi-Drug Therapy (MDT) at fixed in or centers a nearby village of moderate to low endemic areas/district
3. Intensified health education and public awareness campaigns to remove social stigma attached to the disease.
4. Prevention of Disability & Medical Rehabilitation
5. Leprosy Training of General Health Services functionaries
6. Information Education and Communication (IEC) using Local & Mass Media for reduction of Stigma & Discrimination.
7. Monitoring & Evaluation
8. Inter-sectoral collaboration

#### Infrastructure

NLEP was implemented through the establishment of Leprosy control units (LCU), Survey Education and Treatment centers (SET) and urban leprosy centers. The leprosy control units were established in endemic areas with one medical officer, two non medical supervisors and twenty para medical workers. Each LCU covered a population of 4.5 lacs. The staff at SET center comprised of one paramedical worker for 20-25 thousand population and one non medical supervisor for 5 paramedical workers. The SET centers were attached to the PHCs and were under the medical officer in charge of PHC. Mobile leprosy treatment units provide services to leprosy patients in non endemic areas. Each mobile unit consisted of one medical officer, one non medical supervisor, two paramedical workers and a driver. There were two MLTU for moderately endemic and one for low endemic states.

At state level state leprosy officer was the chief coordinator and technical advisor to the concerned state govt. At the center, leprosy division of directorate general health services was responsible for planning, supervision and monitoring of the program. The division is under the control of Deputy Director General who advised govt on all anti leprosy activities. Presently NLEP has been integrated into the general health services system under NRHM. The program will run under the

same guidelines of GOI but will conform to Indian Public Health Standards as laid down under the mission. The minimum services available at the community health center should be diagnosis of leprosy, treatment of cases, management of reactions and advice to patients on disability prevention & care.

**MDT :** The details are given in Table - 2, 3 and 4

Table - 2 : MDT Regimen		
Type of leprosy/ Duration of treatment	Type of regimen	Characteristics
PB (Pauci - bacillary) Six pulses in 6-9 consecutive months	PB (Adult) / PB (child) Less severe type	1-5 patches &/ or involvement of one nerve
MB (Multi bacillary) Twelve pulses in 12-18 consecutive months	MB (Adult)/ MB (child)	More severe type 6 or more skin patches & or involvement of two or more nerves

#### Surveillance after treatment

- PB cases are clinically examined once a year for minimum two years after completion of treatment.
- MB cases are clinically examined once a year for a minimum period of five years after completion of treatment.

Table - 3 : Dosage in Adults	
Multibacillary (Adult)	Rifampicin 600mg monthly given under supervision
	Dapsone 100mg daily self administered
	Clofazimine 300mg once monthly supervised; 50mg daily, self administered (When clofazimine is totally unacceptable owing to discoloration of skin, 250- 375mg of ethionamide or propionamide can be administered as daily dose).
Pauci bacillary (Adult)	Rifampicin 600 mg monthly given under supervision Dapsone 100mg daily self administered

Table 4 : Dosage for children 10-14 years	
Multibacillary (Child)	Rifampicin 450mg monthly given under supervision; Dapsone 50mg daily self administered; Clofazimine 150mg once monthly supervise and 50mg on alternate day, self administered
Pauci bacillary (Child)	Rifampicin 450mg monthly given under supervision; Dapsone 50mg daily self administered

#### Information, Education and Communication (IEC)

**Objectives of IEC in moderately/low endemic states :** This would be to encourage greater voluntary self-reporting, as the strategy for case detection in these states.

**Objectives of IEC in high endemic states :** In five high endemic states, where active search is conducted during MLEC, the objective of IEC is to create general awareness of MLEC and signs and symptoms of leprosy to provide support for and prepare the ground for MLEC. The targets are clients, influencers, and providers, particularly from general health services and private providers. Special client focus groups of IEC in the next phase are women, children, difficult to reach groups-urban remote areas, etc.

### Training

All staff of the general health services in general health services in government hospitals, PHCs, CHCs, are expected to be trained to detect, treat, refer and to prevent and rehabilitate disability.

### Monitoring and Evaluation of NLEP

NLEP has an inbuilt information system for monitoring and supervision of the programme activities at Central, State, District & Peripheral level.

**Simplified Information System (SIS) :** SIS was introduced in 2002 under which simplification of information system was done, so that the newly involved GHC service personnel can easily adapt to the system of record keeping, validation of records, reporting and monitoring of the programme at PHC/Hospital, District and State level. This system has drastically improved recording, reporting and its transmission. The programme is monitored routinely at District, State and Central level through scrutiny of regular monthly reports. The system has been computerized for compilation of district reports at state level.

**Leprosy Elimination Monitoring (LEM) :** LEM exercise was undertaken with WHO support through the NIH&FW, New Delhi, to assess the programme achievement in identified indicators during the year 2002, 2003 and 2004(5). Immediate actions were initiated on the deficiencies observed.

### Involvement of NGOs

NGOs are involved in leprosy elimination activities for many years and their contribution has been a positive impact in reducing the prevalence of leprosy. There are 285 NGOs working in the field of leprosy throughout the country and 54 NGOs are getting grant-in-aid from government of India for Survey, Education and Treatment (SET) scheme. Beside routine activities, some are also providing facilities for hospitalization and disability and ulcer care. Few NGOs are involved in conducting reconstruction surgeries. The NGOs serve in remote, inaccessible, uncovered, urban slums, industrial / labour population and other marginalized population groups. The various activities undertaken by the NGOs are, IEC, Prevention of Impairments and Deformities, Case Detection and MDT Delivery.

**ILEP Agencies :** International Federation of Anti-leprosy Association (ILEP) is actively involved as partner in NLEP. In India ILEP is constituted by 10 Agencies viz. The Leprosy Mission, Damien Foundation of India Trust, Netherland Leprosy Relief, German Leprosy Relief Association, Lepra India, ALES, AIFO, Fontilles - India, AERF - India and American Leprosy Mission. Activities carried out by ILEP are - capacity building of GHC staff, provision of technical support at various level

and providing re-constructive surgery services and support to various NGOs in the country carrying out leprosy related activities.

**Leprosy Institutions :** Four premier Leprosy Institutes are working under Directorate General of Health Services, Ministry of Health & F.W., Government of India viz. CLTRI, Chengalpattu, RLTRI, at Aska, Raipur and Gouripur are involved in research (basic and applied ) in Leprosy and Training of different categories of staff involved for Leprosy elimination. These Institutes also play important role in management of referral patients, providing quality care to chronic ulcer and disabled patients with the help of Minor & Major Reconstructive Surgeries.

### Urban Leprosy Control Programme

To address the complex problem like larger population size, migration, poor health infrastructure and increasing prevalence in urban areas, there was a need for Urban Leprosy Programme. Urban Leprosy Control Programme has been implemented since 2005 under which assistance is being provided by Govt. of India to urban areas having population size of more than 1 lakh. For the purpose of providing graded assistance, the urban areas are grouped in four categories i.e. Township-I, Medium Cities-I, Medium Cities-II, Mega Cities.

### Post Elimination Period - NLEP

In the Post elimination period, NLEP needs to expand the scope of leprosy services provided to the patients, their families and community at large. The aims and objective under the 11th Plan (2007-2012) are as below. These objectives are also in conformity with the global strategy issued by WHO (2006-2010).

1. Further reducing the leprosy burden in the country.
2. Provide good quality leprosy services.
3. Enhance Disability Prevention and Medical Rehabilitation.
4. Increase advocacy towards reduction of stigma and stop discrimination and Strengthen monitoring and supervision.

**New Paradigm :** In view of the need to sustain leprosy services for many years to come, there has to be a shift from a campaign like elimination approach, towards the long term process of sustaining integrated high quality leprosy services, which in addition to case detection and treatment with Multi Drug Therapy, also include prevention of disability and rehabilitation. To get the programme move in the desired direction, the New Paradigms in NLEP have been detailed as below:

**Burden of leprosy :** The burden of leprosy can be looked at in three ways:

- Firstly, the most relevant epidemiological measure of the burden of leprosy is the incidence of disease, which is the number of people developing leprosy during a defined period usually one year. Because leprosy is an insidious disease, number of cases detected/ registered for treatment is generally lower than the actual number of incident cases for that time. Hence, incidence is difficult to measure directly and New Case Detection Rate (NCDR) is used as a proxy for incidence rate.
- Secondly, the burden may be related to the registered prevalence of disease, which is the number of people on



treatment at a certain point of time. Although registered prevalence was a useful indicator to achieve the leprosy elimination milestone, it is not adequate indicator to reflect changes in the epidemiological trend of leprosy.

- Thirdly, the burden of leprosy can be viewed as disability and deformity produced by leprosy.

**Improving the quality of services :** The quality of care depends on the quality of technical supervision provided by the program and availability of strong back up from an effective referral system. Quality leprosy services means treatment by MDT is available at all the health units without any geographical, economic or gender barriers. Services provided are patient-centred; observe patient's rights, including the rights to timely and appropriate treatment, privacy and confidentiality. The quality leprosy services addressing each aspect of case management, based on firm scientific evidence like diagnosis is carried out timely and accurate with supportive counselling, timely treatment with MDT, free of charge in a user friendly environment; appropriate disability prevention interventions; referral for complications and appropriate rehabilitation and maintaining simple records and encourage review and evaluation.

**Prevention and management of impairments and disabilities:** The current situation with regard to the number of persons living with leprosy - related disabilities and impairments may need reassessment, particularly at national level. In addition, programme should ensure that persons affected by leprosy have access to services by other programmes dealing with other disabling diseases or conditions. Interventions aimed at preventing disabilities / impairments from occurring and/or worsening include early detection and effective management of leprosy-related reactions and nerve damage, proper counselling on self care, participation of household members in home based care, development and use of locally produced and culturally and aesthetically acceptable footwear and other appliances.

**Improving community awareness and involvement :** The major theme of community awareness is to provide accurate information about the disease, its curability and availability of services at the nearest health facility. The objective of such IEC efforts should be to encourage self - reporting of new cases and to reduce stigma and discrimination. There are four key messages for the general public include early signs of leprosy, its Curability, encourage people to support leprosy affected people to live a normal a life and no need to fear as disease can be managed just like any of other diseases; can be expressed in many different ways.

**Support of National Rural Health Mission :** ASHA could be utilized for early detection of suspected cases of leprosy, referral of such cases to nearest health centre for confirmation & completion of treatment. *Rogi Kalyan Samities* at PHC, CHC and district hospitals are autonomous registered bodies constituted at each level to facilitate in management of hospitals and delivery of quality care to patients. The NLEP will be benefited by working in coordination with other programs under the NRHM. District Health Mission which is chaired by the president of Zila Parishad may be helpful for advocacy of the program.

## Critical Appraisal

Leprosy in present day scenario is still associated with social stigma. There are various myths related to the disease which interfere with health seeking behavior particularly early detection and treatment. Resistance to anti leprosy drugs i.e Dapsone, Rifampicin and Clofazimine has already been reported in few studies. No alternative regime is presently available for such cases. Achieving elimination will give a false sense of security against transmission of infection. Leprosy is a social disease however no efforts have been made for elimination of social factors related to the disease. There are many problems related to integration of program with general health services. Leprosy has always received low priority when compared to HIV/AIDS. Very little has been done in the area of rehabilitation of leprosy cases.

## Summary

The National Leprosy control programme (NLCP) was launched in 1954. Treatment with MDT was introduced under NLEP in phased manner in the year 1983 and programme was renamed as National Leprosy Eradication Programme. The objectives of NLEP II (2001 onwards) have been To decentralize the NLEP responsibilities to the states/UT, Integration of Leprosy Control Activities with the general health services and To achieve elimination at national level. India achieved elimination of leprosy at National Level in December' 05, when the recorded Prevalence Rate (PR) in the country was 0.95/10,000 population.

The main activities are - Early detection through active surveillance by the trained health workers, Regular treatment of cases by providing Multi-Drug Therapy (MDT) at fixed in or centers a nearby village of moderate to low endemic areas/district, Intensified health education and public awareness campaigns to remove social stigma attached to the disease and Prevention of Disability & Medical Rehabilitation

The other strategies followed were Special Action Project for Elimination of Leprosy (SAPEL) for rural and Leprosy Elimination campaigns for urban areas: It is an initiative aimed at providing MDT services in difficult to reach areas. Modified Leprosy Elimination Campaign (MLEC): It is organizing camps which include a package of teaching, training, intensified IEC, case detection and prompt MDT Modified Leprosy Elimination Campaign (MLEC): It is organizing camps which include a package of teaching, training, intensified IEC, case detection and prompt MDT.

NLEP was implemented through the establishment of Leprosy control units (LCU), Survey education and Treatment centers (SET) and urban leprosy centers. Presently NLEP has been integrated into the general health services system under NRHM. The program will run under the same guidelines of GOI but will conform to Indian Public Health Standards as laid down under the mission. The minimum services available at the community health center should be diagnosis of leprosy, treatment of cases, management of reactions and advice to patients on disability prevention and care.

For Treatment leprosy cases are divided into Paucibacillary (Less severe type 1-5 patches &/or involvement of one nerve ) and Multibacillary (More severe type 6 or more skin patches &



or involvement of two or more nerves). PB cases are clinically examined once a year for minimum two years after completion of treatment. MB cases are clinically examined once a year for a minimum period of five years after completion of treatment.

Monitoring and Evaluation of NLEP is through Simplified Information System (SIS) was introduced in 2002 under which simplification of information system was done, so that the newly involved GHC service personnel can easily adapt to the system of record keeping, validation of records, reporting and monitoring of the programme at PHC/ Hospital, District and State level. was introduced in 2002 under which simplification of information system was done, so that the newly involved GHC service personnel can easily adapt to the system of record keeping, validation of records, reporting and monitoring of the programme at PHC/ Hospital, District and State level.

In the Post elimination period, NLEP needs to expand the scope

of leprosy services provided to the patients, their families and community at large. The aims and objective under the 11th Plan (2007-2012) are to further reduce the leprosy burden in the country, Provide good quality leprosy services, Enhance Disability Prevention and Medical Rehabilitation, Increase advocacy towards reduction of stigma and stop discrimination and Strengthen monitoring and supervision.

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## Pilot Project On Prevention and Control Of Human Rabies Under 11th Five Year Plan

*Puja Dudeja & Ashok K. Jindal*

Rabies is an acute viral encephalomyelitis which is invariably fatal but can be easily prevented. Dog is the principal reservoir of Rabies in India. The goal of rabies control is to prevent human death and control dog rabies so that it no longer remains a major public health problem. This will reduce the socioeconomic losses from the disease. In India, cases of rabies occur throughout the year and in all parts of the country with the exception of Andaman and Nicobar Islands. It is estimated that about 20,000 people die of rabies every year. This figure may not be exact as there is no organized system of surveillance of rabies cases and hence lack of reliable data. There is at present no comprehensive National Rabies control Programme in India. Various organizations are currently involved in control activities without any intersectoral coordination. Existing rabies control activities are being carried out by Municipal Corporations/ Committees, Cantonments etc. in their respective areas.

**Objectives** : The broad objectives of the proposed pilot rabies control programme are firstly, prevention of Human deaths due to rabies and secondly, reducing the transmission of disease in animals.

**Target** : The specific target is reduction of rabies deaths in human beings by at least 50% by the end of Five year plan in the pilot project areas. For verification, the retrospective data will be collected from pilot project areas and continuous surveillance will be maintained till the end of XI five year plan.

**Implementation** : The programme will be implemented as a pilot project, with National Apex Committee for prevention and

control of rabies as the Nodal Agency. The committee will be chaired by DGHS with Animal husbandry Commissioner, Joint Commissioner, Live Stock and Health; Joint Commissioner, Ministry of Information and Broadcasting, Govt of India; Director NICD; Director IVRI Izzatnagar; Director PII, Coonor as members and HOD, Zoonosis Division NICD as member secretary. Initially the programme is proposed to be implemented on pilot basis in two major cities i.e. Delhi and Pune.

**Components of the programme** : There will be 2 components, as follows :

### Human Component

1. Local Health Authorities will make available infrastructure and logistics in the pilot project area, areas for post exposure treatment.
2. Facilities of wound wash will be provided at anti rabies clinic by the local health authorities.
3. Surveillance system will be strengthened to generate reliable data. Attempts will be made to integrate surveillance under IDSP work.
4. Development of trained manpower.
5. Ensuring community participation in IEC activities.
6. Involvement of NGOs and private sector.
7. Strengthening the Nodal agency for human rabies control (NICD, Delhi) for monitoring and evaluation of human component.
8. Operational Research with focus on study of factors leading to rabies deaths and minimizing animal bites.

### Animal Component

1. Vaccination of stray dogs
2. Sterilization of dogs and population management
3. Waste management
4. Dog movement restriction etc.

## Further Suggested Reading

1. Working gps/Steering Committees/Task Force for the 11th five year plan 2007-2012. Plg Com.GOI. Available at <http://planning.comm.nic.in/plans/11thf.htm>.

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India is the first country in the world to establish the National Guinea Worm Eradication Programme in 1983-84 as a centrally sponsored scheme on 50-50 sharing between Centre and States with the objective of eradicating guinea worm disease from the country. The objective of the Guinea Worm Eradication Programme was to achieve zero guinea worm disease incidence in the country. The programme achieved zero guinea worm disease status in 1997, against 40,000 cases occurring annually in 1984. Banwari Lal, 25 years old, from Jodhpur in Rajasthan, was the last case in India in 1996 (1). "Zero" incidence has been maintained since August 1996 through active surveillance and intensified field monitoring in the endemic areas. In the Meeting of WHO in February 2000, India has been certified for the elimination of Guinea Worm Disease and on 15th February 2001, declared India as "Guinea Worm Disease Free (2)".

The important strategies adopted to eradicate the Guinea Worm (GW) were (2) :

1. GW case detection and continuous surveillance through active case search operations and regular monthly reporting.
2. GW case management.
3. Vector Control by the application of Tempos in unsafe water sources eight times a year and use of fine nylon mesh/ double layered cloth strainers by the community to filter Cyclops in all the affected villages.
4. Health education.
5. Trained manpower development.
6. Provision and maintenance of safe drinking water supply on priority in GW endemic villages.
7. Concurrent evaluation and operational research.

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Due to rapid ecological changes, many zoonoses have emerged as epidemics. Leptospirosis causes significant morbidity and mortality in human beings especially in coastal region of the country. The objectives of the programme are to establish surveillance in the country and to reduce morbidity and mortality due to leptospirosis in India. The control programme will be implemented in a phased manner. In the first phase it will be conducted in Kottayam district of Kerala and South Gujrat. The reduction in Morbidity and Mortality would be an indicator of successful implementation of the programme.

**Strategy** : The strategy includes Development of Data Base through routine and IDSP system; Identifying vehicle of transmission; Identification of serovar in prevalent states;

Identifying the causes of upsurge; Strengthening diagnostic facilities; and, Improving management facilities.

**Initiatives** : The three major factors responsible for leptospirosis are salinity of soil, adequate moisture and presence of microorganisms in reservoir / carrier hosts. Intersectoral coordination among the departments of National Bureau of Soil Survey and Land Resource Management, Department of Meteorology, Rodent control Board of India and department of Animal Husbandry of endemic states will be taken. The areas from where the disease has not been reported but where similar ecological factors prevail will be separately earmarked as 'Leptospira Prone Areas'. A monitoring and evaluation system for above activities will be set up (1).

### References

1. Working gps/Steering Committees/Task Force for the 11th five year plan 2007-2012. Plg Com.GOI. Available at <http://planning.comm.nic.in/plans/11thf.htm>.

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The **Red Ribbon** is an international symbol of AIDS awareness that is worn by people all year round and particularly on World AIDS Day (December 1) to demonstrate care and concern about people living with HIV/AIDS and to remind others of the need for their support and commitment. The concept of a World AIDS Day originated at the 1988 World Summit of Ministers of Health on programs for AIDS prevention. Since then, it has been taken up by Govts., International organisations and charities around the world.



**Evolution** : Evolution of National AIDS control programme is given in Table - 1.

Table 1

Year	Remarks
1986	First HIV case reported in India
1987	AIDS control programme was launched
1992	Ministry of Health and Family Welfare set up a National AIDS Control Organization (NACO)
1986-1992	Surveillance launched in 55 cities in the three states and the programme activities were left to the states without a strong central guidance
1992-1997	National AIDS Control Project (Phase I), extended to 1999(1)
1999-2004	National AIDS Control Programme (Phase II), extended to 2007
2002	National AIDS Prevention & Control Policy (2)
2002	National Health Policy : Zero level growth of new HIV/AIDS by 2007
2007-2012	National AIDS Control Programme (Phase III)

### National AIDS Control Programme Phase I (1992-99)

During this phase, the National AIDS Control Project was developed for prevention and control of AIDS in the country. The ultimate objective of the project was to slow the spread of HIV to reduce future morbidity, mortality, and the impact of AIDS by initiating a major effort in the prevention of HIV transmission. There was a nation wide capacity building in managerial and technical aspects of the programme. It also aimed at increasing awareness and condom usage in targeted high risk population.

### National AIDS Control Programme Phase II (1999-2004)

The Phase II of the National AIDS Control Programme has become effective in 1999. It is a 100% Centrally sponsored scheme implemented in 32 States/UTs and 3 Municipal Corporations namely Ahmedabad, Chennai and Mumbai through AIDS Control Societies. The focus in this phase was to slow the spread of HIV infection, decrease the mortality and morbidity associated with HIV infection and minimize the socioeconomic impact resulting from HIV infection(3,4).

### National AIDS Control Programme Phase III (2006-12)

NACP-III is based on the experiences and lessons drawn from NACP-I and II, and is built upon their strengths.

**Goal** : To halt and reverse the epidemic in India over the next five years by integrating programmes for *prevention, care and support and treatment*.

**Objectives** : To reduce the rate of incidence by 60 per cent in the first year of the programme in high prevalence states to obtain the reversal of the epidemic, and by 40 percent in the vulnerable states to stabilise the epidemic.

#### Strategy

- Prevent infections through saturation of coverage of high-risk groups with targeted interventions (TIs) and scaled up interventions in the general population.
- Provide greater care, support and treatment to larger number of People Living with HIV/AIDS (PLHA).
- Strengthen the infrastructure, systems and human resources in prevention, care, support and treatment programmes at district, state and national levels.
- Strengthen the nationwide Strategic Information Management System.

#### Programme Implementation

**Intensive coverage of High Risk Groups through targeted interventions** : Surveys conducted under NACP II indicated presence of high risk groups in all parts of the country and a focused strategy was launched to raise their awareness, motivating them to adopt safe behavior, improving their access to preventive services and tools such as condoms. NACP III will aim at increasing the coverage of such services especially for high risk groups, identified as sex workers and their clients, transgender population, men having sex with men (MSM) and IV drug users in urban and rural areas. The 'bridge population' identified as truck drivers, street children, prison inmates and migrant workers would also receive special attention under NACP III. The essential elements of target interventions proposed under NACP III are access to behaviours change communication, prevention services such as condoms, STI services, needles and syringes, treatment services in form of STI clinics, drug substitutions for IV drugs, antiretroviral therapy and creation of an enabling environment under all project sites.

**Intensification of interventions among general populations:** Although 99 % of Indian population is not infected, a high level of vulnerability exists, especially, among young people, women, migrant workers and marginalized populations. NACP

III aims at reducing risk, vulnerability and stigma through increased awareness and targeted behavior change. The program is considered to be effective when 99 % of population can recall three modes of HIV transmission and two methods of prevention. This is to be achieved through increased awareness through communication, social mobilization & advocacy and through integration and expansion of integrated HIV related services like HIV counseling, testing, STI treatment, Prevention of Parent To Child Transmission and Post Exposure Prophylaxis (PEP) at sub district hospital, community health centers and PHCs.

**Sexually Transmitted Disease (STD) Control Program :** Evidence suggests that likelihood of contracting HIV infection is 8-10 times higher in presence of other STDs, particularly genital ulcers. In view of the established relationship between HIV and STIs, Min of Health & Family welfare adopted a policy of integrating HIV/AIDS and STD control within the existing health care system. Under the program, emphasis is given to comprehensive treatment of STIs at primary health care level and integration of non-stigmatized services with greater accessibility and acceptability by patients and community, while maintaining confidentiality and privacy of the patients. NACO took over the STD control program (in operation since 1946) in 1992 and made it an integral component of AIDS control policy. After overcoming the shortcomings of the erstwhile STD control program (like poor accessibility, stigma), NACP III continues to provide STI services based on syndromic approach, with the aim to improve etiological management of STIs (5). The broad objective of STI control program under NACP III are to reduce STD infections, thereby controlling HIV transmission by minimizing a risk factor and to prevent short and long term morbidity & mortality due to STDs. This is to be achieved through the following strategies :

- (i) Development of adequate & effective program management by strengthening existing STD clinics, appointing STD program officers in State AIDS control societies and identification of district nodal officers who would supervise working of STD clinics.
- (ii) Promotion of IEC activities for prevention of transmission of STD & HIV infections in form of activities to educate people for responsible sexual behavior, safer sex and greater condom usage.
- (iii) Improving case management including diagnosis, treatment, counseling, partner notification and screening for other diseases, in form of two sets of guidelines for PHC level and for referral of STD specialists.
- (iv) Increasing access to health care for STD by strengthening existing STD clinics, increasing health seeking behavior through IEC & NGOs and establishing first Referral Units in collaboration with Dept of Family welfare.
- (v) Creating facilities for diagnosis & treatment of asymptomatic infections by providing trained lady medical officer and sensitizing community through family Health Awareness Campaigns for early detection and referral to PHCs.

*(Details of syndromic approach to management of STDs is given in detail in the chapter on STDs).*

### **Family Health Awareness Campaign (FHAC)**

These are campaigns for 15 days, organized by the states to address the issue of RTIs/STDs and HIV/AIDS. The objectives of the campaign are :

1. To raise awareness levels regarding HIV/AIDS in rural and slum area and other vulnerable groups of the population.
2. To make people aware about the services available under the public sector for management of HIV/AIDS.
3. To facilitate early detection and prompt treatment of RTI/STD cases by utilizing the infrastructure available under primary health care system including provision of drugs.
4. To strengthen the capacity of medical and paramedical professionals working under health care system to respond to HIV/AIDS epidemic adequately.
5. To use safe blood from licensed blood banks and blood storage centers.
6. To be aware that HIV can be transmitted from the infected mother to her baby during pregnancy, delivery and breast feeding.

**Voluntary Counseling and Testing (VCT) :** VCT specifically involves increasing availability and demand for voluntary testing including joint testing of couples, training grassroots health workers in HIV counseling and providing counseling through blood banks and through STI clinics. Under NACP III, it is envisaged that at least one voluntary testing centre would be established in every district. Pretesting counseling (before HIV testing) essentially prepares an individual for undergoing HIV test, identifying high risk behavior. Post test counseling helps the client to understand the importance and meaning of negative or positive HIV test, benefits of changing the high risk behavior and constructively handling the marital and sexual needs.

**HIV testing :** Under the present HIV testing policy of Govt of India, there is no rationale for mandatory HIV testing of any individual. It is established that any form of mandatory testing usually drives 'underground' those who are at highest risk due to stigma & discrimination and is thus counter-productive in the long term. According to present HIV policy, HIV testing is carried out on voluntary basis with adequate pretest and post-test counseling. Govt of India has formulated a comprehensive HIV testing policy, in accordance to WHO guidelines, which states that :

- (i) No individual shall be made to undergo any form of mandatory HIV testing.
- (ii) HIV testing shall not be imposed as a precondition to employment or for providing health care facilities during employment.
- (iii) Adequate facilities for voluntary testing with pretest and post - test facilities will be made available throughout the country in a phased manner, so as to have at least one HIV testing centre in every district.
- (iv) Disclosure of HIV status to spouse of the person will depend entirely on willingness to part with such informations. However, all efforts should be made so that the individual voluntarily shares such information with family, to ensure proper home based care.
- (v) Different testing strategies are to be adopted under different circumstances, as under :



- **Mandatory testing** : Screening in blood banks for blood safety. However, testing in all blood banks will be undertaken on collected blood samples in an unlinked & anonymous manner so as to only identify the status of blood sample and not of the donor.
- **Unlinked and anonymous testing** : To be undertaken for epidemiological surveys and HIV surveillance to monitor the trend of HIV infection in community.
- **Voluntary and confidential testing** : To be undertaken as confirmatory testing for subclinical infections/clinical management and as voluntary testing.
- **Need based testing** : To be undertaken with explicit consent, for research purpose, after ensuring all ethical considerations.

For screening of donated blood, a single test by either Rapid or ELISA method is enough to eliminate possibility of HIV infected blood. For epidemiological surveys, the same procedure is adopted with one or two of Rapid/ELISA/Simple, which has high sensitivity. In such cases, testing is unlinked and anonymous and result is not given to the person. For clinical management and for confirmation of HIV status of individuals who voluntarily ask for it, testing using different antigen preparation. The result of HIV testing in such cases has to be disclosed only after proper pre-test and post-test counseling of the concerned individual.

**Prevention of Parent To Child Transmission (PPTCT)** : Various studies have indicated that chemoprophylaxis (in the form of Nevirapine) before delivery in case of HIV-infected pregnant woman significantly reduces mother-to-child transmission rate from 33 % to 8.4 % at birth or 10.1% at age of two months. The intervention cost has been worked out to Rs.175 per women, which is a very cost effective method to prevent perinatal HIV infection. NACP III envisages that antenatal clinics will be used for imparting HIV education to pregnant women through trained counselors. Special emphasis would also be given to drug prophylaxis linked with infant feeding, nutritional support and contraception. Drug regimes used for chemoprophylaxis would be modified according to emerging evidence of efficacy of the drugs.

**Occupational Health and HIV/AIDS** : NACP III has addressed the issue of expanding HIV/AIDS response at work place. Under NACP III, specific guidelines have been formulated in collaboration with employers, workers organizations, ministries and civil society, with the aim to strengthen response to HIV and mitigate the effect of the diseases at work place. The key areas for intervention at work place are prevention of HIV/AIDS, management & mitigation of impact at work place, care & support for infected workers and reducing stigma and discrimination at work place.

**Universal Protection & Post Exposure Prophylaxis (PEP)** : Under NACP III, health care worker will be provided specific protection against occupational exposure to HIV. NACP III recommends following measure after occupational exposure :

- Rapid testing facility for HIV testing.
- Exposure with HIV should be considered a medical emergency.
- Chemoprophylaxis should be started within 4 hours after exposure.

- Chemoprophylaxis should be reviewed on 1, 3 and 6 months interval.
- Under NACP III, only following drugs are approved for post exposure prophylaxis :
  - Zidovudine - 300 mg twice daily for 4 weeks
  - Lamivudine - 150 mg twice daily for 4 weeks
  - Indinavir - 800 mg thrice daily (only as part of expanded regime)
  - Saquinavir - 600 mg thrice daily.

**Blood Safety Program** : In India, blood banking infrastructure is highly decentralized and there is acute shortage of trained manpower, equipment and financial resources necessary to provide the desired quality of blood. In addition, there is often shortage of blood which encourages private blood banks with inadequate infrastructure and quality control.

Blood safety has remained an integral part of NACP since its inception an NACP III has included the objectives of :

- Ensuring organized blood banking services at State/District level
- Educating & motivating community about importance of voluntary blood donation
- Enforcing quality control for all units of blood to be infused.

**Condom Promotion Program** : In India, heterosexual transmission constitutes the major transmission route of HIV and condom usage remains the single most effective and practical method to prevent HIV transmission. Accordingly, Condom Promotion program under NACP III proposed that there should be no moral, religious or ethical inhibition in promoting condom usage among sexually active individuals, especially those who practice high risk behavior(6). Under NACP III, it is envisaged to convince people to use condom not only for family planning but also as the best preventive measure against HIV, convince commercial sex workers and their clients to use condoms as means to prevent sexually transmitted diseases including HIV and to make available low cost, good quality condoms to people all over the country easily at the time and place where they will need them. The objective of Condom Promotion Program is to ensure easy access to acceptable, good quality and affordable condoms with the view to promote safe sex. The following are used as indicators for success of Condom Promotion Program under NACP III :

- Percentage of persons who report easy availability of condoms within 500 meters of the place where they need them.
- Percentage of persons reporting consistent use of condom in sexual encounters with non- regular partners in last 30 days.
- Percentage increase in number of non-traditional outlets for condoms, like post offices, shopping malls etc.

**University Talk AIDS Project (UTA)** : UTA Project began as early as Oct 1991 with partnership between National Service Scheme (NSS), Dept of Youth Affairs & Sports and NACO. The project aims to generate awareness among students on HIV related issues through seminars, talks workshops and written material. The program also deals with related issues pertinent to youth like drug abuse, relationship, courtships, marriage and thus aims to enhance life style skills among the youth.

**Treatment for opportunistic infections** : It was previously available at district level; would be now available at CHC and PHC levels. Drugs would be given free at all govt hospitals and few NGOs with good track record in providing HIV care would also be incorporated for treating HIV. NACP III also proposes close linkage between NACP and RNTCP since tuberculosis remains the most common and most lethal opportunistic infection among HIV infected individuals.

- (a) Anti retroviral therapy to as many infected individuals has been attempted under NACP III. NACP III proposes partnerships and through community partnership and ownership. Seropositive women who have participated in PPTCT program, children below 15 years with HIV/AIDS, PLHA referred under targeted interventions (such as for commercial sex workers, truck drivers or migrant workers) and AIDS patients getting treatment from govt ART centres will be given priority for ART. It is proposed that by 2010, as many as 1,84,000 individuals would be on ART.
- (b) NACP III also proposes to establish DNA PCR facility for diagnosis of HIV in children through selected national referral centres, to meet the requirement due to increasing number of infected children.

**Capacity Building** : Under NACP III, capacity building at national, state and district levels is envisaged through multiple strategies to meet the fast evolving challenges of HIV epidemic in the country. Possible centres for imparting training, identified by a multidisciplinary standing committee (including an epidemiologist, economist, microbiologist and public health, marketing, communication specialists among others), will identify training needs at various levels and also help states to plan their training. In addition, capacity building under NACP III will include issues of program management, finance and procurement of infrastructure human resource and medicines at various levels.

#### Monitoring & Evaluation

**HIV Surveillance** : Effective and accurate HIV surveillance is essential to monitor progress of the control program. NACP III undertakes HIV surveillance with the objective to estimate incidence, prevalence, morbidity and mortality due to HIV and also to identify behavioural and biological markers on progress of preventive program.

One of the significant achievements of NACP is a credible HIV sentinel surveillance system. Information gathered through HIV sentinel surveillance, behavioural sentinel surveillance and STD surveillance helps in tracking the epidemic and provides the direction to the programme. Under NACP-III, PPTCT surveillance and ANC surveillance system are planned to be included in the programme. Surveillance for HIV infection comprises of four broad areas : HIV Sentinel Surveillance, AIDS Case Surveillance, Behavioural Surveillance and Sexually Transmitted Infections (STI) Surveillance. HIV Surveillance closely monitors and tracks the level, spread and trends of the epidemic as well as the risk behaviours that predispose the growth of epidemic. Inputs from the robust sentinel surveillance system of India, routine AIDS Case reporting, and periodic behavioural surveillance surveys give direction to the programmatic efforts by showing the impact of the interventions and areas that need focus of different initiatives.

**HIV Sentinel Surveillance** : HIV Sentinel Surveillance is undertaken every year jointly by National AIDS Control Organisation (NACO) and Min of Health & Family Welfare since 1998, with the aim of updating HIV estimates for the country. Under this program, HIV prevalence in the country is estimated based on HIV prevalence recorded at designated sentinel surveillance sites (such as STD clinics, de-addiction centers and intervention centers for female sex workers) for different risk groups. Women attending antenatal clinics are taken to be representative of the general population. Blood samples collected (between 01 Aug - 31 Oct) by unlinked anonymous method are tested at regular intervals annually and the data is used for epidemiological analysis and estimation of HIV prevalence in the country. The HIV Sentinel Surveillance System of India has greatly evolved over time covering all the districts of the country as well as all the high risk population groups. Annual HIV Sentinel Surveillance is conducted among Pregnant women attending Antenatal clinics, Patients attending STI Clinics, Female Sex Workers, Injecting Drug Users, Men who have Sex with Men, Migrant Population, Long distance Truckers, Eunuchs and Fisher folk. Based on HIV Sentinel Surveillance data, all the districts in the country are categorised into four categories for priority attention in the programme.

**Behaviour Surveillance Survey ( BSS )** : BSS throws light on the knowledge, awareness and behaviours related to HIV/ AIDS among general population, youth as well as among different high risk group communities. It also provides rich inputs to understand the impact of the intervention efforts being undertaken through NACP (7). BSS is undertaken to provide behavioural measurement for recording trends of high risk behavior among selected population groups. A set of 9 indicators, as under were used on three occasions to assess the trends.

(a) *Knowledge indicators* : These include Proportion of respondents who know the following : 2 acceptable ways to prevent STDs; that condoms prevent STDs; 2 acceptable ways to prevent HIV; and, that condoms prevent HIV.

(b) *Behaviour Indicators* : These include proportion of respondents who report heterosexual intercourse with non-regular partner in the last year and proportion of respondents who report condom usage during last sexual intercourse with non regular partner in the last year

(c) *Prevalence of Urethritis* among male respondents who report symptoms of urethritis during last one year or proportion of male respondents who sought treatment from qualified medical practitioners for urethritis in the last year.

(d) *Appropriate perception of risk indicators* : This pertains to proportion of respondents with high risk behavior who perceive that they can get infected with HIV.

India's response to HIV epidemic is influenced by the available surveillance data, implementation capacities and political commitment at state and national level. Apart from the sentinel surveillance, nationwide Computerised Management Information System (CMIS) provides strategic information on programme monitoring and evaluation. However, in the planning of NACP-III it was felt that data from sentinel surveillance and CMIS are not sensitive enough to detect the

emerging hot spots of the epidemic. To overcome this, NACO, in its third HIV/AIDS programme introduced *Strategic Information Management System (SIMS)* at national and state levels to focus on strategic planning, monitoring, evaluation, surveillance and research. It is aimed to provide effective tracking and response to HIV epidemic. The system assigns clear responsibilities to all programme officers and facilitates data flow and feedback at various levels.

### Core Services at District level

In packaging of services, care is taken for the special needs of the region and availability of complementary health care system. In high prevalence districts, the full spectrum of preventive, supportive and curative services are available in medical colleges or district hospitals. These hospitals provide HIV/AIDS prevention services including treatment and cure for sexually transmitted infections, psycho-social counselling and support for people infected or affected by HIV, management of opportunistic infections and anti-retroviral therapy for people living with HIV/AIDS, counselling and testing facility for prevention of parent to child transmission of HIV infection, specialised paediatric HIV care and treatment / referral for specialist needs such as surgery, ENT and ophthalmology etc.

**Care and Support for Children** : Approximately 50,000 children below 15 years are infected by HIV every year. So far, care and support response to these children was at a very minimal level. NACP-III plans to improve this through early diagnosis and treatment of HIV exposed children; comprehensive guidelines on paediatric HIV care for each level of the health system; special training to counsellors for counselling HIV positive children; linkages with social sector programmes for accessing social support for infected children; outreach and transportation subsidy to facilitate ART and follow up, nutritional, educational, recreational and skill development support, and by establishing and enforcing minimum standards of care and protection in institutional, foster care and community-based care systems.

**Treatment** : HIV infection is not the end of life. People can lead a healthy life for a long time with appropriate medical care. Anti-retroviral therapy (ART) effectively suppresses replication, if taken at the right time. Successful viral suppression restores the immune system and halts onset and progression of disease as well as reduces chances of getting opportunistic infections - this is how ART is aimed to work. Medication thus enhances both quality of life and longevity. Adherence to ART regimen is therefore very vital in this treatment. Any irregularity in following the prescribed regimen can lead to resistance to HIV drugs, and therefore can weaken or negate its effect. ART is now available free to all those who need it. Public health facilities are mandated to ensure that ART is provided to people living with HIV/AIDS (PLHA). Special emphasis is given to the treatment of sero-positive women and infected children. ART is initiated depending upon the stage of infection. PLHA with less than 200 CD4 (white blood cells/ mm<sup>3</sup>) require treatment irrespective of the clinical stage. For PLHA with 200-350 CD4, ART is offered to symptomatic patients. Among those with CD4 of more than 350, treatment is deferred for asymptomatic persons. There are 127 ART centres operating in the country as of June 2007. By 2012, 250 ART centres will become functional across the country in order to provide people living with HIV/

AIDS better access to treatment.

**Paediatric Care and Support** : The primary goal of paediatric prevention, care and treatment programme is to prevent HIV infection to newborns through Prevention of Parent To Child Transmission (PPTCT) and provide treatment and care to all children infected by HIV.

**Research** : Beginning NACP-III, NACO has positioned itself as the promoter and coordinator of research on HIV/AIDS not only in India, but the entire South Asia region through partnership and networking with national academic and other institutions in the region. This initiative will enhance NACO's knowledge and evidence base of the various aspects of the epidemic.

**Strengthening decentralization and expanding health systems** : Under the NACP-III, decentralization of HIV services and convergence of services with the Reproductive Child Health Programme is envisaged; with strengthening of the capacities of the districts to manage prevention, treatment, care and support programmes.

**Prioritization of districts for programme implementation:** National AIDS Control Programme - III envisages district level planning and implementation of all the programmatic initiatives. For the purpose of planning and implementation of NACP-III, all the districts in the country are classified into four categories based on HIV prevalence in the districts among different population groups for three consecutive years. The definitions of the four categories are as follows :

**Category A** : More than 1% ANC prevalence in district in any of the sites in the last 3 years.

**Category B** : Less than 1% ANC prevalence in all the sites during last 3 years with more than 5% prevalence in any High Risk Group (HRG) site (STD/FSW/MSM/IDU).

**Category C** : Less than 1% ANC prevalence in all sites during last 3 years with less than 5% in all HRG sites, with known hot spots (Migrants, truckers, large aggregation of factory workers, tourist etc).

**Category D** : Less than 1% ANC prevalence in all sites during last 3 years with less than 5% in all HRG sites with no known hot spots or no or poor HIV data.

### Critical appraisal

Due to stigma attached with HIV/AIDS, people living with the disease face a lot of discrimination. The program does not lay much emphasis to this important issue. Rehabilitation of sex workers who are HIV positives has been neglected in the program and needs special budgetary allocation. When the program started no targets were fixed and the program could not be evaluated properly due to non existence of indicators. Provision of free ART may eat the budget of other important communicable diseases. NACP has been conspicuously silent on structural socioeconomic vulnerabilities and the root cause of continuing flow of subpopulation into situations involving high risk behavior. It offers nothing to address these vulnerabilities through creating viable, holistic alternatives for those presently entrapped. The concept of voluntary and confidential testing is not being implemented in true spirit. Many Indians are tested for HIV without their knowledge and consent especially for those undergoing surgeries.



## Summary

The first HIV case was reported in 1986. National AIDS Control Programme was launched in 1987. The programme was in phase I from 1992-1997(extended to 1999), phase II (1999-2004) and is presently in phase III from 2007-2012. The Goal of NACP is to halt and reverse the epidemic in India over the next five years by integrating programmes for *prevention, care, support and treatment*. The Objectives are to To reduce the rate of incidence by 60 per cent in the first year of the programme in high prevalence states to obtain the reversal of the epidemic, and by 40 percent in the vulnerable states to stabilise the epidemic.

The Strategy in phase III has been to prevent infections through saturation of coverage of high-risk groups with targeted interventions (TIs) and scaled up interventions in the general population, Provide greater care, support and treatment to larger number of People Living with HIV/AIDS(PLHA), Strengthen the infrastructure, systems and human resources in prevention, care, support and treatment programmes at district, state and national levels and to Strengthen the nationwide *Strategic Information Management System*.

The activities which are included are - Intensive coverage of High Risk Groups through targeted interventions, Intensification of interventions among general populations, Sexually Transmitted Disease (STD) Control Program, Family Health Awareness Campaign (FHAC), Voluntary Counseling and Testing (VCT), Prevention of Parent to Child Transmission (PPTCT), Universal Protection & Post Exposure Prophylaxis (PEP), Blood Safety Program, Condom Promotion Program, University Talk AIDS Project (UTA), Treatment for opportunistic infections and Monitoring & Evaluation.

For HIV testing different strategies have been adopted for different situations such as (a) Mandatory testing : screening in blood banks for blood safety. However, testing in all blood banks will be undertaken on collected blood samples in an unlinked & anonymous manner so as to only identify the status of blood sample and not of the donor. (b) Unlinked and anonymous testing : To be undertaken for epidemiological surveys and HIV surveillance to monitor the trend of HIV infection in community. (c) Voluntary and confidential testing: To be undertaken as confirmatory testing for subclinical infections/clinical management and as voluntary testing. (d) Need based testing : To be undertaken with explicit consent, for research purpose, after ensuring all ethical considerations.

For care and support of children, NACP-III plan envisages early diagnosis and treatment of HIV exposed children; comprehensive guidelines on paediatric HIV care for each level of the health system; special training to counsellors for counselling HIV positive children; linkages with social sector programmes for accessing social support for infected children; outreach and transportation subsidy to facilitate ART and follow up.

ART is initiated depending upon the stage of infection. PLHA with less than 200 CD4 (white blood cells/ mm<sup>3</sup>) require treatment irrespective of the clinical stage. For PLHA with 200-350 CD4, ART is offered to symptomatic patients. Among those with CD4 of more than 350, treatment is deferred for asymptomatic persons.

National AIDS Control Programme - III envisages district level planning and implementation of all the programmatic initiatives. For the purpose of planning and implementation of NACP-III, all the districts in the country are classified into four categories based on HIV prevalence in the districts among different population groups for three consecutive years. The definitions of the four categories are as follows : *Category A* : More than 1% ANC prevalence in district in any of the sites in the last 3 years. *Category B* : Less than 1% ANC prevalence in all the sites during last 3 years with more than 5% prevalence in any HRG site (STD/FSW/MSM/IDU). *Category C* : Less than 1% ANC prevalence in all sites during last 3 years with less than 5% in all HRG sites, with known hot spots (Migrants, truckers, large aggregation of factory workers, tourist etc). *Category D*: Less than 1% ANC prevalence in all sites during last 3 years with less than 5% in all HRG sites with no known hot spots or no or poor HIV data.

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In May 1988, the World Health Assembly committed the member nations of the World Health Organization (WHO) to achieving the goal of global eradication of poliomyelitis. This goal is defined as (1):

- No cases of clinical poliomyelitis associated with wild poliovirus, and
- No wild poliovirus found worldwide despite intensive efforts to do so.

WHO Regions that have been certified as polio-free are the Americas (last case in 1991, Peru; Region certified polio-free in 1994), the Western Pacific Region (last case in 1997, Cambodia; Region certified 2000), and the European Region (last case in 1998, Turkey; Region certified 2001).

### Strategy

The primary strategies for achieving this goal are:

**Attaining high routine immunization** : By immunizing every child aged <1 year with at least 3 doses of oral poliovirus vaccine (OPV). Paralytic polio can be caused by any of 3 closely-related strains (serotypes) of poliovirus. Trivalent OPV (OPV3) provides immunity against all 3 types. Three routine OPV doses should be received by infants at ages 6, 10 and 14 weeks.

**National Immunization Days (NIDs)** : By conducting Pulse Polio Immunization (PPI) programme by providing additional OPV doses to every child aged <5 years at intervals of 4-6 weeks. The aim of NIDs/PPI is to "flood" the community with OPV within a very short period of time, thereby interrupting transmission of virus throughout the community. Intensification of the PPI programme is accomplished by the addition of extra immunization rounds, adding a house-to-house "search and vaccinate" component in addition to providing vaccine at a fixed post. The number of PPI rounds conducted during any particular year is determined by the extent of poliovirus transmission in the country. The modified IPPI (Intensified Pulse Polio Immunization) strategy included vaccination of children through fixed booth approach on first day, followed by extensive house-to-house search of missed children for vaccination.

**Surveillance of Acute Flaccid Paralysis (AFP)** : Identify all reservoirs of wild poliovirus transmission. This includes AFP case investigation and laboratory investigation of stool specimens collected from AFP cases, which are tested for polioviruses in specialized laboratories.

**Mopping-up immunization** : When poliovirus transmission has been reduced to well-defined and focal geographic areas, intensive house-to-house, child-to-child immunization campaigns are conducted over a period of days to break the final chains of virus transmission.

### Evolution of Polio vaccination in India

This is presented in Table - 1

In 1999 - 2000, with a view to reach the global goal of reaching zero incidence of polio by 2000 AD, a strategy to intensify PPI

was adopted. The strategy consisted of four nation-wide PPI rounds in the months of October, November, December 2000 and January 2001; followed by two sub-national rounds in 8 States of Assam, Bihar, Gujarat, Madhya Pradesh, Orissa, Rajasthan, Uttar Pradesh and West Bengal and routine immunization, especially in the poor performing States. During 1999, Supplementary Immunisation Activities (SIAs) were intensified, with the addition of house-to-house vaccination after an initial day of fixed-site activity (2).

**Table - 1**

Year	Remarks
1978	Vaccination against polio was initiated under Expanded Programme on Immunization (EPI)
1984	Coverage achieved was around 40% of all infants with 3 doses of Oral Polio Vaccine (OPV)
1985	Universal Immunization Programme (UIP) was launched
1995	The number of reported cases of polio declined from 28757 during 1987 to 3265 in 1995. Pulse Polio Immunization (PPI) Programme was launched in 1995-96 to cover all children below the age of 3 years
1996-97	To accelerate the pace of polio eradication, the target age group was increased to all children under the age of 5 years
1997	National Polio Surveillance Project was launched by Govt. of India & World Health Organization

**Summary of cases** : Decadal trend of polio cases is given in Table - 2 (3).

**Table - 2**

Year	No. of cases
1998	1934
1999	1126
2000	265
2001	268
2002	1600
2003	225
2004	134
2005	66
2006	676
2007	874
2008	420 (P1:25, P3:325)

Source : See reference (3)

### AFP Surveillance

The strategy to eradicate wild poliovirus is two-fold, viz., immunization and surveillance. The objective of AFP surveillance is to detect the exact geographic locations where wild polioviruses are circulating in the human population. All

cases of acute flaccid paralysis in children aged <15 years are rigorously investigated by a trained medical officer, with collection of stool specimens to determine if poliovirus is the cause of the paralysis. Analysis of the location of polioviruses isolated from AFP cases allows programme managers to plan immunization campaigns (Pulse Polio Immunization).

**Case Definition** : Acute flaccid paralysis is defined as any case of AFP in a child aged <15 years, or any case of paralytic illness in a person of any age when polio is suspected.

**Acute** : Rapid progression of paralysis from onset to maximum paralysis; **Flaccid** : Loss of muscle tone, “floppy” - as opposed to spastic or rigid; **Paralysis** : Weakness, loss of voluntary movement. Any case meeting this definition undergoes a thorough investigation to determine if the paralysis is caused by polio.

#### Components of AFP Surveillance

1. Case Notification
2. Case and laboratory investigation
3. Outbreak Response Immunization (ORI) and active search of cases in community
4. 60 days follow up, cross notification & tracking of cases

An AFP case detected by health workers is reported to local health authorities and to state and national bodies. Case investigators are sent to confirm the diagnosis and collect faecal samples that are transported to the nearest laboratory for virus culture. This is followed by Outbreak Response Immunization (ORI), wherein all children less than 59 months in the area are given an additional dose of OPV. At least 500 children are vaccinated under ORI. Along with ORI, an intensive search is carried out for more cases of AFP. The case definition includes any child less than 15 years with history of flaccid/floppy paralysis. The AFP cases are revisited after 60 days of onset of paralysis to check for residual weakness/neurological deficit. The confirmation of paralytic polio is based on the review after 60 days and the laboratory report of the stool specimen. The suspected stool samples are sent to WHO recognized National Laboratories where poliovirus culture and identification are carried out. If poliovirus is found, the samples are forwarded to one of the Regional Reference Laboratories where VDPV and wild poliovirus are differentiated.

#### National Polio Surveillance Project

The National Polio Surveillance Project is a collaborative project of Govt. of India & the World Health Organization and managed by the latter. Currently a team of more than 250 Surveillance Medical Officer (SMO), Sub-Regional Coordinator (SRC) and Regional Coordinator (RC) are spread across the country who comprise the field staff of project. They are supported by a network of 9 Polio National Laboratories, which undertake the Virological Investigation of AFP (Acute Flaccid Paralysis) cases. The central headquarter unit of the project - The National Polio Surveillance Unit (NPSU) provides logistical & technical backup to the field staff.

In October 1997, active surveillance of Acute Flaccid Paralysis was established to meet the demands of Polio Eradication. SMOs with Government counterparts established Reporting Units for reporting of occurrence of AFP cases to the District, State & National levels; timely case investigation & collection of stool

specimen from AFP cases and its shipment to laboratories. AFP Surveillance at the local level is institution based through a comprehensive network of reporting sites which includes health facility reporting units & informers.

#### Critical appraisal (4)

A critical juncture has been reached in eradication of poliomyelitis in India. The tools are available which are proven to be effective across the world. The large disparity in routine vaccine coverage among various regions of the country is hampering the eradication efforts. Compounding the problem is the social mobility from migrant labour moving to urban conglomerates. Eradication efforts need to be focused on these high risk groups, including mop-up activity for absentee and defaulter immunisation. Community participation remains the key to success and has to be ensured for better compliance. The importance of ensuring cold chain has to be stressed to maintain vaccine potency. Potency checking of OPV is hardly done after the inception of the Vaccine Vial Monitor (VVM) into IPPI. A review of this may be necessary to ensure that a potent vaccine is used. As we near the control of wild-virus transmission, Vaccine Associated Paralytic Polio (VAPP) is a real danger. The introduction of Injectable Polio Vaccine may be an option, at least in the better performing areas like Kerala and the North East. Combination of DPT with IPV in the UIP has been suggested and may have to be done in the near future.

#### Summary

Polio eradication is defined as - No cases of clinical poliomyelitis associated with wild poliovirus, and No wild poliovirus found worldwide despite intensive efforts to do so. The primary strategies for achieving this goal are attaining high routine immunization, National Immunization Days (NIDs), Surveillance of Acute Flaccid Paralysis (AFP) and Mopping-up immunization. On NID, OPV doses to every child aged <5 years at intervals of 4-6 weeks. The aim of NIDs/PPI is to “flood” the community with OPV within a very short period of time, thereby interrupting transmission of virus throughout the community.

**AFP Surveillance:** The objective of AFP surveillance is to detect the exact geographic locations where wild polioviruses are circulating in the human population. The Components of AFP Surveillance are Case Notification, Case and laboratory investigation, outbreak response immunization and active search of cases in community and 60 days follow up, cross notification and tracking of cases.

The National Polio Surveillance Project is a collaborative project of Govt. of India & the World Health Organization and managed by the latter for active surveillance of Acute Flaccid Paralysis; was established to meet the demands of Polio Eradication.

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Surveillance is essential for the early detection of emerging (new) or re-emerging (resurgent) infectious diseases. In the absence of surveillance, disease may spread unrecognized by those responsible for health care or public health agencies, because sick people would be seen in small numbers by many individual health care workers. By the time the outbreak is recognized, it may be too late for intervention measures. Continuous monitoring is essential for detecting the 'early signals' of outbreak of any epidemic of a new or resurgent disease. Surveillance data can be effectively used for the purpose of social mobilization to help the public participate actively in controlling important diseases. This will go a long way in reducing the burden of disease in the community.

IDSP is a decentralized; state based *Surveillance Project* (IDSP) which will be able to detect early warning signals of impending outbreaks and help initiate an effective response in a timely manner. It will also be expected to provide essential data to monitor progress of on-going disease control programs and help allocate health resources more optimally. IDSP will also facilitate the study of disease patterns in the country and identify new emerging diseases (1).

**Aim & Objectives** : The aim is to improve the information available to the government health services and private health care providers on a set of high-priority diseases and risk factors, with a view to improving the on-the-ground responses to such diseases and risk factors. The objectives are :

1. To establish a decentralized state based system of surveillance for communicable and non-communicable diseases, so that timely and effective public health actions can be initiated in response to health challenges in the country at the state and national level.
2. To improve the efficiency of the existing surveillance activities of disease control programs and facilitate sharing of relevant information with the health administration, community and other stakeholders so as to detect disease trends over time and evaluate control strategies.

### Activities & Components

1. Establish and Operate a Central-level Disease Surveillance Unit.
2. Integrate and strengthen disease surveillance at the state and district levels.
3. Improve laboratory support.
4. Training for disease surveillance and action.

The details are shown in the Table - 1

**Implementation** : IDSP will monitor a limited number of conditions based on state perceptions including 13 core and 5 state priority conditions for which public health response is available. District, State & Central Surveillance units will be set up so that the program is able to respond in a timely manner to surveillance challenges in the country including emerging epidemics. It will integrate surveillance activities in the country under various programs and use existing infrastructure for its function. Private practitioners / Private hospitals / Private laboratories and medical colleges will be inducted into the program as sentinel units. Uniform high quality surveillance activities will be ensured at all levels. Following actions will be taken for successful implementation :

- (i) Limiting the total number of diseases under surveillance and reducing overload at the periphery.
- (ii) Developing standard case definitions.
- (iii) Developing formats for reporting.
- (iv) Developing user friendly manuals.
- (v) Providing training to all essential personnel.
- (vi) Setting a system of regular feed back to the participants on the quality of surveillance activity. District Public Health Laboratory will be strengthened to enhance capacity for diagnosis and investigations of epidemics and confirmation of disease conditions. Use of information technology will be done for communication, data entry, analysis, reporting, feedback and actions. A national level surveillance network will be established up to the district level.

**Disease conditions under the surveillance program** : Integration of Surveillance under various disease control programme : Under IDSP surveillance activities carried out under National Disease Control Programmes relating to Malaria, Tuberculosis, HIV/AIDS, Diseases under RCH (Measles, Polio, Acute Diarrhoeal Diseases) and state specific diseases would be integrated (See Table - 2).

Table - 1

Component	Activities
1.	Ministry of Health and Family Welfare (MOHFW) will establish a new Disease Surveillance Unit. It will give support to states surveillance units and help in coordination. It will also help in change of diseases in the system.
2.	It will integrate and strengthen disease surveillance at the state and district levels, and involve communities and other stakeholders, in particular, the private sector.
3.	This involves upgrading laboratories at the state level, in order to improve laboratory support for surveillance activities. Adequate laboratory support is essential for providing on-time and reliable confirmation of suspected cases; monitoring drug resistance; and monitoring changes in disease agents. It also includes introducing a quality assurance system for assessing and improving the quality of laboratory data.
4.	The first three components will require a large and coordinated training effort to reorient health staff to an integrated surveillance system and provide the new skills needed.

<b>Table - 2 : Disease conditions under the IDSP</b>		
<b>Surveillance</b>	<b>Group of diseases</b>	<b>Examples</b>
<i>Regular Surveillance</i>	Vector Borne Water Borne Respiratory Diseases Vaccine Preventable Diseases Diseases under eradication Others Other International commitments Unusual clinical syndromes	Malaria Acute Diarrhoeal Disease (Cholera), Typhoid Tuberculosis Measles Polio Road Traffic Accidents Plague Meningoencephalitis / Respiratory (Causing death / hospitalization) Distress Hemorrhagic fevers, other undiagnosed conditions
<i>Sentinel Surveillance</i>	Sexually transmitted diseases/Blood borne: Other Conditions	HIV/HBV, HCV Water Quality, Outdoor Air Quality (Large Urban Centers)
<i>Regular periodic surveys</i>	NCD Risk Factors	Anthropometry, Physical activity, Blood Pressure, Tobacco, Nutrition, Blindness
<i>Additional State Priorities</i>	Each state may identify up to five additional conditions for surveillance	

### Response to the Surveillance Information at various levels (Fig. - 1)

1. **At Central Level** : The response functions at the central surveillance committee level will include Development of national guidelines for case definitions and disease control, compilation and analysis of SSU reports (quarterly), reporting to World Bank, coordinate external quality assurance activities. The CSU will also advise SSUs on disease control measures, Monitor situation and response (continuously), notify international public health agencies, seek and coordinate international assistance if necessary.

2. **At State Level** : The response functions at the state surveillance committee level will include : Advise to DSUs on disease control measures, monitor situation and response, notify CSU, and deployment of state rapid response team if necessary, Compilation of DSU reports (monthly), assess reporting performance of DSUs (monthly), reporting to CSU (monthly) and feedback to DSUs (monthly).

3. **At District Level** : The response functions at the District surveillance committee level will include : Initiation of outbreak investigation through Rapid Response Teams (RRT), provide coordination to Outbreak response activities involving CHCs, initiate disease control measures and treatment, notify SSU, facilitate private / public Partnership in outbreak response. It will also include Data entry of sentinel data from institutions not linked directly (weekly), analysis including calculation of case counts and descriptive epidemiology (weekly), monitoring and evaluation including assess accuracy and completeness of submitted reports (weekly), collection and trend analysis of water quality, air quality, and road accident data.

4. **At CHC / PHC Level** : The response functions at the MO i/c CHC and MO i/c PHC level will include Verification of reports of outbreaks from health worker (within 24 hours), verification of reports of Outbreaks in the rumor registry (within 48 hours), disease-specific control activities (immediately), collection and transport of biological samples to lab, reporting of suspected and confirmed cases to DSU (within 24 hours), IEC and integration with Village health committee, and outbreak investigation, under DSU directions. The actions will also include verification of local health worker case reports (weekly), verification of laboratory reports (weekly), and Feedback to local health workers (weekly).

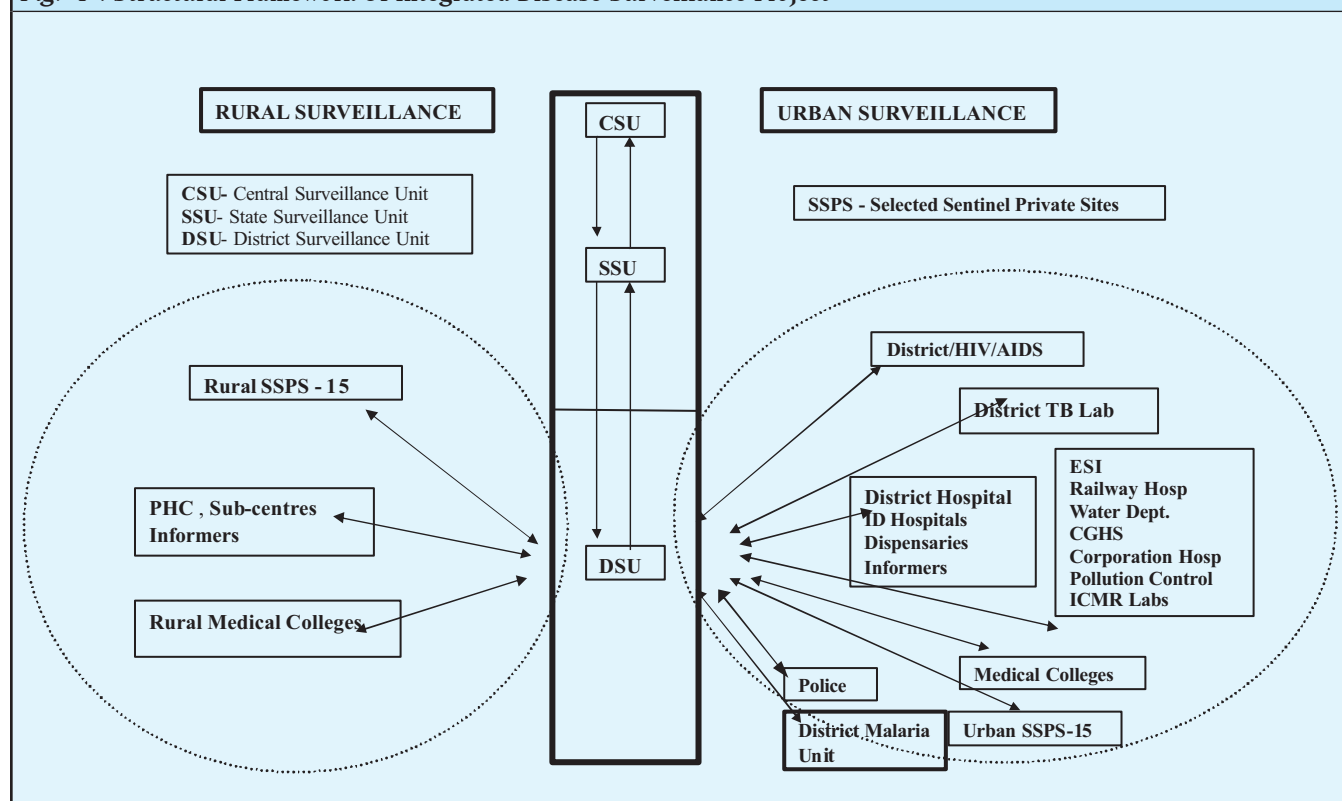
5. **At Local Health Worker Level** : The response functions will include : Informing MO PHC/CHC, Active search for similar Cases, Collection and transport of biological samples to lab, and IEC activities. The actions will also include monitoring of illnesses and reporting to CHC, and to refer patients to PHC / CHC.

**Phasing** : IDSP will be implemented in three phases (2) as follows : Phase I (FY 2004-05), Phase II (FY 2005-06) and Phase III (FY 2006-07).

**Conclusion** : Surveillance is the essence of a disease control program. By setting up a decentralized, action oriented, integrated and responsive program, it is expected that IDSP will avert a sufficient number of disease outbreaks and epidemics and reduce human suffering and improve the efficiency of all existing health programs. Such a program will also allow monitoring of resource allocation and form a tool to enhance equity in health delivery.



**Fig. -1 : Structural Framework Of Integrated Disease Surveillance Project**



## Summary

IDSP is a decentralized, state based *Surveillance Project* which will be able to detect early warning signals of impending outbreaks and help initiate an effective response in a timely manner. It will also be expected to provide essential data to monitor progress of on-going disease control programs and help allocate health resources more optimally.

The *aim* is to improve the information available to the government health services and private health care providers on a set of high-priority diseases and risk factors, with a view to improving the on-the-ground responses to such diseases and risk factors. The objectives are : To establish a decentralized state based system of surveillance for communicable and non-communicable diseases, so that timely and effective public health actions can be initiated in response to health challenges in the country at the state and national level; To improve the efficiency of the existing surveillance activities of disease control programs and facilitate sharing of relevant information with the health administration, community and other stakeholders so as to detect disease trends over time and evaluate control strategies.

The components are to Establish and Operate a Central-level Disease Surveillance Unit, Integrate and strengthen disease surveillance at the state and district levels, Improve laboratory support and Training for disease surveillance and action.

The implementation is through District, State & Central Surveillance units. There will be Regular Surveillance (Vector Borne, Water Borne, Respiratory Diseases, Vaccine Preventable Diseases and Diseases under eradication), Sentinel Surveillance (Sexually transmitted diseases/Blood borne conditions), Regular periodic surveys (NCD Risk Factors )and each state may identify up to five additional conditions for surveillance.

The flow of information will be from Local Health Worker to CHC MO / PHC MO, to District Surveillance Committee, to State Surveillance Committee and finally to Centre Surveillance Committee. IDSP will be implemented in three phases : Phase I (FY 2004-2005); Phase II (FY 2005-2006); and Phase III (FY 2006-2007).

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Mental disorders form an important public health priority, both in terms of the numbers of people suffering from mental disorders and due to the burden of these disorders in the community (1, 2). These conditions include the severe forms of mental disorders like psychoses, substance abuse and mental retardation. Of the health conditions contributing to the disability adjusted life years (DALYs), of the top 10 conditions, four are mental disorders.

**Objectives** : NMHP was started in 1982 with the following objectives (3):

1. To ensure availability and accessibility of minimum mental health care for all in the near foreseeable future, particularly to the most vulnerable sections of the population.
2. To encourage mental health knowledge and skills in general health care and social development.
3. To promote community participation in mental health service development and to stimulate self-help in the community.

NMHP envisaged integration of mental health care with general health care and welfare (4).

**Implementation** : A model for delivery of community based mental health care at the level of district was evolved and field-tested in Bellary district of Karnataka by NIMHANS between 1986-1995. This model was adapted as the District Mental Health Programme (DMHP) and it was implemented in 27 Districts across 22 states/UTs in the 9th five year plan beginning in the year 1996.

**Barriers to Implementation of the Programme:**

1. Shortage of trained manpower in the field of mental health.
2. Social stigma & lack of knowledge of psychiatric patients & their families.
3. Negative attitude of general practitioners, primary care physicians & other specialists.
4. NGOs/Voluntary Organizations do not find this field attractive.
5. Inadequate staff & infrastructure of mental hospitals and psychiatric wings of medical colleges.
6. Uneven distribution of sparse resources limiting the availability of mental health care to those living in urban areas.

#### NMHP during the 10th Five Year Plan

An evaluation of the NMHP was undertaken in 2003 and the programme was re-strategised to incorporate the following changes and it became from single pronged to a multi-pronged programme for effective reach and impact on mental illnesses. Main strategies of NMHP during the 10th plan period are as follows:

1. Expansion of DMHP to 100 districts all over the country.
2. Strengthening and Modernization of Mental Hospitals.

3. Up gradation of Psychiatry wings in the General Hospitals/ Medical Colleges.
4. IEC Activities.
5. Research & Training in Mental Health for improving service delivery.

#### District Mental Health Programme

Its main objective is to provide basic mental health services to the community & to integrate these with other health services. The programme envisages a community based approach to the problem, which includes:

1. Training of mental health team at the identified nodal institutions.
2. Increase awareness about Mental Health problems.
3. Provide service for early detection & treatment of mental illnesses in the community (OPD/Indoor & follow up).
4. Provide valuable data & experience at the level of community at the state & center for future planning & improvement in service & research.
5. Strengthening and Modernization of Mental Hospitals.

#### Identified thrust areas based on experience gained during 10th Five Year Plan

1. To expand DMHP in an enlarged & more effective form.
2. Strengthening/modernization of remaining mental hospitals in order to modify from largely custodial role to therapeutic role.
3. Upgrading Departments of Psychiatry in Medical Colleges & enhancing the Psychiatric content of the medical curriculum at the UG/PG level.
4. Information, Education and Communication activities for creating awareness and reducing stigma.
5. Research & Training in Mental Health.
6. School Mental Health Programme.
7. Involvement of NGOs & Public Private Partnership in Community based care of mentally ill patients to fill the service gap in mental health delivery.

#### Revised Framework of 11th Five Year Plan

The revised approach for the programme in eleventh five year plan will recognize the importance of mental health care and will concentrate on providing counselling, medical services, and establishing helplines for all, especially people affected by calamities, riots and violence(5). The following actions are envisaged :

1. There is a need to empower the PHC doctor to offer care to mentally ill persons at the PHC.
2. There is a need to improve public awareness and facilitate community participation.
3. The psychiatric departments of Medical Colleges have to be upgraded to enhance better training opportunities.
4. Mental Hospitals that offer tertiary care to be improved to make treatment acceptable to the patients.

#### Indicators in 11th plan

1. No of districts that have successfully implemented DMHP
2. Improvement in service care in mental hospitals
3. Lowering of stigma attached to mental illnesses
4. Increased awareness of mental disorders

## Strategies

1. Integrating mental health with primary health care through NMHP.
2. Providing of tertiary care institutions for treatment of mental disorders.
3. Eradicating stigmatization of mentally ill patients and protecting their rights through regulatory institutions like central and state mental health authorities.

## Critical Appraisal

Successful implementation of mental health is a big challenge for all. With a large population of mentally ill in our country and very few psychiatrists being available, less than one psychiatrist is available for every 3 lacs population. The psychiatrist / population ratio in rural areas that account for 70% of country's population, could well be under one for every million. There is a need to strengthen district mental health programmes and enhance its visibility at the grass root level. The manpower gaps in the field of psychiatry are required to be filled up. The NGOs have to join hands in this programme and help in Community Based care of mentally ill. Preventive and promotive aspects of the programme have to be focused and looked in addition to treatment of serious mental ailments. IEC activities have to be strengthened and training of general practitioners in mental health is required to be emphasized upon. Optimal mix of different mental health care services is given in Table 1(6,7). There is a need for integrating the mental health components in national level programmes like the ICDS, education system, and use of traditional systems like yoga, meditation, so that the mental health promotive activities become part of the programme.

## Summary

NMHP was started in 1982 with the objective of ensuring availability and accessibility of minimum mental health care for all in the near foreseeable future, particularly to the most

vulnerable sections of the population. To encourage mental health knowledge and skills in general health care and social development, To promote community participation in mental health service development and to stimulate self-help in the community. NMHP envisaged integration of mental health care with general health care and welfare.

The objectives of the programme in the eleventh five year plan are to empower the PHC doctor to offer care to mentally ill persons at the PHC, improve public awareness and facilitate community participation, upgradation of psychiatric departments of Medical Colleges have to be upgraded to enhance better training opportunities.

The strategies in the eleventh plan include integrating mental health with primary health care through NMHP, Providing of tertiary care institutions for treatment of mental disorders and eradicating stigmatization of mentally ill patients and protecting their rights through regulatory institutions like central and state mental health authorities.

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## National Cancer Control Programme

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Cancer is an important public health problem in India with nearly 7-9 lakh new cases occurring every year in the country. It is estimated that there are 20-25 lakh cases of cancer in the country at any given point of time. In India over 70% of the cases report for diagnostic and treatment services in advanced stages of the disease, resulting in poor survival and high mortality rates (1). With the objectives of prevention, early diagnosis and treatment, the National Cancer Control Programme (NCCP) was

launched in 1975-76. In view of the magnitude of the problem and the requirement to bridge the geographical gaps in the availability of cancer treatment facilities across the country; the programme was revised in 1984-85 and subsequently in December 2004.

**Goals & Objectives :** The goals and objectives are (2) :

1. Primary prevention of cancers by health education regarding hazards of tobacco consumption and necessity of genital hygiene for prevention of cervical cancer.
2. Secondary prevention i.e. early detection and diagnosis of cancers, for example, cancer of cervix, breast cancer and of the oro-pharyngeal cancer by screening methods and patients' education on self examination methods.

3. Strengthening of existing cancer treatment facilities, which were inadequate.
4. Palliative care in terminal stage cancer.

Global
<ul style="list-style-type: none"> <li>• Cancers cause 12 per cent of deaths</li> <li>• Second leading cause of death in developed countries accounting 21 % (2.5m) of all deaths</li> <li>• Second leading cause of death in developing countries accounting for 9.5% of all deaths (3.8m)</li> </ul>
India
<ul style="list-style-type: none"> <li>• One of the ten leading causes of death</li> <li>• There are 1.5-2 million cancer cases at any given point of time</li> <li>• 7 lakh new cases of cancer and 3 lakh deaths occur annually due to cancer</li> <li>• The common sites for cancer in India are oral cavity, lungs, oesophagus and stomach in males and cervix, breast and oral cavity among females</li> </ul>

**Existing Schemes under National Cancer Control Programme (3)** : This is shown in Table - 1.

The programme was revised in December 2004. There are 5 schemes under the revised programme (4)

**1. Recognition of New Regional Cancer Centres (RCCs)** : In order to augment comprehensive cancer care facilities in regions of the country lacking them, new RCCs are being recognized.

**2. Strengthening of Existing RCCs** : A one-time grant of Rs. 3.00 crores is provided to the existing RCCs in order to further strengthen the cancer treatment facilities in the existing centres.

**3. Development of Oncology wing** : The scheme aims to correct the geographical imbalance by providing financial assistance to Government institutions (Medical Colleges as well as Government Hospitals) for enhancing the cancer care facilities.

**4. District Cancer Control Programme (DCCP)** : The DCCP will be implemented by the Nodal Agency, which may be an RCC or an Oncology Wing. The aim is to strengthen District Hospitals in 2-3 congruent districts for early detection and appropriate treatment or referral.

**5. Decentralized NGO Scheme** : This scheme has been devised to promote prevention and early detection of cancers. Non- Governmental Organizations (NGO) will implement these activities under the coordination of the Nodal Agency, which will be an RCC or an Oncology Wing.

#### District Cancer Control Programme

This programme was launched in 1990-91 and under this programme each state and union territory is advised to prepare their projects on health education, early detection, and pain relief measures. For this they can get up to Rs. 15 lakhs one time assistance and Rs. 10 lakhs for four years recurring assistance. The district programme has five elements:

1. Health education.
2. Early detection.
3. Training of medical & paramedical personnel.
4. Palliative treatment and pain relief.
5. Coordination and monitoring.

The District programmes are linked with Regional Cancer Centres/ Government Hospitals/ Medical Colleges. For effective functioning each district where programme has started to have one District Cancer Society that is chaired by local Collector/ Chief Medical Officer. Other members are Dean of medical college, Zila parishad representative, NGO representative etc.

#### National Cancer Registry Programme (NCRP)

National Cancer Registry Programme was launched in 1982 by Indian Council of Medical Research (ICMR) to provide true information on cancer prevalence and incidence. There are five population-based urban cancer registries in Mumbai, Bangalore, Chennai, Bhopal, Delhi and a rural registry at Barsi in Maharashtra and six hospital-based registries at Chandigarh, Dibrugarh, Thiruvananthapuram, Bangalore, Mumbai and Chennai. The NCRP provides data on regional difference and time

**Table - 1 : Existing Schemes under National Cancer Control Programme**

Scheme	Remarks
Financial Assistance to Voluntary Organisations	For IEC activities and early detection of cancer
District Cancer Control Scheme	District projects are given financial assistance to carry out health education, early detection and pain relief measures. Under this scheme one time financial assistance of Rs.15.00 lakhs is provided to the concerned State Government for each district project with a provision of Rs.10.00 lakhs every year for the remaining four years of the project period.
Cobalt Therapy Installation	To strengthen the cancer treatment facilities, the financial assistance of Rs. 1.0 crore is given to charitable organisations and 1.5 crores for government institutions is provided for procurement of teletherapy and brachytherapy equipments etc. This is one time grant as at present.
Development of Oncology Wings in Govt. Medical College Hospitals	The aim is to fill geographical gaps. One time financial assistance of Rs.2.00 crores is provided by the centre for purchase of equipment.
Regional cancer institutes	There are 25 Regional Cancer Research and Treatment Centres recognised by Government of India and recurring grant of Rs.75 lakhs is being given to these Regional Cancer Centres.



trends in cancer prevalence so that appropriate modifications in the ongoing programmes could be made.

#### Objectives of NCRP

1. To generate authentic data on the magnitude of cancer problem in India.
2. To undertake epidemiological investigations and advice control measures.
3. Promote human resource development in cancer epidemiology.

In the XI five year plan, the focus will be on community based cancer prevention and control strategies. We are in the process of establishing OncoNET India, a network connecting 25 Regional Cancer Centres and 100 peripheral centres thus facilitating telemedicine services and continued medical education.

#### Critical appraisal

The programme however has mainly contributed to the development of radiation oncology services rather than making any headway in the direction of prevention and early detection (5). There is no organised screening programme for any of the common cancers in the country. Most cancer centers provide only opportunistic screening services. Research and training was one of the objectives of the programme but was neglected during implementation of the programme.

#### Summary

National Cancer Control Programme (NCCP) was launched in 1975-76. The goals & objectives are primary prevention of cancers by health education regarding hazards of tobacco consumption and necessity of genital hygiene for prevention of cervical cancer; Secondary prevention i.e. early detection

and diagnosis of cancers, for example, cancer of cervix, breast cancer and of the oro-pharyngeal cancer by screening methods and patients' education on self examination methods, Strengthening of existing cancer treatment facilities and palliative care in terminal stage cancer.

Existing Schemes under National Cancer Control Programme are Financial Assistance to Voluntary Organisations, District Cancer Control Scheme, Cobalt Therapy Installation, Development of Oncology Wings in Govt. Medical College Hospitals and Recognition of New Regional Cancer Centres. The elements of district programme are Health education, Early detection, Training of medical & paramedical personnel, Palliative treatment and pain relief and coordination and monitoring.

National Cancer Registry Programme was launched in 1982 by Indian Council of Medical Research (ICMR) to provide true information on cancer prevalence and incidence. The NCRP provides data on regional difference and time trends in cancer prevalence so that appropriate modifications in the ongoing programmes could be made.

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2. Y.N. Rao, Sudhir Gupta and S.P. Agarwal. National Cancer Control Programme: Current Status & Strategies: 50 years of cancer control in India.
3. Ministry of Health and Family Welfare. GOI
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### National Programme for Prevention & Control of Diabetes, Cardiovascular Diseases & Stroke

*Puja Dudeja & Ashok K. Jindal*

The World Health Report of 2002 states that Cardiovascular Diseases (CVD) will be the largest cause of death and disability in India by 2020. Non Communicable Diseases (NCDs), especially Cardiovascular Diseases (CVDs), Diabetes Mellitus, Cancer, Stroke and Chronic Lung Diseases have emerged as major public health problems in India, due to an ageing population and environmentally driven changes in behaviour. It is estimated that in 2005, NCDs accounted for 5,466,000 (53%) of all deaths (10,362,000) in India. The estimated burden of common NCDs are; 2.4 million Ischemic Heart Diseases, 37.8 million diabetes, 2.4 million cancers and 0.93 million stroke. Compared with all other countries, India suffers the highest loss in potentially productive years of life, due to deaths from

cardiovascular disease in people aged 35-64 years (9.2 million years lost in 2000). The common risk factors are Tobacco, Alcohol, Diet and Physical inactivity.

#### Rationale for Having a Common Programme for the Prevention and Control of Diabetes, CVD and Stroke

1. Diabetes is an important risk factor for both the major forms of cardiovascular disease (coronary heart disease and stroke).
2. CVD is the major cause of death and disability in persons with diabetes.
3. Common risk factors underlie CVD and diabetes: unhealthy diets, physical inactivity and over weight are common to both.
4. High blood pressure often precedes and predicts the onset of clinical diabetes by several years. This has led to 'hypertension' being regarded as a pre-diabetic condition.
5. Clinical trials have shown that, mortality reduction and increased survival are better achieved by blood pressure control than even by blood sugar control, in persons with diabetes.

- Persons with CVD or diabetes require similar lifestyle therapy and often similar drug therapy for prevention of complications (diet; physical activity; smoking cessation; cholesterol lowering drugs; aspirin; ACE inhibitors; other blood pressure lowering drugs).
- Persons with diabetes frequently need to be screened for CVD and risk factors of CVD.
- Proven lifestyle interventions which can prevent the onset of diabetes (diet and physical activity) are similar to those proven to reduce the risk of developing hypertension, coronary heart disease or stroke.

The strategic approaches and operational elements for prevention and control of CVD and diabetes are thus similar or closely interlinked, whether it is primordial prevention, primary prevention or secondary prevention (reducing the risk of complications after the onset of disease).

**Implementation** : The NPDCS will be implemented in a phased manner with a pilot being done in the Preparatory Phase 2006-07. Subsequently, the programme would be implemented across the country through select institutions over the XI Five Year Plan.

**Aim of the Programme** : Prevention and control of common NCD risk factors through an integrated approach and reduction of premature morbidity and mortality from DM, CVD and Stroke (1).

#### Long term objectives

- Reduce prevalence of risk factors of common NCDs.
- Reduce morbidity and mortality due to Diabetes, Cardiovascular diseases and Stroke.
- Building capacity of health systems to tackle NCDs and improvement of quality of care.

#### Immediate objectives

- Primary prevention of major Non Communicable Diseases through Health Promotion.
- Surveillance of NCDs and their risk factors in the population.
- Capacity enhancement of health professionals and health systems for diagnosis and appropriate management of NCDs and their risk factors.
- Reduction of risk factors of NCDs in the population.
- Establish National Guidelines for management of NCDs.
- Development of strategies/ policies for prevention of NCDs in the country through Inter ministerial collaborations/ coordination.
- Community empowerment for prevention of NCDs.

#### Summary

The NPDCS will be implemented in a phased manner with a pilot being done in the Preparatory Phase 2006-07. Subsequently, the programme would be implemented across the country through select institutions over the XI Five Year Plan. The aim of the Programme Prevention and control of common NCD risk factors through an integrated approach and reduction of premature morbidity and mortality from DM, CVD and Stroke. In the long term the programme envisages, reduction in prevalence of risk factors of common NCDs, reduction in morbidity and mortality due to Diabetes, Cardiovascular diseases and Stroke and building capacity of health systems to tackle NCDs and improvement of quality of care.

#### References

- Annual Health Report 2006-07. Ministry of Health and Family Welfare. Govt. of India.

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## National Iodine Deficiency Diseases Control Programme

*Puja Dudeja & Ashok K. Jindal*

Iodine, an essential micronutrient with daily requirement of 100-150 mg, plays an important role in normal human growth and development. It has been widely recognized that deficiency of iodine not only contributes to goitre but also is an important risk factor for preventable mental retardation; it affects reproductive functions and impairs child's learning ability. The disorders produced as a result of nutritional iodine deficiency are classified as "Iodine Deficiency Disorders (IDD) or IDD syndromes" (1).

The History of Iodine Deficiency Control Programme in our country is given in Table 1.

Table 1

S. No.	Year	Event
1.	1954-1962	Prospective study on iodine deficiency disorders in Kangra valley
2.	1962	National Goitre Control Programme (NGCP)
3.	1982	Technical goitre control review committee recommended to declare entire country goitre prone
4.	1983	Universal iodisation of salt in the country
5.	1992	NGCP was redesignated as National Iodine Deficiency Disorders Control Programme* (NIDDCP)

\* The title has been changed in view of the wide spectrum of Iodine Deficiency Disorders like mental and physical retardation, deaf mutism, cretinism, high rates of abortion etc. and the Govt. commitment to overcome all other Iodine Deficiency Disorders apart from Goitre, through Universal Iodisation of salt.

## Programme Implementation (2)

**Responsibilities :** It is a 100 percent centrally assisted programme. The Ministry of health and Family Welfare is the nodal ministry for policy decisions on NIDDCP. The central Nutrition and Iodine Deficiency Disorders Cell at the Directorate General of Health Services is responsible for the implementation of NIDDCP. The Salt Commissioner's office under the Ministry of Industry is responsible for licensing, production and distribution of iodated salt to States/UTs. This office is also responsible for monitoring the quality of iodated salt at production level and distribution of same in the country. The Salt Commissioner in consultation with the Ministry of Railways arranges for movement of iodated salt from production centres to the states/UTs on a priority basis. The best indicator for monitoring the impact of iodine Deficiency Disorders Control Programme is neonatal hypothyroidism.

The Government's goal of NIDDCP is to reduce the prevalence of iodine deficiency disorders below 10 percent in the entire country by 2012 AD.

### *The Objectives of NIDDCP are as under*

1. Survey to assess the magnitude of the IDD
2. Supply of iodated salt in place of common salt
3. Resurvey after every 5 years to assess the magnitude of the IDD and the impact of iodated salt on it
4. Laboratory monitoring of iodated salt and urinary iodine excretion
5. Health education and publicity

### *Other components of the strategy are*

- (i) Testing of salt at manufacturing level.
- (ii) Testing of salt at Consumption level.
- (iii) Testing of Urine samples at District/State level.
- (iv) Monitoring the Thyroid status of new borns through screening of cord Blood samples.
- (v) Strengthening of Central Iodine Deficiency Disorder Control Cell at the Headquarters.
- (vi) Strengthening of Training including establishment of Iodine Deficiency Disorder Training Programme.
- (vii) Information, Education and Communication.

**IDD Control Cell :** Each state has an IDD Control Cell which carries out periodic surveys regarding the prevalence of IDD and coordinates with central IDD cell. The functions of this cell are as under:

1. Checking iodine levels of the salt with wholesalers and retailers within the state and coordinating with food and civil supplies department.
2. The distribution of iodated salt within the state through open market and public distribution system.
3. Creating demand for iodated salt.
4. Monitoring consumption of iodated salt.
5. Conducting IDD surveys to identify the magnitude of IDD in various districts.
6. Conducting training.
7. Dissemination of information, education and communication.

**Benefits of IDD control (3) :** IDD is one of the three micronutrient deficiencies declared to be eliminated by WHO, the other two being vitamin A deficiency and iron deficiency. Apart from minimizing human misery, IDD control makes it possible to have better education to the children, high labour productivity and better quality of life. See Table - 2.

Table - 2		
S. No.	Reduction	Benefits
1	Mental deficiency	Higher work output in school and work place
2	Autism	Reduced cost of custodial and medical care
3	Spastic diplegia	Reduced educational cost from reduced absenteeism and grade repetition and higher academic achievement by the student

**Critical Appraisal :** IDD control cells have not been established in all the states. The process of setting up iodine monitoring laboratory for estimation of iodine content of salt and urinary iodine excretion is slow. Lack of resources and trained manpower restricts the quality control of iodated salt at the consumer level. A lot needs to be done to create a felt need for the programme activities among the masses. Medical and para medical manpower needs to be trained on the subject.

## Summary

The disorders produced as a result of nutritional iodine deficiency are classified as "Iodine Deficiency Disorders (IDD) or IDD syndromes". In 1962 National Goitre Control Programme was launched, however the title has been changed in 1992 to NIDDCP to cover the wide spectrum of Iodine Deficiency Disorders.

The goal of NIDDCP are to reduce the prevalence of iodine deficiency disorders below 10 percent in the entire country by 2012 AD. The Objectives of NIDDCP are to survey to assess the magnitude of the IDD, supply of iodated salt in place of common salt, resurvey after every 5 years to assess the magnitude of the IDD and the impact of iodated salt on it, laboratory monitoring of iodated salt and urinary iodine excretion and Health education and publicity. IDD Control Cell in each state has been established which carries out periodic surveys regarding the prevalence of IDD and coordinates with central IDD cell.

## References

1. CD Alert June 2005 Vol.9: No.6
2. Tiwari BK. Revised guidelines on National Iodine Deficiency Disorders Control Programme. Directorate General of Health Services. Ministry of Health and Family Welfare. October 2006.
3. T Jaya Krishnan, M. C. Jeeja. Iodine deficiency disorders in school children in kanur district. Discussion paper no 41. 2002. June 2005 Vol.9: No.6. Kerala research programme on local development. Centre for development studies. Tiruvantapuram.

Puja Dudeja &amp; Ashok K. Jindal

Hearing loss is the most common sensory deficit in humans today. As per WHO estimates in India, there are approximately 63 million people, who are suffering from significant auditory impairment; this places the estimated prevalence at 6.3% in Indian population; of these, a large percentage is children between the ages of 0 to 14 years. With such a large number of hearing impaired young Indians, it amounts to a severe loss of productivity, both physical and economic.

### Objectives

1. To prevent the avoidable hearing loss on account of disease or injury.
2. Early identification, diagnosis and treatment of ear problems responsible for hearing loss and deafness.
3. To medically rehabilitate persons of all age groups, suffering with deafness.
4. To strengthen the existing inter-sectoral linkages for continuity of the rehabilitation programme, for persons with deafness.
5. To develop institutional capacity for ear care services by providing support for equipment & material and training personnel.

**Long term objective :** To prevent and control major causes of hearing impairment and deafness, so as to reduce the total disease burden by 25% of the existing burden by the end of eleventh five year plan.

### Strategies

1. To strengthen the service delivery including rehabilitation.
2. To develop human resource for ear care.
3. To promote outreach activities and public awareness through appropriate and effective IEC strategies with special emphasis on prevention of deafness.
4. To develop institutional capacity of the district hospitals, community health centers and primary health centers, selected under the project.

### Programme Execution & Expansion (1)

A pilot project, to be conducted in 25 districts derived from 10 states and one union territory, is already in the first phase of implementation. This will run from 2006 to 2008. In the remaining four years of the 11th Five year plan, it is proposed to expand this programme to include a total of 203 districts covering all the states and Union territories of India by 2012. The expansion will be done in a phased manner, with inclusion of 45 new districts each year. At the end of the plan, it is proposed to cover 50% of the districts in all the pilot states (except Uttar Pradesh) and 25% of the districts in all the other states/UTs.

### Components of the Programme

**1. Manpower training and development :** For prevention, early identification and management of hearing impaired and deafness cases, training would be provided from medical college level specialists (ENT and Audiology) to grass root level

workers. The training of PHC doctors and health functionaries would be provided by Rehabilitation Council of India.

**2. Capacity building :** for the district hospital, community health centers and primary health center in respect of ENT/ Audiology infrastructure.

**3. Service provision including rehabilitation :** Screening camps for early detection of hearing impairment and deafness, management of hearing and speech impaired cases and rehabilitation (including provision of hearing aids), at different levels of health care delivery system.

**4. Awareness generation through IEC activities :** For early identification of hearing impaired, especially children so that timely management of such cases is possible and to remove the stigma attached to deafness.

### Expected Benefits of the Programme

The programme is expected to generate the following benefits in the short as well as in the long run :

1. Large scale direct benefit of various services like prevention, early identification, treatment, referral, rehabilitation etc. for hearing impairment and deafness as the primary health center/community health centers/district hospitals largely cater to their need.
2. Decrease in the magnitude of hearing impaired persons.
3. Decrease in the severity/extent of ear morbidity or hearing impairment in large number of cases.
4. Improved service network for the persons with ear morbidity/hearing impairment in the states and districts covered under the project.
5. Awareness creation among the health workers/grassroot level workers through the primary health centre medical officers and district officers which will percolate to the lowest level as the lower level health workers function within the community.
6. Larger community participation to prevent hearing loss through panchyati raj institutions, *mahila mandals*, village bodies and also creation of a collective responsibility framework in the broad spectrum of the society.
7. Leadership building in the primary health centre medical officers to help create better sensitization in the grassroot level which will ultimately ensure better implementation of the programme.

### Summary

The programme is a part of eleventh five year plan with the objective of preventing and controlling major causes of hearing impairment and deafness, so as to reduce the total disease burden by 25% of the existing burden by the end of eleventh five year plan. The Components of the Programme are Manpower training and development to grass root level workers, Capacity building - for the district hospital, community health centers and primary health center in respect of ENT/ Audiology infrastructure, Service provision including rehabilitation in the form of Screening camps, management of hearing and speech impaired cases and rehabilitation (including provision of hearing aids), at different levels of health care delivery system and awareness generation through IEC activities.

### References:

1. Working gps/Steering Committees/Task Force for the 11th five year plan 2007-2012. Plg Com.GOI. Available at <http://planning.comm.nic.in/plans/11thf.htm>.



*Puja Dudeja & Ashok K. Jindal*

National Programme for Control of Blindness was launched in the year 1976 as a 100% centrally sponsored scheme with the goal to reduce the prevalence of blindness from 1.4% to 0.3%. India was the first country to launch the National Programme for Control of Blindness. Due to a large population base and increased life expectancy, the number of blind particularly due to senile disorders like Cataract, Glaucoma, Diabetic Retinopathy etc. is expected to increase. Among the emerging cause of blindness, diabetic retinopathy and glaucoma need special mention. 2 percent of India's population is expected to be diabetic. 20 percent of diabetics have diabetic retinopathy and this number is likely to grow in future. India is committed to reduce the burden of avoidable blindness by the year 2020 by adopting strategies advocated for Vision 2020: The Right to Sight. The prevalence and causes of blindness and future goals are given in Table - 1.

### Objectives

The objectives of the programme are (1) :

1. To reduce the backlog of blindness through identification and treatment of blind.
2. To develop Eye Care facilities in every district.
3. To develop human resources for providing Eye Care Services.
4. To improve quality of service delivery.
5. To secure participation of Voluntary Organizations in eye care.

**Table - 1 : Prevalence and causes of Blindness & Future Goals**

Year	Population Prevalence (%)	Remarks
1971-74	1.38	Cataract was leading cause (75% of blindness)
1986-89	1.49	Cataract blindness increased to 80%. Trachoma and Vitamin A related blindness reduced.
2001-04	1.10	Cataract reduced to 63%. Refractive error second leading cause (20%). Glaucoma and diabetic retinopathy emerging causes.
2007	--	Goal for 10th plan : 0.8%
2010	--	Goal under "Vision 2020 Initiative": 0.5%

### Programme Implementation

India is a vast country having 28 States and 7 Union Territories with 593 districts, with an average population of nearly two million per district. The programme implementation has

been decentralized up to the district level where District Blindness Control Societies (DBCS) have been set up as the nodal agencies. Members of the DBCS include officials from District Administration, Health, Education and Social Welfare Departments, media, community leaders and NGOs/Private Sectors involved in eye care. These societies directly receive funds from the Government. The concept is to establish a bottom up approach in dealing with blindness through multisectoral and coordinated efforts. These societies are responsible for identifying blind in every village, organize diagnostic screening camps at suitable locations, arrange transportation of patients to the designated facilities, and ensure follow up. The states have State ophthalmic cell under directorate of health services and state health societies. At the apex National institute of ophthalmology (Dr. Rajendra Prasad Centre for ophthalmic sciences in AIIMS, New Delhi) has been established. Various other regional institutes have been developed. Medical colleges have been upgraded under NPCB and few of them are providing training to ophthalmic assistants.

**School Eye Screening Programme :** Under this the children aged 10-14 years are being screened by trained teachers and those suspected to have refractory error are seen by ophthalmic assistants and corrective spectacles are prescribed.

### Constraints

1. **Inequitable distribution of eye surgeons :** There are an estimated 12,000 eye surgeons in India with an average of 1 surgeon for 1,00,000 population. There is a wide disparity between urban and rural areas. This disparity has led to significant differences in services offered / sought by the public.
2. **Suboptimal utilization of human resources:** It is estimated that about 40 percent of eye surgeons in government section are non operating surgeons. They are either practicing medical ophthalmology/refraction services or providing general medical care.
3. **Inadequate number of paramedical eye personnel**
4. **Suboptimal coverage :** Govt. facilities, NGO and private sector are usually located in urban/ periurban areas. Geo-physically remote and socioeconomically backward population remains underserved.
5. **Over emphasis on cataract :** The problem of corneal blindness, Glaucoma and diabetic retinopathy has not been adequately addressed. Similarly pediatric ophthalmology and low vision has received low priority.
6. **Lack of public awareness :** Rural, illiterate and under privileged population are not fully aware about various interventions that are available to restore vision. Integration of the programme is limited and therefore rural health workers are also not motivating potential beneficiaries.

### Major challenges ahead

1. In-depth study of epidemiology of blindness
2. Comprehensive eye care programme
3. Reaching the underserved population
4. Development of sustainable infrastructure
5. Technological advancement in eye care
6. Human resource development
7. Quality of care

### Strategies during XI plan

1. Strengthening advocacy and motivation by involvement of village panchayat, local bodies, grass root NGOs, women group and formal and informal leaders.
2. Human resource development.
3. Infrastructure development.
4. Grant in aid to state blindness control societies and district blindness control societies.
5. Involvement of private practitioners.
6. Increased IEC activities.

**Vision 2020 - The Right to Sight Initiative** : The global initiative, "VISION 2020: The Right to Sight" is a collaborative response initiated by the World Health Organization (WHO) and the International Agency for the Prevention of Blindness (IAPB) to combat the gigantic problem of blindness in the world. It was launched in Geneva in 1999. The diseases covered under Vision 2020 are (2) :

1. Cataract
2. Trachoma
3. Onchocerciasis (not a problem in India)
4. Childhood blindness
5. Refractive Errors and Low Vision

These conditions have been chosen on the basis of their contribution to the burden of blindness and the feasibility and affordability of interventions to control them. Each country will decide on its priorities based on the magnitude of specific blinding conditions in that country. Under this initiative, five basic strategies to combat blindness are :

1. Disease prevention and control.
2. Training of personnel.
3. Strengthening the existing eye care infrastructure.
4. Use of appropriate and affordable technology.
5. Mobilization of resources.

Vision 2020 will serve as a common platform to facilitate a focused and coordinated functioning of all the partners in eliminating avoidable blindness by the year 2020. It will further develop and strengthen the primary health/eye care approach to the problem of avoidable blindness. Broad regional alliances will be sought to eventually develop a global partnership for eye health.

**Cataract** : Cataract is the major cause of blindness in the world. The aim is Elimination of cataract blindness (person with vision less than 3/60 in both eyes).

**Trachoma** : Trachoma is the second cause of blindness in sub-Saharan Africa, China and the Middle-Eastern countries. The aim is to eliminate blindness due to trachoma. Trachoma is to be controlled through the implementation of the SAFE strategy integrated within primary health care in all communities identified as having blinding trachoma within a country. This includes the following:

- i) Assessment to identify communities with blinding trachoma.
- ii) Delivery of community-based trichiasis Surgery by trained paramedical staff (S of SAFE).
- iii) Antibiotic treatment (either tetracycline eye ointment or oral azithromycin) for children with active disease (A of SAFE).
- iv) Promotion of Facial cleanliness (F of SAFE) and

Environmental improvement (E of SAFE), including personal hygiene and community sanitation as part of primary health care.

### Childhood Blindness

**Vitamin A deficiency** : To achieve and sustain the elimination of blindness due to vitamin A deficiency.

**Surgically avoidable causes** : To control blindness in children from cataract, glaucoma and retinopathy of prematurity (ROP)

**Refractive Errors and Low Vision** : Spectacles are an essential part of the treatment of many eye patients. Their provision is therefore an integral part of eye care delivery. Elimination of visual impairment (vision less than 6/18) and blindness due to refractive errors or other causes of low vision. This aim goes beyond the elimination of blindness and also includes the provision of services for individuals with low vision.

**Implementation** : The proposed structure for implementation of Vision 2020 is vision centre at the primary level, Service centre at the secondary level and Training centre and centre of excellence at the tertiary level.

### Summary

National Programme for Control of Blindness was launched in the year 1976. India was the first country to launch the National Programme for Control of Blindness. The objectives are to reduce the backlog of blindness through identification and treatment of blind, to develop Eye Care facilities in every district, to develop human resources for providing Eye Care Services, to improve quality of service delivery and to secure participation of Voluntary Organizations in eye care.

The programme implementation has been decentralized upto the district level where District Blindness Control Societies (DBCS) have been set up as the nodal agencies. These societies are responsible for identifying blind in every village, organize diagnostic screening camps at suitable locations, arrange transportation of patients to the designated facilities, and ensure follow up.

The Constraints for implementation are inequitable distribution of eye surgeons, suboptimal utilization of human resources, suboptimal coverage, over emphasis on cataract and lack of public awareness. The global initiative, "VISION 2020: The Right to Sight" is a collaborative response initiated by the World Health Organization (WHO) and the International Agency for the Prevention of Blindness (IAPB) to combat the gigantic problem of blindness in the world. It was launched in Geneva in 1999. The diseases covered under Vision 2020 are Cataract, Trachoma, Onchocerciasis, Childhood blindness and Refractive Errors and Low Vision.

Under this initiative, five basic strategies to combat blindness are disease prevention and control, training of personnel, strengthening the existing eye care infrastructure, use of appropriate and affordable technology and mobilization of resources.

### Further Suggested Reading

1. Annual Health Report 2006-07. Ministry of Health And Family Welfare. Government of India.
2. Working gps/Steering Committees/Task Force for the 11th five year plan 2007-2012.Plg Com.GOI.Available at [http://planning comm.nic.in/plans/11thf.htm](http://planning.comm.nic.in/plans/11thf.htm).

Puja Dudeja &amp; Ashok K. Jindal

**(A) National Oral Health Programme**

Oral diseases such as dental caries, periodontal diseases, malocclusion and oral cancers constitute an important public health problem in India today. Oral diseases have a great impact on systemic health and is now established that periodontal diseases has far reaching effects on various systemic diseases like low birth weight, Diabetes, Heart disease, Respiratory diseases, Stroke, Atherosclerosis etc. Oral cancer prevalence is highest in India, causing high morbidity and mortality. National oral health program is a pilot project on oral health started in the year 1999 by DGHS and the Ministry of Health and Family Welfare. Under this project, All India Institute of Medical Sciences has been made a nodal agency.

**Programme targets :** These are given in Table - 1.

Table - 1

Oral Diseases	Age Group	Prevalence (%) 2005	Status by 2012(%)
Dental Caries	All	40-50	<30
Periodontal diseases	15+	45	<35
Malocclusion	9-14	32.5	25
Oral cancer	35+	0.03	0.02
Fluorosis	All	5.5	4

**Components**

1. Oral Health Education by involving health workers, school children, teachers and mass media.
2. Production of IEC Material for awareness generation.
3. Formulation of modules for trainers (Dental surgeons), Health Workers and School Teachers.

The main focus of this project is on primary prevention which is the most cost effective, appropriate and desirable.

The project was reviewed by National Institute for Health and Family Welfare in 2004 and following recommendations were made:

1. The program to be divided into several implementation phases giving reasonable time frames and goals to be achieved in each phase.
2. Centre to provide technical support to the states by forming various committees and one time financial support.
3. The states to be responsible for implementation of the programme by involving the education department, school teachers, health workers and by developing adequate infrastructure and facilities.
4. Modification of the existing IEC material with respect to the local situation in the states and in consultation with agencies like Central Health Education Bureau, Indian

Institute of Mass communication, media division of MoHFW. The messages of oral and dental health should be merged with other IEC materials being developed by the centre and state governments.

**Strategies for future**

**1. Oral Health Education :** Use of primary health care approach: It is recommended to spread the messages of oral health care and strengthening of existing infrastructure. Health care workers to be an important part of the programme in spreading health awareness. Health care workers to be trained in providing pain relief and refer the case for further investigation and treatment.

- Development of IEC material and use of mass media in spreading awareness.
- Involvement of NGOs in delivery of oral health education.
- Networking with other departments like Dept. of Education and Social Welfare in imparting oral health education to the school children.

**2. Manpower and infrastructure development for primary and secondary prevention of oral diseases :** Mobile Dental Clinics to provide on the spot diagnostic, preventive, interceptive and curative services to the people and school children in far flung rural areas of the state, should be made available.

**3. Strengthening school health services :** Good oral habits and practices learnt early in life would help reduce the disease burden later in life.

**Critical Appraisal**

Oral health care has not been given sufficient importance in our country. Most of the district hospitals have the post of a dental surgeon but they lack in equipment, machinery and material. Even when the equipment exists, the maintenance is poor. Oral health has not been discussed in National Health Policy 2002 and National Rural Health Mission also does not have any mention of oral health services either. The treatment of Oro-dental diseases is enormously expensive and no Govt. across the globe can bear the cost for dental treatment for its entire population. It is suggested that Govt. should bear the cost for primary and secondary prevention completely and may impose cost to cost pricing for the treatment part at all levels.

**(B) National Programme for Prevention of Fluorosis**

Fluorosis, a public health problem, is caused by excess intake of fluorides through drinking water/food products/industrial pollutants, over a long period. It results in major health disorders like dental fluorosis, skeletal fluorosis and non skeletal fluorosis besides inducing ageing.

**Level of fluoride :** The fluoride content in drinking water in India is about 0.5mg/l but in fluorosis endemic areas, the natural water have been found to contain as much as 3-12 mg/l of fluoride. A concentration of 0.5 - 0.8 mg/l is considered safe limit in India. In temperate climate where intake of water is low, the optimum level of fluorine in drinking water is accepted as 1mg/l (2).

**Problem statement :** Fluoride endemicity has been reported in 196 districts of 19 states & UTs of the country. The affected



population with fluorosis is about 66 million in the country. Based on excess level of fluoride content in No. of district, the States/UTs have been classified as mild, moderate and severe endemic State/UTs of Fluorosis. States like Andhra Pradesh, Assam, Bihar, Chhattisgarh, Delhi, Gujarat, Haryana, Jharkhand, Karnataka, Kerala, Jammu & Kashmir, Madhya Pradesh, Maharashtra, Orissa, Punjab, Rajasthan, Uttar Pradesh, Tamil Nadu, West Bengal are affected from fluorosis. In all these states, the drinking water has high fluorine content.

### Why a National Programme?

At present there is no National level Programme for Fluorosis Control. Data regarding prevalence of Fluorosis is based on studies conducted by different groups over a period of time. Surveys at a National level regarding prevalence have not been conducted so far. For provision of safe drinking water, Government of India supplements the efforts of State Government and UTs by providing funds under the Accelerated Rural Water Supply Programme (ARWSP). The chairman of National Human Rights Commission reviewed the fluorosis situation in the country and recommended a National Programme for the same in the XI plan(3).

### Objectives

1. To assess the intake of fluoride by assessing its presence in all sources of drinking water, consumption of foods rich in fluoride and intake through industrial emissions at the district in the endemic states.
2. To coordinate the activities in relation to fluorosis being carried out in various departments/Ministries like M/o rural Development, D/o Drinking Water, RGNDWM, Education, Social Welfare, NICD, M/o H & FW.
3. To impart training to medical doctors and paramedicals of the districts for early diagnosis of Fluorosis.
4. To develop IEC material from Policy Level to the community personnel.

**Strategies :** The following strategies are to be adopted :

1. Conducting fluoride survey regarding fluoride level in all drinking water sources, food product sources, and industrial emissions if there is industry in the project district.
2. Launching of extensive Fluorosis prevention and control programme in coordination with Dept. of drinking water, Ministry of Environment, Ministry of Information and Broad casting, Ministry of Social Justice and Empowerment and Ministry of Health & Family Welfare.
3. Establishment of testing of fluoride facility in water, food and blood in each district of programme area.
4. Imparting training programme to medical and paramedicals of the programme districts to diagnose Fluorosis cases including deformity cases.
5. To develop extensive IEC material in relation of Fluorosis.
6. To implement the decision of Central Programme Implementation Committee under DGHS.

**Project Area :** In the beginning, the programme for prevention and control of Fluorosis, can be implemented in 5 districts selected from each of the following zones of the country based on prevalence of fluorosis, geographical distribution, weather,

etc. on a pilot basis.

- (a) Southern Zone (One district)
- (b) Western Zone (One district)
- (c) Northern zone (One district)
- (d) Eastern zone (One district)
- (e) Central zone (One district)

The Pilot Programme will be implemented in first two years time including impact evaluation of various strategies/components of the programme. Third year onwards, the Programme will be expanded to cover about 100 districts of 19 States depending on availability of funds.

### (C) Programme for the Elderly

India, as the second most populous country, has 76. 6 million people at or over the age of sixty ( 2001 Census) constituting about 7. 7 % of its total population. Life expectancy has increased from around 59 years in the 1970s to 63 years currently, and is expected to cross 70 years by the year 2020. The proportion of elderly in India is set to rise dramatically in the next few decades.

**Care of elderly :** The Health of the elderly requires comprehensive care with preventive, curative & rehabilitative services. Unlike the developed countries, India does not have a well structured Geriatric Health services, thus leading to a relatively ad hoc system of health care delivery for the elderly. In this scenario, there is a need for a specialized geriatric health service, which recognizes the elderly as being a vulnerable population.

**Programme Vision :** A society where persons aged 60 years and above will have the peace of mind and sense of security that arises from the knowledge that they have access to quality health care at all times.

**Programme Mission :** A community based holistic care system, which offers every citizen above the age of 60 years the opportunity to participate in a health care programme, which includes preventive, curative and emergency health care services of high quality.

**Goal :** To improve the access to promotive, preventive, curative and emergency health care among elderly persons.

### Objectives

1. Provide comprehensive health care to the elderly by preventive, curative and rehabilitative services.
2. Train Health professionals in Geriatrics, including supportive care and Rehabilitation.
3. Develop scientific solutions to specific elderly health problems by research into Geriatric and Gerontology.

**Programme Implementation :** The national program for health care of the elderly will be a centrally funded program. The entire Geriatric population will be covered by the 2 national institutes of Ageing, one in North India and the other in south India, eight identified regional centres (each implementing Geriatric Health Care in about 3 to 4 states). Under the control of these two institutes, one teaching medical college/Tertiary level hospital in each state to develop the Geriatric Unit which will include the Outpatient services, Acute care, Subacute Care and Long term care units. The health professionals trained here will be sent to the district level centres for Geriatric Health Care delivery.



## (D) Nutritional Programmes & Integrated Child Development Services (ICDS)

*Details of various National Nutritional Programmes and ICDS programme are discussed in an exclusive chapter in the section on nutrition.*

## (E) Water Supply and Sanitation Programme

**Evolution** : The Ministry of Rural Development has been taking initiatives to provide safe drinking water in all rural habitations. The National Water Supply and Sanitation Programme was initiated in 1954 with the objective of providing safe water supply and adequate drainage facilities to the entire urban and rural population of the country. In 1972 a special programme known as Accelerated Rural Water Supply Programme (ARWSP) was started to supplement the national water supply and sanitation programme. The Govt of India launched International Drinking water Supply and Sanitation Decade Programme in 1981. Other programmes like Prime Minister's Gramodaya Yojana - Rural Drinking Water (PMGY-RDW), have been implemented to resolve drinking water crisis in rural habitations. These programmes also give importance to rainwater harvesting, sustainability of sources and community participation.

### Accelerated Rural Water Supply Programme (ARWSP)

#### Objectives

1. To ensure coverage of all rural habitations and especially reach the unreached with access to safe drinking water;
2. To ensure sustainability of the systems and sources;
3. To tackle the problems of water quality in affected habitations;
4. To institutionalize the sector reform initiative in rural water supply sector.

#### Programme Implementation

Rural water supply is a State subject. States have been taking up projects and schemes from their own resources for the provision of safe drinking water. State Governments decide the implementing agencies for the programme. The agencies may be the Public Health and Engineering Department (PHED), Rural Development Department or the Panchayati Raj Department. Implementation is also taken up by the Government Boards / Nigams / Agencies in a few States. All projects and schemes proposed under ARWSP are approved by the State Level Scheme Sanctioning Committee.

**Role of Panchayats** : As per the 73rd Amendment to the Constitution of India, the subject of rural water supply is vested with the Panchayati Raj Institutions (PRIs). The Panchayats are to play a major role in providing safe drinking water and managing the systems and sources in their respective areas. They can be involved in the implementation of schemes, particularly in selecting the location of handpumps, standposts and spot sources.

**Sub-Mission** : Sub-Mission programmes of the Government of India were launched with the objective to provide safe drinking water facilities in rural habitations affected by water quality problems like fluorosis, arsenic, brackishness, excess iron, nitrate etc. The States undertake these projects. For ensuring source sustainability through rainwater harvesting,

artificial recharge etc. State Governments also use funds under Sub-Mission. Powers have been delegated to the States for sanctioning Sub-Mission projects.

### Prime Minister's Gramodaya Yojana (Rural Drinking Water)

Prime Minister's Gramodaya Yojana (PMGY) was launched by the Prime Minister in 2000-01.

**Goal** : To provide basic necessities to the people in rural areas for improvement of the physical quality of life.

**Components** : Primary education, Primary health, Rural shelter, Rural drinking water, nutrition and rural electrification are the six components of PMGY. 10 per cent of the PMGY funds have been earmarked for rural water supply.

#### Objectives

1. Emphasize on taking up projects and schemes for water conservation, rainwater harvesting, water recharge and sustainability of drinking water sources in areas under Drought Prone Areas Programme (DPAP) and Desert Development Programme (DDP); overexploited dark and grey Blocks and other water stress and drought affected areas
2. Take up projects/schemes to tackle quality related problems and for providing safe drinking water to uncovered and partially covered habitations.

**Swajaldhara** : It is a community led participatory programme launched in 2002, aimed at providing safe drinking water in rural areas. It also includes building awareness among the village community on the management of drinking water projects, including better hygiene practices and encouraging water conservation practices along with rain water harvesting. It has two components. The first is for a gram panchayat or a group of panchayats at the block/tehsil level and the second at the district level.

## (F) Rural Sanitation

The concept of sanitation connotes a comprehensive definition, which includes liquid and solid waste disposal, food hygiene, personal, domestic and environmental hygiene. Although the concept of sanitation has undergone qualitative changes during the years, there has been a very limited change in the sanitation condition of rural India.

### Central Rural Sanitation Programme (CRSP)

CRSP was launched in 1986 and aims at improving the quality of life of the rural people and to provide privacy and dignity to women in particular.

#### Objectives

1. Improving the general quality of life in rural areas.
2. Accelerating coverage in rural areas.
3. Generating demand through awareness creation and health education.
4. Controlling incidence of water and sanitation related diseases.

#### Programme components

1. To construct individual sanitary latrines for households Below Poverty Line (BPL) with subsidy, where demand exists.

2. To encourage other households to buy facilities through markets including sanitary marts.
3. To assist in setting up of sanitary marts.
4. To launch awareness campaigns in selected areas.
5. To establish sanitary complex for women.
6. To encourage locally suitable and acceptable models of latrines.
7. To promote total sanitation in villages through construction of drains, soakage pits for liquid and solid waste disposal.

**Subsidy for household latrines :** Subsidy is given for simple and less expensive latrines. A duly completed household sanitary latrine comprises only a Basic Low Cost Unit (BLCU) without any super structure.

**Strategy for School Sanitation :** School Sanitation is a vital component of sanitation. It is proposed to construct toilets in all rural schools (separate complex for boys and girls) by the end Government machinery, NGO participation and IEC campaigns, provision for an alternate delivery system and more flexible demand-oriented construction norms are also stressed.

### (G) Minimum Needs Programme

It started in 1975 with the objective of providing certain basic minimum needs and improve the living standards of the people. Its bigger objective is social and economic development of the community, particularly the underprivileged and under-served population. The programme includes the following components.

- (a) Rural Health
- (b) Rural Water Supply
- (c) Rural Electrification
- (d) Elementary Education
- (e) Adult Education
- (f) Nutrition
- (g) Environmental improvement of Urban Slums
- (h) Houses for landless labourers

It laid emphasis on establishment of PHC, subcentres to improve rural health. To improve the nutritional status, it aimed at providing nutritional support to eligible persons, to expand "Special nutrition programme" to all the ICDS projects, and to consolidate the mid-day meal programme and link it to health, potable water and sanitation.

### (H) 20 - Point Programme

It is an *agenda* for national action to promote social justice and economic growth. It was restructured in 1986 with the objective of "eradication of poverty, raising productivity, reducing inequalities, removing social and economic disparities and improving the quality of life". At least 8 of the 20 points are related, directly or indirectly, to health. These are: Point 1 - Attack on rural poverty; Point 7 - Clean drinking water; Point 8 - Health for all; Point 9 - Two - child norm; Point 10 - Expansion of education; Point 14 - Housing for the people; Point 15 - Improvement of slums; and Point 17 - Protection of the environment.

### References

1. Working gps/Steering Committees/Task Force for the 11th five year plan 2007-2012. Plg Com. GOI. Available at <http://planning comm. nic. in/plans/11thf.htm>.

2. Ravindranathan I. Essential trace elements in food. Nutrition 2001, 35(3): 9-32
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4. Working gps/Steering Committees/Task Force for the 11th five year plan 2007-2012. Plg Com. GOI. Available at <http://planning omm.. nic. in/plans/11thf.htm>. Study Exercises

## Study Exercises

### MCQs & Exercises on National Health Programmes

*Puja Dudeja & Ashok K Jindal*

1. Which of the following is true with respect to goals of RCH - II? (a) IMR < 45/1000 (b) MMR < 100/100000 (c) Both of above (d) None of above
2. The long term objective of RCH - II is to achieve a stable population by (a) 2045 (b) 2050 (c) 2015 (d) 2055
3. Centchroman (non steroidal contraceptive) has been developed by (a) Indian Institute of Population Sciences (b) National Institute of Health and Family Welfare (c) All India Institute of Medical Sciences (d) Central Drug Research Laboratory, Lucknow
4. Reducing MMR < 200/100000 is a goal of (a) National Health Policy 2002 (b) National Population Policy (c) Tenth five year plan (d) RCH II
5. Home visits for postnatal care for mother and new born under RCH II are done on (a) Day 2 and 5 (b) Day 3 and 7 (c) Day 1 and 3 (d) Day 3 and 5
6. Which of the following is not a critical element of First Referral Unit in RCH II? (a) Availability of surgical interventions (b) Newborn care (c) Blood storage facility on a 24 hr basis (d) Easy accessibility
7. A total number of \_\_\_\_\_ tablets of iron with folic acid are given to a pregnant woman by health worker (a) 100 (b) 70 (c) 150 (d) 200
8. Under National Nutritional Anemia Prophylaxis Program the strength of iron and folic acid in tablets is (a) 60 mg elemental iron and 0.5 mg folic acid (b) 100 mg of elemental iron and 0.5 mg folic acid (c) 100 mg of elemental iron and 0.1 mg folic acid (d) 60 mg elemental iron and 0.1 mg folic acid
9. Janani Suraksha Yojana (JSY) aims at reducing maternal and neonatal mortality rate by (a) Promoting institutional delivery (b) Health education (c) Distribution of iron and folic acid tablets to the mothers (d) All of the above
10. Under IMNCI the pink colour chart refers to a treatment at (a) Out patient facility (b) Home management (c) Give injection/oral drops (d) Urgent referral
11. The objective of national programme for prophylaxis against blindness in children due to vitamin A deficiency is to decrease the prevalence of Vitamin A deficiency to (a) 0.1 % (b) 0.2 % (c) 0.3 % (d) 0.001 %
12. The objective of national programme for prophylaxis against blindness in children due to vitamin A deficiency is being implemented through (a) RCH programme (b) National programme for control of blindness (c) UIP (d) None of above
13. Goal of National tuberculosis control programme is

- (a) To eradicate TB (b) To decrease the transmission of TB (c) To treat all sputum +ve patients (d) To decrease the incidence of TB to such a low level that is no longer a major public health problem (e) BCG vaccination of all infants
14. Which of the following is an objective of RNTCP? (a) To achieve at least 70 percent cure rate of the newly diagnosed sputum smear-positive TB patients (b) To detect at least 85 percent of new sputum smear-positive patients after the first goal is met (c) To achieve at least 85 percent cure rate of the newly diagnosed sputum smear-positive TB patients (d) Both A & B
  15. Which of the following is not a component of DOTS ? (a) Political and administrative commitment (b) Systematic monitoring and accountability (c) Supervised treatment to ensure the right treatment (d) Health education
  16. Which of the following statement is false? (a) Duration of Intensive phase of Category I is 8 weeks (b) Duration of Continuation phase of Category II is 22 weeks (c) Duration of Intensive phase of Category II is 12 weeks (d) None of the above
  17. The total number of doses in category II is (a) 78 doses (b) 102 doses (c) 108 doses (d) 76 doses
  18. Which of the following Anti tubercular drug is bacteriostatic? (a) Streptomycin (b) Ethambutol (c) INH (d) Rifampicin
  19. DOTS plus strategy is for treatment of (a) HIV with TB (b) Malaria with TB (c) MDR TB (d) All the above
  20. Drug used in chemoprophylaxis of TB is (a) INH (b) Rifampicin (c) Both of above (d) None of above
  21. Under NAMP, radical treatment of falciparum malaria is given for (a) 1 day (b) 5 days (c) 7 days (d) 14 days
  22. All of the following statements about NAMP are true except: (a) MBER should be equal to fever rate of the month in the community (b) Trends in SPR can be utilized for predicting epidemic situations in the area (c) Annual blood examination rate is calculated from the number of slides examined per 100 cases of fever (d) For calculating ABER and MBER the denominator is common
  23. Function of FTD is best denoted by: (a) Diagnosis of cases + spraying (b) Collection of slides + treatment of fever (c) Only treating fever cases (d) Treatment + slide collection + spraying
  24. Which of the following diseases are not included under NVBDCP ? (a) Malaria (b) Japanese Encephalitis (c) Viral encephalitis (d) Dengue
  25. Choice of insecticide for Kala Azar elimination under NVBDCP is (a) Malathion (b) DDT (c) Malathion + DDT (d) DDT
  26. A person wants to visit a malaria endemic area of low level chloroquine resistant falciparum malaria. The best chemoprophylaxis is : (a) Chloroquine (b) Proguanil + Chloroquine (c) Sulphadoxin + pyrimethamine (d) Mefloquine
  27. A malaria survey is conducted in 50 villages having a population of one lakh. Out of 20000 slides examined, 500 turned out to be MP positive. The SPR is (a) 20% (b) 5% (c) 25% (d) 0.4%
  28. Which of the following is an indicator for operational efficacy? (a) API (b) ABER (c) AFI (d) SPR
  29. Anti-malarial month is (a) April (b) May (c) September (d) June
  30. Which of the following statements is false? (a) Lymphatic filariasis has been targeted for elimination in 2015 (b) Strategy for elimination is by Annual Mass Drug Administration of DEC for 5 years or more (c) Children less than 2 yrs are not included in Annual Mass Drug Administration (d) DEC is safe in Pregnancy
  31. Which one of the following strategies is aimed at AIDS control in India ? (a) Detection and treatment of AIDS cases in the community (b) Detection and isolation of HIV infected persons in the community (c) Immune-prophylaxis of the risk groups (d) Community education behavioral change
  32. AIDS was first detected in India in the year (a) 1975 (b) 1981 (c) 1986 (d) 1991
  33. Which of the following is not true about National AIDS control Programme? (a) Sentinel surveillance methodology have adopted (b) Community based screening for prevalence of HIV taken up (c) Early diagnosis and treatment of STD is a major strategy to control spread of HIV (d) Formulating guidelines for blood banks donors & dialysis units
  34. National Leprosy Eradication programme was started in (a) 1949 (b) 1955 (c) 1973 (d) 1983
  35. Elimination in leprosy stands for (a) Reduce the number of cases to < 1/10,000 population (b) Reduce the number of cases to < 1/1000 population (c) No case of leprosy in a region for 5 years (d) 100 percent treatment of all cases
  36. Which one of the following statements is not correct regarding National Leprosy Eradication Programme (NLEP) (a) Multibacillary leprosy treatment is recommended for one year (b) Skin smear examination is done for classification into paucibacillary and multibacillary (c) Special Action Project for Elimination of leprosy is for rural areas (d) Surveillance for two years for a treated case of paucibacillary leprosy to be carried out
  37. India was declared 'Guinea Worm disease free' in the year (a) 1996 (b) 2000 (c) 2001 (d) 2002
  38. National Mental Health programme was started in (a) 1992 (b) 1983 (c) 1994 (d) 1985
  39. Which of the following is not a component of AFP SURVEILLANCE? (a) Case notification (b) Case in Laboratory investigation (c) Out break response and active search in community (d) Attaining high routine immunization
  40. Which of the following is not a strategy for achieving Polio Eradication? (a) Attaining high routine immunization (b) National Immunization Days (NIDs) (c) Surveillance of Acute Flaccid Paralysis (AFP) (d) Mopping-up immunization (e) None of the above
  41. National Mental Health Programme is (a) Vertical programme (b) Integrated Programme (c) None of the above
  42. National Cancer Control Programme was started in (a) 1976 (b) 1986 (c) 1970 (d) 1992
  43. Under National Cancer Control Programme, oncology wings were sanctioned to - (a) Regional Cancer Institutes (b) District Hospital (c) Medical College Hospitals (d) Voluntary Agencies treating cancer patients
  44. National Cancer Registry Programme (NCRP) was started by (a) Ministry of Health and Family Welfare (b) Indian

- Council of Medical Research (c) Collaboration of (a) and (b) (d) None of the above
45. The goal of NIDDCP is (a) To reduce the prevalence of iodine deficiency disorders below 10 percent in the entire country by 2012 AD (b) To reduce the prevalence of iodine deficiency disorders below 5 percent in the entire country by 2012 AD (c) To reduce the prevalence of iodine deficiency disorders below 10 percent in the entire country by 2010 AD (d) None of the above
46. The best indicator for monitoring the impact of Iodine Deficiency Disorders Control Programme is (a) Prevalence of goiter among school children (b) Urinary iodine levels among pregnant women (c) Neonatal hypothyroidism (d) Iodine level in soil
47. Which one of the following is not a target disease under 'Vision 2020: The Right to Sight' (a) Refractive error (b) Trachoma (c) Corneal blindness (d) Diabetic retinopathy
48. SAFE strategy in vision 2020 is for which eye condition (a) Trachoma (b) Cataract (c) Onchocerciasis (d) Childhood blindness
49. Vision 2020 'The right to sight' includes all except (a) Trachoma (b) Epidemic conjunctivitis (c) Cataract (d) Onchocerciasis
50. ICDS is running under (a) Ministry of health and Family Welfare (b) Ministry of Women and child development (c) Collaboration of both of above (d) None of above
- Answers :** (1) b; (2) a; (3) d; (4) c; (5) b; (6) d; (7) a; (8) b; (9) a; (10) d; (11) c; (12) a; (13) d; (14) c; (15) d; (16) b; (17) b; (18) b; (19) c; (20) a; (21) b; (22) c; (23) b; (24) c; (25) d; (26) b; (27) c; (28) b; (29) d; (30) d; (31) d; (32) c; (33) b; (34) d; (35) a; (36) b; (37) c; (38) a; (39) d; (40) e; (41) b; (42) a; (43) c; (44) c; (45) a; (46) c; (47) d; (48) a; (49) b; (50) b.

*Sunil Agrawal*

An important aspect of Preventive Medicine and Public Health is legislative control or legislative power. These laws protect public health at large but it should maintain the balance between individual autonomy and community protection and its actions should be directed to improve the health status in the community. The characteristics of public health laws are:

1. Responsibility of government as a right to provide adequate health and health services to all citizens.
2. Public health laws protect community health rather than individual's health.
3. Public Health contemplates the relationship between the state and the population.
4. Public health laws deals with the delivery of public services based on scientific methodologies e.g. Purification of water.
5. The laws acts as important guidelines for the state, community and individuals.

To achieve the fundamental goals of our constitution various acts and rules are enacted.

**Act :** Act means statutes or laws adopted (enacted) by a national or state legislative assembly or other governing body.

**Rules:** Rules are explicit statements that tell an individual what he or she ought to do or ought not to do.

Important legislations in India pertaining to public health and its protection are grouped in the following categories for the

purpose of better understanding:

1. Health Facilities and Services
2. Disease Control and Medical Care
3. Human Resources
4. Ethics and Patients Rights
5. Pharmaceutical and Medical Devices
6. Radiation Protection
7. Hazardous Substances
8. Occupational Health and Accident Prevention
9. Health of the Elderly, Disabled, Rehabilitation and Mental Health
10. Families, Women and Children
11. Smoking, Alcoholism and Drug Abuse
12. Social Security and Health Insurance
13. Environmental Protection
14. Nutrition and Food Safety
15. Health Information and Statistics
16. Intellectual Property Rights
17. Custody, Civil and Human Rights
18. Other Aspects not covered by any heading above

Under the constitutional provisions, the government of India owes its population social security, health services, safety, environmental protection, equal opportunity and justice. The methods adopted by the government to deliver these services are through framing policies, execution of legislation and implementation of programs. The provision of an act is further explained in detail in rules and regulations. Public health officials enforce rules through following ways:

- a) Permits, licenses and registrations
- b) Administrative orders
- c) Civil penalties
- d) Injunctions



Legislations are not an end in themselves. They have to be executed in letter and spirit by a responsible society and the officials responsible for their implementation. Often these legislations may not be able to bring about the desired result. There are many factors responsible for lack of effectiveness of these legislations, viz., Lack of awareness, Lack of implementation, Corruption, Lack of infrastructure, Inconsistency and, Inadequacy. To overcome these problems Government of India has initiated *National Legal Literacy Mission in 2005* to impart knowledge and education on various legal aspects including those related to Public Health. This programme seeks to sensitise, and create awareness among people about their legal rights, acts and regulations and interpretation of legal jargon.

#### **Laws in relation to Health Facilities and Services**

- Indian Red Cross Society Act, 1920
- All India Institute of Medical Sciences Act, 1956
- Post Graduate Institute of Medical Education and Research, Chandigarh, Act, 1966
- Bureau of Indian Standards Act and Rules, 1986, 1987
- National Institute of Pharmaceutical Education and Research Act, 1998
- Clinical Establishment Acts
  - a. Nursing Homes Registration Acts
  - b. State Clinical Establishment Acts and Rules

#### **Laws in relation to Disease Control and Medical Care**

- Epidemic Diseases Act, 1897
- Indian Aircraft Act and Rules, 1934, 1954
- Indian Port Health Rules, 1955
- Medical Termination of Pregnancy Act, 1971, 1975
- Transplantation of Human Organs Act and Rules, 1994, 1995, 2002
- Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act and Rules, 1994, 1996, 2002, 2003

#### **Laws in relation to Human Health Care Resources**

The professional ethics, quality control of education programmes, standards etc. are important for all the systems of medicine, hence there are acts and regulations which are enumerated below:

##### **Allopathy**

- Indian Medical Council Act and Rules, 1956, 1957, 1965, 1993, 2001, 2002.
- Medical Council of India 1994, 1998, 2000, 2001
- Establishment of New Medical Colleges, Higher Course Regulations, 1993.
- Eligibility Requirement for Taking Admission in Undergraduate Medical Course in a Foreign Medical Institution Regulations, 2002.

##### **Indian System of Medicine and Homeopathy**

- Indian Medicine Central Council Act and Regulations, 1970, 1989, 2005
- Homeopathy Central Council Act, 1973, 2002
- Homeopathy Education Courses, Standards, 1983
- Homeopathy Practitioners (Professional Conduct, Etiquettes and Code of Ethics) Regulations, 1982

##### **Dentistry**

- Dentist Act, 1948, 1993

- Dental Council of India Regulations, 1955, 1956, 1984, 2006
- Dental Council (Election) Regulations, 1952
- BDS, MDS Course Regulations, 1983
- Establishment of Dental Colleges, 1993

##### **Pharmacy**

- Pharmacy Act, 1948
- Pharmacy Council of India - Regulations

##### **Nursing**

- Indian Nursing Council Act, 1947
- Indian Nursing Council Regulations

##### **Rehabilitation**

- Rehabilitation Council of India Act and Regulations, 1992, 1997, 1998

#### **Laws in relation to Ethics and Patients Rights**

- Consumer Protection Act and Rules, 1986, 1987, 2002
- Ethical Guidelines for Biomedical Research on Human Subjects, 2000
- Right to Information Act and Rules, 2005
- Central Information Commission (Appeal Procedure) Rules, 2005

#### **Laws in relation to Pharmaceutical and Medical Devices**

- Drugs and Cosmetics Act, 1940, 2005, 2006
- Drugs Control Act, 1950
- Drug and Magic Remedies (Objectionable Advertisement) Act, 1954
- Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (Ayush) Orders, 2005

#### **Laws in relation to Radiation Protection**

- Atomic Energy Act and Rules, 1962, 1984
- Radiation Protection Rules, 1971
- Radiation Surveillance Procedures for Medical Application of Radiation, 1980, 1989
- Atomic Energy (Working of the Mines, Minerals and Handling of Prescribed Substance) Rules, 1984, 1987
- Safety Code for Medical Diagnostic X-Ray Equipment and Installations

#### **Laws in relation to Hazardous Substances**

- Narcotic Drugs and Psychotropic Substances Act and Rules, 1985
- Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, 1988
- Hazardous Wastes (Management and Handling) Rules, 1989, 2002

#### **Laws in relation to Occupational Health and Accident Prevention**

India is signatory to many International treatise and ILOs convention on occupational health. To bridge the large gap in health status of workers and provide a safe and secure work place certain legislations are required to be enacted to ensure health and safety of the workers, these legislations are as under:

- Workmen's Compensation Act, 1923
- Factories Act 1948, 1987
- Mines Act, 1952, 1957

- Motor Transport Workers Act, 1961
- Personal Injuries (Emergency Provisions) Act, 1962, 1963
- Beedi and Cigar Workers Act, 1966
- Child Labour (Prohibition and Regulation) Act, 1986
- Dock Workers (Safety, Health and Welfare) Rules, 1990
- Public Liability Insurance Act and Rules, 1991
- Building and Other Construction Workers Act, 1996
- Fatal Accidents Act, 1855
- Contract Labour (Regulation and Abolition) Central Rules, 1971

#### **Laws in relation to Elderly, Disabled, Rehabilitation and Mental Health**

- Mental Health Act, 1987
- Central and State Mental Health Rules, 1990
- Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995, 1996
- National Trust for Welfare of Persons with Autism, Cerebral Palsy, Mental Retardation and Multiple Disabilities Act, 1999, 2000

#### **Laws in relation to Family, Women and Children**

- Special Marriage Act, 1954
- Hindu Marriage Act, 1955
- Children Act, 1960
- Dowry Prohibition Act, 1961
- Suppression of Traffic in Women and Girls Act, 1956
- National Commission for Women Act, 1990
- Juvenile Justice (Care and Protection of Children) Act, 2000

#### **Laws in relation to Smoking, Alcoholism and Drug Abuse**

- Cigarettes (Regulation of Production, Supply and Distribution) Act, 1975
- Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act and Rules, 2003, 2004
- Cigarettes and Other Tobacco Products (Prohibition of Sale on Cigarettes and Other Tobacco Products around Educational Institutions) Rules, 2004

#### **Laws in relation to Social Security and Health Insurance**

- Minimum Wages Act, 1948
- Employees State Insurance Act and Rules, 1948, 1950
- Life Insurance Corporation Act, 1956
- Maternity Benefit Act, 1961, 1963
- Insurance Regulatory and Development Authority Act, 1999, 2000, 2001, 2002

#### **Laws in relation to Environmental Protection**

Environmental protection is one of the most important global requirements of today. There are many provisions in the constitution of India to safeguard the environment and state is made responsible for this. There are many Acts in the country to protect the environment and mankind. These are as under:

- Insecticides Act and Rules, 1968, 1971, 1993, 2000
- Water (Prevention and Control of Pollution) Act and Rules, 1974, 1975, 1977, 1978, 2003

- Air (Prevention and Control of Pollution) Act and Rules, 1981, 1982, 1983
- Environment (Protection) Act, 1986, 2002
- Bhopal Gas Leak Disaster Act, 1985, 1992
- Central Board for the Prevention and Control of Water Pollution (Procedure for Transaction of Business) Rules, 1975

#### **Laws in relation to Nutrition and Food Safety**

- Prevention of Food Adulteration Act and Rules, 1954, 1955, 2001, 2002
- Infant Milk Substitutes, Feeding Bottles and Infant Foods Act and Rules, 1992, 1993, 2003
- Atomic Energy (Control of Irradiation of Food) Rules, 1996
- Food Safety and Standards Act, 2006

#### **Laws in relation to Health Information and Statistics**

- Births, Deaths and Marriages Registration Act, 1886
- Registration of Births and Deaths Act, 1969
- Collection of Statistics Act and Rules, 1953, 1959
- Census Act, 1948, 1993

#### **Laws in relation to Intellectual Property Rights**

- Patents Act and Rules, 1970, 1972, 2005
- Arbitration and Conciliation Act, 1996
- Trade Marks Act, 1999
- Laws in relation to Custody, Civil and Human Rights
- Indian Penal Code, 1860
- Unlawful Activities (Prevention) Act, 1967
- Protection of Human Rights Act, 1993

#### **Laws in relation to Other (Miscellaneous) Issues**

- Essential Commodities Act, 1955
- Standards and Weights Measures Act, 1976

### **The Consumer Protection Act (CPA), 1986**

The CPA is a comprehensive legislation in which consumers can approach with complaints to Commissions at the District, state and central level without any lawyers and there is no court fee.

The CPA protects following consumer rights

1. Right to safety
2. Right to be informed
3. Right to choose
4. Right to be heard
5. Right to seek redressal
6. Right to consumer education

Under this Act a complainant can file any allegation in writing about:

- a) A loss or damage suffered as a result of any unfair trade practice adopted by the trader
- b) The goods / service suffers from one or more defects
- c) An excess price is charged than the one displayed for the goods or service

The Supreme Court declared that like other service providers under contract, doctors who offer services for the price offered are also under the same obligation to compensate the purchaser (patient) for any deficiency in the quality of their services. Doctors in government service, charitable clinics providing free service are exempted from CPA. If the cost of the

services or goods and compensation is less than 5 lakhs then the complaint can be filed in the district forum. If the cost is up to 10 lakhs then the complaint is filed with State Commission and for higher amounts the case is registered with National Commission at New Delhi.

The punishment for the guilty under the Act is imprisonment for minimum one month extendable up to three years or fine not less than Rs 2000/- extendable up to Rs 10,000/- or both.

Negligence means that, 'a person who holds himself ready to give medical advice and treatment implied undertakes that he possesses the skills and knowledge for that purpose. Such person when consulted by a patient owes him certain duties namely a duty of care in deciding what treatment to give or a duty of care in the administration of that treatment. A breach of any of those duties gives a right of action for negligence to the patient'.

### Registration of Births and Deaths Act, 1969

In India, vital statistics are generated through Civil Registration System (Registration of births and deaths), sample registration system, decennial population census, rural survey of cause of death, medical certification of causes of death from hospitals and health centres and adhoc surveys conducted by national and international research organizations.

The Registration of Births and Deaths Act was implemented in 1969 with the aim to collect and compile vital statistics which is necessary for planning and administration. The Act has given statutory authority to the Registrar General, India to coordinate the work of civil registration throughout the country. In rural areas, the local registrars are mainly drawn from panchayat, police, health or revenue departments. In urban areas, health officers of the municipalities or corporations or the executive officers are the Registrars.

Every registrar has to register births and deaths, occurring within his/her administrative areas. The information regarding occurrence is to be given within 21 days in both the events of births and deaths. Delayed registration requires late fee and affidavit from notary public. Every registering authority sends periodical returns to the Chief Registrar who in turn sends it to Registrar General of India. Registrar General brings out every year annual report called "Vital Statistics of India".

The Act also provides for medical certification of cause of death. A medical officer has to certify free of cost in the prescribed format, the cause of death if he/she is attending the deceased during his last breath or illness.

### Epidemic Diseases Act, 1897

The Act provides power to exercise for the control and to prevent any epidemic or spread of epidemic in the States or Country. The states may authorise any of its officers or agency to take such measures if the state feels that the public at large is threatened with an outbreak of any dangerous epidemic (Sec. 2). Person who is inspecting, is empowered to determine about the process and authority to take responsibility of all expenses incurred in compensation, travelling, temporary accommodation, segregation of infected person, etc. The State Government can authorise the Dist. Magistrate or other officials to utilise any resources in terms of man, money and material

to mobilise infected persons or community to prevent spread of epidemic. State or Central Government can inspect any ship or vessel leaving or arriving at any port in the territories and take appropriate action as prescribed. Violation of this Act is punishable under sec 188 of the IPC.

### The Drugs and Cosmetics Act, 1940 (Amended in 1964, 1983, 1995)

The Drugs and Cosmetics Act is mainly aimed to regulate the import, manufacture, distribution and sale of Drugs and Cosmetics, presumably for maintaining high standards of medical treatment. Substandard medicines / drugs may cause severe damage to lives of people.

The Act extends to the whole of India. In this Act the drug is defined as, 'All Medicines (Ayurveda, Siddha, and Unani) for internal or external use of human being or animals and all substances (other than food) intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including preparation applied on human body or to destroy insects'.

The Central or State government have power to make rules and appoint inspector to control or inspect any drug or cosmetic for its standardization and safety which can be tested in the Central or State Drug laboratory. The Government can prohibit manufacturing, importing or selling of any drug or cosmetic. Violation of law by any person or corporate manager or owner is liable for punishment for a term which may extend to 3-10 years and shall also be liable to fine which could be five hundred or ten thousand rupees or with both.

Drugs and Cosmetic Rules 1995 contains the list of drugs for which license is required by manufacturer, importers, and exporters. Recently 'in vitro' blood groups, sera and in vitro diagnostic devices for HIV, HBsAg, and HCV are also included in schedule CI. All imported drugs in indigenous manufacturers have to register to control over the quality of imported as well as locally manufacturing kits.

### The Medical Termination of Pregnancy Act, 1971

*(It extends to the whole of India except the State of Jammu and Kashmir.)*

**Registered Medical Practitioners who may terminate Pregnancies :** A pregnancy may be terminated by a Registered Medical Practitioner (RMP) registered under the MCI Act, and those who have undergone 6 months housemanship or 3 years post graduate training in obstetrics and gynaecology or any registered medical practitioner who have conducted 25 cases of MTP in approved institution. Where the length of the pregnancy does not exceed twelve weeks, then one RMP can conduct MTP and if the length of the pregnancy exceeds twelve weeks but does not exceed twenty weeks, opinion of not less than two registered medical practitioners are required to certify the valid reasons as per the law for discontinuation of pregnancy.

**Conditions under which MTP can be carried out :**

**(i) Therapeutic :** The continuance of the pregnancy would involve a risk to the life of the pregnant woman or of grave injury to physical or mental health.



(ii) **Eugenic** : There is a substantial risk that if the child were born, it would suffer from such physical or mental abnormalities as to be seriously handicapped.

(iii) **Social** : When economic and social environment is not suitable for continuation of pregnancy or due to failure of any method used by couple for the purpose of limitation of children.

(iv) **Humanitarian** : It involves pregnancy due to rape.

(v) **Lunatic** : When pregnant woman is mentally not sound or lunatic.

**Note** : No pregnancy shall be terminated except with the consent of the pregnant woman.

**Place where pregnancy may be terminated** : No termination of pregnancy shall be made in accordance with this Act at any place other than :

- (a) a hospital established or maintained by Government, or
- (b) a place for the time being approved for the purpose of this Act by Government.

**Punishment** : Termination of pregnancy not falling under the purview of MTP Act is an offence punishable with rigorous imprisonment for a term which shall not be less than 2 years up to maximum 7 years.

### **The Workmen's Compensation Act, 1923, 1984, 2000**

As per the Workmen's Compensation Act, any worker employed in wide varieties of hazardous occupations by an employer, if suffers an injury, he/she is eligible for compensation. If he dies then legal dependents can claim the benefits provided by the Act. The 'employer' includes any body of persons whether incorporated or not and any managing agent of an employer and the legal representative of a deceased employer and when the services of a workman are temporarily lent or let on hire to another person by the person with whom the workman has entered into a contract of service or apprenticeship means such other person while the workman is working for him;

The disablement means the loss in the earning capacity of a workman in every employment which he was capable of doing at the time of accident. Its effect may be temporary or permanent. To enter into contract of Workmen's Compensation Act, and claim for an occupational disease, he or she should have been employed in the specified occupation for at least 6 months.

The compensation is paid to the workers according to the damage:

1. In case of death, compensation is paid to the dependents; 40 percent of the monthly wage, multiplied by factor or Rs 20,000/- whichever is more.
2. In case of permanent disablement; 50 percent of the monthly wage, multiplied by factor, or Rs.24,000/- whichever is more.
3. In case of partial permanent disablement; the compensation is percentage of that payable in case of total permanent disability as given in schedule I.
4. In case of total or partial temporary disablement; a sum equal to 25 percent of the monthly wages of the workman shall be paid half yearly.

Further details of Workmen Compensation Act and other laws in relation to industrial health are discussed in detail in the section on Occupational health in this book.

### **The Water (Prevention and Control of Pollution) Act 1974**

This Act was passed by the Parliament in 1974 to counter and contain ever growing pollution of natural water resources. This Act is comprehensive in providing the legal basis for prevention and control of water pollution, maintenance and restoration of wholesomeness of water sources in the country.

#### **Definitions**

Under the Act important definitions are:

**a) Pollution** : Pollution means contamination of water or such alteration of the physical, chemical or biological properties of water or such discharge of any sewage or trade effluent or of any other liquid, gaseous or solid substance into water as may, or is likely to create a nuisance or render such water harmful or injurious to public health or safety, or to domestic, commercial, industrial, agricultural or other legitimate uses, or to the life and health of animals or plants or of aquatic organisms.

**b) Sewage Effluent** : Sewage Effluent means effluent from any sewerage system or sewage disposal works and includes sullage from open drains.

**c) Trade Effluent** : Trade Effluent includes any liquid, gaseous or solid substance which is discharged from any premises used for carrying on any industry, operation or process, or treatment and disposal system, other than domestic sewage.

To execute the aforesaid purposes, the Act provides for the constitution of Central, State and Joint Boards having prescribed powers and functions. These boards are to be called Pollution Control Boards. The main function of the Central Board shall be to promote cleanliness of watercourses in different areas of the States. The Board has been conferred the power to perform several functions i. e., advisory to the Central Govt; co-ordinating the activities of the State Boards; provide technical assistance and guidance to the state board, carry out and sponsor investigations and research relating to problems of water pollution and their abatement; plan and organize training of persons engaged or to be engaged in programmes for prevention and control; collect, compile and publish technical and statistical data related to the subject; to lay down, modify or annul the standards for a water course; plan and cause to be executed, nationwide programmes and so on.

The Board may establish or recognize laboratories to enable it to perform its functions including the analysis of samples of water, sewage or trade effluents. The State Boards, under the guidance of Central Board, are similarly responsible to plan and execute comprehensive programmes in their respective territories. They have also been conferred the powers of entry into any premises after giving due notice to the owner and collect samples of water, sewage and trade effluents for analysis and recommend necessary legal steps. The State Governments, under advice from the Board, are also authorised to take emergency measures when pollutants have entered or threatened to enter the watercourse due to accidental or unforeseen event or act of omission or commission. A joint Board is set up on subjects of



common interest by mutual agreement either between adjacent states or between the states(s) and the Central Govt. when the latter has been appointed as the executing agency for the Union Territories.

**Punishments :** Any person or organisations which fail to comply with regulations of this Act can be convicted and punished with imprisonment of 3 months or fine up to Rs 10,000/ or with both. If offender repeats the offence then additional fine up to Rs 5,000/ for everyday, during which such failure continues after the conviction for the first such failure.

If the failure continues beyond a period of 1 year after the date of conviction, the offender shall, on conviction, be punishable with imprisonment for a term which shall not be less than 2 years but which may extend to 7 years and with fine.

### **Air (Prevention and Control of Pollution) Act, 1981**

The Air (Prevention and Control of Pollution) Act, 1981 is an Act to provide for prevention, control and abatement of air pollution. The Act is an outcome of the United Nations Conference on the Human Environment held in Stockholm in June, 1972. The Act extends to whole of India.

#### **Definitions**

In this Act, important definitions are -

**(a) Air Pollution :** Air Pollution means any solid, liquid or gaseous substance (including noise) present in the atmosphere in such concentration as may be or tend to be injurious to human beings or other living creatures or plants or property or environment.

**(b) Automobile :** Automobile means any vehicle powered either by internal combustion engine or by any method of generating power to drive such vehicle by burning fuel.

**(c) Control Equipment :** Control Equipment means any apparatus, device, equipment or system to control the quality and manner of emission of any air pollutant and includes any device used for securing the efficient operation of any industrial plant.

**(d) Emission :** Emission means any solid or liquid or gaseous substance coming out of any chimney, duct or fuel or any other outlet.

**(e) Industrial Plant :** Industrial Plant means any plant used for any industrial or trade purposes and emitting any air pollutant into the atmosphere.

**(f) Occupier :** Occupier, in relation to any factory or premises, means the person who has control over the affairs of the factory or the premises, and includes, in relation to any substance, the person in possession of the substance.

#### **Central Pollution Control Board (CPCB)**

The Central Pollution Control Board constituted under Section 3 of the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974), shall, without prejudice to the exercise and performance of its powers and functions under that Act, exercise the powers and perform the functions of the Central Pollution Control Board for the prevention and control of air pollution under this Act.

#### **Functions of Central Board**

- (1) To improve the quality of air and to prevent, control or abate air pollution in the country.
- (2) To advise the Central Government on any matter concerning the improvement of the quality of air and the prevention, control or abatement of air pollution.
- (3) Plan and cause to be executed a nationwide programme for the prevention, control or abatement of air pollution.
- (4) Co-ordinate the activities of the State Boards and resolve disputes among them.
- (5) Provide technical assistance and guidance to the State Boards, carry out and sponsor investigations and research relating to problems of air-pollution and prevention, control or abatement of air pollution.
- (6) Plan and organise the training of persons engaged or to be engaged in programmes for the prevention, control or abatement of air pollution on such terms and conditions as the Central Board may specify.
- (7) Organise through mass media a comprehensive programme regarding the prevention, control or abatement of air pollution.
- (8) Collect, compile and publish technical and statistical data relating to air pollution and the measures devised for its effective prevention, control or abatement and prepare manuals, codes or guides relating to prevention, control or abatement of air pollution.
- (9) Lay down standards for the quality of air.
- (10) The Central Board may establish or recognise a laboratory or laboratories to enable the Central Board to perform its functions under this section efficiently.
- (11) The Central Board may delegate any of its functions under this Act generally or specially to any of the committees appointed by it.

CPCB has power to restrict use of any area, automobile, or industry having or causing air pollution. Any person empowered by pollution control boards shall have right to enter, at all reasonable times as he considers necessary, any place for seizing or examining and testing any control equipment, air sampling, industrial plant, record, register, document or any other material object or for conducting a search of any place in which he has reason to believe that an offence under this Act or the rules has been made.

#### **Punishment**

Whoever fails to comply with the provisions shall be punished with imprisonment for a term which shall not be less than one year and six months but which may extend to six years and with fine, and in case failure to comply continues, an additional fine may be imposed which may extend to Rs 5,000/- for every day during which such failure continues after the conviction for the first such failure.

If the failure continues beyond a period of 1 year after the date of conviction, the offender shall, on conviction, be punishable with imprisonment for a term which shall not be less than 2 years but which may extend to 7 years and with fine.

## The Transplantation of Human Organs Act, 1994

An Act to provide for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs.

### Definitions

In this Act, some important definitions are :

(a) **Brain-stem death** : Brain-stem death means the stage at which all functions of the brain-stem have permanently and irreversibly ceased.

(b) **Deceased Person** : Deceased Person means a person in whom permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place.

(c) **Donor** : Donor means any person, not less than eighteen years of age, who voluntarily authorises the removal of any of his human organs for therapeutic purposes.

(d) **Human Organ** : Human Organ means any part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body.

(e) **Near Relative** : Near Relative means spouse, son, daughter, father, mother, brother or sister.

(f) **Transplantation** : Transplantation means the grafting of any human organ from any living person or deceased person to some other living person for therapeutic purposes.

### Authority for Removal of Human Organs

Any donor may, in such manner and subject to such conditions as may be prescribed, authorise the removal, before his death, of any human organ of his body for therapeutic purposes in writing and in the presence of two or more witnesses use for therapeutic purposes. And no such removal shall be made by any person other than the registered medical practitioner.

### Authority for Removal of Human Organs in Case of Unclaimed Bodies in Hospital or Prison

In the case of a dead body lying in a hospital or prison and not claimed by any of the near relatives of the deceased person within forty-eight hours from the time of the death of the concerned person, the authority for the removal of any human organ from the dead body which so remains unclaimed may be given, in the prescribed form, by the person in-charge, for the time being, of the management or control of the hospital or prison, or by an employee of such hospital or prison authorised in this behalf by the person in charge of the management or control thereof.

### Restrictions on Removal and Transplantation of Human Organs

No human organ removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.

### Registration of Hospitals Engaged in Removal, Storage or Transportation of Human Organs.

No hospital shall commence any activity relating to the removal, storage or transplantation of any human organs for

therapeutic after the commencement of this Act unless such hospital is duly registered under this Act.

### Punishment for Removal of Human Organ without Authority

- (1) Any person who renders his services to or any hospital and who, for purposes of transplantation, conducts, associates with, or help in any manner in, the removal of any human organ without authority, shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to ten thousand rupees.
- (2) Where any person convicted under *sub-section (1)* is a registered medical practitioner, his name shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offence.

### Punishment for Commercial Dealings in Human Organs

#### *Whoever*

(a) makes or receives any payment for the supply of, or for an offer to supply, any human organ; (b) seeks to find a person willing to supply for payment any human organ; (c) offers to supply any human organ for payment; (d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ; (e) takes part in the management or control of a body of persons, whether a society, firm or company, whose activities consist of or include the initiation or negotiation of any arrangement referred to in clause (d); or (f) publishes or distributes or causes to be published or distributed any advertisement.

#### *Shall be*

Punishable with imprisonment for a term which shall not be less than two years but which may extend to seven years and shall be liable to fine which shall not be less than ten thousand rupees but may extend to twenty thousand rupees.

### Punishment for Contravention of any other Provision of this Act.

*Whoever* contravenes any provision of this Act or any rule made, or any condition of the registration granted, thereunder for which no punishment is separately provided in this Act, *shall be* punishable with imprisonment for a term which may extend to three years or with fine which may extend to five thousand rupees.

## The Immoral Traffic (Prevention) Act, 1956

An Act to provide in pursuance of the International Convention signed at New York on the 9th day of May, 1950, for the prevention of immoral traffic. Any person who keeps or maintains or acts or assists in the keeping and management or a brothel, is liable to be punished under this section.

### Definitions

Some of the definitions in this Act are :

(a) **Brothel** : Brothel includes any house, room, conveyance or place, or any portion of any house, room, conveyance or place,

which is used for purposes of sexual exploitation or abuse for the gain of another person or for the mutual gain of two or more prostitutes.

**(b) Prostitution** : Prostitution means the sexual exploitation or abuse of persons for commercial purposes or for consideration in money or in any other kind, and the expression “prostitute” shall be construed accordingly.

**(c) Child** : Child means a person who has not completed the age of 16 years.

**(d) Major** : Major means a person who has completed the age of 18 years.

**(e) Minor** : Minor means a person who has completed the age of 16 years but has not completed the age of 18 years.

#### Offences and Punishments in this Act are:

1. Any person who keeps, or manages, or acts or assists in the keeping or management of, a brothel, shall be liable to be punished with -
  - (a) rigorous imprisonment for not less than 1 year but upto 3 years and also fine upto Rs.2,000/-, on first conviction; and
  - (b) rigorous imprisonment for not less than 2 years but upto 5 years and also fine upto Rs. 2000/-
2. Any person who procures or induces any person for the purpose of prostitution; or takes, causes or induces any person to carry on prostitution, shall be punishable with -
  - (a) rigorous imprisonment for not less than 3 years but upto 7 years; and
  - (b) fine upto Rs. 2,000/-
3. Any person over the age of 18 years who knowingly lives on the earnings of the prostitution of any other person, shall be liable to be punished with imprisonment upto 2 years, or fine upto Rs. 1,000/-, or both.  
But, where such earnings relate to the prostitution of a child or a minor, the offender shall be liable to be punished with imprisonment for a term of not less than 7 years and not more than 14 years.
4. Any person who detains any other person in any brothel, or in or upon any premises, for the purpose of prostitution, shall be liable to be punished with imprisonment for not less than 7 years but upto for life; or imprisonment upto 10 years and also fine.
5. Any person who carries on prostitution in or in the vicinity of public places which are within a distance of two hundred metres of any place of public religious worship, educational institution, hostel, hospital, nursing home or such other public place of any kind as may be notified in this behalf by the Commissioner of Police or Magistrate in the manner prescribed. Any person who commits an offence shall be punishable with -
  - (a) imprisonment for not less than 7 years but for life; or
  - (b) imprisonment upto 10 years and also fine.
6. Any woman who tempts, or attracts, or endeavours to tempt or attract the attention of, any person for the purpose of prostitution; or solicits or molests any person, or loiters or acts to cause obstruction or annoyance to persons or to offend against public decency, for the purpose of prostitution, shall be punishable with -

(a) imprisonment upto 6 months or fine upto Rs. 500/- or both, on first conviction; and (b) imprisonment upto 1 year and fine upto Rs. 500/-, in the event of a second or subsequent conviction.

But, a man who commits any of offences under this section, shall be punishable with imprisonment for not less than 7 days but upto 3 months.

Prostitution is a social evil and indicates poverty, weak social fabric, alcoholism and lower status of women. Immoral traffic will not only lead to lower social morals but also spread of certain killer diseases like STIs, HIV/AIDS etc. There is an increasing prevalence of HIV/AIDS noticed in commercial sex workers.

### The Child Marriage Restraint Act, 1929

The Act extends to whole of India except state of J & K. the Act is expedient to restrain the solemnisation of child marriages.

#### Definitions

Under this Act some definitions are :

**(a) Child** : Child means a person who, if a male, has not completed twenty one years of age, and if a female, has not completed eighteen years of age.

**(b) Child Marriage** : Child Marriage means a marriage to which either of the contracting parties is a child.

**(c) Minor** : Minor means a person of either sex who is under eighteen years of age.

#### Punishments

- a) Any male above eighteen years of age and below 21 years, contracts a child marriage shall be punishable with simple imprisonment which may extend to 15 days, or with fine which may extend to Rs 1,000/- or with both.
- b) Any male above 21 years of age contracts a child marriage shall be punishable with simple imprisonment, which may extend to 3 months and shall also be liable to fine.
- c) Where a minor contracts a child marriage, any person having charge of the minor, whether as parent or guardian or in any other capacity, lawful or unlawful, who does not act to promote the marriage or permits it to be solemnised shall be punishable with simple imprisonment up to 3 months and shall also be liable to fine. It is a cognisable offence and person can be arrested without the warrant or without the orders of a Magistrate.

### Bio Medical Waste (Management and Handling) Rules 1998

This is dealt in detail in an exclusive chapter in this book.

### Municipal Solid Waste (Management and Handling) Rules, 2000

The solid waste generated in urban areas is increasing everyday. The characteristics of the waste generation are changing with more disposable plastic items being wasted along with other non decomposable low combustible items. On an average 0.2-0.5 kg of solid waste per capita per day is generated in the Indian cities and the civic authorities collect about 35 million tons of municipal solid waste every year. There are various reasons for poor management of solid waste in urban areas



such as lack of fund, lack of technology, lack of awareness and people's participation, inadequate staff etc. Under the EPA 1986 to safeguard the environment and human health government of India has laid down Municipal solid waste management rules.

These rules lay down the responsibility of management of solid waste disposal and various standards for disposal of treated leachate. The management of solid waste has been made the responsibility of municipal authority. The district magistrate / deputy commissioner shall have the over all responsibility for the enforcement of the provisions under these rules. Refuse based fuel technology has been advocated by the government and wastes like plastic generate energy but also emits carcinogens such as dioxins into air. By 2020, it is decided that 50 percent of municipal solid waste and 70 percent of the other waste must be recycled.

### Cantonments Act 1924

An Act to consolidate and amend the law relating to the administration of cantonments.

It extends to the whole of India. The important definitions in this Act are:-

#### Definitions

**(a) Assistant Health Officer** : Assistant Health Officer means the medical officer appointed by the officer Commanding-in-Chief to be the Assistant Health Officer for a cantonment.

**(b) Board** : Board means a Cantonment Board constituted under this Act.

**(c) Civil Area** : Civil Area means an area declared to be a civil area by the Central Government.

**(d) Executive Officer** : Executive Officer means the person appointed under this Act to be the Executive Officer of a cantonment.

**(e) Health Officer** : Health Officer means the senior executive medical officer in military employed on duty in a cantonment.

#### Constitution of Cantonment Boards

In Class I cantonments (population exceeding 10,000) & class II Cantonments (population > 2500 but not exceeding 10,000), the Board shall consist of (a) The Officer Commanding the station or such other military officer as may be nominated in his place by the Officer Commanding-in-Chief, the Command; (b) an executive Magistrate nominated by the District Magistrate; (c) the Health Officer; (d) the Executive Engineer; (e) 1, 2 or 3 military officers (depending on the population), nominated by name by the Officer Commanding the station by order in writing.

In Class III Cantonments (population upto 2,500), the Board shall consist of (a) The Officer Commanding the station, or such other military officer as may be nominated in his place by the Officer Commanding-in-Chief, the Command; (b) one military officer nominated by name by the Officer Commanding the station in writing; (c) one member elected under this Act. The Officer Commanding the station, if a member of the Board shall be the President of the Board; moreover, in every Board in which there is more than one elected member, there shall be a Vice-President elected by the elected members only.

**Executive Officer** : For every cantonment there shall be an Executive Officer appointed by the Central Government or by such person as the Central Government may authorise in this behalf. The Executive Officer shall have the following duties :- (a) exercise all the powers and perform all the duties conferred or imposed upon him by or under this Act or any other law for the time being in force; (b) prescribe the duties of, and exercise supervision and control over the acts and proceedings of, officers and other employees of the Board, other than medical officer in charge of the cantonment general hospital or dispensary; (c) be responsible for the custody of all records of the Board; (d) arrange for the performance of such duties relative to the proceedings of the Board or of any Committee of the Board or of any Committee of Arbitration constituted under this Act, as those bodies may respectively impose on him; (e) comply with every requisition of the Board on any matter pertaining to the administration of the cantonment.

### Summary

The Public Health Legislations aims to improve the health status of the community by maintaining the balance between individual autonomy and community protection. Government of India has initiated, National Legal Literacy Mission in 2005 to impart knowledge and education on various legal aspects.

The CPA is a comprehensive legislation in which consumers can approach with complaints to Commissions at the District, state and central level without any lawyers and court fee. Doctors in government service, charitable clinics providing free service are exempted from CPA.

The Registration of Births and Deaths Act was implemented in 1969 with the aim to collect and compile vital statistics which is necessary for planning and administration. The Act has given statutory authority to the Registrar General, India to coordinate the work of civil registration throughout the country. Every registrar has to register births and deaths, occurring within his/her administrative areas. The information regarding occurrence is to be given within 21 days in both the events of births and deaths. The Act also provides for medical certification of cause of death.

The Epidemic Diseases Act, 1897 provides power to exercise for the control and to prevent any epidemic or spread of epidemic in the States or Country.

The Drugs and Cosmetics Act aims to regulate the import, manufacture, distribution and sale of Drugs and Cosmetics for maintaining high standards of medical treatment.

As per the Workmen's Compensation Act, any worker employed in wide varieties of hazardous occupations by an employer, if suffers an injury, he/she is eligible for compensation, provided he is employed for at least 6 months. If he dies then legal dependents can claim the benefits provided by the Act.

The Water (Prevention and Control of Pollution) Act 1974 was passed by the Parliament in 1974 to provide legal basis for prevention and control of water pollution, maintenance and restoration of wholesomeness of water sources in the country. The State Boards, under the guidance of Central Board, are responsible to plan and execute comprehensive programmes in their respective territories.



The Air (Prevention and Control of Pollution) Act, 1981 is to provide for prevention, control and abatement of air pollution. The Central Pollution Control Board constituted under Section 3 of the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974), exercise the powers and perform for the prevention and control of air pollution.

The Immoral Traffic (Prevention) Act, 1956 provides for the prevention of immoral traffic. Any person who keeps or maintains or acts or assists in the keeping and management or a brothel, is liable to be punished under this section. Immoral traffic not only leads to lower social morals but also spread of certain killer diseases like STIs, HIV/AIDS etc.

The Child Marriage Restraint Act, 1929 extends to whole of India except state of J & K. The Act is expedient to restrain the solemnisation of child marriages.

Municipal Solid Waste (Management & Handling) Rules, 2000 was laid down under the EPA 1986 to safeguard the environment and human health. The district magistrate / deputy commissioner shall have the over all responsibility for the enforcement of the provisions under these rules

The Cantonments Act 1924 consolidates and amends the law relating to the administration of cantonments.

## Study Exercises

### MCQs & Exercises

- Following are the ways & means in which public health officials enforce rules: (a) Permits, licenses and registrations (b) Administrative orders (c) Civil penalties Injunctions (d) All of the above
- The factors responsible for lack of effectiveness of public health legislations are (a) Lack of awareness (b) Lack of implementation (c) Corruption (d) all
- CPA protects all of the following consumer rights except: (a) Right to safety (b) Right to be informed (c) Right to seek redressal (d) Right to consumer education (e) Right to follow religion
- Who all are covered under CPA?
- Define 'Drug' as in Drugs and Cosmetics Act, 1940?

### Fill in the blanks

- Public Health laws protect \_\_\_\_\_ rather than individual's health.
- Govt of India initiated National Legal Literacy Mission in 2005 to \_\_\_\_\_.
- The Registration of Births and Deaths Act was implemented in \_\_\_\_\_.
- The information regarding occurrence of birth and death event is to be given within \_\_\_\_\_ in \_\_\_\_\_ the events. Delayed registration requires \_\_\_\_\_.
- Violation of Epidemic Diseases Act, 1897 is punishable under sec \_\_\_\_\_ of the IPC.
- Recently under the Drugs and Cosmetics Act \_\_\_\_\_ and \_\_\_\_\_ are also included in schedule CI.
- As per the Workmen's Compensation Act, disablement means \_\_\_\_\_ and employer' includes \_\_\_\_\_.

- The Water (Prevention and Control of Pollution) Act 1974 states that term 'Pollution' means \_\_\_\_\_ and term 'Trade effluent' includes \_\_\_\_\_.
- Name the Act which is an outcome of the United Nations Conference on the Human Environment held in Stockholm in June, 1972 \_\_\_\_\_.
- "Brain-stem death" under the Transplantation of Human Organs Act, means \_\_\_\_\_.
- Under the Immoral Traffic (Prevention) Act, 1956 "Minor" means a person who has completed the age of \_\_\_\_\_ but has not completed the age of \_\_\_\_\_.
- The Immoral Traffic (Prevention) Act, 1956 defines 'Child' as a person who has not completed the age of \_\_\_\_\_ while under the Child Marriage Restraint Act, 1929 'Child' means a person who, if a male, has not completed \_\_\_\_\_ years of age, and if a female, has not completed \_\_\_\_\_ years of age.
- On an average \_\_\_\_\_ kg of solid waste per capita per day is generated in the Indian cities
- As per the Cantonments Act 1924 in Class I cantonments are with population exceeding \_\_\_\_\_ & class II Cantonments has population \_\_\_\_\_ but not exceeding \_\_\_\_\_. The Class III Cantonments has only population up to \_\_\_\_\_.

**Answers : MCQs :** (1) d; (2) d; (3) e; (4) The Supreme Court declared that like other service providers under contract, doctors who offer services for the price offered are also under the same obligation to compensate the purchaser (patient) for any deficiency in the quality of their services. (5) Under the Drugs and Cosmetics Act, 1940 defines drug as, 'all Medicines (Ayurvedic, Siddha, and Unani) for internal or external use of human being or animals and all substances (other than food) intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including preparation applied on human body or to destroy insects'.

**Fill in the blanks :** (1) community health; (2) to impart knowledge and education on various legal aspects including those related to Public Health; (3) 1969; (4) 21 days, both; (5) 188; (6) 'in vitro' blood groups, sera and in vitro diagnostic devices for HIV, HBsAg, and HCV; (7) disablement means the loss in the earning capacity of a workman in every employment which he was capable of doing at the time of accident, includes any body of persons whether incorporated or not and any managing agent of an employer; (8) 'Pollution' means contamination of water or such alteration of the physical, chemical or biological properties of water or such discharge of any sewage or trade effluent or of any other liquid, gaseous or solid substance into water, any liquid, gaseous or solid substance which is discharged from any premises used for carrying on any industry, operation or process, or treatment and disposal system, other than domestic sewage; (9) Air (Prevention and Control of Pollution) Act, 1981; (10) "brain-stem death" means the stage at which all functions of the brain-stem have permanently and irreversibly ceased; (11) 16yrs, 18yrs; (12) 16yrs, 21yrs, 18yrs; (13) 0.2-0.5kg; (14) 10000, 10000, 2500, 2500.

*Sunil Agrawal*

A disability can be defined as 'an existing difficulty in performing one or more activities which in accordance with the subject's age, sex and normative social role are generally accepted as essential basic components of daily living'. There seems to be lack of reliable data regarding the incidence and prevalence of various disabilities. National Survey Sample Organisation conducted a sample survey in 1991 which estimated that 1.9% of India's population had disability, and 3% of children had delayed development and likely to be Mentally Retarded. Various studies have shown that 4% of India's population has visual impairment and 6-15% children have learning disability. Overall 10% of our child population has special educational needs.

The highest prevalence of disaster in India is seen in Assam and Arunachal Pradesh states with prevalence more than 20 per 1000 population.

The Government of India has been very concerned regarding the problem and has taken a number of steps in this direction. The Ministry of Social Justice & Empowerment (previously welfare) has been identified as the nodal ministry by the government for the welfare of the disabled. The major legal initiatives towards the field of rehabilitation are described below.

#### **Rehabilitation Council of India Act (RCI Act), 1992**

The Government of India set up a Rehabilitation Council, as a registered society under the Societies Registration Act, 1860. Thereafter, this was converted to a statutory body under the Rehabilitation Council of India Act, 1992. It came into force from 31st July, 1993. This is under the administrative control of Ministry of Social Justice and Empowerment. RCI has been established to regulate training programmes in the field of rehabilitation and maintenance of central rehabilitation register, with the following objectives :

- To regulate the training policies and programmes in the field of rehabilitation of people with disabilities.
- To prescribe minimum standards of education and training of various categories of professionals dealing with people with disabilities.
- To regulate these standards in all training institutions uniformly throughout the country.
- To recognise institutions/universities running degree/diploma/certificate courses in the field of rehabilitation of persons with disabilities
- To recognise foreign degree/diploma/certificate awarded by universities/institutions on reciprocal basis;
- To maintain central rehabilitation register of persons possessing the recognised rehabilitation qualification; and
- To encourage continuing rehabilitation education in collaboration with organisations working in the field of disability.

#### **Persons with Disabilities (Equal opportunities, protection of rights and full participation) Act (PWD), 1995**

The legislation called Persons with Disabilities Act, was enacted in 1995 to protect the rights of persons with disabilities, to provide educational opportunities and full participation. The Act enshrines a multisectoral response to rehabilitation of persons with disabilities.

#### **Visual Impairment**

Blind persons are defined as those who suffer from either of the following conditions :

Total absence of sight; Visual acuity not exceeding 6/ 60 or 20/ 200 (Snellen) in the better eye with correcting lenses; Limitation of the field of vision subtending an angle of 20 degrees or worse.

Different reports and studies, world wide shows that 35-45 million people are blind and an additional 110 - 135 million (Table-1) suffer from low vision conditions. As per the global statistics on Blindness 1998, India has approximately 10 million blind persons requiring services. The estimated incidence of blindness in India is 2.13 million per year (1). The common causes of blindness and visual impairment in India are : Cataract, Glaucoma, Corneal ulcer, Xerophthalmia and other forms of vitamin A deficiency, Conjunctivitis, Retinal detachment, Albinism, Astigmatism, Nystagmus, Optic atrophy, Retinitis pigmentosa and Trachoma. The percentage wise distribution of causes of visual impairment in India is cataract (81%), refractive errors (7%), corneal opacity (3%), glaucoma (2%), trachoma (0.2%), malnutrition related blindness (0.04%) and other causes put together (6.76%). The magnitude of blindness in India has multifarious dimensions with most of them having preventable background.

<b>Table - 1 : The estimated prevalence of blindness in India (2004)</b>	
<b>Category</b>	<b>Prevalence per 1000 popn</b>
Male	10.2
Female	12.2
All ages	11.2

#### **National Efforts**

In India, efforts to control blindness were taken by the government during the seventies. The National Programme for Control of Blindness (NPCB) was launched in 1976 with the goal to bring down the prevalence rate of blindness from 1.4% to 0.3% by the end of twentieth century. Since its launch, considerable progress has been made in building up of infrastructure at Primary Health Centres (PHCs), district hospitals, and medical colleges, and in setting up of central and district mobile units for preventive and curative aspects of visual disability. The major work under the programme has been the effective tackling of cataract through large scale involvement of voluntary organizations and the private sector.

## Collaborative Efforts

The WHO and a consortium of International Non-Governmental Development Organizations (INGDOs) have launched a massive scheme called Vision 2020 which states that the avoidable blindness in the developing countries must be prevented by the year 2020. The Danish International Development Agency (DANIDA) entered into bilateral agreement with the Government of India in 1987 with the objective of preventing blindness and also in capacity building in executing prevention related services. The Sight First Programme of the Lions Club International is also targeting many regions in India to prevent avoidable blindness. Similarly World Bank is assisting blindness control projects in India since 1994-95.

## Vocational Rehabilitation

In the process of rehabilitation, employment should aim at normalization, sensitization and advocacy on the abilities of persons with visual impairment. The Persons with Disabilities Act 1995 states that government shall identify posts which can be reserved for persons with disabilities. The employment of persons with visual impairment in India may be classified into following :

Types of Employment
<ul style="list-style-type: none"><li>• Employment opportunity in government jobs through open competition</li><li>• Employment in government sector through reservation</li><li>• Employment opportunity through special drive</li><li>• Employment exchange guided employment in private companies</li><li>• Employment through placement services</li><li>• Employment in special industries for the disabled</li><li>• Employment in vocational / production centres for the blind</li><li>• Family supported employment</li><li>• Self employment</li></ul>

## Schemes and Concessions for Persons with Visual Impairment

**Travel Concession for the Disabled** : A blind person traveling alone or with an escort, by rail, on production of a certificate from Government doctor or a registered medical practitioner, is eligible to get the concession as below. The concession certificate may be issued by the Station Master and blind person may not be present at the station for purchase of the ticket.

Class	First Class	Second Class	Sleeper
% of concession	75	75	75

Similarly, The Indian Airlines Corporation allows 50% concessional fare to Blind persons on all domestic flights. To avail this facility (for blind persons) they have to produce a certificate from a medical practitioner. Air Hostess/Steward will look after the Blind Persons not accompanied by escorts in flight. The Public Relation Officer or the Traffic Officer Incharge at the airport will render necessary assistance to such infirm passengers at the airport of the departure and arrival. Escorts are to pay full fare.

**Communication** : Blind literature packets are exempted from payment of postage. Blind persons are given concessional and on priority telephone connections.

**Customs Concession** : The central government exempts goods like vocational aids or specific equipments which are essential for management, when imported in India by a handicapped or disabled person for his personal use.

**Conveyance Allowance** : In terms of GoI order vide OM 19029/1/78-E.IV (B) dated 31.8.78, as amended from time to time, conveyance allowance is admissible to such of the Central Government employees borne or regular establishment (including work-charged staff) as are Blind or are Orthopaedically Handicapped with disability of lower extremities. Consequent upon coming into force of these orders, such conveyance allowance shall be abolished and instead all such employees may now be paid transport allowance at double the normal rates prescribed under these orders. The allowance shall not be admissible in case such employees have been provided with the facility of Government transport.

**Scheme for Integrated Education for the Disabled Children:** This is a centrally sponsored scheme and was launched in 1974 by the then Department of Social welfare and now with Department of Education since 1982. 100 percent assistance is provided to the states/UTs for education of the child suffering from certain mild handicaps in common schools with the help of necessary aids, incentives and specially trained teachers. The handicapped children are provided with the books and stationary allowance, uniform allowance, transport allowance, reader allowance, escort allowance and subsidized equipments.

## Hearing Impairment

The first school for the deaf in India was started in Bombay Presidency in 1884. By the time India became independent in 1947, there were 38 schools for the deaf. In 1964, Kothari commission recommended the establishment of special schools in every district. All India Institute of Speech and Hearing (AIISH) was established in 1965 at Mysore. In 1983, Ali Yavar Jung National Institute for the hearing handicapped was started at Bombay under the Ministry of welfare, GOI as an apex body for the hearing handicapped.

The Deaf are defined as those in whom the sense of hearing is non-functional for ordinary purposes of life. They do not hear and understand sounds at all events with amplified speech. The cases included in this category will be those having hearing loss less than 90 decibels in the better ear (profound impairment) or total loss of hearing in both ears.

Worldwide there are about 123 million persons with hearing loss majority of them are living in South Asian Countries. In 1991, NSSO estimated that there are 3 million persons with hearing impairment in India. The age wise distribution per 1000 persons with hearing impairment is as shown in Table-2.

Hearing is one of the important factors which determines the 'quality' of life we lead. Irrespective of the age of onset of hearing impairment, it comes in the way of the individual utilizing his potentials to the maximum, be it in terms of speech and language acquisition, education, vocational placement, if



not attended to on time. WHO in 1980 summarised the main causes of hearing impairment in India as infections, neglect and ignorance

<b>Table - 2 : Age wise distribution of hearing impaired</b>		
<b>Age Group (years)</b>	<b>Hearing Impairment</b>	
	<i>Rural</i>	<i>Urban</i>
0-4	NA	NA
5-14	85	80
15-59	387	377
60 & above	526	541

### National Efforts

National Information Centre of Disability and Rehabilitation (NICDR) was established in 1987. This is a nodal agency for creation of awareness regarding the causes and prevention of disabilities, services available for such disabilities etc. In addition to this National Institutes for hearing handicapped and District Rehabilitation Centre mainly for surveys, research and training were established. The setting up of Vocational Rehabilitation Centres (VRCs) by the government has formalized vocational training and rehabilitation. There are currently 17 VRCs that are working towards training of persons with disabilities, while the Training Centre for Adult Deaf (TCAD) at Hyderabad works exclusively for the hearing impaired.

### Other Facilities Available

- Government of India set up the National Advisory Council for the education of the handicapped in 1955.
- All India Federation of the Deaf (AIFD), a voluntary organization was established in 1955.
- Special employment exchanges were started since 1959.
- AIFD established a multi purpose training centre in Delhi in 1960.
- Government started central scheme of assistance and awards scholarships.
- Training centre for the adult deaf was established by Madras Association of the Deaf in Madras, in 1973.
- A school for the partially hearing impaired started in Hyderabad by the Ministry of Welfare.
- Ministry of welfare launched a centrally sponsored Integrated Education scheme, in 1974.
- NCERT developed a department for special education.
- There are 200 medical colleges and hospitals in the country where special medical facilities are provided for ENT problems.

**Travel :** A deaf and dumb person traveling alone (both afflictions together in the same person) on production of a certificate from a government doctor is eligible for rail concession as follows :

<b>Class</b>	<b>First Class</b>	<b>Second Class</b>	<b>Sleeper</b>
% of concession	50	50	50

A deaf & dumb person is permitted to travel by 2-tier A.C. on payment of concessional fare for first class and full surcharge for 2-tier A.C. Sleeper.

## Locomotor Impairment

Today it is estimated, 1.6 percent of the Indians - the figure comes to around 16 million in absolute terms are afflicted with locomotor disabilities. In India's below 14 yr child population, approximately 3 million were afflicted with locomotor disability - the most common cause of which is poliomyelitis, cerebral palsy etc.

The orthopaedically handicapped are those who have a physical defect or deformity which causes an interference with the normal functioning of the bones, muscles and joints. In above definition if inability resulting from afflictions of nervous system is added then it is called locomotor disability. It can be classified as :

- Congenital** - cerebral palsy, CTEV, meningocele, meningo myelocele, phocomelias, congenital dislocation of hip etc.
- Acquired.**
  - Infective - Tuberculosis of spine or joints, poliomyelitis, septic arthritis, chronic osteomyelitis etc.
  - Traumatic - Road traffic accidents, domestic accidents, industrial accidents etc
  - Vascular - Cerebro-vascular disease, peripheral vascular disease, Perthe's disease etc.
  - Others : These include metabolic, neoplastic and degenerative diseases

### National Efforts

An All India Institute of Physical Medicine and Rehabilitation (AIIPMR) came up at Mumbai under the aegis of the central health ministry. The centre's main occupation is to provide rehabilitative services to the locomotor disabled and few non governmental organization also started contributing for locomotor disabled. The Medical Council of India (MCI) sent a directive to all medical colleges to start a department of physical medicine and rehabilitation so that students are exposed to principles of rehabilitation medicine.

The institutions engaged in rehabilitation of the locomotor disabled are National Institute for Rehabilitation Training and Research (NIRTAR), Olatpur in Orissa, National Institute for Orthopaedically Handicapped (NIOH), Calcutta, Institute for the Physically Handicapped (IPH), New delhi.

The Artificial Limbs Manufacturing Corporation of India (ALIMCO), set up at Kanpur as a Government undertaking, mainly for social services and not for profits, started production in October 1976.

The District Rehabilitation Centre (DRC) Scheme was initiated in 1985 by the Ministry of Welfare in collaboration with the National Institute of Disability and Rehabilitation Research (NIDRR) and Department of Education and UNICEF. The services provided by these centres are :

- Prevention and early detection
- Medical intervention and surgical correction
- Fitment of artificial aids and appliances
- Therapeutic services such as Physiotherapy, occupational therapy and speech therapy
- Provision of training for acquisition of skills through vocational training
- Job placement in local industries.



## Facilities and Concessions

**Travel** : State governments offer either full concession or 50 percent concession for traveling in state run buses. As regards rail travel, the Orthopaedically Handicapped person traveling with an escort, on production of a certificate from a Government doctor to the effect that the person concerned is orthopaedically handicapped and cannot travel without the assistance of an escort, is eligible for getting rail concession at the same rates/as mentioned for locomotor handicapped persons. Locomotor Disabled persons (80% and above) are also allowed 50% Concession in Indian Airlines.

## Mental Retardation

During the 1950s, children with moderate mental retardation emerged as focus of concern, largely through the efforts of increasingly well organized parent advocacy groups. This led to formation of National Association for Retarded Children (NARC) in 1950, now known as the Association for Retarded Citizens (ARC). Self advocacy and consumer awareness, that have empowered people with disabilities globally, have made human services to recognize and restructure their programmes and strategies.

Mental Retardation (MR) is prevalent in all societies and cultures and the prevalence is estimated to be around 30 per thousand worldwide. Nearly 75 percent of people diagnosed to have mental retardation fall in the category of mild mental retardation, while the remaining 25 percent have IQ of 50 or below are classified as moderately, severely or profoundly retarded. Nearly 10 percent have associated medical conditions like epilepsy, hyperkinesias or mental illness. Nearly 4 percent of all children with MR have multiple handicaps. In India the prevalence varies from 0.22 to 32.8 per thousand population. Family history and retardation had high association and in rural areas incidence of retardation is more.

## Classification

The DSM-IV classifies four different degrees of mental retardation : mild, moderate, severe, and profound. These categories are based on the functioning level of the individual.

**Mild mental retardation** : Approximately 85% of the mentally retarded population is in the mildly retarded category. Their IQ score ranges from 50-75, and they can often acquire academic skills up to the 6th grade level.

**Moderate mental retardation** : About 10% of the mentally retarded population is considered moderately retarded. Moderately retarded individuals have IQ scores ranging from 35-55. They can carry out work and self-care tasks with moderate supervision.

**Severe mental retardation** : About 3-4% of the mentally retarded population is severely retarded. Severely retarded individuals have IQ scores of 20-40. They may master very basic self-care skills and some communication skills. Many severely retarded individuals are able to live in a group home.

**Profound mental retardation** : Only 1-2% of the mentally retarded population is classified as profoundly retarded. Profoundly retarded individuals have IQ scores under 20-25. They may be able to develop basic self-care and communication skills with appropriate support and training.

## National Efforts

The development of education for the disabled and particularly mentally retarded took a different progressive turn after 1964-66 when the education commission, following the constitutional directives, suggested with emphasis that education for handicapped has to be organized not merely on humanitarian grounds but on grounds of utility by making them useful citizens. The National Policy for Children (1974) came in and measures were intended to cover all children including those who came from weaker sections of society and those who were handicapped. Integrated Education for the Disabled commenced with central funding in 1974.

To make programme planning more realistic, working groups on the education of disabled child were set up in 1981 by the Ministry of Welfare and Ministry of Education and culture, Government of India. The committee suggested special day schools, residential schools, resource teacher programme and partial integration over 20 year time span.

The National Institute for the Mentally Handicapped (NIMH) was established in Secunderabad in 1985. The Early Childhood Care and Education (ECCE) scheme through ICDS, preschool programme, and District Primary Education Programme (DPEP) have included disability education including mental retardation since 1999. From July 1999, RCI started a national level programme, training programme for PHC doctors, to train them in disability management. This national level programme named, "National Programme on Orientation of Medical Officers working in Primary Health Centres to Disability Management", which will train 30,000 medical officers through a three day orientation module. Thakur Hari Prasad Institute of Research and Rehabilitation for the mentally handicapped (THPI), Hyderabad is a NGO run organization. It was established in the year 1968 and made significant contribution in the field of manpower development. The Mental Health Act, 1987 is an act to consolidate and amend the laws relating to the treatment and care of mentally ill persons, to make better provisions with respect to their property and affairs and for connected matters.

## Facilities and Concessions

A mentally retarded person, accompanied by an escort, on production of a certificate in the prescribed form, from a government doctor, is eligible to get the same rate of railway concession as entitled for locomotor handicapped persons.

## Vocational Training

With modern training procedures retarded children can engage in some occupations and achieve at least partial economic independence. Vocational training is therefore of great importance and about 200 institutions in this country offer vocational training. On completion of training, the adult MR person move towards four possible employment :

1. Open employment
2. Supported open employment
3. Sheltered employment
4. Self employment.

**Placement services** : About 10 percent of vocational institutions have taken up this task of not only providing vocational training but placing the adult mentally retarded

person in open employment with little support. Home based self employment in our Indian context are *Agarbatti* making, candle making, running photo copier, chalk making, telephone booths etc.

### Parental Counseling

Several voluntary organizations are engaged in parents counseling through their multidisciplinary approach. The counseling of parents is very important because :

1. They have to deal with the normal development and interpersonal crisis in the MR child.
2. They have to cope with the complications introduced by the reality of child's disability of which they have little knowledge or experience.

### Sports and Recreation

Sports Olympics India was founded in 1988 to provide opportunity for persons with Mental Handicap to participate in National and International sports and games. Sports Olympics India organizes national games to select appropriate candidates for the International special Olympics.

### Foster Care Home

Foster care home is a home away from home, specially mentioned home for children with mental retardation, who require accommodation and special care. Many voluntary organizations and NGOs are running such homes. Here with the help of foster care mothers who impart systematic training and guidance they learn daily routine of home, activities of daily living.

### Others

1. Allotment of public telephone booths on priority to handicapped persons.
2. A scheme of scholarship for pursuing education in special schools run by NGOs.
3. Government servant is eligible to draw Children's Educational Allowance when his MR child goes to school away from the station of his/her posting.
4. Housing boards and urban development authorities have scheme of preferential allotment of plots and housing sites to individuals with disability.
5. The GOI, Department of Personnel and Training in 1991, makes a provision for a choice in the place of posting of parents in government service having a child with MR.

## Facilities and Concessions given by the Central and State Governments for the Disabled

### 1. Employment Opportunity Schemes

**3 percent Reservations in Gr 'C' & 'D' Posts** : As per the order of Government of India reservation of 3% in jobs have been made in Gr.'C' & Gr.'D' posts for the PH persons. The category of handicapped persons benefited are the blind, the deaf and the O.H. Persons with disability will be given preference at the time of recruitment in the identified Gr.'A' and 'B' posts.

**Age Concession** : As per the Government order it has been decided to extend the age concession of 10 years in favour of handicap persons to recruitment to posts filled through the SSC

and through Employment Exchange in Gr.'C' & Gr.'D' posts.

Apart from other employment schemes/reservation in jobs as mentioned earlier for disabled persons, they are also provided relaxation in

**Age** : Upper age limit has been relaxed upto 10 years and if physically handicapped is SC/ST then further 5 years are relaxed in the age criteria.

**Physical fitness** : Physically handicapped persons are not subjected to the usual medical examination by the appointing authorities.

**Qualifications** : Relaxation is also given on various qualifications for different posts. e.g. exemption of typing for appointment to clerical posts.

Another scheme is being developed with the objective of providing assistance to disabled persons in getting gainful employment either through Special Cells in normal Employment Exchanges or through Special Employment Exchanges for physically handicapped persons. The scheme is implemented through Labour Department of State Governments/UT Administrations. Up to 100% financial assistance is provided in the case of Special Cells and 80% in case of Special Employment Exchanges to State Govts./Union Territory Administrations.

### 2. Income Tax Concessions

The following rebates are available. These rebates are available not only to a handicapped person but also to any normal person who has a handicapped person as his / her dependant.

**a) 80DD (Deductions in respect of medical treatment, etc., of handicapped persons)** : When an assessee is suffering from a permanent physical disability (including blindness) or is subject to mental retardation, being a permanent physical disability or mental retardation specified in the rules made in this behalf by the Board, which is certified by a physician, a surgeon, an oculist or a psychiatrist, as the case be, working in a government hospital, and which has the effect of reducing considerably such person's capacity for normal work or engaging in a gainful employment or occupation. The assessee shall, be allowed a deduction of a sum of fifteen thousand rupees only (Rs.15,000/-) in respect of the previous year.

**b) 80 DDA (Deduction in respect of deposit made for maintenance of handicapped dependent)** : In computing the total income of an assessee the amount can be deducted not exceeding twenty thousand rupees (Rs.20,000) paid or deposited by him in the previous year out of his income chargeable to tax, under any scheme framed in this behalf by the Life Insurance Corporation or the Unit Trust of India.

**c) 80 DDB (Deduction in respect of medical treatment etc.):** Where an assessee who is resident in India has, incurred any expenditure for the medical treatment of such disease or ailment for himself or a dependent relative, the assessee shall be allowed a deduction of a sum of fifteen thousand rupees only (Rs.15,000) in respect of that previous year in which such expenditure was incurred.

**d) 80U (Deduction in respect of permanent disability (including blindness))** : In computing the total income of an individual, who is suffering from a permanent physical disability or mental retardation shall be allowed a deduction of

a sum of seventy five thousand rupees (Rs.75,000).

### 3. Financial Assistance to Persons with Disabilities

**(a) National Handicapped Finance & Development Corporation (NHFDc) :** The “National Handicapped Finance and Development Corporation” has been incorporated by Ministry of Social Justice & Empowerment, Govt.of India on 24th Jan, 1997 under section 25 of the Companies Act, 1956 as a company not for profit. It is wholly owned by Govt. of India and has an authorized share capital of Rs. 400 crores (Rupees Four Hundred Crores only). The objectives of this corporation are :

- Promote economic developmental activities for the benefit of persons with disabilities.
- Promote self-employment and other ventures for the benefit/ economic rehabilitation of persons with disabilities.
- Extend loans to person with disability for pursuing general/ professional/ technical education for training at graduate and higher level.
- Assist in the upgradation of technical and entrepreneurial skills of persons with disability for proper and efficient management of production units.
- Assist self-employed individuals/ group of individuals of registered factories/ companies/ co-operatives of disabled persons in marketing their finished goods and assist in procurement of raw materials.

Any Indian Citizen with 40% or more disability and age between 18 and 55 years and annual Income below Rs.60,000/- for urban areas (less than Rs.55,000/-p.a. for rural areas) is eligible for the scheme.

**NHFDc Schemes :** These include loans for setting up small business (Loan upto Rs.20.00 Lakhs), for higher studies, for agricultural activities (Loan upto Rs.5.00 Lakhs), for manufacturing/ production of assistive Devices for disabled persons (Loan upto Rs.25.00 Lakhs), for self employment amongst persons with mental Retardation, Cerebral Palsy and Autism (Loan upto Rs.2.50 Lakhs).

**(b) National Trust for Welfare of Persons with Autism, Cerebral Palsy, Mental Retardation and Multiple Disabilities:** The National Trust for welfare of Persons with Autism, Cerebral Palsy, Mental Retardation and Multiple Disabilities Act, 1999 came into force w.e.f. 30th December,1999. The National Trust supports programmes which promote independence, facilitate guardianship where necessary and address the concerns of those special persons who do not have their family support. The Trust also seeks to strengthen families and protect the interest of persons with autism, cerebral palsy, mental retardation and multiple disabilities after the death of their parents. The Trust is empowered to receive grants, donations, benefactions, bequests and transfers. It is exempted from income tax.

### 4. Central Government Schemes for the Rehabilitation of Persons with Disabilities

#### Ministry of Social Justice and Empowerment

#### a) Scheme to promote Voluntary Action for Persons with Disabilities (Umbrella Scheme)

The enactment of the people with disabilities, equal opportunities and protection of Right Act of 1995 is landmark

legislation and an expression of India's commitment of social justice. The Disability Division of the Ministry of Social Justice and Empowerment has so far been administering the following five grant-in-aid schemes which are being implemented through NGOs :

- Scheme of Assistance to organizations for the disabled.
- Scheme of Assistance to Disabled Persons for Purchase/ Fitting of Aids/Appliances.
- Scheme of Assistance of Voluntary Organization for the Rehabilitation of Leprosy Cured Persons.
- Scheme of Assistance to voluntary Organizations for Special School for Handicapped Children.
- Scheme of Assistance of Organizations for Persons with Cerebral Palsy and Mental Retardation.

#### b) Scheme of Assistance to Disabled Persons for Purchase/ Fitting of Aids & Appliances (ADIP)

**Ministry of Rural Areas & Employment :** Convergence of Poverty Alleviation Programme of the Ministry of Rural Areas and Employment with the ADIP Scheme of Ministry of Social Justice and Empowerment.

- TRYSEM training to disabled.
- Financial assistance to group of persons with disability in rural areas.
- Revision/Modification of Jawahar Rozgar Yojana guidelines, earmarking of funds for persons with disability.
- 3% reservation to persons with disability in the Rural Sanitation programme.
- Earmarking of 3% of funds for the benefits of persons with disability under Indira Awas Yojana.

### 5. Pension and Unemployment Allowance

Some of the state governments have introduced disability pension and unemployment allowance schemes.

### 6. Educational Assistance Schemes

- Ministry of Welfare covers scholarships for general education from class IX onwards and for technical training at certificate, diploma and degree levels.
- Department of Social Welfare provides scholarships to pursue education from class I to class VIII

### 7. Fellowships

The University Grants Commission has reserved 1 percent of the fellowships allocated to the Universities for the handicapped.

### 8. Reservations in Higher Educational Institutions.

A number of State Governments have reserved 3 percent seats in Industrial Training Institutes / Engineering and management Colleges (usually it is 1% each for Visual, Hearing and Locomotor handicapped persons).

### 9. District Rehabilitation Centres

The Government of India launched the District Rehabilitation Centre Scheme in early 1995, to provide comprehensive rehabilitation services to the rural disabled right at their door steps. The scheme, at present, is operational at 11 different districts of the 10 states of our country. These are -

Bhubaneshwar (Orissa); Bilaspur (Madhya Pradesh); Kharagpur (West Bengal); Mysore (Karnataka); Chengalpattu (Tamil Nadu); Sitapur (Uttar Pradesh); Vijaywada (Andhra Pradesh);



Bhiwani (Haryana); Kota (Rajasthan) and Virar (Maharashtra), Jagdishpur (Uttar Pradesh).

**The services provided in the scheme includes -**

- Prevention and Early Detection
- Medical Intervention and Surgical Correction
- Fitment of Artificial Limbs, Aids and Appliances
- Therapeutic Services
- Training for acquiring Vocational Training, Job Placement etc.

#### **10. Regional Rehabilitation Training Centres (RRTCs)**

Four Regional Rehabilitation Training Centres (RRTCs), also been set up at Chennai, Cuttack, Lucknow and Mumbai for training and manpower development in the field of rehabilitation particularly for the DRCs. The RRTCs also have been conducting training programmes for Communities, Parents and even for Persons with Disabilities themselves.

#### **11. Science and Technology Project in Mission Mode on Application of Technology for the Welfare and Rehabilitation of the Handicapped**

The objective of the scheme is to coordinate and fund the research projects for generation of new technology in terms of development of assistive devices for large scale use by the disabled. The focus of S&T Mission Mode scheme is to design, develop and standardize new and innovative assistive devices of better materials, design and technology for fabricating high quality modern state of the art assistive devices.

Several products have been successfully developed, to name a few such as plastic aspheric lenses for the low vision persons, B.K. Prosthesis, inter-pointing Braille writing frame, PU Foam foot, multifunctional wheelchair, feeding aid for spastic etc. developed under the Mission Mode. The implementation of this scheme is through 100% funding to the research/scientific institutions through Rehabilitation Technology Centre.

#### **12. Scheme for Setting up of Composite Regional Centre for Persons with Disabilities**

It has been approved to set up Composite regional Centres for persons with disabilities in different parts of country. The basic objective of setting up Composite Resource Centres (CRCs) is to create the infrastructure required for training and manpower development, research and providing services to persons with disabilities, particularly in those parts of the country where much infrastructure is lacking at present. The Centres would be expected to function as the Outreach Centres of National / Apex Institutes, presently functioning under the Ministry and will facilitate the process of capacity building at local levels, in regions, in which these are being set up. The proposed centers would also carry out the following objectives.

- To serve as Resource Centre for rehabilitation and special education of persons with disabilities. To start with, short term and orientation courses will be taken up.
- To establish linkages with existing medical, educational and employment services, following the principles of community-based rehabilitation and offer extension services in the rural areas.
- To develop strategies for delivery of rehabilitation services suitable to the socio-cultural background of the region.

- To undertake designing, fabrication and fitment of aids and appliances.
- To undertake services of education and skill development leading to enhancement of opportunities for employment, rehabilitation, mobility communication, recreation and integration in society.

First such Composite Regional Centre has started functioning at Srinagar and the second Composite Regional Centre has started functioning at Lucknow since 2000.

#### **13. Scheme for Setting up Regional Rehabilitation Centres for Persons With Spinal Injuries and other Orthopaedic disabilities**

It has been approved to establish four Regional Rehabilitation Centres for Persons with Spinal Injuries and other Orthopedics Disabilities in the country, as a Centrally Sponsored Scheme on 90 : 10 Centre : State sharing basis. These Centres would provide facilities for treatment and rehabilitation services to the spinally injured and persons with other orthopaedic disabilities. The Indian Spinal Injuries Centre, New Delhi, a Centre of Excellence will provide the required technical support for setting up of these centres and will also function as Referral Centre.

Various services to be provided by the Centre will include :

- Diagnostic Facilities
- Equipped Physio-Occupational Therapy
- In patient beds facility
- Minor Operation Theatre
- Artificial Limbs and appliances fitting centre
- Vocational Training
- Teaching and Training to health personnel & community workers.

#### **14. National Awards for People with Disabilities**

The Ministry of Social Justice & Empowerment has been giving National Awards since 1969 on the International Day of Disabled Persons on 3rd December every year. The Awards are given in different categories, namely best employer of disabled, outstanding employee, placement officer, best individual, institution, barrier-free environment, creative disabled person and National Technology Awards involved in the rehabilitation and welfare of persons with disabilities.

Institution of Awards has created awareness amongst the disabled persons both in public and private sector and brought them in the mainstream.

#### **15. Others**

- (a) Handicapped persons are exempted from payment of application and examination fee as prescribed by UPSC/ SSC
- (b) Assistance to Disabled persons for purchase / fitting of aids/appliances to procure durable, sophisticated and scientifically manufactured aids and appliances to promote their physical, social and psychological rehabilitation.
- (c) Assistance to voluntary organizations working for the disabled welfare. Financial support is given up to maximum limit of 90 percent of the total project cost.
- (d) Assistance to voluntary organizations working for the rehabilitation of leprosy cured persons both in rural and



urban areas. Financial support is given up to maximum limit of 90 percent of the total project cost. Programmes like awareness generation, early intervention, educational and vocational training, economic rehabilitation, social integration etc are undertaken in the schemes.

- (e) Physically handicapped owners of motorized vehicles are granted exemption from the payment of road tax by the state government and are eligible to claim refund upto 50 percent of the expenditure incurred by them on purchase of petrol/diesel from recognized dealers subject to certain ceilings. The scheme is operative through District Social Welfare Officers or Tehsildars or any other equivalent authority.

## Important Organisations and Centres

### National Level Rehabilitation Institutes

- Ali Yavar Jung National Institute for the Hearing Handicapped (AYJNIHH), Mumbai
- National Institute of Mentally Handicapped (NIMH), Secunderabad
- National Institute of Visually Handicapped (NIVH), Dehradun
- National Institute for the Orthopaedically Handicapped (NIOH) rechristened as Dr. Shyama Prasad Mukherjee National Institute for Orthopaedically Handicapped, Kolkata
- National Institute for Rehabilitation Training & Research, Cuttack.
- The Institute for the Physically Handicapped, Delhi.

### Associated Organisations

- Artificial Limbs Manufacturing Corporation of India (ALIMCO)
- Dr. Ambedkar Foundation
- Institute for the Physically Handicapped (IPH), rechristened as Deen Dayal Upadhyay Institute of Physically Handicapped
- National Handicapped Finance and Development Corporation (NHFDC)
- National Trust for the Welfare of Persons with Autism, Cerebral Palsy, Mental Retardation and Multiple Disabilities
- National Institute of Social Defence (NISD)
- Office of the Chief Commissioner for Disabilities
- Swami Vivekanand National Institute of Rehabilitation, Training and Research (SVNIRTAR).

## Summary

WHO has defined rehabilitation as “the combined and coordinated use of medical, social, educational and vocational measures for training and retraining the individual to the highest possible level of functional ability”. The GOI has set up a Rehabilitation Council in 1860, converted to a statutory body under the Rehabilitation Council of India Act, 1992 to regulate training programmes in the field of rehabilitation, under the aegis of the Ministry of Social Justice & Empowerment. The Persons with Disabilities Act was enacted in 1995 to protect the rights of persons with disabilities, to provide educational opportunities and full participation.

The National Programme for Control of Blindness (NPCB) was

launched in 1976 with the goal to bring down the prevalence rate of blindness from 1.4% to 0.3% by the end of twentieth century and considerable progress has been made since its launch. The WHO and a consortium of international non governmental development organizations (INGDOs) have launched Vision 2020 with aim to prevent the avoidable blindness in the developing countries by the year 2020. DANIDA in 1987 and World Bank since 1994-95 are in agreement with GOI for assisting in control projects and capacity building.

The first school for the deaf in India was started in Bombay Presidency as back as 1884. Following recommendation of Kothari Commission, All India Institute of Speech and Hearing (AIISH) was established in 1965 at Mysore and Ali Yavar Jung National Institute for the hearing handicapped was started at Bombay in 1983. WHO in 1980 summarized the main causes of hearing impairment in India as infections, neglect and ignorance. National Information Centre of Disability and Rehabilitation (NICDR) was established in 1987 for creation of awareness regarding the causes and prevention of disabilities, services available for such disabilities etc. In 1991, NSSO estimated that there are 3 million persons with hearing impairment in India. Currently 17 VRCs that are working towards training of persons with disabilities, while the Training Centre for Adult Deaf (TCAD) at Hyderabad works exclusively for the hearing impaired.

In India around 16 million are inflicted with locomotor disabilities of which around 3 million are below 14 yr child population- the most common cause of which is poliomyelitis, cerebral palsy etc. The institutions engaged in rehabilitation of the locomotor disabled are All India Institute of Physical Medicine and Rehabilitation (AIIPMR), Mumbai; National Institute for Rehabilitation Training and Research (NIRTAR), Olatpur in Orissa; National Institute for Orthopaedically Handicapped (NIOH), Kolkata; Institute for the Physically Handicapped (IPH), New Delhi; and the Artificial Limbs Manufacturing Corporation of India (ALIMCO), Kanpur. The District Rehabilitation Centre (DRC) Scheme was initiated in 1985 by the Ministry of Welfare in collaboration with the National Institute of Disability and Rehabilitation Research (NIDRR) and Department of Education and UNICEF.

Mental Retardation (MR) is prevalent in all societies and cultures and in India the prevalence varies from 0.22 to 32.8 per thousand. National Association for Retarded Children (NARC) formed in 1950 is now known as the Association for Retarded Citizens (ARC) focusing on children with moderate mental retardation. Integrated Education for the Disabled commenced with central funding in 1974 and working groups on the education of disabled child were set up in 1981 to make it more realistic. National Institute for the Mentally Handicapped (NIMH) was established in Secunderabad in 1985. The Early Childhood Care and Education (ECCE) scheme and District Primary Education Programme (DPEP) have included disability education since 1999. From July 1999, RCI started “National Programme on Orientation of Medical Officers working in Primary Health Centres to Disability Management”, which will train 30,000 medical officers through a three day orientation module. The Mental Health Act, passed in 1987 to consolidate and amend the laws relating to the treatment and care of

mentally ill persons, to make better provisions with respect to their property and affairs and for connected matters.

Facilities and Concessions given by the Central and State Governments for the Disabled

1. Employment Opportunity Schemes
  - 3 percent Reservations in Gr 'C' & 'D' Posts
  - Age Concession of 10 years in favor of handicap persons to recruitment to posts filled through the SSC and through Employment Exchange in Gr.'C' & 'D' posts.
  - Physically handicapped persons are not subjected to the usual medical examination by the appointing authorities.
  - Relaxation is also given on various qualifications for different posts. Eg exemption of typing for appointment to clerical posts.
  - Getting gainful employment either through Special Cells in normal Employment Exchanges or through Special Employment Exchanges for physically handicapped persons.
2. Income Tax Concessions are applicable to not only to a handicapped person but also to any normal person who has a handicapped person as his / her dependant :
  - 80DD -Deductions in respect of medical treatment, etc., of handicapped persons
  - 80 DDA -Deduction in respect of deposit made for maintenance of handicapped dependent
  - 80 DDB -Deduction in respect of medical treatment etc.
  - 80U -Deduction in respect of permanent disability including blindness
3. Financial Assistance to Persons with Disabilities is available through :
  - National Handicapped Finance & Development Corporation (NHDFC)
  - National Trust for Welfare of Persons with Autism, Cerebral Palsy, Mental Retardation and Multiple Disabilities
4. Central Government Schemes for the Rehabilitation of Persons with Disabilities :
  - Scheme to promote Voluntary Action for Persons with Disabilities (Umbrella Scheme)
  - Scheme of Assistance to disabled persons for purchase/ fitting of aids & appliances (ADIP).
  - Convergence of Poverty Alleviation Programme of the Ministry of Rural Areas and Employment with the ADIP Scheme of Ministry of Social Justice and Empowerment
  - Revision/Modification of Jawahar Rozgar Yojana guidelines
  - Earmarking of 3% of funds for the benefits of persons with disability under Indira Awas Yojana.
5. Pension and Unemployment Allowance
6. Educational Assistance Schemes
7. Fellowships
8. Reservations in Higher educational Institutions
9. District Rehabilitation Centres
10. Regional Rehabilitation Training Centres (RRTCs)
11. Science and Technology Project in Mission Mode on Application of Technology for the Welfare and Rehabilitation of the Handicapped
12. Scheme for Setting up of Composite Regional Centre for Persons with Disabilities
13. Scheme for Setting up Regional Rehabilitation Centres

for Persons With Spinal Injuries and other Orthopaedic disabilities

14. National Awards for People with Disabilities.

## Study Exercises

**Long Question :** Discuss the various Facilities and Concessions given by the Central and State Governments for the Disabled

### MCQs

1. Which ministry has been made responsible by the government for the welfare of the disabled ? (a) Ministry of Social Justice & Empowerment (b) Ministry of Health and Family Welfare (c) Ministry of Labour (d) None
2. Blindness as per WHO classification is includes all except: (a) 3/60 (finger counting at 3 meters) to 1/60 (finger counting at 1 meter) (b) 1/60 to light perception (c) No light perception (d) 6/60 to 3/60
3. WHO in 1980 summarized; the main causes of hearing impairment in India as : (a) Infections (b) Neglect (c) Ignorance (d) All
4. The most common cause of locomotor disability in India among below 14 yr child population : (a) poliomyelitis (b) cerebral palsy (c) both of above (d) congenital causes
5. AIIPMR, Mumbai established under the aegis of : (a) Ministry of Social Justice & Empowerment (b) Ministry of Health and Family Welfare (c) Ministry of Labour (d) None
6. Integrated Education for the Disabled commenced in : (a) 1977 (b) 1974 (c) 1983 (d) 1965
7. National Institute for the Mentally Handicapped (NIMH) was established in 1985 at : (a) Bangalore (b) Secunderabad (c) Mysore (d) Mumbai
8. Possible employment for a mentally handicapped individual are : (a) Supported open employment (b) Sheltered employment (c) Self employment (d) All
9. In India Regional Rehabilitation Training Centers is not located at (a) Chennai, (b) Cuttack, (c) Lucknow (d) Secunderabad
10. Who all amongst the international agencies are providing collaborative support to GOI in prevention and control of Blindness : (a) DANIDA (b) World Bank (c) WHO (d) all of above

### Fill in the Blanks

1. National Survey Sample Organisation in 1991 estimated that \_\_\_\_\_ of India's population had disability, and \_\_\_\_\_ of children had delayed development and likely to be Mentally Retarded.
2. Rehabilitation Council of India Act was passed in \_\_\_\_\_ and came into force from \_\_\_\_\_.
3. Commonest causes of blindness and visual impairment in India are : \_\_\_\_\_, \_\_\_\_\_ & \_\_\_\_\_.
4. National Programme for Control of Blindness (NPCB) was launched in \_\_\_\_\_ with the goal to bring down the prevalence rate of blindness from \_\_\_\_\_ to \_\_\_\_\_ by the end of twentieth century.
5. \_\_\_\_\_ commission recommended the establishment of special schools for hearing impaired in every district.
6. The Deaf are defined as those having hearing loss more than \_\_\_\_\_.

- \_\_\_\_\_ in the \_\_\_\_\_ ear (profound impairment) or \_\_\_\_\_ loss of hearing in both ears.
- Currently \_\_\_\_\_ VRCs are working towards training of persons with disabilities.
  - Training Centre for Adult Deaf (TCAD) at \_\_\_\_\_ works exclusively for the hearing impaired.
  - Artificial Limbs Manufacturing Corporation of India (ALIMCO) set up at \_\_\_\_\_ as a Government undertaking, mainly for social services and not for profits, started in \_\_\_\_\_.
  - Examples of Home based self employment for mentally retarded are \_\_\_\_\_, \_\_\_\_\_ & \_\_\_\_\_ etc.
  - District Rehabilitation Centre (DRC) Scheme was initiated in 1985 by the Ministry of \_\_\_\_\_ in collaboration with Department of \_\_\_\_\_ and \_\_\_\_\_.
  - National Association for Retarded Children (NARC) in 1950, now known as the \_\_\_\_\_.
  - Sports Olympics India was founded in \_\_\_\_\_ to provide opportunity for persons with Mental Handicap to participate in National and International sports and games.
  - Upper age limit for physically handicapped has been

- relaxed upto \_\_\_\_\_ years & if physically handicapped is SC/ST then further \_\_\_\_\_ years are relaxed in the age criteria.
- Any Indian Citizen with \_\_\_\_\_ or more disability and age between 18 and 55 years and annual Income below Rs. \_\_\_\_\_ for urban areas and less than Rs. \_\_\_\_\_ for rural areas is eligible for the NHFDC scheme

**Answers : MCQs :** (1) a; (2) d; (3) d; (4) c; (5) d; (6) b; (7) b; (8) d; (9) d; (10) d.

**Fill in the Blanks :** (1) 1.9%, 3%; (2) 1992, jul1993; (3) Cataract, glaucoma & xerophthalmia; (4) 1976, 1.4% to 0.3%; (5) Kothari; (6) 90-dB, better, total; (7) 17; (8) Hyderabad; (9) Kanpur, 1976; (10) *Agarbatti* making, running Photo copier, telephone booths etc; (11) Welfare, Education & UNICEF; (12) Association for retarded citizens; (13) 1988; (14) 10, 5; (15) 40%, 60,000, 55,000.

### Further Suggested Reading

- Status of Disability in India 2000, Rehabilitation council of India, New Delhi, 2000.
- National Health Profile 2007, Central Bureau of Health Intelligence, DGHS, Govt Of India, New Delhi, 2008.

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## Human Manpower Resources in India (Including AYUSH)

Anagha Khot

Human resources are the most precious resource of a country. Globally national health systems are finding it challenging to train, sustain and retain their health workers. While India is being propelled to a position of international eminence, it faces three main groups of challenges: *first*, dealing effectively with unfinished agendas of communicable diseases, maternal and child health, and health systems strengthening; *second*, dealing with new emerging challenges such as premature burden of non-communicable diseases; and *third*, dealing with globalization related issues while contributing to the management and shaping of the global policy environment. In addressing these challenges, the health workforce is confronted by shortages, migration, issues of quality, accountability, public-private coordination, and the complexity of service provision to large and diverse populations.

### Concepts and Definitions(1)

**Human resources for health (HRH) :** HRH (*Used synonymously with 'health manpower, health personnel, or health workforce'*) refers to "people engaged in actions whose primary intent is to enhance health" (World Health Report, 2006). This includes both private and public sectors and different domains of health systems, such as personal curative and preventive care, non-

personal public health interventions, disease prevention, health promotion services, research, management and support services (Fig. - 1).

HRH encompass "all individuals engaged in the promotion, protection, or improvement of population health, including clinical and non-clinical workers." The persons are engaged in any capacity in the production and delivery of health services. These persons may be paid or volunteer, with or without formal training for their functions, and in the public or private sector. (JLI, 2004)

**Health Human Power System :** Health human manpower consists of a system composed of the following inter-related elements :

- Human resources development (HRD), as applied to human resources for health (HRH), includes the planning, production, and management of health personnel.
- Human resources planning "...is the process of estimating the number of persons and the kinds of knowledge, skills, and attitudes they need to achieve predetermined health targets and ultimately health status objectives" (WHO, 1978). Over the years this function has been broadened to include that of formulating human resources policy, in which the word 'policy' refers to statements made by relevant authorities that are intended to guide the allocation of resources and effort.
- Human resources production refers to "...all aspects related to the basic and post-basic education and training of the health labour force. Although it is one of the central aspects of the health manpower (development) process,

it is not under the health system's sole control" (WHO, 1978). The production system includes all the educational and training institutions, which are increasingly a joint responsibility of service and educational institutions.

- Human resources management has been defined as the "mobilization, motivation, development, and fulfilment of human beings in and through work" (WHO, 1978). It "...covers all matters related to the employment, use, deployment and motivation of all categories of health workers, and largely determines the productivity, and therefore the coverage, of the health services system and its capacity to retain staff." Management also encompasses programmes for in-service and continuing professional education, as well as evaluation.

**AYUSH** : An extremely important national initiative in India for ensuring appropriate utilization of technology and manpower of available indigenous systems of health in the country, viz. Ayurved, Yoga & naturopathy, Unani, Siddha, and Homeopathy, which fits very well with the ethos of the community and is quite acceptable by the people.

#### Dimensions of the performance of the health work force (2)

- Coverage refers to the extent to which the work force provides services to the various sub-groups of the population and supplies the whole range of services corresponding to their health needs.
- Productivity corresponds to the output extracted from personnel, such as patients seen per doctor, number of procedures per provider.
- Technical quality is the degree to which providers produce services which (1) respect the accepted technical norms, usually defined by professional associations, and (2) have a positive impact on the health status of users.
- Socio-cultural or service quality refers to the degree to

which providers produce services which are culturally and ethically acceptable to users, meet their expectations, and are organized in a way that makes them accessible.

- Organizational sustainability is the degree to which the work force is utilized in a way that ensures (1) the maintenance of the capacity to provide needed services over time, both in quantitative and qualitative terms, and (2) the adaptation of services to changing needs and circumstances.

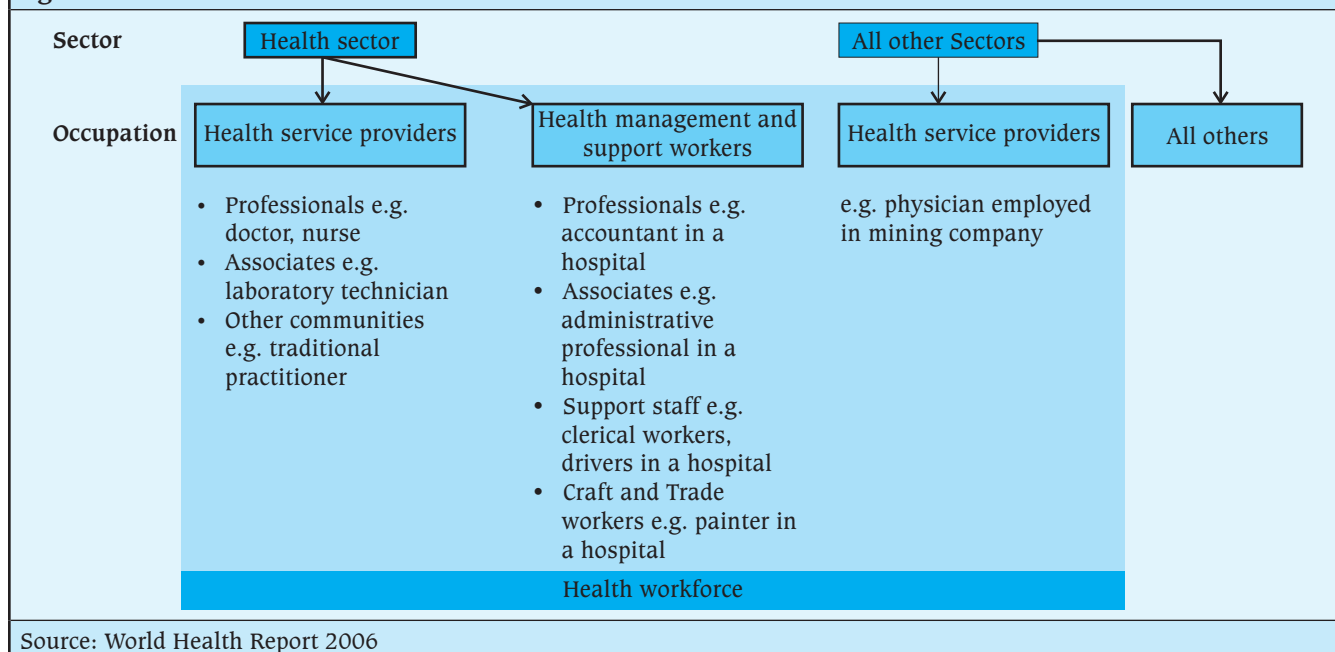
Each of these dimensions, individually or in combination, has an impact on health outcomes, responsiveness, even financial protection

#### Global & Regional Scenario

The WHO estimates that there are a total of 59.2 million full-time paid health workers worldwide (World Health Report 2006). Of these, there are about 39.5 million health service providers and over 19.5 million management and support workers. It is estimated that there is a global shortage of more than 4 million doctors, midwives, nurses, pharmacists, dentists and support workers.

There exist considerable inter-regional as well inter-country variations in terms of availability of human resources. While the WHO South East Asia Region (South East Asia Region herein includes Bangladesh, Bhutan, DPR Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Timor- Leste and Thailand) has a quarter of the world's population, it has only 12 per cent of the global health workforce. On the regional average, there are 29 essential health service providers per 10,000 population. This figure is well below the global average of 62 (See Fig. - 2 & 3). In addition, the Region also faces the imbalance in their distribution of these health workers, mainly between rural and urban areas as well as across the public and private sector.

**Fig. - 1 : Health Workers in All Sectors**





*Some of the critical issues that countries are grappling to address include :*

- Addressing issues of shortages of human resources
- Numerical and distributional imbalances of human resources that are not only wasteful but contribute to poor coverage of health services
- Poor training and technical skills of health personnel that impede the effective delivery of health care
- Inefficient skills- mix of health personnel
- Over-burdened district staff
- Personnel management issues involving non-existent career structures
- Inadequate staff supervision
- Lack of support and poor working environment
- Lack of opportunities for personal development and several other factors that lead to inefficient delivery of health care
- Migration of health personnel

### Health Workforce in India

The state of human resources for health in India is diverse and multifaceted. They range from rigorously trained biomedical specialists and super-specialists at one end to an assortment of community and household based healers at the other. One half of this continuum is abounding with trained and qualified doctors of allopathic or modern biomedicine, psychiatrists, dentists, radiographers, a range of paramedical professionals - nurses, pharmacists, laboratory technicians, and a number of allied personnel - policy makers, health planners and managers, social workers, psychologists, researchers, health educators and promoters, and health technologists. While the other half is replete with the richness of India's traditional healing systems. Here one finds professionally trained and University qualified practitioners of Ayurvedic, Unani, Homeopathic, Siddha and Naturopathic medical traditions. One also comes across informally trained providers through apprenticeships, traditional and household birth attendants, a variety of healers and community or household elders learned in the art of traditional healing and indigenous remedies. These human resources can also be categorized into a public sector & a private sector.

**A brief profile of main categories of health workforce is given below:**

#### 1. Doctors

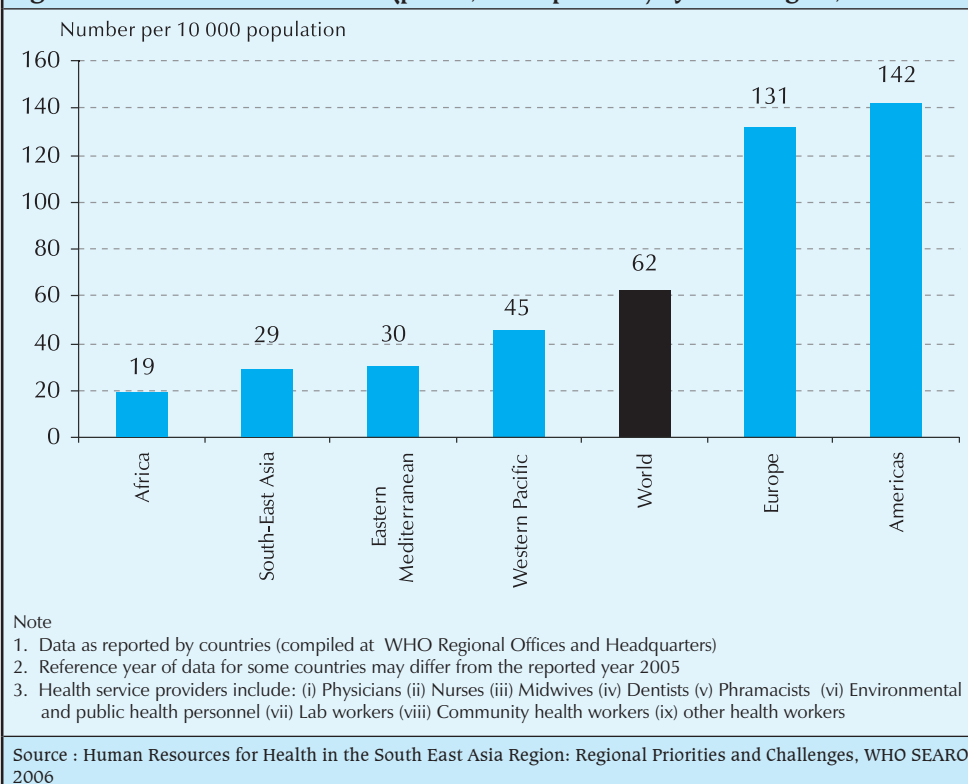
As of 2007, a total of 6,96,747 allopathic medical practitioners practicing in the different states in India and, are registered with the different State Councils.

Alongside, as on 2006, about 78096 dental surgeons were registered with different State Dental Councils. Table - 1 provides a state-wise overview of government allopathic doctors and dentists and average population covered. Moreover, around 26,252 allopathic doctors are part of the government's network of rural Primary Health Centres (PHC) and Community Health Centres (CHC) across the country (See Table - 2 & 3). However, a comparison of these public sector doctors in the public system reveals sharp contrasts. Also, over 80% of the qualified private health care providers are concentrated in cities, towns and urban areas. In terms of the public health sector, a total of 22,608 doctors are located in PHCs and 5,117 specialists are posted at CHCs. Despite this there is a shortfall of about 1,410 doctors at the PHC and about 9,455 specialists at the CHC. A look at the data relating to specialists at CHC shows that in spite of around 10,615 positions being sanctioned, there are around 50% vacant positions.

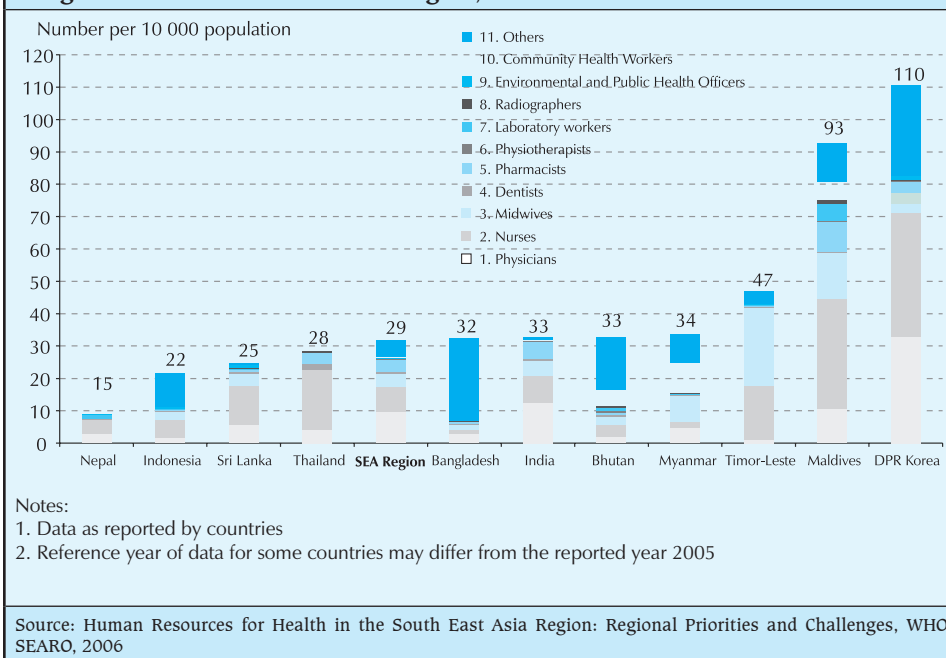
Alongside, around 72,5338 AYUSH doctors are practicing in the different states in India and, are registered with the different State Councils Table 4 and 5 provide an overview of AYUSH (traditional medicine) infrastructure and human resources.

All this data, clearly indicates the rural-urban divide in distribution of health personnel in the country. Various States have designed and implemented innovative measures to address these shortages of manpower in rural areas. Compulsory rural postings, incentives for rural posting and hiring of private specialists for providing essential services are some of the initiatives undertaken by the States. Integrating of AYUSH practitioners into general health service delivery system is yet another measure to enhance the reach of health

**Fig. - 2 : Health Service Providers (per 10,000 Population) by WHO Region, 2005**



**Fig. - 3 : Number of Health Service Providers (per 10000 Population) for selected categories in countries of the SEA Region, 2005**



services in the community. Anesthetists and obstetricians are essential if CHCs are to function as FRUs. In order to meet these demands, the National Board of Examinations has expanded its post graduate equivalent courses and most states have also started training in-service MBBS doctors in short-term courses of anesthesia and emergency obstetric care.

## 2. Nurses and Midwives

The auxiliary staff is the backbone of the health system as they are the first point of contact between the health system and community. As of 2007, a total of 150,9196 nurses (ANM, GNM and LHV) are registered in India (See Table - 6) The number of nurse midwives positioned in PHCs and CHCs is about 29,776 and the shortfall is 17,262 (See Table - 7).

Migration of nurses (in-country and out-country) is one of the critical areas of concern.

Right from the Bhole Committee, different committees have emphasized the need to develop a huge pool of auxiliary health personnel to enhance the service delivery especially primary health care. The National Rural Health Mission (NRHM) has provided for additional ANM in high priority states as well as filling up of existing vacancies. Under RCH-II programme, some of the States too have experimented with additional ANM in sub-centers to boost the reach of RCH services.

## 3. Pharmacists

Pharmacists are an important source of health care provision, in rural as well as urban areas (Ray and Bhaduri, 2001). Even though they may not be perceived as doctors, households are known to procure modern medicines directly from pharmacists without going through a medical consultation. As of December 2007, around 681,692 pharmacists are registered in India (See Table - 6). At the level of PHCs and CHCs, 17,919 pharmacists

are in place, while there exist a shortfall of around 4,910 pharmacists (See Table - 8).

## 4. Paramedical and other health workers

There exists a gamut of other health workers - male health workers, health assistants, block extension educators, laboratory technicians, radiographers, Accredited Social Health Activist (ASHA) amongst others across various levels of the health system. Besides nurses and pharmacists, there are around 12,101 laboratory technicians, around 4,068 block extension educators, 20,234 male health assistants and 62,881 male health workers, currently in position at different levels of the health system (Rural Health Statistics, 2007). Even out of the sanctioned posts, a significant percentage of posts are vacant at all the levels (See Tables - 9 & 10). There is a need to develop this category of

health staff both to increase the reach of primary health care delivery as well as to allow trained professionals to deliver specialized services to a larger population.

## Education and Training

Standardization and quality of education and training imparted in colleges is of utmost importance for development of human resources in health. The various statutory councils like the Medical Council of India (MCI), the Dental Council of India (DCI), Indian Nursing Council (INC), Central Council of Indian Medicine (CCIM), Central Council of Homeopathy (CCH), Pharmacy Council of India (PCI) and Rehabilitation council of India (RCI) are the appointed authorities establish uniform standards of higher qualifications in medicine; granting permission/recognition to educational institutions/ practitioners; registration of doctors with recognized medical qualifications and address issues of ethics and standards of practice amongst others.

In India, the number of allopathic medical colleges had increased steadily during the years after Independence. There was a rapid growth of medical colleges from 25 in 1947 to 106 in 1981 and now to 289 (encompassing 31298 seats at the MBBS level). Also, the colleges are not evenly distributed with the poorer states having a lesser number and the growth of medical colleges in the private sector has been tremendous. The report of the NCMH shows that there are 7,700 undergraduate seats in the north compared to 18,000 in the south: a total admission capacity of 25,500 seats per year. There are 55% seats in the public sector, a fall from 99% in 1950. This shows a rapid privatization of medical education, particularly in the Southern and richer states. For example in the states of Kerala, Karnataka, Tamil Nadu, Andhra Pradesh, Gujarat, Punjab, Haryana and Gujarat medical seats increased from

about 60 in 1950 to over 9,500 in 2004. In contrast, in the states of Bihar, Jharkhand, Orissa, UP, Uttaranchal, Assam, North Eastern states, Rajasthan etc. seats increased from 0 in 1950 to less than 1000 in 2004 (NCMH, 2005). Some of this growth has been attributed to India's liberalized economy post 1990 which saw investments in medical education increase as a response to favourable market conditions. This development has the potential to further widen educational disparities between the states. The high educational expenses involved are also one key factor that compels graduate doctors to look for better financial opportunities rather than practice in rural and primary care settings. There is at present an acute shortage of good teaching faculty in medical colleges, particularly acute in pre and para clinical subjects like anatomy, physiology, biochemistry, pathology microbiology, pharmacology, forensic medicine and community medicine (NCMH, 2005).

Training of ANMs and multipurpose workers is conducted through an elaborate network of State Institutes of Health and Family Welfare (SIHFW), Health and Family Welfare Training Centers (HFWTC), District Training Centers (DTCs) and ANM Training Centres (ANMTCs). As of March 2006, there are 336 ANM/MPW(F) Schools funded by Govt of India, 42 LHV promotional schools established by Govt of India and 56 MPW(M) training centres in the country. However, several of these suffer from shortages of good faculty and adequate budgets. Inadequate faculty implies poor quality of education. This is also true of nursing education, which has also witnessed shortfalls in the quality of education due to inadequate infrastructure, insufficient budgets, non-adherence to student-teacher norms, lack of commitment and accountability in educators for clinical supervision and guidance and insufficient hands-on training for students. In 2004, 61.2% of the 635 nursing schools and 165 nursing colleges were found unsuitable for teaching. De-recognition by the Indian Nursing Council has no impact as they continue to function with the permission of the State Nursing Councils (NCMH, 2005). There are also no specialized nursing disciplines in India like nurse anaesthetists or nurse practitioners as no formal system exists for the training of nurses and midwives to keep them abreast with the latest developments in the field.

The Pharmacy Council of India governs the education and functioning of the pharmacists in India. The minimum qualification required for registration is a D. Pharm. - a 2-year Diploma in Pharmacy. Higher qualifications include a 4 year Bachelor's degree (B.Pharm.), a 2-year Masters' degree (M.Pharm.) or a doctorate in pharmacy. Despite the presence of the Pharmacy Council, there are numerous unregulated and unauthorized pharmacy training centers that produce diploma trained pharmacists, whose skills are likely to be short of the required standards of registered pharmacists. Around 2% pharmacists were unaccounted for in the pharmacy workforce study in India (International Pharmaceutical Federation, 2006). In the case of paramedical professions too, like pharmacy and Laboratory technology, there is considerable diversity and dilution of standards of education. Pharmacy education is guided by a pharmacy council but in absence of enforcement of regulations, many unlicensed institutions provide diploma courses in pharmacy. There is no separate council to guide the

training of laboratory technicians.

Recommendations concerning regulation of education, curriculum reforms and reorganization of statutory councils to maintain standards and quality of education have been the provided by different expert committees. Continuing education was recognized as an important measure to update the knowledge and skills of health personnel. Towards this objective, CME programmes were initiated in the 6th Plan period with National Academy of Medical Sciences as the nodal agency. While CME of medical personnel has received attention, CME of other categories of health personnel and their in-service training opportunities have had not been discussed adequately.

During the past few years, there has been an increase in dialogue and discussions on strengthening and reforming public health among the national, regional and state-wide public health associations. Public health education in India is provided at undergraduate level for medical, dental, veterinary, nursing and other allied health sciences by departments of preventive and social (P&S) medicine. There are about 210 departments of P&S medicine, which include 90 private institutions. The postgraduate programme at MD level is conducted in more than 60 institutes, while the Diploma in Public Health is provided in more than 13 institutes. Several postgraduate courses are provided as Diplomas, Masters, MD and Doctoral levels, in various public health disciplines. Alongside, several institutes of public health are being strengthened or are in the process of being established.

### **Selected Key Challenges of Human Resources in India**

There exist various advantages as well as human resource related challenges in India. The advantages include availability of skilled work force; existence of an established system of training and educational institutions for medical and para-medical education; commitment by government to rural and population health. While some challenges are specific to the public and / or private sector, others are more cross cutting in nature.

**1. Information about Human Resources :** The exists lack of complete and current empirical data on different categories of medical, paramedical and allied human resources, required for efficient planning and forecasting, especially in the private sector. There is no adequate information about the private sector. Available data is primarily limited to the public sector. Furthermore, whatever data exists, it is not regularly updated and also, tends to concentrate on doctors and nurses. Moreover, available data shows large inter-state variations.

The existing registration systems of professional councils do not have robust processes for renewing registration; thus, data do not reflect attrition and dropouts. For instance, the Medical Council of India (MCI) gives comprehensive information on the total number of doctors in the country registered with various State Medical Councils. The data is available both State wise and year wise. However, the MCI data is cumulative and does not take into consideration attrition due to death, retirement, out of practice or migration within or outside the country. The MCI register does not give specific information regarding the



specialty or distribution of doctors. While, information of the number of specialists can be obtained from the membership of various professional bodies/associations, such information is limited as it gives information about the members alone. The Northeastern states except Assam and Sikkim do not have their own State councils and doctors passing out from these States are registered elsewhere. Further, a doctor may be registered with more than one State council in cases where one is practicing in a State other than the one where s/he is first registered. This may lead to duplication of registration of doctors. Also, the total available figures may represent an inflated version of the numbers of workers that are currently available for the health system. Attrition, migration is not reflected in any of this data. Similar issues affect the functioning of other existing Councils. No separate councils/registers exist for paramedical personnel like laboratory technicians, radiographers, opticians, speech therapists, physiotherapists etc; and in case of nurses and pharmacists information of their location and distribution is not available.

**2. Management of Human Resources in Health :** The performance of health system depends to a large extent on the development of its human resources. This includes framing policies for human resource development and management. Some of the areas which need attention include- recruitment, posting, transfer, clear job functions, match between the skills and functions, living and working conditions, professional development opportunities, transfer guidelines, performance based incentives, motivation, management & information and technology use for HR development. While meeting its own needs, the health system should also be able to match the aspirations of health personnel and provide opportunities for their personal as well as professional growth.

The public health system in India is plagued by issues of low motivation amongst its staff, high attrition rate, low productivity amongst others. The existing management policies and practices are out dated and ineffective - there is sharp public- private wage differential; unattractive incentive systems; unclear work roles, lack of recognition for good work; inadequate opportunities for career advancement and personal development; the recruitment, promotion and retirement policies are outdated; transfer policies tend to be unclear, further complicated by excessive political interference in transfers; there is a mismatch between functions and skills of staff; there is a lack of career development opportunities and of in-service training opportunities, poor working and living conditions for staff, and lack of systematic performance appraisals and monitoring and supportive supervision. Last, but not the least, private practice by government doctors is also common, thereby impact delivery of health services.

**3. Shortage of human resources :** Issues exist around numeric inadequacy of human resources. For instance, there is acute shortage of specialists (obstetricians, paediatricians, & anaesthetists, and of women doctors in rural areas). There are insufficient trained personnel for meeting the country's needs and demands for curative, preventive and promotive health. In part, this could be attributed to insufficient institutional capacity for production of health professionals, in particular, specialists; women doctors; public health workers and health

managers; paramedical personnel. Moreover, large vacancies exist for key cadres in public sector across levels of health care system. This in turn, could be due to low / no incentives; poor working conditions etc. Irregular staff attendance or absenteeism aggravates the shortages. Overseas and in-country migration of personnel (doctors, nurses and paramedical) is also common leading to further shortages.

**4. Inequitable distribution of human resources :** Human resources are inequitably distributed between the public and private sectors, across states and regions, between rural and urban areas. For instance, 80-90% of all qualified and trained resources are present in the private sector (including AYUSH) and in urban "better off" areas. In part this could be attributed to a lack of deployment policies.

**5. Skill Mix Issues :** In order to cater to the health needs of the community and deliver promotive, preventive and curative health care, it is essential to have the right skill mix at all levels of health care. The skill mix is to be planned in a way to optimally utilize the available resources (including human resources) as well as to deliver the required services. Staffing of health facilities has to be directed towards providing personnel with the right skills. At the same time, it is also pertinent to enhance the skills of health personnel to function in situations demanding application of two or more skills.

Orientation of medical personnel especially those exclusively dealing with clinical services to preventive & promotive aspects, public health management and epidemiology has been recognized as important way to train medical personnel meeting the needs of our country. Having built huge infrastructure and health personnel, it is essential to review the skill mix of personnel at different levels of care and carefully plan the staffing and delivery pattern. There is a distinct shortage of managerial and public health skills, especially at senior levels of the system.

**6. Inadequate institutional infrastructure and capacity for education and training of all categories of HR :** The need for trained human resources is enormous in India. For instance, under the National Rural Health Mission (NRHM) 6000 Block Mission Team and Block Resource Groups; 600 District level Mission Teams and Resource Groups; 35 State/UT level Mission Teams and Resource Centres; 1.75 lakh ANMs, 26000 LHV's, 26000 Staff Nurses; 26000 Medical Officers into Skilled Birth Attendants and 2 lakh ANMs, Nurses, etc at induction level need to be trained and supported. In spite of large scaling up initiatives, the existing institutional infrastructure is not adequate to meet the health requirements of the country.

Furthermore, the education and training of human resources is affected due to low funding, lack of quality faculty, lack of effective regulation of the private sector, persisting and unchanged legacy of conventional educational models; sub-optimal technical standards in medical and paramedical education amongst others.

**7. Competency of health workforce :** In terms of competency of health workforce, pre-service training is not adequately geared to capture the challenges of service delivery; need-based, job oriented training is not yet practiced widely; there is an inadequacy of infrastructure and training equipment ;



several training centres still use outdated teaching methods and materials; quality assurance mechanisms are often lacking and few opportunities exist for continuing education.

### **Possible Strategic Directions for Addressing the Challenges of Human Health Resources in India**

Notwithstanding the various challenges of human resources, attempts are underway to address these critical issues. The launch of the National Rural Health Mission (NRHM) is a laudable step in this regard. Several initiatives for human resource development, manpower augmentation and strengthening of health management are already underway, both at the Centre and in the States/UTs. Some possible strategic directions that could be considered are :

#### **Policy Making & Management**

- Improve evidence base: Understand the health needs and demands of local populations.
- Systematically forecast and plan human resources to maximize responsiveness. The first step would be to set evidence based rather than population based norms; assessment of current workforce and future requirements with respect to the needs and demands of the population and the health system (A variety of diagnostic and planning tools are available and have been used in developing countries that use simulation models and scenario planning for forecasting, projecting and planning human resource. (Starkiene et al 2005). The WPRO/RTC health workforce planning workbook is one such tool that provides steps for developing an HR plan and includes a simple computer based planning model (Dewdney, 2001).
- Need for human resources policy to be integral component of the health policy / policy documents.
- States to be persuaded to sanction posts for human resources especially for key public health cadres.
- Increase age of retirement for specialists from 60 to 62, Specialists could be allowed to continue upto 65 years provided willing to serve in underserved areas.
- Improve information systems: Professional councils could streamline and enforce periodic renewal of registration.
- Decentralizing human resource planning to local bodies and to district level.
- Public private partnerships-for curative and preventive/promotive and non-clinical, especially for urban areas.
- Need for better understanding of the impact of migration on health care delivery, financial implications and health outcomes. Presently there is lack of adequate data on the nature of migration of health personnel in India.

#### **Education & Training**

- Increase training institutions for all types of health workers
- Relaxed norms for new medical colleges, especially in states without medical colleges
- Establishment of medical colleges in the public sector
- Existing manpower may have to be given short term course in public health
- Wherever possible PG seats in medical colleges to be increased on priority
- Explore possibility of a certificate course for accrediting informal providers including AYUSH practitioners

#### **Enhancing Coverage**

- Systematic forecasting and planning: based on needs rather than universal population size based norms
- Pool and optimize all available resources - allopathic & AYUSH; formal & informal
- Changing skill-mixes: allopathic & non-allopathic, formal & informal, doctors, nurses & paramedics to meet local health needs & demands
- Use of technology: computers, telemedicine, mobile phone technology, etc. to maximize reach and efficiency of all available health workers
- Innovations in medical education: reintroducing the shorter licentiate courses, recruiting students from rural educational backgrounds, incentives for rural service
- Innovative public private partnerships for increasing access to curative as well as preventive and promotive health care

#### **Addressing Motivation**

- Clear job roles and performance appraisals. Some States have develop job descriptions for various categories of staff
- Opportunities for in-service training and continuous professional development
- Financial and non-financial incentives for good work: linking promotions with qualifications/training and abilities rather than with seniority, and reducing political interference in transfers and promotions
- Better working conditions and safety from occupational hazards

#### **Competence Building**

- Create a cadre of community based providers who will be willing and able to live and work in rural areas, may be through revival of licentiate courses
- Improving standards of health education: improving technical skills as well as ration use of medicines and technologies
- Multi- skilling : e.g. an AYUSH practitioner trained in some essential allopathic treatments, training nurses as nurse anesthetists and as skilled birth attendants and training PHC doctors in emergency obstetric care and psychiatry
- Increase cadre of health providers who are trained in public health

#### **Regulation**

- Strengthening existing legislation and regulatory bodies to foster quality assurance for all categories of human resources.
- Innovative regulation - self regulation/peer regulation (e.g. accreditation); social franchising for informal sector.
- Licensing to ensure minimum standards.
- Decentralization of regulatory functions with strengthening of management capacity at all levels, including panchayati raj institutions.

To conclude, the health sector in India is at cross roads with having to deal with communicable diseases on one hand and rapidly increasing incidence of non-communicable lifestyle diseases on the other. This together with strengthening of health systems to deliver affordable, accessible and equitable services has been the thrust area of planning in recent years. One of the

key challenges in programme planning is the development and management of human resources.

In course-plotting the map for development of health sector, successive Five Year Plans have addressed various issues related to human resources and have recommended measures for building up this critical resource pool. From time to time, the Government has set up expert Committees to examine the existing health systems and provide recommendations on specific issues. Health workforce has featured prominently in these recommendations. Presently, various initiatives are underway to address these human resource challenges, both

by the government across levels as well as other stakeholders. Adopting a multi-stakeholder approach with strong impetus on capacity building, addressing of systemic issues such as governance and stewardship, evidence based action and developing implementable initiatives would help address these human resource challenges.

## References

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**Table - 1 : State/UT wise Number of Govt Allopathic Doctors & Dentists & Average Population Served in India 2007 (Prov)**

S. No.	State/ UT	No. of Doctors	No. of Dental Surgeons	Projected Population as on 1.3.2007 in thousand	Population served/ Doctor served	Population served / Dental Surgeon	Reference period
1	Andhra Pradesh	4487	131	81554 (80712)	17988	616122	01.01.2007
2	Arunachal Pradesh	405	40	1184	2923	29600	01.01.2008
3	Assam	2103	20	29053 (27478)	13066	1373900	01.01.2004
4	Bihar	Data not received		92208			
5	Chhatisgarh	Data not received		22934			
6	Goa	562	44	1540 (1492)	2655	33909	01.01.2007
7	Gujarat	2712	43	55808 (52429)	19332	1219279	01.01.2004
8	Haryana	1802	303	23743	13176	78360	01.01.2008
9	Himachal Pradesh	NA	272	6526 (5988)		22015	01.01.2000
10(a)	Jammu Division	1279	93	11099 (10941)			01.01.2007
10(b)	Kashmir Division	1590	313	01.01.2008			
11	Jharkhand	1234	12	29745 (28388)	23005	2365667	01.01.2005
12	Karnataka	4175	229	56909 (56258)	13475	245668	01.01.2007
13	Kerala	3315	76	33535	10116	441250	01.01.2008
14	Madhya Pradesh	3662	N.A.	67569	18451	01.01.2008	
15	Maharashtra	5061	43	106386 (100030)	19765	2326279	01.01.2004
16	Manipur	653	35	2336	3577	66743	01.01.2008
17	Meghalaya	580	19	2500	4310	131579	01.01.2008
18	Mizoram	247	26	958	3879	36846	01.01.2008
19	Nagaland	293	15	2145 (2068)	7058	137867	01.01.2005
20	Orissa	5079	16	39276	7733	2454750	01.01.2008
21	Punjab	3545	230	26391 (25724)	7256	111843	01.04.2005
22	Rajasthan	5979	106	63408	10605	598189	01.01.2008
23	Sikkim	220	26	583	2650	22423	01.01.2008
24	Tamil Nadu	7107	166	65629	9234	395355	01.01.2008
25	Tripura	719	36	3449	4797	95806	01.01.2008
27	Uttar Pradesh	6766	NA	186755 (162289)	23986	N.A.	01.01.2000
26	Uttarakhand	1051	54	9365 (9219)	8772	170722	01.01.2007
28	West Bengal	6113	444	86125	14089	193975	01.01.2008
29	A & N Islands	113	6	434	3841	72333	01.01.2008
30	Chandigarh	1414	55	1161 (901)	637	16382	01.01.2002
31	D & N Haveli	16	1	281	17562	281000	01.01.2008
32	Daman & Diu	27	2	227 (216)	8000	108000	01.01.2007
33	Delhi	3629	71	16484 (14273)	3933	201028	01.01.2003
34	Lakshadweep	22	1	73 (69)	3136	69000	01.01.2005
35	Puducherry	582	65	1146	1969	17631	01.01.2008
	Total	76542	2993				

Notes: (1) Projected Population shown in the brackets relates to the reference period. (2) Tamil Nadu, the information relates to only the allopathic doctors in PHCs (3) Uttar Pradesh figure for 1.1.2000 includes Uttarakhand also. (4) NA - Not Available; Source: Directorates of State Health Services

**Table - 2 : Doctors At Primary Health Centres (As On March, 2007)**

S. No.	State/UT	Required <sup>1</sup> [R]	Sanctioned [S]	In Position [P]	Vacant [S-P]	Shortfall [R-P]
1	Andhra Pradesh	1570	2497	2214	283	*
2	Arunachal Pradesh	85	78	78	0	7
3	Assam	610	NA	NA	NA	NA
4	Bihar	1648	2078	1850	228	*
5	Chhattisgarh	518	1542	1154	388	*
6	Goa	19	46	46	0	*
7	Gujarat	1073	1073	1034	39	39
8	Haryana	411	580	350	230	61
9	Himachal Pradesh	443	628	628	0	*
10	Jammu & Kashmir	374	668	643	25	*
11	Jharkhand	330	3927	2323	1604	*
12	Karnataka	1679	2237	2041	196	*
13	Kerala	909	1345	1558	*	*
14	Madhya Pradesh	1149	1149	869	280	280
15	Maharashtra	1800	1800	1191	609	609
16	Manipur	72	62	103	*	*
17	Meghalaya	103	127	106	21	*
18	Mizoram	57	57	39	18	18
19	Nagaland	84	53	53	0	31
20	Orissa	1279	1353	1353	0	*
21	Punjab	484	634	350	284	134
22	Rajasthan	1499	1527	1318	209	181
23	Sikkim	24	48	38	10	*
24	Tamil Nadu	1181	2260	1984	276	*
25	Tripura	75	161	150	11	*
26	Uttarakhand	232	272	182	90	50
27	Uttar Pradesh	3660	NA	NA	NA	NA
28	West Bengal	922	922	811	111	*
29	A& N Islands	20	36	36	0	*
30	Chandigarh	0	0	0	0	0
31	D & N Haveli	6	6	6	0	0
32	Daman & Diu	3	5	5	0	*
33	Delhi	8	31	23	8	*
34	Lakshadweep	4	4	4	0	0
35	Puducherry	39	68	68	0	*
	All India <sup>2</sup>	22370	27274	22608	4920	1410

Notes : NA : Not Available; \* : Surplus

(1) One per each Primary Health Centre (2) For calculating the overall percentages of vacancy and shortfall, the States/UTs for which manpower position is not available, should be excluded. *Source : Rural Health Statistics, March 2007.*



Table - 3 : Total Specialists [Surgeons, OB&GY, Physicians & Paediatricians] at CHCs (As On March, 2007)						
S. No.	State/UT	Required <sup>1</sup> [R]	Sanctioned [S]	In Position [P]	Vacant [S-P]	Shortfall [R-P]
1	Andhra Pradesh	668	444	166	278	502
2	Arunachal Pradesh	124	4	0	4	124
3	Assam	400	NA	NA	NA	NA
4	Bihar	280	280	104	176	176
5	Chhattisgarh	472	700	49	651	423
6	Goa	20	14	3	11	17
7	Gujarat	1092	322	82	240	1010
8	Haryana	344	95	39	56	305
9	Himachal Pradesh	284	NA	NA	NA	NA
10	Jammu & Kashmir	320	276	142	134	178
11	Jharkhand	776	63	139	*	637
12	Karnataka	1016	843	691	152	325
13	Kerala	428	424	115	309	313
14	Madhya Pradesh	1080	947	503	444	577
15	Maharashtra	1628	1628	448	1180	1180
16	Manipur	64	30	1	29	63
17	Meghalaya	104	3	1	2	103
18	Mizoram	36	0	0	0	36
19	Nagaland	84	0	0	0	84
20	Orissa	924	496	NA	NA	NA
21	Punjab	504	343	177	166	327
22	Rajasthan	1348	878	600	278	748
23	Sikkim	16	16	5	11	11
24	Tamil Nadu <sup>3</sup>	944	821	725	96	219
25	Tripura	40	2	2	0	38
26	Uttarakhand	196	163	79	84	117
27	Uttar Pradesh	1544	1110	413	697	1131
28	West Bengal	1384	692	624	68	760
29	A& N Islands	16	12	0	12	16
30	Chandigarh	8	4	4	0	4
31	D & N Haveli	4	1	1	0	3
32	Daman & Diu	4	0	0	0	4
33	Delhi	0	0	0	0	0
34	Lakshadweep	12	0	0	0	12
35	Puducherry	16	4	4	0	12
	All India <sup>2</sup>	16180	10615	5117	5078	9455
Notes : NA: Not Available; * Surplus. (1) One per each Community Health Centre (2) For calculating the overall percentages of vacancy and shortfall, the States/UTs for which manpower position is not available, should be excluded (3) Break up of Specialist Doctors not available. Source : Rural Health Statistics, March 2007.						

<b>Table - 4 : State/UT wise Number of Registered AYUSH Doctors in India as on 1.1.2007</b>						
<b>State/UT</b>	<b>Ayurveda</b>	<b>Unani</b>	<b>Siddha</b>	<b>Naturopathy</b>	<b>Homoeopathy</b>	<b>Total</b>
Andhra Pradesh*	15231	5022	0	374	9422	30049
Arunachal Pradesh	0	0	0	0	94	94
Assam	442	0	0	0	669	1111
Bihar	132981	4202	0	0	27864	165047
Chattisgarh	794	9	0	0	221	1024
Delhi	3088	1625	0	0	3149	7862
Goa	290	0	0	0	274	564
Gujarat	20985	256	0	0	8503	29744
Haryana	18726	2212	0	0	5570	26508
Himachal Pradesh	7236	456	0	0	1111	8803
Jammu & Kashmir	1952	1956	0	0	0	3908
Karnataka	20352	1121	4	234	5003	26714
Kerala	15068	64	1326	0	9273	25731
Madhya Pradesh*	47602	609	0	2	9380	57593
Maharashtra	63030	4079	0	0	38407	105516
Meghalaya	0	0	0	0	240	240
Nagaland*	0	0	0	0	1997	1997
Orissa*	4448	17	0	0	3106	7571
Punjab	18424	4033	0	0	3742	26199
Rajasthan*	23861	1619	0	0	4778	30258
Tripura	0	0	0	0	145	145
Tamil Nadu	3612	1014	5051	278	17268	27223
Uttar Pradesh	51240	13289	0	0	27790	92319
Uttranchal	1065	41	0	0	0	1106
West Bengal	3234	4934	0	0	39547	47715
Chandigarh*	0	0	0	0	297	297
<b>Total</b>	<b>453661</b>	<b>46558</b>	<b>6381</b>	<b>888</b>	<b>217850</b>	<b>725338</b>
<i>Source : Dept. of AYUSH, MOH&amp;FW / GOI as quoted in National Health Profile 2007</i>						

*Table 5: Infrastructure Facilities and human resources under AYUSH (as of 1.4.2007)*

Facilities	Ayur-veda	Unani	Siddha	Yoga	Naturo-pathy	Homoeo-pathy	Amchi	Total
Hospitals	2398	268	281	8	18	230	1	3204
Beds	42963	4489	2401	135	722	10851	22	61583
Dispensaries	13914	1010	464	71	56	5836	86	21437
Regd. Practioners	453661	46558	6381		888	217850		725338
(i) Institutionally Qualified	324242	23982	2926		839	154240		506229
(ii) Non Institutionally Qualified	129419	22576	3455		49	63610		219109
(i) AYUSH Colleges(UG &PG)	242	40	8		10	185		485
(ii) Admission Capacity (UG& PG)	12216	1817	460		385	14509		29387
(i) Colleges (UG)	240	39	7		10	183		479
(ii) Admission Capacity(UG)	11225	1750	350		385	13425		27135
(i) Colleges (PG)	62	7	3			33		105
(ii) Admission Capacity (PG)	991	67	110			1084		2252
Exclusive PG Colleges	2	1	1			2		6
Admission Capacity (Exclusive PG)	40	28	30			99		197
Manufacturing Units	7621	321	325			628		8895

Note : Total Figures of hospitals and beds and dispensaries includes one Hospital with 22 Beds and 86 Dispensaries of Amchi system respectively.  
Source: <http://indianmedicine.nic.in/summary-of-infrastructure.asp> Accessed: September 2008

**Table - 6 : State/UT Wise Number of Registered Nurses & Pharmacists In India**

State / UT	Total No. of Registered Nurses in India as on 31.3.2007			Pharmacists as on 31.12.2007
	<i>A.N.M.</i>	<i>G.N.M.</i>	<i>LHV</i>	
Andhra Pradesh*	98,455	88,457	2,480	82,306
Arunachal Pradesh				347
Assam	16,657	12,082		2,429
Bhopal				1,381
Bihar*	7,501	8,883	511	4,163
Chattisgarh	953	1,207	1,352	
Delhi	1,416	13,707		22,010
Goa				466
Gujarat	36,007	86,523		20,948
Haryana*	13,172	17,186	694	7,249
Hlmachal Pradesh	9,276	8,077	415	2,818
Jharkhand	2,019	1,801	137	
Karnataka*	47,407	64,308	6,836	76,854
Kerala	27,926	83,335	7,797	7,531
Lakshdweep				3,082
Madhya Pradesh	26,355	93,892	1,069	
Maharashtra	29,430	88,740	554	106,220
Meghalaya*	623	1,524	90	269

State / UT	Total No. of Registered Nurses in India as on 31.3.2007			Pharmacists as on 31.12.2007
	<i>A.N.M.</i>	<i>G.N.M.</i>	<i>LHV</i>	
Mizoram	1,559	1,593		398
Nagaland				1,553
Orissa*	30,716	46,31 1	172	14,312
Pondicherry				1,716
Punjab*	18,152	45,801	2,584	35,290
Rajasthan*	22,239	37,667	850	18,214
Tamil Nadu	53,383	163,561	11,083	151,973
Tripura	987	874	144	257
Uttar Pradesh*	26,956	17,827	2,763	30,276
Uttarakhand*		58		
West Bengal	56,293	47,114	11,655	89,630
Total	527,482	930,528	51,186	681,692
Note: (1) Assam = Assam+Arunachal Pradesh+Manipur+Nagaland (2) Maharashtra = Maharashtra+Goa (3) Punjab = Punjab +J &K (4) Tamil Nadu = Tamilnadu + Andaman & Nicobar Islands +Puducherry (5) West Bengal = West Bengal+Sikkim				
* Last year data for registered nurses in India; ** Estimated				
ANM: Auxiliary Nurse Midwives; GNM : General Nursing and Midwives LHV: Lady Health Visitors				
Source: Indian Nursing Council, Pharmacy Council of India as quoted in National Health Profile, 2007				

<b>Table - 7 : Nurse Midwife/Staff Nurse At PHCs &amp; CHCs (As On March, 2007)</b>						
S.No.	State/UT	Required <sup>1</sup>	Sanctioned	In Position	Vacant	Shortfall
		[R]	[S]	[P]	[S-P]	[R-P]
1	Andhra Pradesh	2739	2742	2373	369	366
2	Arunachal Pradesh	302	105	105	0	197
3	Assam	1310	NA	NA	NA	NA
4	Bihar	2138	1662	1425	237	713
5	Chhattisgarh	1344	676	540	136	804
6	Goa	54	141	141	0	*
7	Gujarat	2984	2769	1585	1184	1399
8	Haryana	1013	689	411	278	602
9	Himachal Pradesh	940	1199	484	715	456
10	Jammu & Kashmir	934	244	68	176	866
11	Jharkhand	1688	474	451	23	1237
12	Karnataka	3457	3229	3100	129	357
13	Kerala	1658	2811	3064	*	*
14	Madhya Pradesh	3039	941	901	40	2138
15	Maharashtra	4649	4129	2774	1355	1875
16	Manipur	184	151	169	*	15
17	Meghalaya	285	223	174	49	111
18	Mizoram	120	391	243	148	*
19	Nagaland	231	520	520	0	*
20	Orissa	2896	657	637	20	2259
21	Punjab	1366	740	448	292	918
22	Rajasthan	3858	9891	8425	1466	*
23	Sikkim	52	45	90	*	*
24	Tamil Nadu	2833	NA	NA	NA	NA
25	Tripura	145	125	268	*	*
26	Uttarakhand	575	145	129	16	446
27	Uttar Pradesh	6362	NA	NA	NA	NA
28	West Bengal	3344	944	858	86	2486
29	A & N Islands	48	108	108	0	*
30	Chandigarh	14	13	13	0	1
31	D & N Haveli	13	12	20	*	*
32	Daman & Diu	10	12	12	0	*
33	Delhi	8	10	4	6	4
34	Lakshadweep	25	13	13	0	12
35	Puducherry	67	225	223	2	*
	<b>All India<sup>2</sup></b>	<b>50685</b>	<b>36036</b>	<b>29776</b>	<b>6727</b>	<b>17262</b>
Notes : NA - Not Available; * Surplus. (1) One per Primary Health Centre and seven per Community Health Centre (2) For calculating the overall percentages of vacancy and shortfall, the States/UTs for which manpower position is not available, should be excluded. <i>Source : Rural Health Statistics, March 2007.</i>						



**Table - 8 : Pharmacists at PHCs & CHCs (As on March, 2007)**

S. No.	State/UT	Required <sup>1</sup>	Sanctioned	In Position	Vacant	Shortfall
		[R]	[S]	[P]	[S-P]	[R-P]
1	Andhra Pradesh	1737	1686	1614	72	123
2	Arunachal Pradesh	116	31	31	0	85
3	Assam	710	NA	NA	NA	NA
4	Bihar	1718	989	439	550	1279
5	Chhattisgarh	636	749	467	282	169
6	Goa	24	27	26	1	*
7	Gujarat	1346	1364	814	550	532
8	Haryana	497	463	372	91	125
9	Himachal Pradesh	514	443	303	140	211
10	Jammu & Kashmir	454	456	456	0	*
11	Jharkhand	524	689	310	379	214
12	Karnataka	1933	1935	1472	463	461
13	Kerala	1016	1038	995	43	21
14	Madhya Pradesh	1419	1419	215	1204	1204
15	Maharashtra	2207	2367	1976	391	231
16	Manipur	88	79	26	53	62
17	Meghalaya	129	145	113	32	16
18	Mizoram	66	69	35	34	31
19	Nagaland	105	85	85	0	20
20	Orissa	1510	2040	1984	56	*
21	Punjab	610	736	680	56	*
22	Rajasthan	1836	2375	2355	20	*
23	Sikkim	28	28	0	28	28
24	Tamil Nadu	1417	1442	1349	93	68
25	Tripura	85	47	56	*	29
26	Uttarakhand	281	281	281	0	0
27	Uttar Pradesh	4046	NA	NA	NA	NA
28	West Bengal	1268	1614	1341	273	*
29	A& N Islands	24	28	28	0	*
30	Chandigarh	2	2	2	0	*
31	D & N Haveli	7	6	6	0	1
32	Daman & Diu	4	4	4	0	0
33	Delhi	8	13	11	2	*
34	Lakshadweep	7	11	11	0	*
35	Puducherry	43	63	62	1	*
	All India <sup>2</sup>	26415	22724	17919	4814	4910

Notes: NA: Not Available; \*: Surplus

(1) One per each Primary Health Centre and Community Health Centre (2) For calculating the overall percentages of vacancy and shortfall, the States/UTs for which manpower position is not available, should be excluded. Source : Rural Health Statistics, March 2007.

**Table - 9 : Average Number of H.W.[M] per Health Assistant [M] and Average Rural Population Covered by a HW(M) (As on March, 2007)**

S. No.	State/UT	Number in position		Number of HW[M] Per HA [M]	Average rural population [2001] covered by an H.W. [M]
		H.W. [M]	HA [M]		
1	Andhra Pradesh	6127	1920	3	9042
2	Arunachal Pradesh	23	26	1	37830
3	Assam	NA	NA	NA	NA
4	Bihar	1240	634	2	59933
5	Chhattisgarh	2852	2940	1	5837
6	Goa	134	15	9	5053
7	Gujarat	3347	2421	1	9483
8	Haryana	425	106	4	35363
9	Himachal Pradesh	1270	361	4	4317
10	Jammu & Kashmir	377	334	1	20231
11	Jharkhand	4291	118	36	4883
12	Karnataka	3762	837	4	9274
13	Kerala	4266	794	5	5526
14	Madhya Pradesh	6560	1168	6	6765
15	Maharashtra	6097	1800	3	9148
16	Manipur	420	52	8	3788
17	Meghalaya	273	87	3	
18	Mizoram	303	57	5	1477
19	Nagaland	300	15	20	5491
20	Orissa	3392	168	20	9224
21	Punjab	1375	208	7	11707
22	Rajasthan	2528	714	4	17125
23	Sikkim	147	8	18	3272
24	Tamil Nadu	1503	303	5	23235
25	Tripura	268	93	3	9901
26	Uttarakhand	656	417	2	9619
27	Uttar Pradesh	5732	4061	1	22969
28	West Bengal	5178	550	9	11153
29	A & N Islands	0	0	0	0
30	Chandigarh	8	0	0	11515
31	D & N Haveli	9	3	3	18892
32	Daman & Diu	17	3	6	5933
33	Delhi	0	NA	NA	NA
34	Lakshadweep	1	4	0	33683
35	Puducherry	0	17	0	0
	All India	62881	20234	3	11808

Notes: NA= Not Available; HA= Health Assistant, HW= Health Worker, Source : Rural Health Statistics, March 2007.

**Table - 10 : Average Number of HW[F]/ ANM Per Health Assistant [F]/ LHV and Average Rural Population Covered by an HW(F)/ ANM (As on March, 2007)**

S. No.	State/UT	Number in position		Number of HW[F]/ANM per HA [F]/ LHV	Average rural population [2001] covered by HW [F]/ ANM
		HW [F]/ ANM	HA [F]/ LHV		
1	Andhra Pradesh	12000	1564	8	4616
2	Arunachal Pradesh	454	16	28	1916
3	Assam	5719	NA	NA	4059
4	Bihar	8904	491	18	8346
5	Chhattisgarh	3667	709	5	4539
6	Goa	196	12	16	3454
7	Gujarat	7071	267	26	4488
8	Haryana	1909	73	26	7872
9	Himachal Pradesh	1836	283	6	2986
10	Jammu & Kashmir	1588	62	26	4802
11	Jharkhand	4372	278	16	4792
12	Karnataka	7244	1170	6	4816
13	Kerala	5634	740	8	4184
14	Madhya Pradesh	8590	350	25	5166
15	Maharashtra	9598	1718	6	5811
16	Manipur	487	55	9	3266
17	Meghalaya	608	75	8	3066
18	Mizoram	421	57	7	1063
19	Nagaland	342	15	23	4816
20	Orissa	6768	726	9	4622
21	Punjab	2515	264	10	6400
22	Rajasthan	12271	1358	9	3528
23	Sikkim	267	18	15	1801
24	Tamil Nadu	10351	1612	6	3373
25	Tripura	642	62	10	4133
26	Uttarakhand	1785	159	11	3535
27	Uttar Pradesh	21900	2128	10	6011
28	West Bengal	9900	1227	8	5833
29	A & N Islands	127	20	6	1889
30	Chandigarh	22	0	0	4187
31	D & N Haveli	38	3	13	4474
32	Daman & Diu	24	3	8	4202
33	Delhi	51	19	3	18524
34	Lakshadweep	22	0	0	1531
35	Puducherry	116	12	10	2807
	All India	147439	15546	9	5035

Notes : Figures are provisional; NA = Not Available. HW= Health Worker, HA= Health Assistant, LHV= Lady Health Visitor  
Source : Rural Health Statistics, March 2007.

Amit Sengupta

The promotion of Health needs to address a large number of areas, such as nutrition, environment, economic and social well being etc. Within this larger framework, access to essential medicines is a major determinant of health outcomes and an integral, and often crucial, component of health care. It has been estimated by different sources that 50% to 80% of the Indian population are not able to access all the medicines that they need. The World Medicine Report (2004) of World Health Organization finds that India is the country with largest number of people (649 million) without having access to essential medicines. Given that India today is the 4th largest producer of drugs in the world and exports medicines to over 200 countries, this is clearly an unacceptable situation.

In an ideal situation all medicines that are researched and marketed should enhance therapeutic goals. Unfortunately the actual situation in the medicines market is much more complex. There are several issues that need to be addressed in order to pursue the broad goal of ensuring access to all medicines that a population may need.

The first issue relates to the price of medicines. Medicine prices often become a major determinant of access, especially in a country such as India where the income poor constitute a majority of the population. Studies indicate that poorer populations spend a larger proportion of health care expenditure in buying medicines. A World Bank Study suggests that out-of-pocket medical costs alone may push 2.2% of the population below the poverty line in one year (India - Raising the Sights: Better Health Systems for India's Poor, World Bank, May, 2001). The situation is compounded by the fact that, in India, the proportion of private expenditure, of the total expenditure on health is one of the highest in the world - 84% as compared to just 16% public expenditure.

### The Concept of Essential Drugs

We shall turn later to one obvious way of addressing this problem, which is to do with mechanisms designed to control medicine prices. Another approach to ensuring access has been promoted by the World Health Organisation since 1978. It is called the "Essential Drugs" Policy. The policy starts from an understanding that it is necessary for countries to prioritise which medicines should be made available to all its population(1). Each country would need to develop its priorities based on the country's existing demographic profile and disease prevalence rates. The WHO defines "Essential Drugs" as those "that satisfy the health care needs of the majority of the population". The WHO further suggests that "they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford".

The WHO, periodically, publishes a "Model" list of essential drugs (the first model list was published in 1978), but countries are encouraged to develop their own model lists, based on local

conditions. The use of such lists have led to the improvement in the quality of health care and the reduction of costs. The broad criteria (2) that are recommended for selection of drugs for inclusion in such a model list include the following:

1. The disease burden in a particular country and data on the efficacy, safety and comparative cost-effectiveness of available treatments. The evaluation process bases itself on a comparison between various drug products and on cost/benefit considerations. The advantage of a new treatment over the existing one is then compared to its extra cost. Such information has proved very helpful in taking informed decisions about the selection of essential drugs. When adequate scientific evidence is not available on current treatment of a priority disease, choice of certain drugs may either be deferred until more evidence becomes available, or a choice can be made based on expert opinion and experience.
2. Stability of medicines in various conditions (temperature, humidity etc.), the need for special diagnostic or treatment facilities (i.e. if the use of a drug requires facilities for monitoring biochemical or other parameters in the patient) and pharmacokinetic properties are also considered if appropriate.
3. It is recommended that most essential medicines should be formulated as single compounds. Fixed-ratio combination products are selected only when the combination has a proven advantage in therapeutic effect, safety or compliance over single compounds administered separately, viz. combinations to treat Tuberculosis and Malaria.
4. As cost is an important factor that determines access, the ability of populations to afford a drug (or of the public health system to be able to procure it) is an important consideration. In cost comparisons between medicines, the cost of the total treatment, and not only the unit cost of the medicine, is considered. Cost and cost-effectiveness comparisons are made among alternative treatments within the same therapeutic group. However, the absolute cost of treatment does not constitute a reason to exclude a medicine from the Model List if other selection criteria are met (i.e. if medicines required to treat a disease of major public health importance are expensive, but no cheaper alternatives that are safe and effective are available, then the medicines should be included in the list).
5. As the list is aimed at facilitating availability, countries are also encouraged to factor in issues such as local manufacturing capability and availability.

It needs to be underlined that the formulation of a national essential drugs list is only the *first* step towards the realisation of a policy to promote access to essential medicines. For the list to be useful, its application needs to be integrated in the formulation of a national medicines policy. This would mean that the national policy should include measures to ensure that the medicines in the national list are available to all who need them, are affordable and of good quality, and ideally are locally manufactured so that a reliable and constant supply is ensured.

*Second*, the national policy on use of medicines should promote the use of medicines on the list as a matter of first choice, both



in the public and private sector. This requires constant updating of the knowledge of prescribers, so that prescription practices are tailored to the essential list. Further, the essential drugs list should be accompanied by the development of evidence-based standard treatment guidelines. If prescribers are trained to use the essential drugs list as a guide, they also become more familiar with a relatively small set of medicines and are better able to recognise and report adverse events related to medicines use. Moreover, a limited range of drugs in the supply system may lead to economies of scale and competition between manufacturers, further reducing the costs.

An Essential Drugs Policy has been critiqued in certain quarters as one that restricts the freedom of practitioners to prescribe according to their choice. To the contrary a well designed Essential Drugs Policy is geared towards assisting prescribers in making a choice based on the best available evidence. An Essential Drugs list, ideally, should include all medicines that are necessary to treat more than 95% of illnesses that a physician is likely to encounter. This means that a policy based on the Essential Drugs List does not preclude the use of medicines outside the list, when it is so warranted.

An Essential Drugs List also needs to be dynamic, that is it needs to be updated periodically (every 2-3 years) in order to be able to capture recent advances in therapeutics and changes in disease prevalence scenarios. The WHO's model list is also a graded list of essential drugs, and countries are encouraged to do the same. A graded list indicates at which level of care (primary, secondary, tertiary) a certain medicine should be recommended. So while some medicines may be needed for all levels of care (e.g. an antipyretic like paracetamol), others may be needed at the secondary and tertiary levels only, or at the tertiary level only. The grading that is built into an essential drugs list is also a helpful planning tool, as it helps public health authorities to decide which medicines should be made available at appropriate levels.

### Rational Use of Medicines

As we have seen above, an Essential Drugs Policy is a prerequisite for ensuring that physicians prescribe medicines based on sound scientific evidence. An ideal situation would be one where the only medicines that are available for prescribing, are those that are scientifically validated and are recommended in standard text books that students read in medical college. Unfortunately the real situation is very different, and students fresh out of college are suddenly confronted with a plethora of medicines that they have read little or nothing about. This happens because rational treatment goals and the goals of commerce that are pursued by drug manufacturers, are largely at variance. Drug manufacturers are driven by the need to maximise profits, not by the need to optimise therapeutic goals.

In India, an average family spends Rs.2,000 in buying medicines and on diagnostics. It has been estimated that at least 50% of this expenditure is incurred on irrational or unnecessary drugs and diagnostic tests. This adds up to a colossal waste of Rs.15,000 - 20,000 crores every year, and amounts to an average unnecessary drain of Rs.1,000 per year for every family. The first, and best known, part of irrational practices in

health care is related to irrational prescription of drugs. WHO has defined irrational prescribing as use of a therapeutic agent when the expected benefit is negligible or nil or when its usage is not worth the potential harm or the cost.

**Irrational drug prescribing** : It can occur when the medication prescribed is incorrect, inappropriate, excessive, unnecessary or inadequate. Accordingly, the types of Irrational Prescribing are:

1. **Incorrect prescribing**: This means the use of wrong medicines to treat a disease or the use of medicines when no medicines are required.
2. **Inappropriate prescribing**: This pertains to use of medicines that are not suitable for the particular patient, viz. use of medicines that may be harmful in pregnancy, in children, in older people, etc.
3. **Over prescribing**: This is related to use of too many different kinds of drugs to treat a disease, when fewer (or just one) drugs would have sufficed. It also includes use of drugs for long periods, when a shorter course of treatment is adequate.
4. **Multiple prescribing**: This means the prescription of more than one drug of the same kind (i.e. drugs which have the same effect) to treat a disease
5. **Under prescribing**: This has to do with prescribing medicines for too short a duration or in inadequate dosage.

All these irrational practices are rampant in India. The reasons are manifold. One is to do with the proliferation of a large number of drugs in the Indian market that are either irrational or useless. With rapid developments in Science and Technology there has been an explosion in the number of drugs which are available in the market. Unfortunately only a small minority of drugs entering the market offer an advantage over existing drugs. A study in the U.S. showed that of the 348 new drugs introduced from the 25 largest US drug companies between 1981 and 1988 : 3% made an "important potential contribution to existing therapies"; 13% made a "modest potential contribution; and 84% made "little or no potential contribution". A more recent study by the French journal, *Prescrire International*, estimated that out of 2257 medicines introduced in the global market between 1981 and 2000, 0.31% were a major therapeutic innovation and 2.96% were an "important" therapeutic innovation, while 63.23% "does not add to existing clinical possibilities". The situation in India is no different and probably worse, given the fact that our Drug Control mechanisms are much more lax than in developed countries. The only reason why Indian studies are not available is because there is virtually no mechanism in India to monitor the use of irrational and hazardous drugs.

As a consequence there are an estimated 60,000 to 80,000 brands of various drugs available in the Indian market. On the other hand the WHO lists a little over 350 drugs which can take care of an overwhelming majority (over 95%) of the health problems of a country. In this situation of extreme anarchy the task of an already overstretched Drug Control Authority becomes almost impossible to cope with. A majority of the estimated 80,000 products in the market are either hazardous, or irrational or useless.

The pharmaceutical companies and the government regulatory bodies need to share the blame for allowing such a situation to develop. But all this would not be possible without the active involvement of the medical profession, who contribute by prescribing such irrational and useless drugs. One reason for this is the fact that there is almost no source of regular unbiased, authentic information on drugs available in the country. Given the rapid changes in treatment procedures and introduction of a large array of new drugs, medical practitioners need to update their knowledge regularly. Such a system of continuing medical education is largely absent in this country, and most doctors do not find the need to take time out from their busy practice to update their knowledge by reading the most recent books and journals. Thus we have the sad practice of a bulk of medical practitioners depending on promotional material supplied by Pharmaceutical companies. Obviously such promotional material only provides information to doctors, with a view to maximising the sale of the products being promoted. It thus makes it possible to sell a large number of useless and irrational drugs.

The problem is not limited to just a question of irrational or useless or harmful drugs. Rational, or even life saving drugs can be used in an irrational manner. The commonest problem is the unnecessary use of drugs. Thus, often we see expensive antibiotics being used for trivial infections. Moreover this is often accompanied by wrong dosage schedules. Another problem is the prescription of a large number of drugs for a simple ailment, when one or few drugs would have sufficed. Doctors, in many cases, when they are not sure of the diagnosis prescribe a large no. of drugs to cover for all the possibilities. Thus a patient coming with fever may be given some antibiotic, a drug to treat malaria, a drug to treat typhoid, etc. It may turn out that the patient was just suffering from a viral fever, which could have been treated with some paracetamol tablets, only. Such prescription practices increase the cost to the patient, unnecessarily exposes the patient to potential side effects, and in the case of antibiotics leads to drug resistance, i.e. a situation when these antibiotics become useless when they are really required.

Patients must also realise that if a Doctor advises no drugs, he is giving as valuable (or in some cases more) advice as someone who prescribes a large number of drugs. All illnesses do not require drugs -- in fact a large number of illnesses are "self limiting", i.e. the body cures itself without the use of drugs.

While the costs of individual drugs is very important, what affects patients is the total cost of treatment. Irrational drug use increases treatment costs, at times enormously, by promoting use of drugs when they are not indicated. Such use has implications for health outcomes too, and at the same time add unnecessarily to treatment costs. While a lot of anecdotal references are available that indicate this, unfortunately there are few systematic studies that quantify the impact of irrational drug use on costs. A single District study (3) done in Satara, Maharashtra, in the 1990s, provides some indication of the massive costs of irrational drug use. The study showed that due to irrational prescribing, 69% and 55% of the money spent on prescriptions in the private and public sector respectively, was a waste. Projected to the whole district, this wastage amounts

to Rs.17.7 crores out of the total drug supply of Rs.22 crores. It concluded that if all the patients in Satara district were to be adequately and rationally treated, the drug-expenditure would have been less than the amount actually spent on drugs in the District (both public and private included) - Rs.20.61 crores, compared to the total drug expenditure of Rs. 21.84 crores. If we extrapolate the results of this study to the national level, it would mean that the present expenditure on drugs in the country is adequate to treat all patients, if rational prescribing norms were adhered to.

### **Promotion of Medicines by Medicine Companies**

Irrational prescribing and aggressive promotion of medicines by drug companies go hand in hand. Companies spend large amounts to promote medicines, and this is particularly so when they need to promote medicines that are irrational and their use is contrary to scientific evidence. There is insufficient data in India to quantify the impact on drug prices. An indication may however be found from a recent study in the US (4), that examined the quantum spent on promotion by US drug companies in the US market. The study concluded that the drug industry spent around US\$61,000 in promotion per physician in 2004, and further that as a percentage of US domestic sales promotion consumed 24.4% of the sales.

Effective medicines have an obvious marketability and demands are self-generating. But any drug that is therapeutically not valid needs artificial generation of demands and contributes to unethical marketing practices. Irrational prescribing practices are often initiated and maintained by marketing techniques of the drug industry. The industry spends 20% of its annual sale or about Rs. 3,000 crores in advertising; this works out to about Rs. 50,000 per doctor per annum and each doctor prescribes drugs worth Rs. 250,000 per annum.

Drug companies have been known to use incomplete or misleading evidence to promote irrational medicines. Physicians are sought to be influenced by a variety of inducements and sponsorships. Such a practice gets perpetuated also because prescribers depend on information provided by drug companies, as there is scant availability of unbiased information on the rational use of medicines.

Unlike in India, many countries control the promotion of medicines through ethical guidelines, such as the model guidelines authored by the WHO (5). Policies in India need to consider the fact that large investments made by drug companies push up medicine costs and promote irrational prescription practices.

### **Prescribing of Medicines by Generic (non-proprietary) Names**

A fresh medical graduate is often confronted with a situation that medical college seldom prepares them for - the need to make sense of a huge variety of brand names of medicines. While medical education relies almost entirely on familiarising students with the scientific names of medicines (i.e. generic or non-proprietary), an overwhelming bulk of prescribing is done by the use of Brand (proprietary) names. The promotion of generic prescription has always been seen as a primary requirement for ensuring of rational use of medicines. It is globally acknowledged that aggressive promotion of Branded

medicines by pharmaceutical companies, much of which is unethical, leads to irrational prescription practices. Prescriptions based on Brand names also allow commonly prescribed branded drugs to be priced much higher than generic equivalents. In India the situation is further compounded by a lack of avenues and requirements for continuing medical education - thereby leaving doctors at the mercy of pharmaceutical companies to update their knowledge about newly introduced medicines. This opens the door for prescription practices that are driven, on many occasions, not by therapeutic needs but by promotion of specific brands.

For efforts aimed at encouraging prescription of medicines by their generic names to be successful, there are some crucial areas that need to be addressed. Critiques of the mandatory introduction of generic prescription argue that prescriptions based on generic names compromises the ability of doctors to prescribe quality medicines. The argument is premised on the belief that there is a major variation in the quality of medicines in the Indian market, thereby requiring brand names to identify quality drugs. While the concern for quality is not incorrect, it is also true that substandard drugs are also produced or marketed by large companies with big reputations - both Indian and Foreign. It is also a common practice today for big companies to get their drugs manufactured in the small scale sector. Thus the issue is really one of implementing quality control measures at all levels - which if not done will always compromise attempts to promote prescriptions by generic names. If issues about quality remain doctors could well just shift to prescribing by the generic name and identify the company as well. This would defeat the whole purpose of introducing generics to foil monopoly pricing based on brand images.

The other issue is the necessity to have qualified pharmacists at retail outlets for medicines. This is a requirement if Chemists are to have the authority to substitute generic versions of the same drug. Today there are not enough pharmacists to service all medicine shops and the issue needs to be addressed. What also needs to be ensured is that pharmaceutical companies do not start targeting Chemists more aggressively to promote their drugs once generic names are introduced.

### **Pricing of Medicines**

Finally, the big issue that determines the access to medicines for poor people, relates to how medicines are priced. The WHO states (6) : "In 1975, less than half the world's population were estimated to have regular access to essential medicines. New estimates from the 1999 World Medicines Survey show that this fraction has fallen to around one third. However absolute number of people without access has remained unchanged, at about 1.7 billion. Getting the right medicines to the people who need them at the time they need them remains a major challenge."

Studies indicate that poorer populations spend a larger proportion of health care expenditure in buying medicines. Given, that a very large portion of this cost is borne by patients themselves, there is clear evidence that the cost of medicines is a major barrier to access to health care. A World Bank Study(7) suggests that out-of-pocket medical costs alone may push 2.2% of the population below the poverty line in one year.

The situation is compounded by the fact that the proportion of private expenditure, of the total expenditure on health is one of the highest in the world - 84% as compared to just 16% public expenditure. The NSS (National Sample Survey) 55th round on consumer expenditure shows that 77% of health expenses in rural areas and 70% in urban areas is on medicines alone. Poorer the people, larger the share of expenses on medicines.

Clearly the situation requires attention from regulatory agencies in the form of controls on the prices of medicines. Price control is a form of market regulation that limits the capacity of the supplier to set the price of a product. Price control usually takes the form of a maximum price (ceiling), which means that the supplier is allowed to set a lower price. The mechanics of price control usually differ from country to country, but the end result is normally the same: the pharmaceutical companies are prohibited from charging a market-based price for the products they manufacture. Interestingly, most developed countries implement price regulation for pharmaceuticals that cover the majority of their population. The methods of regulating prices vary. In stark contrast, the majority of developing countries do not regulate pharmaceutical prices.

India introduced a very stringent regime of price control on medicines in 1978, whereby the prices of 378 medicines were controlled. However, in the last thirty years the price control regime, that is administered by the Drug Price Control Order (DPCO) has been significantly relaxed. Today only 74 medicines are under price control, and as the last time the list of medicines under control was drawn up was in 1995, many of the medicines under price control have ceased to be of importance.

The decontrol of medicine prices in India in the last 30 years have been premised on the argument that drug prices do not need to be controlled if there is competition in the market, i.e. if there are several companies who market the same medicine under different brand names. However the experience has been that this assumption is largely false. This is shown to be so by the fact that most top-selling brands are more expensive than brands of other companies making the same medicine, and in some cases the most expensive among all competitors.

The reason why competition in the market does not depress medicine prices is manifold. First, in the pharmaceutical market the decision to buy a drug is not taken by the consumer but is based on a Doctor's prescription or a pharmacist's choice. Prescription practices of doctors are prone to being influenced by marketing strategies of drug companies, and chemists are also influenced by inducements provided by companies. Second, unlike in the case of consumer goods, patients do not have the choice not to buy if they are in need of medicines. Third, in India over 80% of medicines are bought by patients from their own finances. This is the reverse of the situation in most developed and many developing countries, where public health insurance or the public health services provide for over 80% of medicines consumed. Thus patients in India, especially poor patients bear the brunt of high medicine prices.

The shift in policies in India, that has led to most medicines being outside price control today, have been increasingly questioned. The Government is believed to be actively considering the imposition of price controls on a much larger number of medicines.



## Drug Policy Formulation in India

Drug policies in India are formulated by the Ministry of Chemicals and Fertilizers. In addition, in 1997, the National Pharmaceutical Pricing Authority (NPPA) was instituted as an independent body to take decisions on pricing. The Ministry of Health and Family Welfare looks into the issues of quality, manufacturing, sales and distribution of drugs. These two functions are performed in isolation and there is minimal co-ordination between the two major areas of policy making in the pharmaceutical sector.

As a consequence the drug policy focuses only in the areas of production and pricing. Drug policies, thus formulated, have not incorporated a focus on health. In successive policies, the emphasis has shifted to addressing the viability of the private pharmaceutical industry. In the absence of a coherent link between health needs and the policies on drug pricing, issues of equity have been generally ignored.

In addition there are other Acts that regulate the use of medicines. The prominent ones are the Drugs and Cosmetics Act that deals with manufacturing and quality norms, prescribing norms etc. and the Magic Remedies Act that deals with the promotion and advertising of medicinal products. The Drug price Control Order (DPCO) lays down regulations for controls over drug prices. The Magic Remedies Act, especially is outdated, and requires a major overhaul as it contains provisions that are of little or no relevance in today's context.

According to guidelines formulated by the WHO (8), a national drug policy is a commitment to a goal and a guide for action. It expresses and prioritizes medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and the private sectors and involves all the main actors in the pharmaceutical field. In the broadest sense, a national drug policy should promote equity and sustainability of the pharmaceutical sector. The present practice in of drug policy making in India is thus at variance of such accepted norms.

There is thus, the need to formulate a National Pharmaceutical Policy that addresses the critical issue of universal access to essential medicines. Such a policy needs also to harmonise different aspects of the Drugs and Cosmetics act and the Magic Remedies Act. This policy should be prepared by an intersectoral committee of the Ministry of Health & Family Welfare and Ministry of Chemicals & Fertilizers after discussions with all sections that have a stake in the pharmaceutical sector. The two should jointly constitute a National Drugs and Therapeutic Authority, which should be a statutory body with powers to regulate all aspects of the National Pharmaceutical Policy.

## Summary

Access to essential medicines is a major determinant of health outcomes and an integral, and often crucial, component of health care. An approach to ensuring access has been promoted by the World Health Organisation since 1978 called the "Essential Drugs" Policy. It defines "Essential Drugs" as those "that satisfy the health care needs of the majority of the population". The

WHO further suggests that "they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford". The WHO, periodically, publishes a "Model" list of essential drugs but countries are encouraged to develop their own model lists, based on local conditions. The national policy should include measures to ensure that the medicines in the national list are available to all who need them, are affordable and of good quality, and ideally are locally manufactured so that a reliable and constant supply is ensured. An Essential Drugs List also needs to be dynamic, that is it needs to be updated periodically.

WHO has defined irrational prescribing as use of a therapeutic agent when the expected benefit is negligible or nil or when its usage is not worth the potential harm or the cost. Irrational drug prescribing can occur when the medication prescribed is incorrect, inappropriate, excessive, unnecessary or inadequate. Irrational prescribing and aggressive promotion of medicines by drug companies go hand in hand. Policies in India need to consider the fact that large investments made by drug companies push up medicine costs and promote irrational prescription practices. The promotion of generic prescription has always been seen as a primary requirement for ensuring of rational use of medicines.

Finally, the big issue that determines the access to medicines for poor people relates to how medicines are priced. Clearly the situation requires attention from regulatory agencies in the form of controls on the prices of medicines. Price control is a form of market regulation that limits the capacity of the supplier to set the price of a product. In India the price control regime, administered by the Drug Price Control Order (DPCO) needs to be more stringent.

Drug policies in India are formulated by the Ministry of Chemicals and Fertilizers. In addition, in 1997, the National Pharmaceutical Pricing Authority (NPPA) was instituted as an independent body to take decisions on pricing. The Ministry of Health and Family Welfare looks into the issues of quality, manufacturing, sales and distribution of drugs. These two functions are performed in isolation and there is minimal co-ordination between the two major areas of policy making in the pharmaceutical sector. In addition there are other Acts like Drugs and Cosmetics Act, the Magic Remedies Act, Drug price Control Order (DPCO) that regulate the use of medicines. There is thus, the need to formulate a National Pharmaceutical Policy that addresses the critical issue of universal access to essential medicines and need for joint constitution of ministries to form a National Drugs and Therapeutic Authority, which should be a statutory body with powers to regulate all aspects of the National Pharmaceutical Policy.

## Study Exercises

**Long Question :** What are the possible approaches/policies to ensure universal accessibility and availability of Drugs? Describe Essential drug policy in India.

**Short Notes :** (1) Essential Drug policy (2) Rational prescribing of drugs



### MCQs

1. It is recommended that essential drug list in any country is to be updated at least every (a) 1-2 yrs (b) 2-3 yrs (c) 6 months (d) 3 months
2. Irrational drug prescribing can occur when the medication prescribed is (a) Incorrect (b) Inappropriate (c) Excessive (d) All the above
3. In India Drug policies are formulated by the Ministry of (a) Chemicals and Fertilizers (b) National Pharmaceutical Pricing Authority (c) Ministry of Health and Family Welfare (d) None of the above
4. An Essential Drugs list, ideally, should include all medicines that are necessary to treat more than \_\_\_% of illnesses that a physician is likely to encounter. (a) 100 (b) 95 (c) 90 (d) 50

**Answers :** (1) b; (2) d; (3) a; (4) b.

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## Medical Education in India

There were 30 medical colleges in India at the time of independence which have expanded to 262 medical colleges now. The annual turn out is of about 24000 medical graduates every year. The system of medical education in India is basically westernized and hospital oriented since its origin about 150 years ago. This has not undergone much change over all these years. There is still lack in the production of basic doctors, competent enough to provide primary health care and meet the requirements at the grass root level. Health related education and training has become more urban oriented, doctor-centric and technology-driven; the quality, quantity and distribution of the health oriented human resources being produced leaves much to be desired. Over the years, the bulk of the growth in medical education institutions has occurred in the richer states, potentially leading to increased regional inequity in access.

### Aim of medical education

The aim of medical education is to:

1. Impart theoretical knowledge about patient care and health needs.
2. Teach practical procedures for diagnosis, treatment, communication and management.
3. Create competence and motivation to serve the health needs of the country and its people.

### Current Scenario

The medical education system in India is a heterogeneous system. It is broadly classified into:

- Allopathy, or Non Indian System of Medicine (NISM)
- Indian Systems of Medicine and Homeopathy (ISMH)

There are at present, the following number of recognized

medical, dental and nursing colleges in the country, with the respective number of seats:

1. Medical: Colleges = 262; Seats = 30558
2. Dental: Colleges = 204; Seats = 11850
3. Nursing: Colleges = 116; Seats = 2845

### Higher Organisation

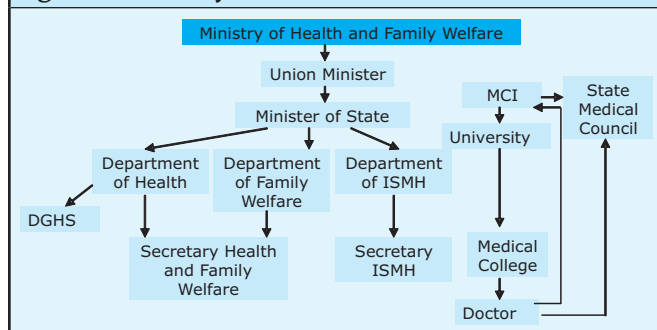
The medical education system in India comes under the Ministry of Health and Family Welfare which has the Department of Health, the Department of Family Welfare and the Department of ISMH. It is headed by the Union Minister. There is also a Minister of State for Health and Family Welfare. The Health Secretary is an IAS officer who looks after the affairs related to the Department of Health and the Department of Family Welfare, whereas the Department of ISMH has its own Secretary. The Director General of Health Services is associated with the Department of Health. Besides, there are various technical officers in the department. The flow chart is shown in figure-1.

**The Medical Council of India :** The Medical Council of India was established as a statutory body under the provisions of the Indian Medical Council Act, 1933 which was later repealed by the Indian Medical Council Act, 1956. A major amendment in the Indian Medical Council Act, 1956 was made in 1993 to stop the mushroom growth of medical colleges, increase of seats and starting of new courses without prior approval of the Central Government in the Ministry of Health and Family Welfare. The main functions of the Council are:

1. Maintenance of uniform standards of medical education at undergraduate and post-graduate level
2. Maintenance of Indian Medical Register
3. Provisional/permanent registration of doctors with recognised medical qualifications and registration of additional qualifications

- 4 Reciprocity with foreign countries in the matter of mutual recognition of medical qualifications.

**Fig. - 1 : Hierarchy of Medical Education in India**



**Universities and Deemed Universities :** The function of the universities is to ensure proper and systematic instruction, teaching, training and research in the institutions affiliated to them. They ensure balanced growth in the various fields of medical sciences and also maintain uniformity in various courses offered by the institutions affiliated to them. A doctor passes out of a medical college affiliated to a university and gets registered with the MCI and/or the State Medical Council in order to practice medicine.

### Structure of Medical Education in India

Most of the medical colleges in the country are located in urban areas. There is a geographic mal-distribution of the medical colleges all over the country. The six states of Maharashtra, Karnataka, Andhra Pradesh, Tamil Nadu, Kerala and Gujarat have a total of 63% of the medical colleges and 67% of total medical seats in the whole country. The North Eastern states, on the contrary, have only 3% of medical colleges. Almost 50% medical colleges in the country are in the private sector. This number has more than doubled from 60 in 2000 to 131 in 2006. The number of seats at the undergraduate level has increased by nearly 5 times while the number of institutions has increased by eight times during 1970 to 2004.

**ISMH :** The developments in ISMH education parallel these trends. The number of ISMH institutions increased by nearly 70 percent over the last two decades. Nearly 82 percent of all ISMH enrollment capacity in training and 76 percent of all ISMH training institutions are in the private sector. Almost all of the increase in ISMH institutions during the last two decades has occurred in states with the richest of the population. The Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) was established as Department of Indian Systems of Medicines and Homoeopathy (ISM & H) in Ministry of Health & Family Welfare in March, 1995, to oversee the educational process in this system.

### Process of Medical Education

**Selection of Students :** The selection of students is based on the marks obtained by students on the basis of a MCQs test. The test is usually directed towards testing of mere recall of facts. The humanistic approach, attitudes and communication skills are hardly assessed. Merit in the board examinations or

competitive tests is not combined with any aptitude test (except in few institutions that have their own entrance exam) to form the criteria for selection tests. However, there is also non-availability of appropriate objective instruments for testing aptitude in large number of students at present. Besides, the private medical colleges offer subsidized “merit seats”, based on a common entrance exam. Remaining seats are offered through “management” quota, apparently on considerations of merit, but do require substantial fees.

**Teachers :** Criteria are laid down explicitly by the MCI in terms of the basic University or equivalent qualification, the experience, the number of papers published (in national and international journals), as well as the number of teachers authorized to a particular type of medical institution.

**Courses :** For the undergraduate, the course is for a period of 5 1/2 years. The pattern of curriculum is split up as follows:

- 1 year: basic sciences
- 1 1/2 years: para-clinical sciences
- 2 years: clinical subjects

Compulsory rotatory internship has to be there for a period of 1 yr after completing the final year. Recent recommendation has been of a compulsory rural phase for all graduates before they can be awarded the bachelor's degree. For the post-graduate, there are three main types of “post-graduate” training opportunities:

- 3 year residency programs i.e. MD or MS
- 1 or 2 year long diploma training programs and DNB

For super specialization, there are super-specialty residency programs in medical and surgical specialties for those who have completed the MD/MS or the DNB.

**Curriculum :** The curriculum is well laid out. Horizontal and vertical integration of the subjects is advocated e.g. anatomy with physiology and anatomy with surgery, respectively. The division into theory classes and practicals for all subjects as well as topics is well laid out.

**Assessment :** Periodic assessment is advocated, both objective and subjective. But actually, it is the textual knowledge that is mainly assessed.

**Internship :** Compulsory rotatory internship for a period of one year is there, following the completion of the undergraduate course. 3 months each is laid down in the field of medicine (and allied subjects), surgery (and allied subjects), obstetrics and gynaecology and preventive and social medicine.

**Specialisation :** All medical graduates are eligible for specialization after completion of internship. Seats for the same are available through an all India exam, state PG medical entrance exams and PG medical entrance exams of private institutions.

### Issues

**Current Scenario :** The medical education system in India is more westernized. The western model has not been adapted well to Indian realities. The settings for training are different than the ground realities. Doctors are usually not competent enough to provide primary health care. Medicine used to be a highly sought after profession earlier. But it is minus the “nobleness” now. The status is falling now and it is losing the

luster. Over the years, there has been a disproportionate growth of institutions which has been more in richer states. This has lead to increased regional inequity.

**Higher Organisations :** The higher organizations tend to have a dictatorial approach. The MCI wants at least a particular number of teachers in a medical institution, at the same time itself being the body which has a documented deficiency of many at all levels. It is ironical when the MCI itself fails to understand such problems and derecognises institutions for lack of teaching faculty. Often there are politically motivated decisions as well as vested interests, with many politicians owning medical colleges. At the top positions in the government, there are bureaucrats instead of technocrats who handle the affairs related to medical education. The former can hardly be trusted for their knowledge of technical matters as the latter can be.

**ISMH :** It is not clear as to where do these doctors practice. Many are in competition with allopaths. Many more actually are practicing allopathy. This is happening especially in the private nursing homes and clinics where they are employed at lesser salary and allowed to practice allopathy. Also, we do not know of any regulatory body for them like the MCI.

### **Issues with Process of Education**

**Selection of Students :** The selection of students is by MCQs tests. This involves a mere recall of facts. There is no subjective assessment of aptitude of the students. At the same time, it is actually difficult to do an aptitude test on such a large scale, as lakhs of students appear in the medical entrance exams every year. In assessing the students by a MCQs test alone, the approach, attitudes and communication skills are hardly assessed.

**Selection of Teachers :** While selecting teachers, aptitude to teach is hardly assessed. A good student may not be a good teacher since there is a difference in acquiring knowledge and being able to impart the same. Adequate training in the techniques of teaching is rarely imparted to them. Teachers are not held accountable to the students. The teacher's performance is taken for granted and his or her competence in teaching is never questioned. There isn't much accountability and monitoring of the teaching faculty towards fulfillment of their teaching responsibilities. Besides this, it is observed that research is taking precedence these days over patient care, in the clinical specialities.

The last inspection conducted by the MCI showed that a large number of doctors are claiming employment as medical teachers in more than one medical college at the same time. It was being observed that the names of the doctors shown as medical teachers in a particular medical college were getting repeated in the inspection reports of certain other medical colleges, in the same proximity of time. Apparently, the medical colleges and the medical teachers were indulging in such activities only to show to the inspection team of the Council that the colleges concerned are fulfilling the minimum requirement for the teaching staff for seeking permissions/renewals. The pathetic state can be gauged by the fact that there are reports that even in government medical colleges, teachers are transferred from one college in the state to another, just before an anticipated

MCI inspection, so as to show to the inspecting team that there is no shortage of teaching staff !

**Continuing Medical Education :** The concept of Continuing Medical Education (CME) is a good one that helps keep the professionals abreast of the latest knowledge. But a resistance to change has been observed on the part of doctors. Most lack motivation to attend CMEs. These days, CMEs have been reduced more to pharmaceutical industry driven activities only. Many doctors utilize this opportunity for furthering their own careers.

**Curriculum :** The pattern of curriculum is fragmented. Subjects are taught in isolation. There is little or no integration of the basic sciences with the clinical disciplines. Often there is neglect of realities of rural and remote areas. The medical graduate, after passing out, finds himself more at home in better developed countries, than in the villages of India since he has been trained at an institute akin to a tertiary care set-up. There is over-burdening with theoretical knowledge. Due attention is not given to subjects like medical ethics, behavioral sciences, communication skills and managerial skills. This puts the medical graduate at a disadvantage when after passing out he/she gets posted to a PHC and has to manage the men, materials and money all alone.

Over the years, there has been a tendency to increase the number of subjects in which the student is to be independently assessed. For instance, fifty years back, medical curriculum had 10 subjects which were to be studied in 5 years; today a medical student has to cope up with 13 subjects in 4 ½ years; the number of subjects may further increase in the next couple of years to come.

**Assessment :** It is common knowledge that learning is driven by the method of assessment. Examinations are knowledge dominated rather than skill oriented. Performance of students is assessed in comparison to other students (peer-referenced), or norm-referenced rather than a standard criterion (criterion-referenced). This is what happens in practice, since most of the examinations in medicine do not have a clear criteria laid down beforehand for the purpose of assessment. Regular feedback is not provided to students during the training. There is dilution of the requisite standards of teaching and the transparency in examinations and results are also doubtful in most institutions.

A senior faculty of a premier medical college in India says, "We accept racehorses and turn out asses", meaning thereby that we accept the best students into the college after an entrance exam, but do not teach them as they should be taught, before they pass out as doctors.

**Clinical Skills :** Investigative medicine has largely taken over these days. This is likely to increase the cost of medical care and learning. Learning on the part of the students is inadequate to make a sound clinical judgement. Skills of traditional clinical bedside history taking, physical examination, formulation of differential diagnosis, and planning a diagnostic and management plan for various problems are not well inculcated.

**Internship :** The period of internship is not effectively utilised to develop and refine clinical skills. More often it is utilised



for preparation of postgraduate entrance examinations. Irregularities in attendance have been observed, especially during rural attachments. Lack of interest has been noticed in case of medical officers under whom the interns get attached. Rural works, preventive activities are not attractive to interns who are not motivated at the end of their undergraduate days. Moreover they feel that 6 months period of rural internship is too long a period which deprives them of the clinical experience in hospitals that they value more. Internship is more about completion in paper at most places and less to do with acquiring skills. Ground realities observed in studies conducted showed that 30% students had not performed simple procedures like recording the weight of mother and infant, 30-40% had never given any immunization while 70% had never prescribed common contraceptive methods like condom or oral pill.

**Specialisation :** There is inadequate training for service in rural areas. There is a lack of production of “basic” doctors who are able to deliver primary health care at the community level. Medicine, surgery and their super specialties are more popular among the fresh graduates. Less importance is given to community based education compared to institution or hospital-based education.

**Privatisation of Medical Education :** Measures are required to ensure proper regulation of medical education in these institutions by the medical council. Growing merchandisation of medical education has been observed in certain private institutions. Certain such institutions have been found to be substandard. Improper admission practices under the management quota have been observed. There is compelling evidence that many private medical colleges are short of staff and infrastructure, including hospital beds.

### Recommendations

In view of the above mentioned problems, following recommendations are put forward:

- 1 Increase in the number of human resources at all levels should be done
- 2 Shortage of experienced teachers should be met
- 3 Performance of teachers should be assessed from time to time
- 4 Teachers should be made more accountable
- 5 There should be revamping of the teacher training at all levels and promotion of development of teaching aids to retain student attention in classrooms
- 6 Academic recognition should be given to the teachers for their contribution
- 7 It is important to encourage and reward teachers who show a flair for teaching and adopt innovative teaching methods
- 8 Career prospects of teachers need to be enhanced, by giving promotions more frequently, rather than stagnation at certain appointments
- 9 There is a need to shift from knowledge dominated examinations to more skill oriented examinations for the students
- 10 Assessment should predominantly be based on the core curriculum and should be criterion referenced, i.e. the performance of students is assessed against a standard

criterion and not just in comparison to others

- 11 Radical changes are required in the evaluation system to encourage scientific thinking and promote better understanding of basic science concepts
- 12 Objective and subjective feedback to students should be given to help them improve their deficiencies, instead of a mere verbal input on their performance
- 13 Thrust is needed during the training in the basic skills in human resource management, leadership qualities (ability to lead a health care team) and providing cost effective care in rural/non-hospital settings
- 14 Internship training should be revamped so that it is not just a repeat learning of the skills but should be aimed at delivery of health services
- 15 A formal assessment at the end of internship can ensure proper utilisation of this period for development of skills
- 16 Greater importance needs to be given to community based education rather than institution or hospital-based education
- 17 PG entrance examinations should be made more suitable for testing higher level of knowledge and skills rather than mere recall of facts
- 18 There is a need to urge medical students to look at specialising in disciplines on considerations other than their market value
- 19 The profession should be made financially more gainful
- 20 At the top positions in the government, in addition to the bureaucrats, there is a need for more technocrats to handle the affairs related to medical education
- 21 The state-wise skewed distribution of doctors should be corrected by providing adequate and as far as possible, equal facilities in all states
- 22 Rural health services need to be made more attractive - by improvements in position, pay, facilities and job satisfaction
- 23 New institutions need to be raised in rural and backward areas (In the 11th Five Year Plan: 2007-12, the government plans to set up six institutions like the All India Institute of Medical Sciences and upgrade 13 existing medical institutions)

There is a need to revamp the medical education system in our country. The aim of professional education in health must be production of a cadre of professionals who would have competence as well as motivation to serve the health needs of the country and its people as a whole. The number and type of medical training institutions in India is entirely disproportionate to the actual needs of the vast majority of people. We must train professionally competent doctors and bring back the nobleness in the profession. Concurrent concepts and modalities of implementation are not conducive to our achieving the aims of medical education in India. And although India is, no doubt, still producing good doctors, the standards vary to an alarming extent. That most young doctors - irrespective of their ability, emerge with a jaundiced view of the integrity of the medical system is probably no bad thing. It prepares them for the future; they have to be politically aware. Being bright and highly motivated is simply not enough. Therefore, there is a need to change.



## Summary

At the time of independence, there were 30 medical colleges in India, which have expanded to 262 medical colleges now. The annual turn out is of about 24000 medical graduates every year. The system of medical education in India is basically westernized and hospital oriented since its origin about 150 years ago. There is still lack in the production of basic doctors, competent enough to provide primary health care and meet the requirements at the grass roots level. Most of the medical colleges in the country are located in urban areas. There is a geographic mal-distribution of the medical colleges all over the country. Currently, the medical education system in India is broadly classified into Allopathy, or Non Indian System of Medicine (NISM) and Indian Systems of Medicine and Homeopathy (ISMH). It comes under the Ministry of Health and Family Welfare which has the Department of Health, the Department of Family Welfare and the Department of ISMH. It is headed by the Union Minister. There is also a Minister of State for Health and Family Welfare. The Director General of Health Services is associated with the Department of Health. The Medical Council of India is the apex body that regulates the medical education in India. The selection of students is on the basis of a MCQ test that tests mere recall of facts. For the undergraduates, the course is for a period of 5 1/2 years whereas for the post-graduates it is for 3 years (MD/ MS) and 1 or 2 years (Diploma). The curriculum is well laid out. Horizontal and vertical integration of the subjects is advocated. But actually the pattern of curriculum is fragmented and the subjects are taught in isolation. Both objective and subjective periodic assessment is advocated. Besides, the concept of CME is advocated that have been reduced merely to pharmaceutical industry driven activities these days. Many doctors utilize this opportunity for furthering their own careers. Irregularities in the placement of teaching faculty were observed during the last MCI inspection. Investigative medicine has largely taken over these days. This is likely to increase the cost of medical care and learning. Skills of traditional clinical bedside history taking, physical examination, formulation of differential diagnosis, and planning a diagnostic and management plan for various problems are not well inculcated. The period of internship is not effectively utilised to develop and refine clinical skills. More often it is utilised for preparation of postgraduate entrance examinations. Irregularities in attendance have also been observed. Measures are required to ensure proper regulation of medical education in private institutions by the MCI as well as similar regulation of the ISMH colleges. The aim of professional education in health must be production of

a cadre of professionals who would have competence as well as motivation to serve the health needs of the country and its people as a whole. Therefore, there is a need to revamp the medical education system in our country.

## Study Exercises

**Long Question :** Critically review the current medical education system in India.

### MCQs:

1. A medical graduate needs to get his degree registered with the following: (a) Ministry of Health and Family Welfare (b) MCI (c) State Medical Council (d) MCI and/ or State Medical Council
2. The Ministry of Health and Family Welfare has the following departments: (a) Dept. of Health and Dept. of Family Welfare (b) Dept. of Health, Dept. of Family Welfare and the Dept. of ISMH (c) Dept. of Family Welfare (d) Dept. of Health
3. The various departments under the ministry are headed by: (a) Secretary, Dept. of Health and Family Welfare (b) Secretary, Dept. of Health (c) Secretary, Dept. of Health, Family Welfare and ISMH (d) Secretary, Dept. of Health & Family Welfare and the Secretary, Dept. of ISMH
4. ISMH comprises of: (a) Ayurveda, Yoga, Unani, Siddha and Homoeopathy (b) Allopathy, Yoga, Unani, Siddha and Homoeopathy (c) Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (d) Allopathy, Yoga & Naturopathy, Unani, Siddha and Homoeopathy
5. The Indian Medical Register is maintained by: (a) Ministry of Health and Family Welfare (b) MCI (c) State Medical Council (d) Both the MCI and State Medical Council

**Answers:** (1) d; (2) b; (3) d; (4) c; (5) b.

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*(This chapter is based on the proceedings of a professional seminar on the subject held at Dept. of Community Medicine, AFMC, Pune, presented by Dr (Ms) Sukhmeet Minhas and moderated by Dr (Ms) S Mankar).*

*Kunal Chatterjee***Urban Slums**

The growth of slums in the cities has accompanied the pace of their industrialisation. Migration of people from rural to urban areas has compounded the housing problem in the latter and these people settle in shanty towns and slums in the fringes of the cities. Majority of them are economically backward, less educated and poorly paid workers prone to ill health due to overcrowding, poor housing, unsanitary environment and poverty. As per the 2001 census in the country, in cities with population of over one million, nearly one-fourth of the population reside in slums. Slum areas include the recognised and unrecognised slums, temporary settlements and pavement dwellers of whom the latter two are the poorest and the most needy.

**Problems in urban slums**

**Change in the environment :** The necessities enjoyed freely by slum dwellers while residing in rural areas, become commodities in the urban areas such as drinking water, cooking fuel, housing space etc. Marginal increase in income for the urban poor does not by itself assure better living conditions. Relative difference in income and wealth with the rich in the cities drives up the prices of food, health care goods and essential commodities, making them unaffordable to the poor. The change in environment for the people who have migrated to slums from rural areas has strong impact on their livelihood.

**Social support :** Consumption of public goods such as water, infrastructure and electricity is higher by the richer people, who also enjoy the subsidies provided by the government for these goods. The urban laws look upon migration as the root cause of all problems in the cities, as a result the migrants are denied the right to housing, their infrastructure is neglected and they are not provided easy access to basic health care. This aggravates the economic dependency already prevalent in the urban poor.

**Access to water supply :** Water supply in urban slums is usually not satisfactory. Per capita consumption of water in slums is less than in non-slum areas in a city. Water is supplied in common water points in slums. Overcrowding reduces the quantity available per head and subsoil water through borewells also does not prove sufficient. At times contamination of ground water table due to proximity to industries affects its quality thereby reducing the available water supply even further.

**Sanitation in surroundings :** As a result of higher population density in the slums, the total quantity of garbage and other wastes generated is higher, though the per capita solid waste is lower as compared to the non-slum areas. Solid wastes in slum areas are not appropriately disposed due to various reasons such as low awareness among the dwellers regarding waste hazards, segregation of wastes is not attempted, high rate of recycle of any material which has a perceived use, waste

bins are not kept in sufficient numbers, waste carriage to final disposal site is infrequent, streets are narrow inhibiting access to lorries/ vans and stray animals / birds have easy access to the bins thereby dispersing the wastes in the surrounding area.

**Sewage disposal :** Disposal of sewage in slums is inadequate or at times rudimentary. The public toilets installed for this purpose are insufficient in number and not cleaned properly. The slum dwellers resort to open air defecation in nearby areas. Storm water drains and *nullahs* flowing near the settlements are frequently used for this purpose, creating filth and insanitation. The most vulnerable in this community are young children, elderly and women who also suffer the most due to improper toilet facilities. Lack of adequate water for cleaning or bathing increases their vulnerability and diarrhoeal diseases are highly endemic in this population.

**Care in illness :** Slum dwellers are subjected to various diseases brought about by interplay of factors such as poverty, ignorance and poor health infrastructure. Numerous studies have found high levels of malnutrition among the under 5 years old residing in these areas. The children below 5 years show high levels of stunting suggesting chronic malnutrition equal to that seen in the remote areas of the country. A study has also revealed that approximately 27% of infants in slums had a low birth weight as compared to 18% of those born in non-slum areas. Anaemia among the pregnant women is a major cause of maternal and perinatal mortality. Urban poor also spend substantially on childhood illnesses such as respiratory infections, diarrhoeal diseases as well as on tuberculosis, HIV/ AIDS etc. The latter two have shown rising trends in the slum population.

**Level of health care :** There are consistent differences seen in the health care between slums and the non-slum areas in the cities. This is marked in the reproductive and child health care with studies revealing only about 55% women in slums having received three or more antenatal check ups compared to 74% of the non-slum population. The levels of institutional delivery and awareness of safe delivery practices also differ between the slum and non-slum areas. Immunisation coverage among children in urban slums is poor and so is the health care service available to residents. Besides, the treatment seeking behaviour in these areas is influenced by the negative-gender attitudes, which compounds the discrimination against the women and young & vulnerable group.

**Social issues :** Violence against vulnerable people in the slums is widely prevalent. The most affected are the women. Alcoholism and drug abuse envelop the slum youth who are uneducated or unemployed and this results in their getting involved in anti-social activities.

**Strategies for health care of the slum dwellers**

**Comprehensive health policy :** There is a need for a comprehensive policy to focus on the health needs of the slum population. Governments in different countries need to focus on the requirements of the urban poor and the strategies for improvement of their health care need to be adopted accordingly. The various aspects covered under this policy could be:

- Involvement of the community in all aspects of health care delivery. This should be encouraged by the local/ municipal bodies

- Generate the demand for health services including the preventive and curative services
- Involvement of the local non governmental organisations, medical practitioners and practitioners of traditional medicine in the community
- Create a secure economic environment in which the dwellers do not feel a threat due to illnesses or hospitalisations
- Special funds could be created in the State government health plans to cater to the health care in slum areas and disadvantaged groups.

**Provision of the basic necessities :** The policy should enunciate the means and the method to provide basic necessities to the slum dwellers, including nutritious diet with the locally and seasonally available food, safe and wholesome drinking water in adequate quantities for the family, system of hygienic disposal of excreta and the availability of healthy housing conditions.

**Network of services :** There is a need to generate a network of health care services such that the facilities are easily accessible to all the sections of population. Special emphasis should be given to the most vulnerable sections of slum dwellers as described above and also the pavement dwellers and temporary settlers who are not ordinarily included in the slum rehabilitation schemes. These networks could include the following:

**Free health care** should be available on-site, adequate to the local needs, functional and non-discriminatory in nature such that it is universally acceptable in the spirit of health for all.

**Outreach services** which are able to provide for the most peripheral of populations and also able to empathise with and understand their health care needs.

**Referral services** should be integrated with the health care and outreach services such that comprehensive health care is available to the slum inhabitants.

**Curative services :** The health infrastructure in the urban slum areas needs to be strengthened at all the tiers to cover the entire slum area. A health care centre could be created as a first tier to cater to primary health care requirement of community. Similar attempt has been made in the Urban health care model by the Government of India by creating Urban Health Posts. The health care centre should be equipped to provide basic health facilities and reach the most vulnerable population. It should have necessary manpower to function the centre. The services provided should be OPD based including Reproductive & Child Health (RCH), first aid, treatment for common ailments, basic laboratory service, counselling, ancillary services and facility for referral to second tier of health care. The second tier of facility should be appropriately identified for referral such as hospitals, maternity homes and nursing homes. Private partners should be identified at each level of care to improve the coverage and quality of services.

**Preventive services :** Primary care should be integrated with preventive health care services. Immunisation of children and pregnant women should be carried out on priority as per laid down schedule. The immunisation days at the health centres should be communicated to all people. The workers at the health centres should teach the community to adopt safe and

healthy family planning practices. Active and passive disease surveillance should be established at the first tier, which could integrate with the state/central surveillance network. Voluntary workers could be identified and involved in conduct of preventive care activities in the slum community.

**Involvement of NGOs and self-help groups :** Aim of provision of urban health care is to be able to reach each and every person or group with these services. Involvement of community in identifying their health needs and improving their health awareness could be achieved with the help of these organisations. Volunteers could be identified from the community, who could spare 3-4 hours a day to provide outreach services. They would also be integrated with other slum development activities.

**Income generating activities :** The volunteer groups, NGOs and State health authorities could motivate the community members to be involved in income generating activities especially the ones where the youth could be addressed. Community leaders could be asked to lead in this regard. Slum development activities could help in diverting the youth from anti-social activities to more productive work.

**Public-private partnerships :** Partnerships between the urban local bodies, family welfare organisations and State government will improve the chance of success of the urban health schemes for the slums. Coordination between various State departments such as engineering, health and education would help in making the schemes sustainable and improve overall sanitation services in slum areas.

**Monitoring :** Health Management Information Systems should be established in slums to measure health data in the population, for future policy planning. At present this data is inadequately received at the State level. Baseline indicators should be determined from health surveys. These could include morbidity, mortality indicators, immunisation coverage, infant and neonatal care, safe delivery/abortion practices and so on. Periodic review of the implementation of these schemes could be carried out by establishing programme management units at district and State levels.

### **Tribal Health and Health Care of Population in Remote Areas**

Tribal people inhabit various geographic and climatic zones in different countries in the World. Their vocations range from hunting, gathering, nomadic living to living in societies with settled culture in harmony with nature. In India majority of the tribal population live in remote areas and their problems depend on their remoteness from the rest of the communities as well as their indigenous customs and traditions. Tribal communities in the country belong to more than 400 linguistic and cultural groups, with some states having almost fifty percent tribal population.

#### **Nature of problems**

**Urbanisation and industrialisation :** The rich heritage of knowledge, expertise and age old wisdom passed over generations in the traditional communities have been endangered by urbanisation and industrial growth. Oppression, land exploitation and degradation of environment have dented their simple ways of cohabitation with nature.



**Diseases and deficiencies** : Tribal communities are more prone to communicable diseases and nutritional deficiencies. Major health problems include respiratory infections, malaria, diarrhoeal diseases and skin infections. Women are more affected by anaemia, complications during pregnancy such as toxaeimias, prolonged labour, abnormal foetal presentations etc. The maternal, perinatal and infant mortality rates are quite high. Some tribal communities are also exposed to environmental pollutants and effects of progressive land/forest degradation severely depleting their habitat.

**Social issues** : Tribal communities and those living in remote areas depict a higher rate of alcohol intake and substance abuse. The harmonious living with nature is disturbed; lack of employment and awareness, availability of cheap or spurious liquor, trading in opium and narcotic drugs increases their vulnerability to these behaviours.

**Awareness and utilisation of health facilities** : The level of awareness regarding health facilities among the tribal community is fairly low. In a study carried out in Bastar district of Madhya Pradesh, it was found that only 40% population knew about subcentres and PHCs. Where services are available, indigenous people are often reluctant to use them because of insensitive staff at the health centres. Most communities still rely on the traditional systems of medicines to address their health problems.

**Availability of infrastructure** : Government health care facilities are usually inadequately available in tribal and remote areas. Buildings, equipments, drugs and other supplies and health personnel are insufficient in these places. NGOs and self help groups therefore take up the cause of providing health care and social mobilisation of tribals.

#### Strategies to improve health care

**Identifying the objectives** : To assess the unmet needs in tribal communities, stimulate the demand for health care services, improve service coverage, and ensure accessibility and acceptability of these services by the community.

**Strengthen health infrastructure** : Government health infrastructure should be upgraded. Policies should be made to relax qualifications for personnel to suit local requirements, effective remuneration and turnover of health personnel in these areas ensured. Institutions such as the Panchayati Raj Institutions should be encouraged to help communities in various health care activities, besides the socio-economic development of the community. Referral services should be made organised and effective.

**Promote community participation** : Involve people to map inaccessible areas, community based organisations could participate in outreach services, volunteers could be involved in improving awareness and education of community. Existing health functionaries such as Anganwadi workers under in Indian villages could create demand for services for women and children.

**Involvement of Non Governmental Organisations** : NGOs with good track records should be encouraged to take responsibility for managing MCH services as well as support the public health facilities in tribal communities and remote areas. Practitioners of traditional systems of medicine should also be involved in

health care.

**Behaviour Change Communication strategies** : Local area specific IEC activities should be planned. The tribal leaders and persons of prominence in the community should be taken into confidence for developing such communication strategies, which should be based on values, beliefs and practices locally prevalent.

**Development of human resources** : Promoting training in midwifery for the community volunteers and local married women in supporting the health care activities in these communities.

#### Summary

**Urban Slums** : The Migration of people from rural to urban areas has compounded the housing problem in the latter and these people settle in shanty towns and slums in the fringes of the cities. There are some unique problems faced by the people in urban slums. High prices of food, health care goods and essential commodities are making them unaffordable. They are denied the right to housing, their infrastructure is neglected and they are not provided easy access to basic health care; Scarcity of water supply and overcrowding reduce the quantity available per head. Solid wastes in slum areas are not appropriately disposed due to various reasons and disposal of sewage in slums is inadequate or at times rudimentary. Slum dwellers are subjected to various diseases brought about by interplay of factors such as poverty, ignorance and poor health infrastructure. Malnutrition among the under 5 years old, Low birth weight, Anaemia among the pregnant women and childhood illnesses such as respiratory infections, diarrhoeal diseases as well as on tuberculosis, HIV/AIDS etc. have shown rising trends in the slum population. Violence against vulnerable people in the slums is widely prevalent. Alcoholism and drug abuse envelop the slum youth who are uneducated or unemployed and this results in their getting involved in anti-social activities.

There is a need for a comprehensive policy to focus on the health needs of the slum population. Governments in different countries need to focus on the requirements of the urban poor and the strategies for improvement of their health care need to adopt accordingly. The policy should enunciate the means and the method to provide basic necessities to the slum dwellers, including nutritious diet with the locally and seasonally available food, safe and wholesome drinking water in adequate quantities for the family, system of hygienic disposal of excreta and the availability of healthy housing conditions. Health Management Information Systems should be established in slums to measure health data in the population, for future policy planning.

**Tribal Health** : In India majority of the tribal population live in remote areas and their problems depend on their remoteness from the rest of the communities as well as their indigenous customs and traditions. Urbanisation, industrialisation, Oppression, land exploitation and degradation of environment have dented their simple ways of cohabitation with nature. Tribal communities are more prone to communicable diseases and nutritional deficiencies. Major health problems include respiratory infections, malaria, diarrhoeal diseases and skin



infections. Women are more affected by anaemia, complications during pregnancy such as toxaeimias, prolonged labour, abnormal foetal presentations etc. The maternal, perinatal and infant mortality rates are quite high. Some tribal communities are also exposed to environmental pollutants and effects of progressive land/forest degradation severely depleting their habitat. Strategies to improve health care in Tribal areas are to Identifying the objectives, Strengthen the health infrastructure, Promote community participation, Involvement of Non Governmental Organisations and Behaviour Change Communication strategies.

## Study Exercises

**Long Questions :** (1) Discuss the Health problems faced by people in Urban Slums and Suggest measures for the same (2) Discuss the Health problems existing in people in Tribal

areas and Suggest measures for the same.

**Short Notes :** (1) Urban Slums (2) Tribal Health (3) Strategies for health care of the slum dwellers.

## MCQs

1. As per the 2001 census in the country, in cities with population of over one million, the percentage of the population residing in slums is (a) 10 (b) 15 (c) 25 (d) 30
2. The percentage of infants in slums having low birth weight as compared to 18% of those born in non-slum areas is (a) 7% (b) 27% (c) 37% (d) 42%
3. The percentage of women in slums having received three or more antenatal check ups compared to 74% of the non-slum population is (a) 35% (b) 55% (c) 70% (d) 10%

**Answers :** (1) c; (2) b; (3) b.

*RajVir Bhalwar*

In our vast country, a number of extremely important, scientifically appropriate and acceptable systems of indigenous medicine are available. These include the Ayurved system, which is popular mostly in the States of Kerala, Himachal Pradesh, Gujarat, Karnataka, Madhya Pradesh, Rajasthan, Uttar Pradesh and Orissa. The Unani system is particularly popular in Andhra Pradesh, Karnataka, Tamil Nadu, Bihar, Maharashtra, Madhya Pradesh, Uttar Pradesh, Delhi and Rajasthan. The Siddha system is widely acceptable in Tamil Nadu and Kerala. Homoeopathy is practised all over the country and is especially popular in Uttar Pradesh, Kerala, West Bengal, Orissa, Andhra Pradesh, Maharashtra, Punjab, Tamil Nadu, Bihar, Gujarat and North-Eastern States. These Indian Systems of Medicine and Homoeopathy (ISM&H) were given an independent identity in the Ministry of Health and Family Welfare in 1995 by creating a separate department, which was renamed as Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in November 2003. The department is entrusted with the responsibility of developing and propagating the above-mentioned officially recognised Indian systems of medicine and Homoeopathy.

## Organization

The department is a part of the Ministry of Health and Family welfare, Govt of India and is administratively headed by the Secretary, Dept of AYUSH, assisted by various administrative and technical officials. The Department has two subordinate offices, one public sector undertaking, two statutory organisations, four research councils, eight educational institutions and a national Medicinal plant board (with 35 State/ UT level boards)

under its administrative fold, as per following details :-

**Subordinate Offices :** These include the *Pharmacopoeial Laboratory for Indian Medicine (PLIM)*, located at Ghaziabad, which is the Standard Setting-cum-Drug-Testing Laboratory for Indian Medicine (Ayurveda, Unani and Siddha System) at the National level and the *Homoeopathic Pharmacopoeial Laboratory (HPL)* which is also located at Ghaziabad for the purpose of laying down standards and testing for identity, purity and quality of Homoeopathic Medicines.

**Public Sector Undertaking :** There is one PSU, viz., the *Indian Medicine Pharmaceutical Corporation (IMPCL)*, located in Almora, Uttaranchal, with the prime objective of manufacturing authentic Ayurvedic and Unani medicines according to classical texts, for catering to the needs of dispensaries of Central Government Health Scheme (CGHS), Units of Central Research Councils of Ayurveda and Unani, and state government institutions.

**Statutory Regulatory Councils:** The Central Council of Indian Medicine (CCIM) and the Central Council for Homoeopathy (CCH) were set up under the Acts of Parliament. Ayurveda, Siddha and Unani systems are within the ambit of the Central Council of Indian Medicine, and Homoeopathy is under the Central Council for Homoeopathy. These councils prescribe course curricula, evolve and maintain standards of education and maintain central registers of practitioners of Ayurveda, Siddha, Unani and Homoeopathy respectively. Their main responsibilities are to regulate education and practice of respective systems of medicine and advice the Government regarding education.

**Research Councils:** There are four apex research councils, all located in New Delhi, namely, Central Council for Research in Ayurveda and Siddha (CCRAS), Central Council for Research in Unani Medicines (CCRUM), Central Council for Research in Homoeopathy (CCRH) and Central Council for Research in Yoga and Naturopathy (CCRYN).

**National Apex Institutes:** Eight apex educational institutions are established to promote excellence in Indian Systems of Medicine and Homoeopathy education. For each system there is a national institute, viz.- National Institute of Ayurveda, Jaipur; National Institute of Siddha, Chennai; National Institute of Unani Medicines, Bangalore; Morarji Desai National Institute of Yoga, New Delhi; National Institute of Naturopathy, Pune and National Institute of Homoeopathy, Kolkata. The Rashtriya Ayurveda Vidyapeeth has been established at New Delhi.

### **Broad Goal, Strategies and Activities**

**Broad Goal of the Programme:** Mainstreaming of AYUSH in the health care service delivery system, with a view to strengthen the existing public health system.

**Strategies :** Mainstreaming of AYUSH is one of the key strategies under the National Rural Health Mission (NRHM) under which it is envisaged that all PHCs/CHCs would be provided AYUSH facilities under the same roof. AYUSH manpower would be arranged either by relocation of AYUSH doctors from existing dispensaries or from contractual hiring of AYUSH doctors under NRHM funds. The other infrastructure and supply of medicines to PHCs/CHCs would be done through the Centrally Sponsored Scheme of Hospitals and Dispensaries which has received a very good response from States in the last two years of the 10<sup>th</sup> five year Plan. The following are the main strategies of this programme:

- Integrate and mainstream ISM&H in health care delivery system including National Programmes.
- Encourage and facilitate in setting up of specialty centres and ISM clinics.
- Facilitate and Strengthen Quality Control Laboratory.
- Strengthening the Drug Standardization and Research Activities on AYUSH.
- Develop Advocacy for AYUSH.
- Establish Sectoral linkages for AYUSH activities

### **Main Activities**

#### **(a) Improving the availability of AYUSH treatment facilities and integrating it with the existing Health Care Service Delivery System**

- Integration of AYUSH services in various CHC / Block PHC with appointment of contractual AYUSH Doctors.
- Appointment of paramedics where AYUSH Doctors shall be posted.
- Appointment of a Data assistant to support the ISM&H Directorate.
- Strengthening of AYUSH Dispensaries with provision of storage equipments.
- Making provision for AYUSH Drugs at all levels.
- Establishment of specialized therapy centers in District Headquarters Hospitals and Medical Colleges.
- AYUSH doctors to be involved in all National Health Care programmes, especially in the priority areas like IMR, MMR, Control of Malaria, Filariasis, and other communicable diseases etc.
- Training of AYUSH doctors in Primary Health Care.
- All AYUSH institutions will be strengthened with necessary infrastructure like building, equipment, manpower etc.
- One Yoga Therapy Centre will be opened in district Headquarters Hospitals to provide Yogic therapy for

specific diseases and also as a synergistic therapy to all other systems of treatment.

- Block level School Health Programmes to be conducted twice in a year in two groups consisting of 100 students in each group to improve the physical and mental health of the school children.
- It is proposed to create necessary Managerial post in the State and District level for effective supervision and implementation of different activities.
- Necessary vehicles with supporting manpower has also been proposed to strengthen the supervisory joint monitoring visits to health centres to be undertaken by both AYUSH and Health Care Officials at the District level's/State level.

#### **(b) Integration of AYUSH with ASHA.**

- Training module for ASHA and ANMs have to be updated to incorporate information of AYUSH.
- Training & capacity building to be undertaken by the Director, SIHFW, Bhubaneswar and necessary training material for the purpose to be modified and provided accordingly.
- Drug kit that will be provided to ASHA will contain one AYUSH preparation in the form of iron supplement. But other drugs which are used in the treatment of common diseases, control of communicable diseases as well as drugs promoting the maternal and child health as well as improving quality of life could be included subsequently.

#### **(c) Drug Management:**

- Priority will be given to manufacture of drugs in Govt. Sector Pharmacies, as per their capacity. In case of any surplus funds, drugs will be procured from the market observing all financial formalities of the Govt.
- Provision of Rs. 25,000/- to supply drugs per AYUSH dispensary has been projected as per NRHM norm.
- Provisions of medicines for District AYUSH wings and Specialty Therapy Centres proposed to be operated in the State.

#### **(d) Special Initiatives for Development of AYUSH Drugs.**

##### **(i) Strengthening the Quality Control Laboratory**

- The quantum of Ayurvedic and Homoeopathic medicines used / procured in both public and private health sectors is huge. There has been wide ranging concern about spurious, counterfeit and sub standard drugs. In order to prevent the spread of sub-standard drugs and to ensure that the drugs manufactured or sold or distributed throughout the state are of standard quality, drug regulation and enforcement unit has to be established in the state.
- The drug regulatory mechanism to be strengthened at the state level to improve the quality of drugs used in AYUSH and ensure proper standardization. The existing State Drug Testing and Research Laboratory (ISM) at Bhubaneswar shall also be modernised and strengthened for the purpose.

**(ii) Strengthening the Drug Standardisation and Research Activities on AYUSH :** Standardisation and research is an important activity in the process of development of a drug used for preventive and curative purpose. The major drawback in the development of AYUSH is lack of research and development activity on the drugs used for the System. The

following activities will be undertaken to strengthen the drug standardisation and research activities on AYUSH:

- It has been proposed to evaluate the chemical, pharmacological and clinical efficacy of the plant drugs.
- The phytochemical entities responsible for the therapeutic activity of the plant drugs used in AYUSH system will be evaluated through intensive R & D activity.
- The pharmacologically viable drugs will be screened clinically under WHO guidelines to establish the therapeutic activity.
- Clinical trials on different diseases like Psoriasis, Liver disorders, Diabetes, Asthma will be conducted to establish the effect of various drugs used for such diseases.
- It has also been proposed to conduct literary research like translation of manuscripts and its publications.
- Re-vitalisation of the local health traditions and the knowledge of traditional drugs used by experienced local health practitioners will be gathered and documented.

**(iii) Development of Herbariums and crude drug museums:**

- Herbarium will be developed in collaboration with the Forest departments in 15 selected Districts of the State.
- The existing Herbal gardens will be strengthened with necessary infrastructure.
- One State Herbarium at Bhubaneswar shall be developed. This shall enable greater research and study on development and innovation in AYUSH Drugs.
- 10 selected centres will be developed for extraction and preservation of the plants for medicinal use.

**Modalities of Delivery**

- For mainstreaming of AYUSH in NRHM, the personnel of AYUSH may work under the same roof of the Health Infrastructure, i.e. PHC, CHC; however, separate space should be allocated exclusively for them in the same building.
- The Doctors under the Systems of AYUSH are required to practice as per the terms & conditions laid down for them by the appropriate Regulatory Authorities.
- Provision of one Doctor of any of the AYUSH systems as per the local acceptability assisted by a Pharmacist in PHC.
- Provision of one Specialist of any of the AYUSH systems as per the local acceptability assisted by a Pharmacist in CHC.
- Supply of appropriate medicines pertaining of AYUSH systems.
- The already existing AYUSH infrastructure should be mobilized. AYUSH dispensaries that are not functioning well should be merged with the PHC or CHC barring which, displacement of AYUSH clinic is not advised.
- Cross referral between allopathic and AYUSH streams should be encouraged based on the need for the same.
- The specific choice of AYUSH system that should be set up in each state should be decided by the State depending on the local preference.
- AYUSH Doctors shall be involved in IEC, health promotion and also supervisory activities.
- The Indian Public Health Standards (IPHS) pertaining to AYUSH will be developed and also the detailed manpower and other requirements and financial projections for the same will be provided by the Department of AYUSH for further consideration.

**Regulatory Measures**

The Central Acts are in place to regulate education and practice, manufacture of drugs for sale and enforcement mechanism. Ayurveda, Siddha, Unani and Homoeopathy drugs are covered under the purview of Drugs and Cosmetics Act, 1940. Since most of the medicines of AYUSH sector are made from medicinal plant materials, the Department has set up a National Medicinal Plants Board to promote cultivation of medicinal plants and ensure sustained availability of quality raw material. A separate National Policy on Indian Systems of Medicine and Homoeopathy is in place since 2002.

**Infrastructure**

The infrastructure under AYUSH sector consists of 1355 hospitals with 53296 bed capacity, 22635 dispensaries, 450 Undergraduate colleges, 99 colleges having Post Graduate Departments, 9,493 licensed manufacturing units and 7.18 lakh registered practitioners of Indian Systems of Medicine and Homoeopathy in the country. 7 Ayurvedic and 5 Unani drugs have been supplied to 9 States and 4 Cities respectively as part of the on-going National Reproductive & Child Health Programme (RCH) for the treatment of common ailments of pregnant, women and children. As regards mainstreaming of AYUSH in the activities of NRHM, the following was the status as on 30 April 2008 is given in Table - 1.

The details of AYUSH manpower have also been described in detail, earlier, in the chapter on health manpower resources.

**Table - 1**

Parameter	Total
No. of PHCs where AYUSH practitioners have been co-located	3793
No. of AYUSH doctors posted on contractual appointments in CHCs	2199
No. of AYUSH doctors posted on contractual appointments in PHCs	1683
No. of AYUSH paramedics posted on contractual appointments in CHCs	17
No. of AYUSH paramedics posted on contractual appointments in PHCs	629
CHCs where AYUSH facilities are co-located	973
PHCs where AYUSH facilities are co-located	2012

**Budget**

There has been a three fold increase in the Plan budget of the Department in the 10<sup>th</sup> as compared as 9<sup>th</sup> Plan, most of which was on account of scaling up of the budget provision in the last two years of the 10<sup>th</sup> Five Year Plan i.e. 2004 - 2005 and 2005 - 2006 in line with the declared policy of the Central Government to increase the budgetary provision for AYUSH sector for mainstreaming it in the national health care delivery network. The Plan allocation for 2006-07 is Rs. 381.60 crore. It is proposed to scale up Plan provision for Department of AYUSH from Rs.1057.26 crore in the 10<sup>th</sup> Plan to Rs.2486.45 crore in the 11<sup>th</sup> Plan



## Future Course

It has been proposed to further step up the activities under AYUSH during the 11<sup>th</sup> five year plan. The following special steps are contemplated :

**1. Development and Upgradation of AYUSH Institutes/Colleges :** This is one of the Centrally Sponsored Schemes being implemented by the Department for Development of AYUSH Institutions. This Scheme has been in operation since last three plan periods and the present plan period. The scheme has following components:-

- (i) Development of UG colleges.
- (ii) Assistance to P.G. Medical Education
- (iii) Re-orientation Training Programme for AYUSH Personnel.
- (iv) Renovation and strengthening of Hospital wards of Govt./ Govt. aided teaching
- (v) Establishment of computer laboratory.
- (vi) Up-gradation of academy institutes to the status model Institutes of AYUSH.

**2. Strengthening of Hospitals & Dispensaries :** The scheme has the following components

- (i) Setting up of Speciality Therapy Centres and Speciality Clinics of ISM&H
- (ii) Setting up of ISM&H Wings in District Allopathic Hospitals
- (iii) Strengthening of existing AYUSH health care facilities
- (iv) Supply of essential medicines

### 3. Quality Control of AYUSH Drugs

- (i) To establish/strengthen the State Drug Testing Laboratories for ASU&H drugs.
- (ii) To establish /strengthen the State Pharmacies of ASU&H drugs.
- (iii) To strengthen state Drug Controllers on ASU&H enforcement mechanism.
- (iv) To assist AS&U drug manufacturing unit to improve their infrastructure.

## Summary

All the Indian Systems of Medicine and Homoeopathy (ISM&H) were given an independent identity in the Ministry of Health and Family Welfare in 1995 by creating a separate department, which was renamed as Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in November 2003. The Department has two subordinate offices, one public sector undertaking, two statutory organisations, four research councils, eight educational institutions and a national Medicinal plant board (with 35 State/ UT level boards) under its administrative fold.

The broad Goal of the Program is to mainstream the AYUSH in the health care service delivery system, with a view to strengthen the existing public health system. Mainstreaming of AYUSH is one of the key strategies under the National Rural Health Mission (NRHM) under which it is envisaged that all PHCs/CHCs would be provided AYUSH facilities under the same roof.

The main activities are (a) improving the availability of AYUSH treatment facilities and integrating it with the existing Health Care Service Delivery System (b) Integration of AYUSH with ASHA. (c) Drug Management / Provisions of medicines

(d) Special Initiatives for Development of AYUSH Drugs. For mainstreaming of AYUSH in NRHM, the personnel of AYUSH may work under the same roof of the Health Infrastructure and the Doctors under the Systems of AYUSH are required to practice as per the terms & conditions laid down for them by the appropriate Regulatory Authorities. The already existing AYUSH infrastructure should be mobilized. AYUSH dispensaries that are not functioning well should be merged with the PHC or CHC barring which, displacement of AYUSH clinic is not advised. AYUSH Doctors shall be involved in IEC, health promotion and also supervisory activities. The Indian Public Health Standards (IPHS) pertaining to AYUSH will be developed.

The Central Acts are in place to regulate education and practice, manufacture of drugs for sale and enforcement mechanism. Ayurveda, Siddha Unani and Homoeopathy drugs are covered under the purview of Drugs and Cosmetics Act, 1940. A separate National Policy on Indian Systems of Medicine and Homoeopathy is in place since 2002.

The infrastructure under AYUSH sector consists of 1355 hospitals with 53296 bed capacity, 22635 dispensaries, 450 Undergraduate colleges, 99 colleges having Post Graduate Departments, 9,493 licensed manufacturing units and 7.18 lakh registered practitioners of Indian Systems of Medicine and Homoeopathy in the country. It is proposed to scale up Plan provision for Department of AYUSH from Rs.1057.26 crore in the 10<sup>th</sup> Plan to Rs.2486.45 crore in the 11<sup>th</sup> Plan.

It has been proposed to further step up the activities under AYUSH during the 11th five year plan. Some of them are Development & Upgradation of AYUSH Institutes/Colleges, Strengthening of Hospitals & Dispensaries and Quality Control of AYUSH Drugs.

## Study Exercises

**Long Question :** Mainstreaming of AYUSH is one of the key strategies under the National Rural Health Mission (NRHM). Comment and discuss the activities and modalities of delivery of AYUSH

**Short Notes :** (1) Mainstreaming of AYUSH (2) Activities proposed under AYUSH during the 11th five year plan (3) AYUSH Organisation

### MCQs

1. Indian Systems of Medicine and Homoeopathy (ISM&H) was renamed as Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in (a) 2003 (b)2000 (c)2005 (d)2007
2. As per NRHM norm, the amount projected for supply of drugs per AYUSH dispensary is (a) 20000 (b) 25000 (c) 30000 (d)35000
3. Which of the following is a subordinate office under Dept of AYUSH,MOHFW (a) Pharmacopoeial Laboratory for Indian Medicine b) Homoeopathic Pharmacopoeial Laboratory c)Indian Medicine Pharmaceutical Corporation d)all the above

**Answers :** (1) a; (2) b; (3) d.

## References

1. Official website of National Rural health Mission, Dept of Health & Family Welfare, Govt of India, National Informatics Centre, NUAPADA.
2. AYUSH official websites <http://india.gov.in> and <http://mohfw.nic.in>



# 4

**Social, Behavioral and Communication Sciences**



Section 4 : Social, Behavioral and Communication Sciences			
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Social, cultural, psychological and behavioural factors are important variables in the etiology, prevalence and distribution of disease. The way the people live, their habits, beliefs, values and customs are significant determinants of individual and collective health. The behavioural sciences (sociology, social psychology, cultural anthropology) have made significant role in developing better understanding about the social etiology of health problems. It is recognized that causation and spread of a disease does not depend entirely upon biological organism. The cultural and social factors which govern human behaviour also have dominant role to play in the disease process. Any behaviour is determined by a combination of cultural, psychological, social and economical variables. Hence the study of health embraces the totality of life and ways of living.

**Sociology** : Sociology is the science concerned with the organization of structure of social groups. It studies the kinds and cause of variation in social structure, and the processes by which intactness of social structure is maintained. Sociology deals with the study of society. Society is a group of individuals who have organized themselves and follow a given way of life. The behaviour of man depends very much upon his relationship with other fellow beings. Man is a subunit of a small group; the family, while the family is the basic unit of society. Man's behaviour is affected not only by his physical and biological environment but also, to a larger extent by social environments represented by his family.

**Community** : In the simplest terms, a community can be defined as a group of people who have some common characteristics and are bound together by "WE" feeling. This sense of 'we' feeling (i.e., shared togetherness) may be due to a place where they all stay or due to some other common interest.

Accordingly, communities can be either "structural" or else, "functional" communities. Functional communities are non-geographical aggregates which are bound together by some common factor other than geographical place of residence or work; e.g., religion (as, Hindu community), occupation (as medical community), special interest (as cricket lovers) or need (as socially backward communities). Structural communities are organised by geographical or political boundaries. It could be as small as an "indoor patient's community in a hospital" or increasingly larger, according to a "Mohalla", village, slum, city, district, state or even a nation. Community affiliations often provide a source of support for individuals and group. The sense of group identity eases the growth of motivation. For this reason the community is ideal for focal point of programme.

**Culture** : Culture is defined as learned behaviour which has been socially acquired. Culture includes all that man acquired in the mental and intellectual sphere of his individual and social life. It is a product of human societies.

Culture is necessary for human being; it makes life worth

living and socializes man. A culture denotes total way of life. It is recognized that cultural factors are deeply involved in all the affairs of man including health and sickness. The cultural factors such as customs, beliefs, values and religious taboos create an environment that helps in the spread or control of certain diseases and affect health of the community. The cultural factors are deeply involved in matters of personal hygiene, nutritional and breast feeding habits, weaning and rearing practices, family planning, immunization and seeking early medical care.

**Family** : "The Family is a group defined by a sex relationship precise and enduring to provide for the procreation and upbringing of children" (MacIver). The family is a primary unit of all societies. As a cultural unit, the family reflects the culture of wider society of which it forms a part and determines the behaviour and attitudes of its members. The family is an epidemiological unit, and a unit for providing social services as well as comprehensive medical care.

**Family life cycle stages** : A family passes through the following stages in its evolution :

- Married couple - beginning of family
- Child bearing family
- Family with pre- school children
- Family with school age children
- Family with teenage children
- Middle age
- Aging family members/ retirement

#### Role of Family in Health and Disease

Family is the reproductive nucleus of society, a fundamental and social institution whose primary and essential task is to socialize the new born so that they may be placed in life as mature and independent. From the time the child is born, the course of his physical and mental development is determined by his initial experiences with the family. Every society from nomads to city- dwellers has its institution of marriage and stable family life. Through the family, human beings maintain physical continuity by reproduction, maintain social and cultural continuity through training and education.

The health of the child is bound up with the family's internal and external environment even before it is born, and the foetus in the womb can be harmed by the health, nutrition and behaviour of the mother. Undernutrition of mother can give rise to infants born prematurely and of low birth weight with attendant high risks of mortality or damage to the nervous system. Her unborn child can be damaged by familial infections like rubella and syphilis. Subsequent experiences in infancy, in the quality of feeding and method of training for instance may further influence development, physique, stature and personality.

The members of family share a pool of genes and a common environment as well as common modes of thoughts and behaviour and family material and social environment which includes housing, sanitation and diet. A damp overcrowded house encourages streptococcal infections (Rheumatic fever and nephritis). Tuberculosis flourishes in poor and over crowded homes. It is not only infective agents that pass between the members of a family; parents may transmit distorted cultural

perceptions & behavioural norms to their children; thus creating deviant behaviour and failures of adaptation among them.

Familial beliefs and attitudes go a long way in shaping the reasons for health and disease. The various causes for sickness, as understood, may be classified in two categories : Supernatural causes and Physical causes. Supernatural causes include diseases caused by (a) breach of taboos e.g. leprosy, sexually transmitted diseases; (b) wrath of god and goddesses e.g. small pox & chicken pox; (c) spirit intrusion, ghost intrusion and evil eye. The physical causes include excessive heat or cold, wrong combination of foods and impurity of blood etc. Prevention of disease and bringing improvements in the health conditions in any society is dependent upon our ability to understand and improve the social or environmental factors.

As families enter each new developmental stage, transition occurs. Events such as marriage, childbirth, releasing members as adolescents and young adults, and continuing as a couple or single person and aging years move families through new stages. Each new developmental stage requires adaptation and new responsibilities. Each new stage presents opportunities for health promotion and intervention. There are certain functions which are relevant to health behaviour, and are important from the medical sociology point of view.

- **Upbringing of children** : One of the important functions of the family with which medical and health workers are concerned, is the physical care of the dependent young in order that they may survive to adulthood and perpetuate the family. It is important to note that child care (e.g. feeding, nutrition, hygiene, sleep, clothing, discipline, habit training) are passed on from one generation to another. The ideas people have about nutrition exercise; sleep and clothing have a large social component which varies from society to society.
- **Socialization in the family** : By socializing is meant teaching the values of society and transmitting information, culture, beliefs, general codes of conduct, by example and precept, in order to make them fit for membership in the wider society of the family is a part. The family plays the most dominant role in the individual's socialization. The child finds much to learn in the behaviour of his family members, parents, relatives and friends. He imitates them in their mannerisms, behaviour etc. He tries to avoid such activities which are considered bad in the family. It is the family environment which forms his good habits. It is in the family that the child acquires such important qualities as sincerity, sympathy, self submission and realizing responsibilities. The child's first school is his home and family. It is the family which imparts practical education to children concerning the customs in society, preservation of health, love, sympathy, cooperation etc. Learning about health promotion and disease prevention begins at birth, with the family providing the environment for incorporating health in the value system of its members.
- **Influence of family on personality** : The environment of home has a comprehensive influence on the development of personality. In the family the relation of the child with the parents is the most intimate. The cultural development of the child is very much influenced by the behaviour of

the parents. The capacity of an individual to withstand stress and strain and the way in which he interacts with other people is to a large extent determined by his early experience on the family. The family acts as a placenta excluding various influences, modifying others and pass through it and contributes some of its own in laying foundation of physical, mental and social health of the child.

- **Care during sickness** : The family is expected to provide care during sickness and injury of adults and dependents from the public health point of view. Care of women during pregnancy and childbirth is an important function of the family. The joint family provides support, security and encouragement to the aged and handicapped.
- **Family as strength in crisis** : The family is understood as shock absorber. The family is an important source of support. During times of illness and crisis the family is there for the individual. The family provides an opportunity, both for adults and children, for release of tension so that the individual can attain mental equilibrium and strive to maintain a stable relationship with other people. The family has an important function in stabilization of the personality of both adults and children, and in meeting their emotional needs.
- **Problems in families** : The factors in most problem families are usually those of personality and of relationship, backwardness, poverty, illness, mental and emotional instability character defects and marital disharmony. These families are recognized as problems in social pathology. There is a need to render useful service in rehabilitating such families in a community.

The family therefore plays an important part both in health and disease - in prevention and treatment of individual illness, in the care of children and dependent adults, and in the stabilization of the personality of both adults and children.

**Crowd** : In common usage any large number of people gathered in one place is called a crowd. A crowd is potential medium for arousing emotion and for encouraging its expression. Large gathering people provide congenial conditions for emotional contagion. Simulation and suggestions are heightened. The presence of others gives a sense of security and approval and crowds convey a feeling of anonymity. By their very nature casual crowds and mobs are not part of organised system of social relations.

**Mob** : The term refers to one crowd that is fairly unified and single minded in its aggressive intent. Mob action is not usually destructive but tends to be focused on some one target or identity. Mob activity is the most goal oriented and the most dependent upon leadership for its direction

**Sick role** : 'Being Sick ' is not simply a state of fact or condition, it is a specifically patterned social role. To be ill is more than a medical condition. The patient has a customary part to play in relation to his doctor and to his family members of his society & in turn they expect him to behave in certain prescribed ways.

#### **Rights**

- The Sick person temporarily is exempt from normal social roles. The more severe the sickness, the greater the exemption.



- The sick person generally is not held responsible for his condition. Illness considered beyond individuals control therefore not simply curable by willpower.
- The sick person has a right to be taken care of.

### **Duties / obligations**

The sick person has an obligation to try to get well. In this context exemption from normal responsibilities is temporary and conditional upon wanting and trying to get better.

The sick person has an obligation to seek technically competent help from a suitably qualified professional and to cooperate in trying to recover.

**Social Pathology** : Social pathology is the systematic study of human disease in relation to social conditions and disease process outside the human body. The cause is to be found in the society. These include Social Problems ( namely, poverty and destitution, illiteracy and ignorance, migration, lower status of women,, child neglect and child abuse, child labour, drug abuse, juvenile delinquency); social conditions (as housing, environmental sanitation, crime and corruption, stress, suicide) and social circumstances (Viz., stigma, social isolation, vulnerable populations). The causes of social problems, conditions which affect the health of the people are to be understood and actions are to be taken to prevent such problems through health education and rehabilitation.

**Social Diagnosis** : This is made by socio- medical surveys and by study of domestic and social conditions of individuals.

**Social Therapy** : Social therapy offers holistic development centered therapeutic and support services. The approach addresses and supports the total social, emotional and educational needs of young and the entire family. Clinical treatment of any disease with drug should be supplemented with social therapy as far as possible. The Social security measures link between hospital and community, health education, legislation serve as supportive measures.

**Knowledge** : Education is a process of learning undergone by individuals for gaining knowledge, developing attitudes and acquiring skills. Knowledge is the basis of health education where a person gets of information by many modes which become his knowledge. Some apply the term knowledge to what are held to be certainties. Knowledge is intellectual and passive. Awareness can be created through imparting knowledge on a particular topic. e.g. receiving information about harmful effects of smoking.

**Attitudes** : Attitudes are mental habits acquired from social experiences that predispose us to react to specific objects, persons or situations in a definite way. They are the crystallized habits of thoughts that we develop relative to social situations and that set us to respond in a certain manner. An attitude is an enduring system that includes a cognitive component, an emotional (feeling) component and an action tendency. They are manifested in conscious experience, verbal reports, gross behaviour and physiological symptoms. The people are motivated to change attitudes to adopt new health behaviour. e.g. the individuals are motivated to stop smoking through various methods of health education and individuals are ready to change behaviour.

**Practices** : Practices are application to particular and personal situation. Practices are guided by principles under the light of intellect. The individuals modify their behaviour and maintain the change for the rest of their life. e.g. the individual stops smoking after changing attitude.

**Community's social support systems** : In medical practice the ability of a family to provide social support and material aid to dependent members is obvious importance. When patients who are disabled by sickness are reintroduced to normal social life, for example their family relationships and attitudes help to determine the outcome. Support comprises a network of family, friends, co-workers and professionals.

Social assistance implies provision of relief to individuals at critical times without having received any contribution from them. Social assistance is a non-contributory benefit extended to vulnerable groups including women, children and the aged. The community's participation in health programmes and programmes which are developed locally is to be found through situational analysis. The programmes such as aid to families with dependent children, medical aid, family counseling services, crisis support (food, shelter, clothing, fuel), referrals to appropriate medical services, drug de-addiction services, treatment services for alcoholics, delinquency prevention, services for the retarded and emotionally disturbed, income generation, vocational training services are provided by the community through appropriate groups, organizations and agencies. The philosophy behind tertiary prevention of chronic diseases is that it is often possible to live with and die with disease rather than dying from the disease. It is possible to prolong time period of optimal physical functioning and social activity by providing social support and self management services.

**Social Environment** : The social environment includes all those things which arise out of social relationships such as customs, traditions, institutions social conduct, rituals, diet, way of life and economic status. Health is profoundly influenced by the social environment which acts in many ways to shape the contours of disease, in populations as well as individuals. For promotion and protection of health and prevention and control of disease, social environment should be free from harmful agents. Important measures for providing healthy social environment are :

- Social security against fear and want (ESI scheme, old age pension, life insurance, provident fund and health and medical facilities).
- Fair distribution of food and other amenities of life such as housing
- Facilities for exercise and leisure
- Facilities for education for all
- Propagation of healthy customs, freedom of expression and thought
- Protection of property, life and honour
- Safe work place which involves establishing a stimulating work environment and making sure that the work place creates social contacts which do not interrupt the family networks.

**Non-Governmental Organizations (NGOs), Voluntary Organizations :** NGOs form a bridge between the government and community and provide platform for people participation. NGOs are many and diverse. Their scale may be large, medium, and small. Their support may come from external sources, from their own fund raising or from Government. Their principle activity may be direct service to those in need in the community, health education or research. Voluntary organizations could be defined as those organizations which are non- governmental and non profit making in character and not fully funded whether directly or indirectly only by government. Most voluntary organizations have four primary purposes (i) raise money to fund research and programmes (ii) provide education to both professional and the public (iii) provide services to individuals and families affected by the disease and health problem (iv) to advocate for beneficial policies, laws and regulations. (e.g. VHAI, Indian Red Cross Society, Hind Kusht Nivaran sangh, Tuberculosis Association of India etc. )

**Social Security :** Social security means public programmes designed to protect individuals and their families from income losses due to unemployment, old age, sickness or death and to improve their welfare through public services (e.g. medical care) and economic assistance. The term may include social insurance programmes, health and welfare services and various income maintenance programmes.

**Social class and Socio-Economic Status :** Socio-economic standard of people is conventionally expressed in terms of various social classes in which people are distributed which are referred to as social stratification. Social stratification is a horizontal division of society in to several socio-economic layers : each layer or social class has a comparable standard of living, status and life style. Social class is determined on the basis of three parameters of development, namely education, occupation and income. Education determines the knowledge, attitude, and value system of individuals and their socio-economic growth potential. Occupation determines the income generating capacity of individuals and their status. Income determines the purchasing power of individuals and their socio-economic status. On the basis of these parameters populations are divided in to social classes - upper, upper middle, middle, upper lower and lower. These social class gradients have helped to provide a deeper understanding of clinical phenomena. The poor had a higher incidence of some diseases, the rich of others. Health practices too, like the use of health services, welfare and maternity clinics, and methods of infant feeding were found to

be correlated with social class.

**Kuppuswamy's scale :** The socio-economic status scale (urban) developed by Kuppuswamy attempts to measure the socio-economic class of family in urban community. It is based on three variables - education, occupation, and income. A weightage is assigned to each variable according to seven point predefined scale. The total of three weightages gives the socio-economic status score which is graded to indicate the five classes, as per details in Table - 1. To get current income group, a conversion factor based on current All India Consumer Price Index (AICPI) is used, which is given later.

For income, the conversion factor can be obtained by dividing AICPI by 60.04. The income group in the Kuppuswamy's scale are multiplied with the conversion factor to get the appropriate income group (Indian Journal of Pediatrics, volume 70, March 2003). Now, since AICPI in June 2008 was approximately 650, hence  $650 \div 60.04 = 10.83$ . Thus all the income groups in the Kuppuswamy scale in the above table are multiplied with the conversion factor to get the appropriate income group. Thus, the conversion factor 10.83 is multiplied by Rs. 2000 which comes to Rs 21,660/- and rest income groups would be as given in Table - 2.

<b>Table - 2 : Recalculated family income groups of the Kuppuswamy's scale as on June 2008</b>		
<b>Income Original</b>	<b>Modified by using conversion factor (multiplied by 10.83)</b>	<b>Score</b>
> 2000	>21660	12
1000-1999	10830-21659	10
750-999	8122-10829	6
500-749	5415-8121	4
300-499	3249-5414	3
101-299	1093-3248	2
<100	<1093	1

The Total score in Kuppuswamy's classification is calculated as the sum total of the three scores, i.e., Education (A) + Occupation (B) + Income (C) Depending on the total score so computed, the five socio-economic classes are as given in Table-3.

**Table 1 : Kuppuswamy's Socio - Economic Status Scale (Urban)**

<b>Education of head of family</b>	<b>Score</b>	<b>Occupation</b>	<b>Score</b>	<b>Family Income per month</b>	<b>Score</b>
Professional Degree	7	Professional	10	Rs.2000and above	12
Graduate	6	Semi-profession	6	Rs1000-1999	10
Intermediate/Diploma	5	Clerical/shop/farm	5	Rs 750-999	6
High school	4	Skilled worker	4	Rs 500-749	4
Middle school	3	Semiskilled	3	Rs 300-499	3
Primary school	2	Unskilled	2	Rs 101-299	2
Illiterate	1	Unemployed	1	Rs <100	1

Table - 3 : Socio-Economic Class		
Total Score	Class	Description
26 - 29	I	Upper class
16 - 25	II	Upper middle
11 - 15	III	Lower middle
5 - 10	IV	Upper lower
Below 5	V	Lower

**Prasad's Scale** : Dr. B G Prasad's social classification was developed in 1961 and is based on per capita per month income. There are five classes, as follows Upper class (per capita per month income Rs 100 and above); Upper middle (50-99); Lower middle (30-49); Upper lower (15- 29); and Lower (below 15). The income group can be recalculated by multiplying the above mentioned income as mentioned in Prasad's classification with P Kumar's conversion factor i.e.

Conversion factor = (Value of CPI X 4.93) ÷ 100

For example, the AICPI for June 2008 was 650. Thus the conversion factor will be

$(4.93 \times 650) \div 100 = 32.04$ , or roughly, 32. Thus the ranges of per capita per month income of this classification for 2008 will be >Rs 3200; 1600 - 3199; 960 - 1599; 480 - 959; and, < 480.

**Pareek's Scale** : The Socio-Economic Scale (rural) developed by Pareek attempts to measure socio-economic status of a rural family. It is based on the nine items as follows : Caste; Occupation of head of family; Education; Levels of social participation; Land holding; Farm power (prestige animals); Housing; Material possessions; and, Family type. The combined score for the nine items is graded to indicate socio-economic class categories.

## Summary

**Sociology** deals with the study of society. Society is a group of individuals who have organized themselves and follow a given way of life. Man is a subunit of a small group; the family, while the family is the basic unit of society. Man's behaviour is affected not only by his physical and biological environment but also, to a larger extent by social environments represented by his family. A *community* can be defined as a group of people who have some common characteristics and are bound together by "WE" feeling. This sense of 'we' feeling (i.e., shared togetherness) may be due to a place where they all stay or due to some other common interest. Accordingly, communities can be either "structural" or else, "functional" communities. Community affiliations often provide a source of support for individuals and groups. *Culture* is defined as learned behaviour which has been socially acquired. The cultural factors such as customs, beliefs, values and religious taboos create an environment that helps in the spread or control of certain diseases and affect health of the community. The *Family* is a group defined by a sex relationship precise and enduring to provide for the procreation and upbringing of children. The family is a cultural unit, an epidemiological unit, and a unit for providing social

services as well as comprehensive medical care. The Family has an important role to play in Health and Disease. The health of the child is bound up with the family's internal and external environment even before it is born. The members of family share a pool of genes and a common environment as well as common modes of thoughts and behaviour and family material and social environment which includes housing, sanitation and diet. For health promotion and intervention, every family has certain important functions like Upbringing of children; Socialization in the family; laying foundation of physical, mental and social health of the child; Care during sickness especially pregnant women, children, aged and handicapped; providing support in crisis and problems.

Any large number of people gathered in one place is called a *crowd*. A crowd is potential medium for arousing emotion and for encouraging its expression. The term *mob* refers to one crowd that is fairly unified and single minded in its aggressive intent. Mob action is not usually destructive but tends to be focused on some one target or identity. *Social Pathology* is the systematic study of human disease in relation to social conditions and disease process outside the human body. *Social Diagnosis* is made by socio-medical surveys and by study of domestic and social conditions of individuals. *Social Therapy* offers holistic development-centered therapeutic and support services. The approach addresses and supports the total social, emotional and educational needs of young and the entire family.

Education is a process of learning undergone by individuals for gaining *knowledge*, developing attitudes and acquiring skills. *Attitudes* are mental habits acquired from social experiences that predispose us to react to specific objects, persons or situations in a definite way. *Practices* are application to particular and personal situation. *Community's Social Support Systems* comprise a network of family, friends, co-workers and professionals. *Social Assistance* implies provision of relief to individuals at critical times without having received any contribution from them. *Social Environment* includes all those things which arise out of social relationships such as customs, traditions, institutions, social conduct, rituals, diet, way of life and economic status. Health is profoundly influenced by the social environment. Important measures for providing healthy social environment are : Social Security against fear and want, Good Housing with all important facilities, Protection of property, life and honour and Safe work place. *Social Security* : Social security means public programmes designed to protect individuals and their families from income losses due to unemployment, old age, sickness or death. Social stratification is a horizontal division of society in to several socio-economic layers : Each layer or social class has a comparable standard of living, status and life style. Social class is determined on the basis of various scales like Kuppaswamy's scale for Urban and Prasad's scale and Pareek's scale for Rural.

## Study Exercises

**Long Questions** : (1) Describe the role of Family in Health and Disease. (2) Describe the role of Cultural factors in Health and Disease. (3) What is Social environment? How does it affect the health and disease? Enumerate important measures for providing healthy social environment.

**Short Notes :** (1) Social pathology (2) Social Security measures (3) Kuppuswamy's scale.

**MCQs :**

1. Kuppuswamy's scale is based on the following variables except (a) Education (b) Occupation (c) Income (d) Housing
2. According to Kuppuswamy's scale, total score for upper middle class is (a) 11-15 (b) 16-25 (c) 26-29 (d) 29-31
3. According to Kuppuswamy's scale, total score for upper

lower class is (a) 11-15 (b) 16-25 (c) 26-29 (d) 5-10

4. The Socio-Economic Scale developed for rural setup is (a) Kuppuswamy (b) Pareek (c) Prasad (d) None of the above
5. The following are Social security measures against fear and want except (a) ESI scheme (b) Old age pension (c) Housing (d) Life insurance

**Answers :** (1) d; (2) b; (3) d; (4) b; (5) c.

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## Family Health History & Individual Medico - Social History - Taking

*RajVir Bhalwar & SSL Parashar*

It is abundantly clear by now that every disease has a tremendous social component. The various components of sociology, as described in previous chapter, decide whether a given human being will be exposed to the disease process or not; if exposed, whether disease process will perpetuate or not; and finally, what will be the outcome of the disease process. It is therefore extremely important that every Doctor should work up the psycho-social and behavioural components of a patient and not simply the clinical findings / laboratory investigative results, to effectively treat the patient and to prevent recurrence of the disease. For example, going simply by the clinical picture, we may treat a child with dehydration, with i.v. fluids and supportive therapy, and discharge her after a few days as "cured". However, if we did not work up the details of environmental sanitation and water supply at the child's house, the knowledge attitudes and health related practices of the mother, the family size, and so on, for certain the child will keep coming to us. Thus, for having a totalistic or holistic overview of our patient and to really treat the disease effectively, "from the root causes", we must take a proper medico-social history, work out the various sociological parameters and treat, not only the clinical disease, but also the social causes.

Medico-social history taking is, therefore, also an essential requirement at the undergraduate and postgraduate level of medical curriculum, with a view to prepare the general and specialist Doctors to function effectively as Community physicians.

In addition to recording a detailed medico-social history from an individual patient, it is also very important for the public health manager to consider the "family" as a unit of action for her various health care activities. In the previous chapter, we have already emphasized regarding the tremendous impact

that the family has on the health and disease of individual members of the family.

In fact, it would be highly desirable that every Public Health Programme Manager and Medical Officers in-charge of a Primary Health Centre (PHC) / Community Health Centre (CHC) should develop "Family Health Folders" for each and every family in his / her area of health care, on the same lines as Departments of Community Medicine in Medical Colleges; maintain and regularly update such folders in their respective Rural Health Training Centres (RHTCs) and Urban Health Centres (UHCs). The contents of these family folders should be regularly updated by regular visits to the households by medical / paramedical staff, preferably once in six months and definitely once in a year. It would be a further good work if the contents of these folders be entered into a computer database, so as to help in quick retrieval and analysis of data, which would greatly assist in planning and evaluation of public health programmes.

In the present chapter, we shall be dealing with the details of firstly, the 'family health folder' and secondly, regarding medico-social history taking and how to draw conclusions from such history.

## The Family Health Folder & Family Health Records

As said above, it should be an endeavour of all health care providers to ensure that they have a detailed family health folder for each and every family in their area of health care jurisdiction, and these folders should be updated very regularly.

**General description :** The family health folder should be generally 12 inches X 10 inches and preferably having a hard cover to ensure durability. It should have a system so that various cards / papers can be filed in the folder. Having a "multiple leaflet" folder may be even better as it will assist in filing various records separately, for various members of the family, within the same folder.

The cover of the folder should be printed with the name of the PHC / CHC or any other health care providing unit who is responsible for health care of that family, and the address



and telephone number of the health care unit. In addition, the following details should be printed on the cover :

- The “Family Registration Number”. This is a unique number which is allocated to a particular family and acts as a unique identifier for the family, especially when computer based records have been made. The number is unique in that no two families should have the same number. The number may be allocated based on some registration given by the local self governmental body as panchayat, or may be developed by the health care providing unit. What is more important is that whatever system has been developed should be enforced, ultimately taking care that every family under health care has a registration number which is unique for that family. Secondly, every family head should be communicated about the number (preferably, given a laminated card having the number printed on it) and they should be advised to bring the laminated card whenever they come to the health centre.
- The name, father's / husband's name and date of birth of the head of the family.
- The detailed address of the household, including the post office and police station.
- Telephone number or any other contact number.
- The permanent address in case the family is of a “migratory” nature or is not a permanent native of that place.
- The date on which the folder was opened.
- The date on which the folder was last updated as a part of the regular survey for updating the family folders.
- The date on which the folder was updated, since some individual member of the family came in contact with the health care system (e.g., one of the ladies may be seen in an ante-natal clinic).

The inside surfaces of the folder may be provided with pockets made of thick plastic or strong cloth, for keeping important slips.

**Confidentiality of Information** : It should be ensured by the health care providers that all information recorded in the folder should be kept strictly confidential, and used for sole purpose of health / medical care, as per the laid down / acceptable codes of medical ethics.

**Summary-Sheet** : The inside of the front cover should have a printed table, in which the information should be filled up in pencil (to enable making changes); alternatively, the first sheet in the folder should have the information as given in Table-1.

In column (7) of Table - 1, a person who comes to stay temporarily

(as one of the sons who may be working in a town and coming to stay only during festivals) should be indicated accordingly. In column (8), if the person is known to be having any disease, the details should be entered; this should also include entries regarding current pregnancy. The remarks column should include any relevant which is considered to be important for the health care provider to know, at the first glance.

### Sheet for Socio-Demographic Details

The next sheet in the family health folder should be for the socio-demographic details of the family, recording the following details :

- Total number of members in the family
- Distribution according to age and sex

Age groups	Males	Females	Total
Upto 1 year			
1 to 5 years			
6 to 14 years			
15 - 45 years			
45 - 64 years			
> = 65 years			

- Total family income per month (all sources included) Rs.
- Per capita per month family income & Social Class
- Distribution according to Educational level

Educational level	Males	Females	Total
Graduate & above			
Matriculate but not graduate			
Educated more than 5th standard but not literate			
Educated upto 5th standard			
Illiterate			

**Vital Statistics Record Sheet** : Information regarding births, deaths, marriages, divorces, in-migration and emigration should be recorded in this sheet, starting from the day the family folder is commissioned for the particular family, recording the date and details of each such event.

Table - 1

Sl. No.	Name	Date Of Birth	Age	Sex	Relation With Head	Permanent Or Temporary Resident	Current Health Status	Immunisation status	Occupation	Contraceptive use	Remarks
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)

**Sheet for Record of Housing and Environmental Sanitation:** This sheet should record the following information

- General description of the area, approach, access roads
- Evidence of water logging and potential mosquito / housefly breeding points
- Type of house, condition of roof, floor and walls
- Total floor area
- Total living rooms
- Total floor area per person and total space (in cubic feet) per person
- Any evidence of overcrowding
- Area of Doors and Windows
- Ventilation
- Availability of electricity
- Details of water supply (source, safety and potability, quantity, storage)
- Condition of kitchen, eating place and food sanitation practices
- Details of disposal of night soil
- Details of disposal of solid wastes
- Details of disposal of waste water and storm water

**Individual Health Record Sheets :** One health record sheet should be prepared for each individual. It should contain the details of the general health check up as well as the records of results of investigations and hospitalization, if any. The same sheet should continue to have entries of treatment given, as and when the individual reports sick to the health care facility. The special health cards (as ante-natal card, under-fives health card and child health record card) as applicable should also be filed alongwith the general health record card for that individual.

**Special Health Record Sheets :** These would include the ante-natal and post-natal health care card, the under-fives health card and the school-age child health record card. These should be prepared for each individual member of the family, as applicable, as per details given in the relevant chapters in the section on maternal and child health care. These special health record cards should be filed, in the family folder, alongwith the general health record sheet for that individual.

**Sheets for Record of Special Studies / Surveys :** There should be a separate sheet for recording the findings of special studies in respect of the family. For example, if a nutritional survey or a geriatric age group survey and so on have been conducted in that area, the findings of these studies / surveys in respect of the concerned family should be recorded on this sheet.

## Medico-Social History Taking & Family Case Studies

As said earlier, every medical, nursing and paramedical person should view a given disease in totality, in context of the various socio-cultural, psycho-emotive and economic factors which initiate and perpetuate the disease process, and not simply confine themselves to only the medical aspects of the disease. It is for this reason that undergraduate medical and nursing students as well as post-graduate students in the specialty of Preventive & Social Medicine (Community Medicine; Public health) are required to be trained and examined in the various aspects of medico-social case taking and family case studies,

as a part of the University curriculum. Similarly, considering the over-riding importance of the role of family in health and disease, a family is allotted as a project and often during the examination, to be studied and presented as a “unit”, rather than presenting an individual case with a disease.

The details of family-case taking have been already dealt with in detail, earlier in this chapter, while discussing the family health folders. The details of medico-social case work up are being discussed herewith in the succeeding paragraphs.

**Approach to the patient :** Introduce yourself with a friendly greeting, giving your name and status. Explain the purpose of your visit, ask for and remember the patient's name and request permission to interview and examine the patient. Some patients rapidly tire of being questioned or examined, and others may be depressed because they are ill or apprehensive. If there are difficulties in establishing a rapport, try to determine the reason; if in doubt, consult the medico-social worker or nursing staff. Show tolerance, particularly with the elderly and the challenged. Seek first to understand and not judge the patient so that you don't react to patients with criticism, anger or dismissal. Some additional tips for effective medico-social case taking are :

- Maintain good eye contact.
- Listen attentively.
- Facilitate verbally and non-verbally.
- Touch patients appropriately.
- Discuss patients' personal concerns.
- Give the patient your undivided attention
- Keep your notes-taking to a minimum when the patient is talking
- Use language which the patient can understand
- Let patients tell their own story in their own way
- Use open questions initially and specific (closed) questions later
- Clarify the meaning of any lay terms which patients use
- Remember that the history includes events up to the day of interview
- Summarize (reflect back) the story for the patient to check
- Utilize all available sources of information

**The fundamental principles underlying medico-social case work-up :** The basic principle which must be kept in mind while undertaking a medico-social work-up is that while the patient is the core issue, his disease is actually a result of complex psycho social interactions between the patient, his / her family members, the environment at the workplace (including school), the immediate community members comprising of friends and close associates, the community at large within which the patient lives, and the larger society which consists of the governmental and non-governmental systems. A systematic assessment of all these factors is therefore necessary to be able to reach the root of the problem and to effectively plan a holistic therapy, taking care of not only the biological cause of the disease but also the wider social reasons that lead to the causation and perpetuation of the disease. The factors to be considered at various levels are :

**1. Factors Within the Individual :** The following variables should be recorded in detail :

- Age

- Education
- Occupation
- Level of protection against common infectious diseases, by way of immunization or previous infection
- Lifestyle : details of habitual physical exercise, diet, tobacco, alcohol and substance abuse, sexual promiscuity
- Knowledge, Attitudes & Practices (KAP) as regards common diseases and their prevention
- Psycho-Emotive state : whether cheerful and optimistic or anxious / depressed or concerned.
- Separation from family members / near & dear ones.
- Attitudes towards
  - Personal protection, as use of helmets, use of mosquito-nets, etc.
  - Personal hygiene, as regular bathing, hand washing, oral care, etc.
  - Health Care System, whether positive and trusts the health care system or unhappy / skeptical.
  - Attitudes as regards the disease from which the patient is suffering, and his / her concerns as regards it's perceived future course / management / rehabilitation

**2. Factors in the family :** These will include three broad categories of factors, viz., Social Factors, Physical Factors And Psycho-Emotive Factors.

**(a) Social Factors in the Family**

- Type : Whether joint, three generation or nuclear
- Organisation & Composition : Total number of members, head of the family, description of family members by name, age, sex, and position relative to the head.
- Religion and caste
- Education : general level of education; attitudes towards formal education; proportion of members who are professionally qualified / having degree / educated / illiterate
- Occupational patterns in the family
- Income : Total family income; income of the index case; Per capita per month income
- Socio Economic Status according to acceptable scales as Kuppaswamy or Prasad scale.
- Knowledge, Attitudes & Practices in the family, in general towards healthy lifestyle, personal protection and prevention of common diseases.
- Health Care services for the family. These should be assessed in terms of :
  - Availability
  - Accessibility
  - Affordability
  - Quality
  - Utilisation
- Social Aberrations if any in the family, as promiscuity, alcoholism, delinquency

**(b) Physical Factors in the Family :** These will include -

- Housing : General description, type of construction, area & space, ventilation, overcrowding, lighting, other comforts.
- Water Supply : Source, hygienicity, adequacy, storage
- Disposal of night soil, solid wastes, animal wastes, waste

water.

- Food hygiene : Methods of cooking, storage of raw and cooked food, food hygienic practices.
- Nutrition : Assessment of intake of overall calories and major macro / micronutrients; deficiency diseases; relative distribution of food among various members; percentage of monthly income spent on food.
- Exposure to and protection from insect vectors of diseases.

**(c) Psycho-Emotive Factors in the Family :** These include

- Level of Interactions / Bondages
  - Between family members
  - Of family members with the Index Case
- Family Support System : In terms of financial support, physical support (as readiness to physically assist the patient in activities of daily living) and emotional support; and, readiness of family members to provide "support".
- Understanding, by the family members, of the disease and it's determinant psycho-social problems that the patient is facing

**3. Factors in the Workplace :** (Note that for children, school is to be considered as workplace)

- General description of the workplace or school
- Attitude & Support (Emotional, Physical, Financial) on part of
  - Employers / Superiors / Teachers
  - Colleagues / Classmates
  - Subordinates / ancillary staff in school
- Availability of facilities, in school / workplace, to cater to special needs of the patient

**4. Factors in the Immediate Community :** (Immediate community consists of the Village / Mohalla in which the patient is living).

- General description (income levels and standards of living in general, major occupations, general types of housing, educational levels, social aberrations as alcoholism, delinquency, etc.)
- Community Organisation, strength of "we" feeling, cohesiveness between the families in the community.
- Interactions, of various community members, with the Index Case and his / her family members
- General attitude of community towards disease prevention & health care
- Availability of Physical, Financial & Emotional Support Systems within the community.
- Health care facilities available
- Availability of School / Special School catering to the special needs of the index case.
- Availability of NGOs / Voluntary Bodies and description of their capabilities.
- Availability of organised public health & social services as central water supply and it's purification, disposal of wastes, transportation and communications.
- Political will of the community as strength of its representation in elected bodies
- Identification of peers & influential leaders and their capabilities.

**5. Factors in the Community at Large :** This includes the larger social environment as the District / State where the patient is living.

- General Attitude
  - Towards Health maintenance, Disease Prevention & Rehabilitation
  - Towards the disease in question
- Availability of treatment facilities
- Availability of Rehabilitation facilities
- Statutory and Administrative provisions to protect / facilitate the index case.
- Availability of VHAs / NGOs

#### 6. Summarize The Medico-Social Findings

- What are the “*Key Psycho-Social Issues*” in the index case, his / her family, workplace, immediate community and the community at large.
- What is the “*Social Pathology*”, i.e. the major “weaknesses”; for example, in a medico-social case of an adolescent polio affected girl child, the major weaknesses and hence the social pathology operative in that case could be summed up as “Alcoholism in the family” with “Poor purchasing power” with “Adverse attitudes towards the girl child”
- What is the “*Social Diagnosis*” i.e., those adverse psycho-social effects that the social pathology (major weaknesses) would lead to; for example, in the hypothetical example of the case of polio affected girl child, “Gross Physical handicap with Poor Rehabilitation facilities with Broken family and adversely predisposed community” may be identified as the social diagnosis, which will result from the identified social pathology, and will therefore need to be “treated”, the way we treat a disease diagnosed by us.
- What are the “*Major Strengths*” in our case. This will be worked out by analyzing the support systems - Physical, Social, Vocational, Emotional and Financial, which are available within the family, workplace, and community systems, as also the strengths within the index case (as determination, residual abilities, etc.).

#### 7. Write down the Plan of Management & Social therapy

- Write down in a line each, the following, for the case being worked up :
  - The social pathology
  - The social diagnosis
- Write down your summarized analysis of the Strengths, Weaknesses, Opportunities and Threats (SWOT) in this case.
- Write down what all
  - Should be done, ideally, in this case
  - Can be done in this case (“Do-Ability” analysis), after considering the SWOT.
- Write down the overall aim and key objectives for the medical management part as well as the psycho-social management for the case.
- Now, write down a detailed plan for each of the following aspects, indicating “who will do what, how, and in what time-frame”
  - Medical management

- Prevention of Other Diseases and for leading a healthy life
- Disability Limitation
- Physical rehabilitation, eg, physical help for activities of living, for going till the health care centre, etc.
- Vocational rehabilitation - training, education, earning a livelihood, reservation in job and education, etc.
- Emotional Rehabilitation
- Social Security

### Summary

It is abundantly clear by now that every disease has a tremendous social component. Thus, for having a totalistic or holistic overview of our patient and to really treat the disease effectively, “from the root causes”, we must take a proper medico-social history, work out the various sociological parameters and treat, not only the clinical disease, but also the social causes. Medico-social history taking is an essential requirement at both under and postgraduate level but other than focusing on the individual patient, it is also very important for the public health manager to consider the “family” as a unit of action for her various health care activities.

It is highly desirable that Medical Officers in-charge of a Primary Health Centre (PHC) / Community Health Centre (CHC) should develop “Family Health Folders” for each and every family in their area of health care and these should be regularly updated. Family folder should be generally 12 inches X 10 inches, with hard cover and having “multiple leaflets” so as to record separately, for various members of the family, within the same folder. The cover of the folder should be printed with the name, health care providing unit along with the address and telephone number. In addition on the cover it should have “Family Registration Number” (unique number for each family), name and date of birth of the head of the family, detailed address of the household, telephone number, date on which folder was opened and date on which folder was last updated. On the inside of the front cover or the first sheet in the folder should have a printed Summary-Sheet which would have details of all the members of the family. Other details of the family would be recorded on Sheet for Socio-Demographic Details, Vital Statistics Record Sheet, Sheet for record of Housing and environmental sanitation, Individual Health Record Sheets, Special Health Record Sheets, Sheets for Record of Special Studies / Surveys. Finally it should be ensured by the health care providers that all information recorded in the folder should be kept strictly confidential.

All medical professionals should not simply confine themselves to only the medical aspects of the disease but view a given disease in totality. This can be achieved by training in the various aspects of medico-social case taking and family case studies. The various essential aspect of medico-social case work up are, to start with, initial approach to the patient whereby you should introduce yourself with a friendly greeting, try and remember the patient’s name and request permission to interview and examine the patient. Show tolerance, particularly with the elderly and the challenged. Seek first to understand



and not judge the patient so that you don't react to patients with criticism, anger or dismissal.

The basic principle which must be kept in mind while undertaking a medico-social work-up is that while the patient is the core issue, his disease is actually a result of complex psycho social interactions and a systematic assessment of all these factors is therefore necessary to be able to reach the root of the problem and to effectively plan a holistic therapy. For this factors need to be considered at various levels, these are Factors within the Individual which would include age, education, occupation, lifestyle including consumption of tobacco, alcohol etc, Knowledge, Attitudes & Practices (KAP) as regards common diseases, Psycho-Emotive state and attitudes towards personal protection, personal hygiene etc. Factors in the family which would involve taking detail history under following headings Social Factors in the Family, Physical Factors in the Family, Psycho-Emotive Factors in the Family. After family one would like to find out factors in the Workplace, Immediate Community and Community at Large influencing the individual and the disease. Now summarize the Medico-Social findings under the following heads Key Psycho-Social Issues, Social Pathology, Social Diagnosis, Major Strengths. Finally write down the plan of management & social therapy keeping in mind SWOT analysis (Strengths, Weaknesses, Opportunities and Threats) for this case and details indicating "who will do what, how, and in what time-frame".

## Study Exercises

**Short Notes :** (1) Enumerate broad headings under which one would do medico social case work up (2) SWOT analysis.

### MCQs & Exercises

- 1) All are true about "Family Registration Number" except : (a) This is a unique number (b) no two families would have the same number (c) may be given by the central government (d) may be developed by the health care providing unit
- 2) Following dates should be written on the cover except : (a) The date on which one of the family members were vaccinated (b) The date on which the folder was updated, since some individual member of the family came in contact with the health care system (c) The date on which the folder was last updated as a part of the regular survey (d) The date on which the folder was opened
- 3) Immunization status is recorded in : (a) Vital Statistics Record Sheet (b) Sheet for Socio-Demographic Details (c) Summary-Sheet (d) Sheet for record of Housing and environmental sanitation
- 4) Special Health Record Sheets include all except (a) Under-fives health card (b) School-age child health record card (c) Post-natal health care card (d) Ration Card
- 5) For effective medico-social case taking one should : (a) Not Maintain good eye contact (b) Touch patients appropriately

- (c) Not discuss patients' personal concerns (d) Not give patient undivided attention.
- 6) In KAP "P" stands for : (a) Prevention (b) Practice (c) Psycho-emotive state (d) Physical factor
- 7) "SWOT" analysis stand for all except : (a) Strength (b) Weakness (c) Opportunities (d) Treatment.
- 8) Health Care services for the family should be assessed in terms of all except : (a) Availability (b) Accessibility (c) Affordability (d) Accountability
- 9) Socio Economic Status according to Kuppaswamy or Prasad scale is calculated under which broad heading: (a) Social Factors in the Family (b) Physical Factors in the Family (c) Psycho-Emotive Factors in the Family (d) Factors in the workplace
- 10) Physical Factors in the Family include all except : (a) Total no. of family members (b) Housing (c) Water Supply (d) Nutrition
- 11) Family Support System includes : (a) Financial support (b) Physical support (c) Emotional support (d) All of the above
- 12) Immediate community consists of : (a) Village (b) District (c) State (d) Country
- 13) Factors in the Immediate Community include all except : (a) Community Organisation (b) Strength of "we" feeling (c) Interaction between family members (d) Cohesiveness between the families in the community
- 14) "Major strengths" of a case can be worked out by analyzing : (a) Social Diagnosis (b) Social Pathology (c) Psycho-emotive state (d) support systems
- 15) Plan of Management & Social therapy includes all except: (a) Medical management (b) Giving money (c) Disability limitation (d) Emotional support.

### Fill in the Blanks

1. Public Health manager should consider \_\_\_\_\_ as a unit.
2. Family health folder should be updated regularly by visits to household by the paramedics preferably once in \_\_\_\_\_ and definitely once in \_\_\_\_\_.
3. Family health folder should of size \_\_\_\_\_ by \_\_\_\_\_ inches.
4. Factors in the family include three broad categories of factors which are \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_.
5. KAP stands for \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_.

**Answers : MCQs :** (1) c; (2) a; (3) c; (4) d; (5) b; (6) b; (7) d; (8) d; (9) a; (10) a; (11) d; (12) a; (13) c; (14) d; (15) b.

**Fill in the Blanks :** (1) Family (2) 6months; one year (3) 12; 10 (4) Social factors, Physical factors and Psycho-Emotive factors (5) Knowledge, attitudes and practices.

## Further Suggested Reading

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SSL Parashar

Health education is the application of scientific health knowledge or translation of what is known about health into desirable individual and community health behaviour and actions. It removes ignorance and promotes intelligent understanding of individual and community health needs. It helps people to achieve health by their own actions and efforts.

In earlier times, public health dealt with the sanitation of the environment and the control of communicable diseases enforced by law, if found necessary. However stimulating and helping people to assume responsibility for themselves needs understanding people's behaviours and the factors influencing it. Health education attempts to influence the health related knowledge, attitudes and behaviours of individuals and communities. In fact, in contemporary public health practice, providing health education, with a view to achieve positive health related attitudes and behaviour form community members is the most important requirement, be it prevention and control of HIV / AIDS or lifestyle (non-communicable) diseases or prevention of infectious diseases and so on.

**Definition :** Health education is a process that informs , motivates and enables people to adopt and maintain healthy practices and lifestyles. It also advocates environmental changes as needed to facilitate this goal and conduct professional training and research to the same end. In other words, Health education may be defined as a process of bringing about change in the individual's knowledge, attitude and behaviour so as to enable him to achieve health.

Principles of Health Education :

1. *Community involvement* in planning health education is essential. Without community involvement the chances of any programme succeeding are slim.
2. The promotion of *self esteem* should be an integral component of all health education programmes.
3. *Voluntarism* is ethical principle on which all health education programme should be built without it health education programmes become propaganda. Health education should not seek to coerce but should rather aim to facilitate informed choice.
4. Health education should respect *cultural norms* and take account of the economic and environmental constraints face by people. It should seek positively to enhance respect for all.
5. Good *human relations* are of utmost importance in learning.
6. *Evaluation* needs to be an integral part of health education.
7. There should be a responsibility for the *accuracy* of information and the *appropriateness* of methods used.
8. Every health campaign needs *reinforcement*. Repetition of messages at intervals is useful.

## Information Education Communication (IEC)

IEC is a broad term comprising a range of approaches and activities. Visible component of IEC is frequently the material produced and used. Effective IEC makes use of a full range of approaches and activities. IEC activities are grounded in the concepts of primary health care, concerned with individual behaviour change and changes in social or community norms. IEC can be defined as an approach which attempts to change or reinforce a set of behaviour in a target audience regarding a specific problem in a predefined period of time. It is multidisciplinary and client centered in its approach drawing from the field of diffusion theory, social marketing, behaviour analysis and anthropology. Embodied in IEC is the process of learning that empowers people to make decisions, modify behaviours and change social conditions. Activities are developed based upon needs assessments, sound educational principles, and periodic evaluation using a clear set of goals and objectives.

### Communication

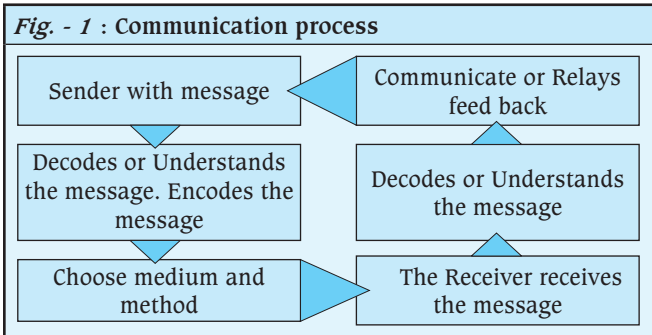
A good working definition for effective communication is to share meaning and understanding between the person sending the message and the person receiving the message. The key element is "understanding."

**Verbal & Non-verbal Communications :** In verbal communication, the tone of voice can communicate feelings and emotions that are as significant as the words being spoken. Accordingly, it is important to choose words that do not offend in any way and that are easily understood. One should avoid using trigger words, jargon, medical or other sophisticated terms. The use of particular languages may be important in reaching all sections of a community. In non-verbal communication, body position, gesture and facial expression, often referred to as body language, can communicate as much as words. It is often through such body language that we express our attitude towards an issue, a person or a person's behaviour. Service provider must become skilled in interpreting the body language of users as this may assist them understanding users' needs and concerns more fully. Service providers must also be aware of their body language and signals they may be unknowingly sending to users (e.g. movements or expressions that indicate fatigue, boredom, fear, frustration, indecision) (women may speak fewer languages than men, for example).

### Communication Process

In health communication we communicate for a special purpose to promote improvements in health behaviour through the modification of the human, social and environmental factors that influence behaviours. It is necessary to understand how communication works. The various components involved in the process of communication are depicted in Fig. - 1.

**Components of the Communication process :** It is apparent that several elements are involved in the process of communication. It will also be appreciated that communication is two way process. This implies that just as the sender (source) is communicating with the receiver; so is also the receiver communicating with the sender. The components are :



**The Sender :** Sender is the source of Communication. Sending the message to the receiver will depend on his personality, mannerism, conviction conduct etc. The following aspects need to be particularly considered with regards to the sender :

- His own competence and expertise in the subject.
- His own convictions about what he speaks.
- His own mannerism, which include non-verbal communication skills.

**The Receiver :** Also called the audiences who are receiving the message sent by sender.

**The Message :** This refers to the information which desires to communicate and must possess the following attributes :

- Message should be precise and to the point
- The ambiguity in the message may create more harms than good.
- The information should vary from person to person or from group to group depending upon their background.
- The message must necessarily contain clear concrete suggestions for action in day to day life of the receiver.

**The Medium (Channel) :** The communication channel through which the message moves from the sender to receiver is the medium. These include the various methods (as lecture or exhibition) and the "aids" (as slides, slide projector) which are utilized to communicate the message.

**Encoding :** This process includes the language expression, gestures and actions utilized for the purpose of making the information intelligible to the receiver. Obviously the receiver must be familiar with the code.

**Decoding :** The process by which the receiver assigns meaning to the symbols transmitted by the sender. In other words, the process by which the receiver understands or interprets the message is called decoding.

**Feed back :** Feedback is the mirror of communication. Feedback is the receiver sending back the message to the sender, the message as perceived. Without feedback communication is one-way. The part of the receiver's response that the receiver communicates back to the sender.

**Propaganda and Advocacy :** Propaganda is merely a publicity campaign aimed presenting a particular thing or concept in a favourable light in such a way that public may accept it without thinking. It is a deliberate attempt planned with a view to altering and controlling ideas and values along predetermines lines. The widely employed techniques are an appeal to emotions, feelings and sentiments. It prevents or discourages thinking by readymade slogans. The knowledge is

spoon-fed and passively acquired. As a mass-communication activity propaganda tends to have short-run situationally-defined aims with an appeal to diverse population on the basis of immediate interest, fears or desires. The objective is to not so much influence the individual deeply as to win his support for some immediate issue.

The aim of ADVOCACY is to place health problems issues on the political agenda and effectively reach the influential group of policy makers, elected representative, professionals and other interest group to formulate and implement policies to create pressure groups and supportive systems in order to respond appropriately to the health problems. It helps in identifying potential allies and building alliances and relevant policy and decision making channels. The information concerning position on the issue is collected and provided. A common understanding among stakeholders concerning issue is created through advocacy and negotiating action on the basis of common understanding is taken. Through advocacy reasoning, influencing, lobbying, pushing and persuading decision makers and other stake holders. The directions of advocacy are; (a) Advocacy for policy design (b) Advocacy for decision making at various levels (c) Advocacy for implementation .There are two types of advocacy : Proactive and Reactive advocacy. Proactive advocacy is bringing a particular issue in to public focus and providing a definite shape for the audience that is sought to be influenced and reactive advocacy entails addressing particular situation or problem once it has already surfaced in the open. It involves addressing attitudes and opinions after they have been formed in the recent past.

### Barriers in Communication

Unplanned distortion during the communication resulting in the receiver obtaining a different message than that sent by the sender is referred to as barriers in communication (also called as "Noise" or "distortions" in communication). These can be :

**Physiological :** Difficulties in hearing, expression.

**Psychological :** Emotional disturbances.

**Environmental :** Noise, invisibility, congestion in the classroom, etc.

**Cultural :** Level of knowledge, understanding and receiver's beliefs, etc.

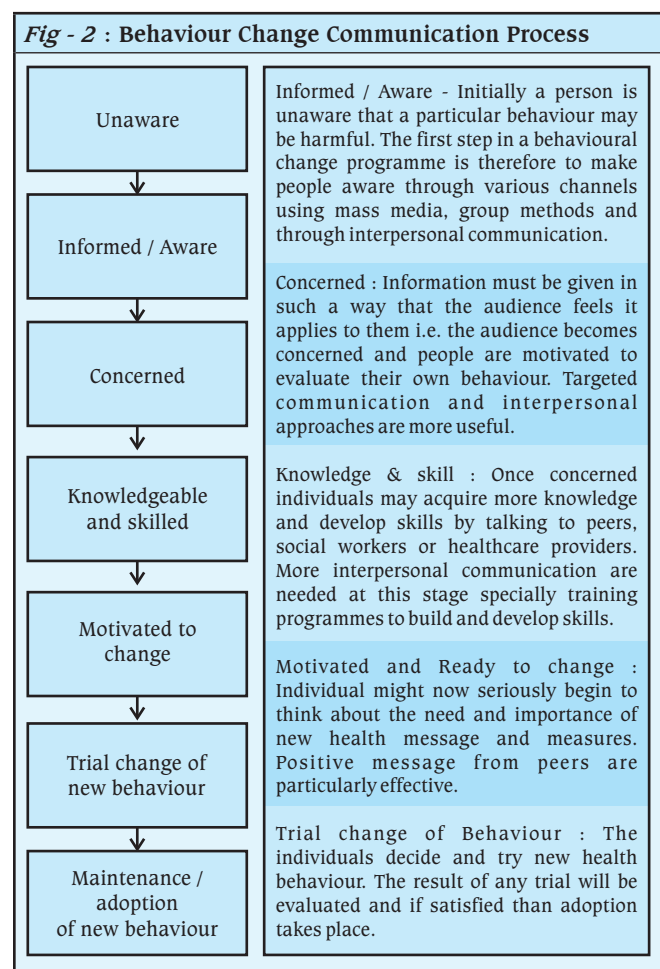
All barriers should be identified and removed for achieving effective communication. One of the main challenges in the design of effective health communication programs is to identify the optimal contexts, channels, content, and reasons that will motivate people to pay attention to health information.

**Communication skills** are required to make communication effective, the following are the skills required at source level. These include greeting skills, speaking skills, listening skills, questioning skills, and summarizing skills. In short communication process would be effective if the communicator has skills in introduction, skills in presenting and skills in conclusion. The non-verbal skills play an important role. It affects the communication process. Body language is an important constituent of non-verbal communication and consists of gesture, postures facial expressions, eye contact, manipulating the eyebrows etc.



## Behaviour Change Communication Process (BCC)

This is depicted in Fig. - 2.



## Components of Health Education Process

Health Education has three broad components :

- Levels of Health Education
- Methods of Health Education
- Activities undertaken in individual methods

**Levels of Health education** : Health education is carried out at three main levels, viz. individual and family, group level and general public (mass) level.

**Individual and Family Health Education** : There are plenty of opportunities for individual health education. It may be administered during personal interviews in the consultation room of the doctor or in the health centre or in the homes of the people. The individual comes to the doctor or health centre because of illness. The opportunities are utilized in educating him on matters of interest - diet, causation and nature of illness and its prevention, personal hygiene, environmental hygiene etc. Topics for health counseling may be selected according to the relevance of the situation. By such individual health teaching, we will be equipping the individual and family to deal more effectively with health problems. The patient will listen more readily to the physician. A hint from the doctor may have

a more lasting effect than volumes of printed word. The nursing staff has also ample opportunities for undertaking health education. Public health supervisors are visiting hundreds of homes; they have plenty of opportunities for individual teaching in working with individual. The health educator must create an atmosphere of friendship and allow the individual to talk as much as possible. It is useful to remember, "An effective communicator is not the one who talks too much but one who listens too much." An effective method of individual education is, Counseling, which is defined as a confidential dialogue between a client and a health care provider aimed at enabling the client the cope with stress and take personnel decisions related to disease. The counseling process includes an evaluation of personal risk of disease transmission and facilitation of preventive behaviour. The aim of counseling must always be based on the needs of the client. The purpose of counseling is three fold : to help clients manage their problems more effectively, to develop unused opportunities to cope more fully, and to help and empower clients to become more effective self helpers in the future. Helping is about constructive change and making a substantive difference to the life of the client. However, ultimately, it is only the client who can make the difference. The counselor is merely an instrument to facilitate that process of change. In the short-term, counsellors use basic skills to help clients make personal decisions about their behaviours. The counsellor's role is to provide accurate and complete information to help the user make her / his own decision about which, if any, part of the service(s) she / he will use. The role of the counsellor is not to offer advice or decide on the service to be used. For example, the counsellor will explain the available family planning methods, their side effects and for whom they are considered most suitable. The user then makes a decision, based on the information given, about which method she / he wishes to use.

**Group Health Education** : Our society contains groups of many kinds - schools children, mothers, industrial workers, patients etc. Group teaching is an effective way of educating the community. The choice of subject in group health teaching is very important it must relate direct to the interest of the group health. The methods in group health education are focus group discussions, health talks, demonstration, panel discussions, workshops etc. The group health education methods are effective in promoting behavioural change, influences opinion, develop critical thinking and increase motivation. Use of "aids" to education greatly facilitates group education. Examples of commonly used "aids" are given in Box - 1.

### Box - 1 : "Aids" in Health Education

<b>Auditory</b> : Radio, Telephone, Audio cassettes, Tape records
<b>Visual</b> : Text Books, Posters, Charts, diagrams, film strips, comic strips, pamphlets, internet
<b>Audio-Visual</b> : Movies, lectures combined with slide presentations, Television.

**Focus Group Discussions (FGD)** : A Focus group discussion is a group discussion of 6-20 persons guided by a facilitator during which group members talk freely and spontaneously about a certain topic or health problem. The purpose of a focus



group discussion is to obtain in-depth information on concept, perceptions and ideas of group on a particular topic.

**Education of the General Public (Mass education) :** For education of the general public we employ “Mass Media” of communication. Mass media are generally less effective in changing human behaviour than individual or group methods because communication is one way. Nevertheless they do have quite an important value in reaching large numbers of people with whom there is no contact in a short period of time. The continuous dissemination of information and views about health through all the mass media contribute in creating awareness and raising of the level of knowledge in the community. Examples of Mass-Media are given in Box - 2.

**Box - 2 : Examples of “Mass Media”**

Television; Radio; News Paper; Films; Health Magazines; Posters ; Health Exhibitions; Health Museums; Printed Materials

For effective health education mass media should be used in combination with other methods. Television, News Paper, and Radio are the most basic channel of health information communication. In addition, the internet is one of the new channels of health information communication that is becoming more popular. The internet and other advance communication technologies such as mobile telephone message and satellite television are important channel for health information communication. They have had more influence in the younger generation and in urban community. These communication channels are emerging and being adapted rapidly in the movement toward modernization.

The communication of health information is important for changing knowledge, attitudes and behaviour. Suitable communication methods are adopted by health care providers. Thus the integration of communication methods has much potential and more effective strategies.

**Methods of Health Education :** Methods are generic descriptions of how change is to be brought about within the target group; for example, mass media and community development are two terms being used to describe a host of health education activities. While planning health education programs, it is not that any method can be used (as delivering lectures to all concerned) but rather the most appropriate method most suited for the topic and the target audience should be selected. The available methods are listed in Box - 3 (2).

**Activities in Health Education :** The various methods of health education, as enumerated above, are utilized through different activities, depending on the objectives and the type of target audience. For example, a small group / focus group discussion can be undertaken using a LCD projected slide show, or through a flip chart, or may be simply an open multi-way discussion without using any teaching aid. Similarly, mass education process may be through the activities of traveling through the streets with a loud speaker or by inserting TV footages or through a documentary cinema. The appropriate of the method and how this method is going to be processed (i.e., the activities) should be decided by the health education planner.

**Box - 3 : Commonly Used Health Education Methods**

Individual Instruction (as counseling, patient instruction)
Lecture - Discussion
Educational Television / Computer (Use of television, computer and internet for viewing of prepared programs)
Audio-Visual Methods (See Box - 1)
Mass Media Methods (See Box - 2)
Peer Group Discussion / Focus Group Discussions
Programmed learning (use of teaching machines or programmed texts)
Simulation & games (games, dramatizations, role playing)
Inquiry Learning (an approach in which students formulate and test their own hypothesis)
Behavioral change methods (including behavior modification and skill development methods)

**Central Health Education Bureau (CHEB)**

Central Health Education Bureau (CHEB) is an apex institution created in 1956 at Delhi under the Director General of Health Services (DGHS) Min. of Health and Family Welfare, Govt. of India for health education and health promotion in the country on the recommendation of the Bhore committee and the Planning commission. It plans and formulates programmes for the promotion of health education in the country through organizing training programmes to prepare health education professionals conduct behavioural research, studies in the field of health education and promotion provides training in social research methods to the health professionals, providing training to the teachers, Para medical professionals for promoting health education activities. Production of various printed and electronic mass media material and educational aids is another important activity of the Central Health Education Bureau (CHEB). The objectives of CHEB are as to :

1. Interpret the plans, programmes and achievements of the Ministry of Health and Family Welfare.
2. Design, guide and conduct research in health behaviour, health education processes and aids.
3. Produce and distribute ‘proto-type’ health promotion and education material in relation to various health problems and programmes in country.
4. Train key health and community welfare functionaries in health education and research methods. Evolve effective methodology and tools of training.
5. Help schools and teacher training institutes for health education and health promotion of the school population.
6. Provide guidelines for the organizational set-up, functioning of health education units at the state, district and other levels.
7. Render technical help to official and non-official agencies engaged in health education and health promotion and coordinate their programme.
8. Collaborating with international agencies in promoting health education activities.

**Divisions of the Bureau :** In order to achieve its objectives,

CHEB has four technical and one administrative Division, each headed by a senior officer. These Divisions are :

- Media and Editorial Division
- Health Promotion and Education Division
- School and Adolescent Health Education Division
- Training , Research and Evaluation Division
- Administrative Division

The CHEB provides Pre-service training, in-service training and orientation training (refresher course) to the health personnel.

Since health education of the various social groups of population can be taken by state Govts, a scheme was formulated in 1958 for the establishment of State health education bureau with central assistance. Now the State health education bureau are called Information Education Communication Bureau (IEC).

## Summary

Health education is a process that informs, motivates and enables people to adopt and maintain healthy practices and lifestyles. It is a process of bringing about change in the individual's knowledge, attitude and behaviour so as to enable him to achieve health. It helps people to achieve health by their own actions and efforts. The principles of health education are Community involvement; promotion of self esteem; Voluntarism; respecting cultural norms and taking into account of the economic and environmental constraints; developing good human relations; Evaluation of needs; responsibility for the accuracy of information and the appropriateness of methods and lastly reinforcement.

IEC is a broad term comprising a range of approaches and activities. It can be defined as an approach which attempts to change or reinforce a set of behaviour in a target audience regarding a specific problem in a predefined period of time. It is multidisciplinary and client centered in its approach drawing from the field of diffusion theory, social marketing, behaviour analysis and anthropology. A good working definition for effective communication is to share meaning and understanding between the person sending the message and the person receiving it. It is either Verbal (the tone of voice) or Non-verbal (body language). The various components involved in the process of communication are Sender (source of Communication); the message, encoding and decoding it; the communication channel (as lecture or exhibition) and the "aids" (as slides, slide projector); the Receiver (audience); and the feedback.

Propaganda is merely a publicity campaign aimed presenting a particular thing or concept in a favourable light in such a way that public may accept it without thinking. The aim of Advocacy is to place health problems issues on the political agenda and effectively reach the influential groups. Barriers in Communication can be Physiological (Difficulties in hearing, expression); Psychological (Emotional disturbances); Environmental (Noise, invisibility, congestion in the classroom, etc); Cultural (Level of knowledge, receiver's beliefs). All barriers should be identified and removed for achieving effective communication. In Behaviour Change Communication Process (BCC), Information is given to the unaware people so that they become concerned, acquire more knowledge and develop skills and motivated to change their behavior & adopted a new one.

The three broad components of Health Education are Levels of Health Education, Methods of Health Education and Activities undertaken in individual methods. The three main levels are individual and family, group level and general public (mass) level. The various methods of health education, as enumerated above, are utilized through different activities, depending on the objectives and the type of target audience. An effective method of individual education is counseling and the methods in group health education are focus group discussions, health talks, demonstration, panel discussions, workshops etc. Television, News Paper, and Radio are the most basic channels of health information for general public. For effective health education mass media should be used in combination with other methods. Central Health Education Bureau (CHEB) is an apex institution created in 1956 at Delhi under the Director General of Health Services (DGHS) Min. of Health and Family Welfare, Govt. of India for health education and health promotion in the country on the recommendation of the Bhore committee and the Planning commission. It plans and formulates programmes for the promotion of health education.

## Study Exercises

**Long Question :** Discuss the Principles of Health Education with examples.

**Short Notes :** (1) Principles of Health Education (2) Components of Health Education (3) Components of the Communication process (4) Barriers in Communication (5) Counseling (6) Focus group discussions (7) Mass Media.

**MCQs :**

1. Which of the following is not a one way communication  
(a) Symposium (b) Lecture (c) Group Discussion (d) Stage show
2. The best method of health instruction is (a) Providing reading assignments (b) Organizing film show (c) Setting an example (d) Giving lectures
3. The best way of teaching an urban women about ORS is (a) Lecture (b) Flash cards (c) Role play (d) Demonstration
4. Receiver's false beliefs are a \_\_\_\_\_ type of barrier in communication. (a) Physiological (b) Environmental (c) Cultural (d) Psychological
5. The method which is generally more effective among the following in changing human behaviour is (a) Counseling (b) Focus group discussion (c) Mass media (d) A series of lectures

**Answers :** (1) c; (2) c; (3) d; (4) c; (5) a.

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*RajVir Bhalwar*

In contemporary public health practice, health education of the community (whether small groups or large masses) or of individuals (patients or healthy individuals) is one of the most important health care activity. Medical officers and specialists in Community Medicine (Public health and Preventive Medicine) should therefore be well versed in the various steps to be undertaken while planning, organizing, implementing and evaluating health education programmes. This involves a series of scientific and sequential steps, which are being explained in this chapter.

**Step 1 - Situational Analysis** : The first, and one of the most crucial steps in health education programme planning is "Situational Analysis", also known as "Community Analysis" or "Needs Assessment". This is the essential step for gaining insight into the health problems, so that programmes can be developed and directed towards conditions which are significant issues for the community members. This step of community analysis consists of following five sequential steps, viz. analyzing the community backdrop, analysis of the health status of the community, analysis of the health care system of the community, analysis of social systems of the community, and SWOT analysis. These sequential steps are vital for making the community diagnosis. We discuss each of these steps, as follows.

**Step 1 (a) - Analysing the Community Backdrop** : The first thing is to get to know the area and the community in your health care jurisdiction (or the community for which you are planning the health education program) very well. Drive (preferably walk) around the entire area. Find out where are the work places, location of various governmental and non-governmental offices, location of various, markets, eating joints, recreation facilities, industrial areas, schools, hospitals, other health care facilities (as PHCs / subcentres), residential areas, slums, etc. See for yourself the minute details, as what are the roads and other communication systems, the pattern of residential accommodation, water supply system, night-soil disposal system, solid-waste disposal system, and environmental conditions. Don't forget to find out about sensitive issues like defined red-light areas, clandestine sexual avenues, tobacco kiosks, alcohol shops and so on. Listen to the local radio and see the local television programmes, which would further assist you in getting an insight into the community backdrop.

After the initial inspection, define some tentative boundaries that can demarcate the larger area into smaller, more homogenous aggregates. The most obvious choices are the major physical boundaries as major roads, rivers or government boundaries as those delimiting the village or Taluka or district. Another workable method may be to divide the area into five or six "sectors" for purpose of various preventive health care

activities. Having done this detailed exercise, make a detailed "spot map" showing all these various aspects as described above. For a public health manager, developing and regularly updating such spot maps should be considered an indispensable duty. Whenever you take over as the District health Officer / Public Health officer or a health programme manager, the first thing you should do is to undertake a detailed, on-ground assessment of your area under health cover and update the spot maps. Similarly MOs in-charge of PHCs / CHCs should assess the details and update the spot maps for their respective areas.

Find out the details of the socio-demographic characteristics of the community under your health care. Find out the total population, distribution according to social status, according to age groups, according to women and children, and further according to the different geographical sectors that you have made to demarcate the community. See the main occupations, industry and business patterns. Now write down the details in a textual form, complemented by the spot maps, tables of various demographic characteristics and other graphics. It is important to develop a written document at this stage since it will come very handy later on while implementing the health education programme. It is very desirable that all Public Health programme managers should always keep such a written document, duly updated, since it will be an essential and basic document for planning all health care activities including health education; the document can also be placed before the Governmental Administrators, as and when they visit them.

**Step 1 (b) - Analysis of Community Health Status** : In this step, the data related to important epidemiological parameters is collected from various sources as hospital records, official reports, and, if required, by a quick sample survey (Details of important epidemiological parameters and sources of epidemiological information have already been covered in the section on "Epidemiology"). The main parameters, depending upon requirements include Birth rate, death rate, IMR, MMR and Neonatal MR according to major socio-economic categories (as age groups, sex and social class). Thereafter, mortality and hospitalization rates per 1000 (or per lac) population are worked out, for the past 3 years, for the leading 10 or 15 causes, separately for males, females and children (preferably for different age groups). These rates give us a clear idea of the leading causes of death and disease for various age and sex groups. These rates are then compared with the rates for various leading causes of death and hospitalization that have occurred, overall, in the state or in the country, to see if there is any particular difference in the leading causes of ill health between the area where we are planning our health education activities and the overall state or country. The data should be arrayed in simple tables, showing the names of leading diseases in the first column, the rates per 1000 (or per lac) in the second column and the overall rates in the state / country in the third column.

Sources which need to be explored to obtain this information include Census office, Registrar of vital events, Civil hospital/ PHC / CHC and Private hospital records and interviews with medical practitioners / government Doctors.



An additional and extremely important part of this step is to also obtain data on health-behaviour related aspects of the clientele. This is best done by undertaking a cross-sectional and quick survey from a representative sample, obtaining data on leading lifestyle factors (diet, exercise, tobacco and alcohol use, obesity and sexual practices), personal hygiene and use of personal-protective measures (use of road safety and occupational safety devices, protection against insect vectors of diseases, bathing, hand washing and oral hygiene) and on water and food hygiene practices. This quick survey may bring forth some very important issues (which may not be evident by simple comparison of routine mortality / morbidity data) and which need to be tackled by health education programmes.

**Step 1 (c) - Analysis of Community Health Care System :** The third step of situational analysis (community analysis) is to collect and analyse data describing the resources for providing health care (both curative as well as preventive) as are available to the community. This is undertaken by describing, firstly, the formally recognized health institutions, as government and private hospitals, dispensaries, health centres, sub-district hospitals, preventive health care programmes and institutions executing them. Secondly, informally recognised practitioners as those of traditional systems are described. The medical and paramedical manpower is thereafter described, as number of physicians, surgeons, according to sub-specialties, nursing personnel, health / sanitary workers, laboratory trained personnel and so on. The organization of service delivery, referral systems and local health departments are studied. Finally the “grey areas” in health care, including communities/ locations which are underserved or disadvantaged are identified. The last step is important since community groups who are actually in maximum need of health education are usually also the ones who are underserved / disadvantaged or living in inaccessible areas.

**Step 1 (d) - Analysis of Community's Social Organization and Support Systems :** In this step, the social structure and the social support systems are studied and analysed. The overall organisation of the community, the major community groups, the interaction between various community groups, the peers / leaders, the opinion formers and the political climate is studied. In addition, the various “Support Systems” available in the community (Voluntary organizations, NGOs, agencies which can organise financial assistance, charitable organizations, and so on) are studied, with a particular reference to how these can be gainfully utilized in relation to the proposed health education programmes.

**Step 1 (e) - Analysis of Strengths, Weaknesses, Opportunities and Threats (SWOT) :** Strengths are advantages that are of a permanent nature and exist in the community ethos or in the general environment, and they must be gainfully utilized by the health provider; e.g. conservative attitude of a community is a strength for anti-alcohol educational programme. Weaknesses are disadvantages of permanent nature in the community ethos or environment which will need to be neutralized or bypassed for success of the programme; e.g. conservative attitude in the community may be a disadvantage while launching a sex education programme for school children. Opportunities are temporary, often flitting occurrences which the health provider

should always be on the look-out for and utilize them to her benefit; e.g. if an outstanding sportsperson becomes the mayor of the city, it is an opportunity to contemplate launching a community educational program for healthy lifestyle and physical fitness. Threats are temporary phenomena which may be inimical to the programmes; recent occurrence of vaccine related adverse effects among children may be a threat to educational program for promoting vaccination coverage and this would need to be either circumvented or else tackled energetically.

**Step 2 - Making the “Community Diagnosis” :** This is a vital step, wherein we identify the “target populations” and their health problems. The first step in making the community diagnosis is to summarize the findings of the earlier step of “situational analysis” (community analysis), through sub-steps 1 (a) to 1 (e). This summary will give us an idea of the “needs” of the community. The needs so identified are of 2 categories; firstly the “professionally assessed needs” also called as the “normative” needs, i.e. those needs which are worked out by the health care provider, based on community analysis data. This would include the leading causes of morbidity and mortality (as chicken pox, hepatitis, injuries, etc.) and leading determinants of diseases (as smoking, inadequate levels of physical exercise, dietary patterns, sexual promiscuity, etc.). Secondly, equally important are the “felt needs” of the target population, i.e. those areas of concern which are articulated most commonly by the target population. These felt needs are the most pressing problems experienced by groups and individuals in the target population and usually reflect the problems currently in focus (1 - 4).

In short, in the step of community diagnosis, we clearly define the following aspects. A consolidated statement clarifying these undermentioned issues would serve as the basic guideline for further planning of our health education programme :

- *What are the “target communities” which are to be addressed by our proposed health education, or by other health care programmes or by a combination of health education and health care programmes? Delimiting the target audience(s) will define premises of our proposed programme and help us focus our entire energies on to these defined groups, with a view to get the maximum results. Target communities are those groups or subgroups which have the maximum ill-health (mortality, morbidity or unhealthy lifestyle) and are likely to give significant results, if concerted health education programmes are focused on them.*
- *What are the major health problems as assessed by us which need to be addressed by health education programmes or health care programmes?*
- *Besides our assessed needs, what are the other “felt needs” of the target audiences, which should also be addressed either by health education or other health care programmes.*

**Step 3 - Defining the “Premises” and “Goal” of the Proposed Programme :** Premises are the outer boundaries within which our proposed programme will function; we will not be going out of these limits in so far as the particular programme is concerned. Thus, this helps us focus our attention our



programme and our goal and not mix up our actions with other issues. Premises are generally defined in terms of the population characteristics, place, time and the broad issues which will be the concern of the programme. While defining the premises and the goal, one should be clear that while a number of issues may be identified as major “needs”, it is not necessary (and also not usually feasible) to address all these identified needs through health education programmes. Some of the needs would be better resolved using public health or other medical care approaches. For example if we have two major issues as HIV - AIDS and problem of open defaecation, we may, depending on the situation, decide to focus on HIV - AIDS through educational efforts and tackle the problem of open defaecation by sanitary measures. It is therefore important to clearly delineate at this stage, which of the needs will be addressed by health education programme and which would be addressed by other public health / medical care steps.

Once we have defined the premises and sorted out the “needs” according to which all will be addressed by our proposed health education programme, we enunciate the overall “goal” of the programme. Goals are broad statements which reflect the end result that we desire to achieve, i.e. they are the intended consequences of the program (5). Program goals should not be confused with “educational goals”, which will be discussed later under step - 6.

**Step 4 - Consolidating Data on Knowledge, Attitudes and Behaviours :** It is apparent that the ultimate goal of any health education program is to increase the knowledge and obtain a favourable change in attitudes and behaviour by the target population. Hence, we will need data as regards the current state in respect of the knowledge, attitudes and behavior, for the goals that have been identified. Behaviour should be assessed in terms of “events” and “outcomes”. An event is the actual behaviour (e.g. smoking, sexual promiscuity); an outcome is the result of that event (e.g. IHD, AIDS). A sample survey of the target population, if the same has not been done in step 1 (b), should be now undertaken and data on current levels should be recorded (6 - 9).

**Step 5 - Assemble the Planning Group / Coordination Council:** Community health education cannot be accomplished by a single health educator. All representatives from the community, especially those who can facilitate the program should be approached to consent for being a part of the planning group (also sometimes called as coordination council or governing board). From this step onwards, all plans are discussed and finalized, progress monitored and difficulties sorted out by personal involvement of members of this group. This group should include the public health manager / health education specialist, who should be the secretary of this group. The chairperson is usually an eminent / influential political or administrative person. The members include technical specialists, administrators and above all, representatives of each of the target populations identified earlier.

Once a planning group has been constituted, all members should be given an initial briefing to orient all members as regards the various aspects of the program. This activity is very relevant since many of the members may not be very aware about the technical intricacies of health education and medical care, as

also about the details and sequence of planning process.

**Step 6 - Reconfirming the program goals, enunciating the educational goals and the objectives :** Once a planning group has been formed, one of the first activities to be undertaken by this group is to firstly, reconfirm that the original program goal (vide step - 3) is finally acceptable or else it needs to be changed. Secondly, the group should enunciate broad statements, for different identified “needs” and different target groups, as to what the educational process aims at finally achieving. The overall program goal should be kept in mind when formulating the educational goals. The educational goals should be stated in precise language so that all members of the planning group thoroughly understand the exact intention of the statements (5, 10).

Having specified the educational goals, the educational objectives are enunciated. As compared to goals, which are generalized & broad statements, objectives are precise statements which indicate as to how the goal will be realized. For one goal, there could be a number of objectives. Objectives should be specific, measurable and quantifiable in terms of magnitude of change and time-line. Within each objective, the parameter which will measure change is called the “indicator” and the magnitude of change proposed to be achieved is called the “target”. For example, in an objective “Proportion of persons who are smokers should reduce from current 45% to 25% in next 2 years”, the statement “Proportion of persons who are smokers” is an indicator while the part “reduce from current 45% to 25% in next 2 years” is a target.

**Step 7 - Resource Analysis :** The important issue at this stage is how we can convert the desired objectives into an effective “action plan” so that the objectives can be achieved. For this purpose, we have to now analyse our resources, i.e. what all do we have to take action. In general, resources are analysed in terms of 3 broad headings, viz. men, money and material. Resource analysis for manpower would include the medical and paramedical personnel, and other key personnel as epidemiologists, trained health educators, data operators and statisticians, along with their locations, who would be available for the health education program, either full-time or part-time. This aspect of manpower also includes the ‘supportive manpower’ as political leaders, administrative authorities and peers who would support the program. Money refers to assessment of funds / finances which will be required for development of health education material, training material, communications and transport, purchase of health educational and medical equipment if required, payment of salaries, etc. The source of finances could be government (public funds) or funds generated by voluntary / non-governmental organizations. Finally, material refers to technical equipment, expendables and logistics. This would need assessment of various aspects like availability of class-rooms, lecture halls, buildings, electricity, announcement systems, projection systems as slide / overhead projectors, computers, LCD projectors, posters and charts for exhibitions and mobile panels for posters; models, and so on. In addition, equipment pertaining to “logistics” as vehicles for transportation of target population, petrol, tentages, generators, etc., would also need to be assessed, as required. It is only after making a detailed assessment of resources (already available

and expected over reasonable period of time), that the program planner would be able to decide as to how best can an action plan be drawn to meet the objectives; at this stage, it may also be a consideration to drop one or two objectives if adequate resources are not available.

**Step 8 - Identify Methods and Activities for Health Education** : In the earlier chapter, we have deliberated on the various types of methods (as lectures, focus group discussions, exhibitions, mass media communication methods etc.) and the activities that are conducted within each of these methods. Detailed decisions should now be taken to see which particular method(s) will be most appropriate to address the objectives for different target groups, and within each method, what all educational activities will be undertaken. The details of the decided methods and activities for each target group should be written down.

**Step 9 - Writing and disseminating the Action Plan (Implementation Plan)** : Having clearly enunciated the methods and activities, a detailed action plan should be written down. This is a detailed document which clearly specifies as to *who will do what, to whom all, where, in what manner and how frequently*. The document should specify all details of

- Dates / days of the week or month and timings, on which the educational sessions will be held for the entire duration of the educational program.
- The locations at which the sessions will be held.
- Who all will attend the sessions at the particular locations, dates and time.
- Who will be administratively responsible for ensuring that the target audience reaches the particular location of educational session, well in time.
- Who will be responsible for providing the administrative support.
- Who will conduct the session.
- Who will be responsible for technical aspects of the session.
- Who will be the overall coordinator for the educational activities.

The details should be discussed by the Program Planning Committee (PPC) and then issued by a senior administrative officer to all concerned.

**Step 10 - Implementation and Evaluation** : Once the instructions for implementation have been issued, the health educator's responsibilities further increase since he is now not only responsible for providing health education to the various target populations but also often responsible for coordination of the various administrative aspects, and to ensure that all aspects of the program progress as scheduled in the action plan. In real life scenarios, everyday there will be problems, which would need to be actioned and rectified. Sometimes the vehicle may not turn up to ferry the health educator's team and equipment, sometimes the officer responsible for administrative coordination for one of the target populations may simply forget that there was a session planned for that day, sometimes a holiday may be announced suddenly on the day of planned session. All these issues need to be visualized and addressed. In health education programmes & for that matter in any public health program, perseverance and determination always pays.

Alongwith implementation of action plan, evaluative process also needs to be planned and conducted. As explained in detail in the section on epidemiology (planning & evaluation of programs), evaluation is undertaken for six different aspects, viz. relevance, adequacy, process, and outcome (including efficacy, effectiveness and efficiency). In the usual settings of health education programs, evaluation is undertaken for "process" (i.e. whether the activities are being undertaken as planned) and for outcome (i.e. to what extent the objectives have been met). Evaluation for process is to be undertaken concurrently, say once in 3 months for a program planned for 1 to 2 years. Outcome evaluation is undertaken both, concurrently (e.g. what percentage of target population have shown improvement in knowledge and behaviour) and terminal evaluation at the end of the program (whether targets as envisaged at the planning stage have been achieved). It should be remembered that evaluation should always be an ongoing process, with the drawbacks/deficiencies noticed further analysed and change in program actions undertaken to rectify defects that have been identified.

**Step 11 - Writing the Final Report** : Once the program has been completed or terminated for whatsoever reasons, the program planner must write down a detailed report of the program, including the background, the target audience, the educational and program objectives, the action plan, details of process, final results, and recommendations for future programs. Such report is invaluable in assessing the current program and also serves as a basic reference document for any subsequent health education programs.

## Summary

To make an effective IEC campaign the public health functionaries must be aware of various steps to be undertaken in planning, organizing, implementing and evaluating health education programmes so as to make it successful. The first step in this regards is situational analysis which aims at gaining insight in the health problems of the community to enable us to make a community diagnosis. It involves analyzing the community backdrop in the defined area, by taking the information about socio-demographic characteristics and other issues of relevance. Thereafter, analysis of community health status is done by collecting data about important epidemiological parameters about health problems of the communities from various readily available sources or by a quick sample survey. Thereafter, the community health care system is analysed so as to find what all are present and what all are lacking. Based on the collected information, a SWOT analysis is done to identify the Strengths, Weaknesses, Opportunities and Threats in the community.

The next step involves making a community diagnosis based on the situational analysis. The aspects which are clearly defined in community diagnosis are target communities, professionally assessed needs and felt needs of the communities. The third step includes defining the premises and goals of the programme. Premises are the outer boundaries within which our proposed programme will function and goals are broad statements which reflect the end result that we desire to achieve. In the fourth step, data as regards the current state of knowledge, attitudes and behaviours is assessed by a sample survey of target population.

In the next step, the planning group / coordination council is assembled. This includes the public health manager / health education specialist as the secretary, an eminent / influential political or administrative person as chairperson, while the other members include technical specialists, administrators, and above all, representatives of each of the target populations identified earlier.

In the sixth step, the planning group reconfirms the original program goal. Having specified the educational goals, the educational objectives are enunciated, and within each objective indicators and targets are defined. In the next step, resources are analysed in terms of men, money and material. Men include primary manpower as health care workers and supportive manpower. Money refers to assessment of funds/ finances which will be required, while material refers to technical equipment, expendables and logistics. It is only after making a detailed assessment of resources that the program planner would be able to decide as to how best an action plan can be drawn to meet the objectives. In the eighth step, detailed decisions are taken to see which particular method(s) of health education will be most appropriate to address the objectives for different target groups, and within each method, what all educational activities will be undertaken. In the next step, after having clearly enunciated the methods and activities, a detailed action plan should be written down. This is a detailed document which clearly specifies as to who will do what, to whom all, where, in what manner and how frequently.

Finally the programme is implemented and measures are taken to ensure that all aspects of the program progress as scheduled in the action plan. Along with implementation of action plan, evaluative process also needs to be planned and conducted. Evaluation is undertaken for six different aspects, viz., relevance, adequacy, process, and outcome (which includes efficacy, effectiveness and efficiency). Evaluation should always be an ongoing process, with the drawbacks / deficiencies noticed further analysed and change in program actions undertaken to rectify defects that have been identified.

Once the program has been completed or terminated for whatsoever reasons, the program planner must write down a detailed report of the program. Such report is invaluable in assessing the current program and also serves as a basic reference document for any subsequent health education programs.

## Study Exercises

**Long Question :** Describe your plan of planning, conduct and evaluation of a health education programme for HIV - AIDS prevention at the level of a district.

**Short Notes :** (1) Peer Groups (2) Community Diagnosis (3) Assessment of health educational needs

### MCQs & Exercises

*Match the following*

1. Objectives	a. Precise statements which indicate as to how the goal will be realized
2. Goals	b. Parameter which will measure change
3. Indicator	c. Magnitude of change proposed to be achieved
4. Target	d. Generalized & broad statements

### MCQs

- Which of the following is not part of situational analysis: (a) Analysing the Community Backdrop (b) Analysis of Community Health Status (c) Analysis of Community Health Care System (d) Defining target communities
- Which of the following is not a part of community diagnosis : (a) Defining target communities (b) Defining major health problems (c) Defining felt needs (d) Defining the premises
- The aspects considered for outcome evaluation does not include : (a) Relevance (b) Adequacy (c) Process (d) Resources
- The correct order of following steps is : 1. Assemble the Planning Group / Coordination Council; 2.Consolidating Data on Knowledge, Attitudes and Behaviours; 3. Resource Analysis; 4. Reconfirming the program goals, enunciating the educational goals and the objectives (Pick up your choice from one of a, b, c, or d as follows : (a) 1,2,4,3 (b) 2,1,4,3 (c) 2,1,3,4 (d) 1,2,3,4
- The best method for health education on treatment of diarrhea/ ORS use for urban slum population is : (a) Lecture (b) Demonstration (c) Focussed group discussion (d) Symposium
- Resources include all of the below except : (a) Money (b) Material (c) Manpower (d) Methodology
- Which type of study is most convenient to undertake to obtain data on health-behaviour related aspects of the target population : (a) Cross-sectional study (b) Case-control study (c) Cohort study (d) Ecological study
- Source for assessing health status of the community include all except : (a) Census office (b) Registrar of vital events (c) Civil hospital (d) Labor office
- Normative needs is : (a) Needs felt by community (b) Health needs of community assessed by health workers (c) Normal day to day needs of community (d) Needs other than health
- Chairperson of health education programme should be (a) Public health specialist (b) Influential politician (c) Superspecialist doctor of concerned topic (d) Senior teacher

- 11) Target communities are the groups of people who : (a) Have the maximum ill-health (b) Have maximum representation (c) Are the most influential section of society (d) Are poor
- 12) Which of the following is an individual health education method : (a) Lecture (b) Focused group discussion (c) Counseling (d) News paper
- 13) Following is/are the type/s of outcome evaluation : (a) Concurrent (b) Terminal (c) Both (d) None of the above

**Fill In the Blanks**

- 1) "Situational Analysis" is also known as \_\_\_\_\_ or \_\_\_\_\_
- 2) \_\_\_\_\_ are advantages that are of a permanent nature & exist in the community ethos or in the general environment.
- 3) The first step in making the community diagnosis is \_\_\_\_\_
- 4) \_\_\_\_\_ are those areas of concern which are articulated most commonly by the target population.
- 5) \_\_\_\_\_ are the outer boundaries within which the proposed programme will function.
- 6) \_\_\_\_\_ is a detailed document which clearly specifies as to who will do what, to whom all, where, in what manner and how frequently.

**Answers**

**Match the following** : 1-a; 2-d; 3-b; 4-c.

**MCQs** : (1) d; (2) d; (3) d; (4) b; (5) b; (6) d; (7) a; (8) d; (9) b; (10) b; (11) a; (12) c; (13) c.

**Fill in the Blanks** : (1) Community Analysis, Needs Assessment (2) Strengths (3) To summarize the findings of situational analysis (4) Felt needs (5) Premises (6) Action Plan

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5

## Environmental Health Sciences



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*Sandip Mukherji & Kunal Chatterjee*

Meteorology is the science concerned with the phenomena occurring in the atmosphere. The elements, which comprise the meteorological environment, are atmospheric pressure, air temperature, humidity, rainfall, direction and speed of wind and movement of clouds and weather. In all meteorological observations, the results obtained by different observers at different stations are recorded by instruments, which are similar in form and exposed in the same manner.

Early information about the weather conditions is essential to take preventive measures against its adverse effects. This method is termed as weather forecasting and it also helps in planning for the prevention and control of diseases, predict the level of human efficiency and forecast the dangers of climatic extremes and vagaries on human life. Forecasting the weather and climate is carried out by correlating the present and previous meteorological observations with the norms observed over considerably long retrospective periods. The different elements of weather and the instruments to measure them are discussed in the subsequent paragraphs.

### Measurement of Atmospheric Temperature

Atmospheric temperature measurement is an important data for weather forecasting. This is recorded by a thermometer, which is exposed in open sheds to allow free circulation of air and protected from direct rays of the sun by a thick roof. Both mercury and alcohol thermometers are used for this measurement. Mercury boils at a higher temperature, has an even expansion and is easily visible against the glass background while alcohol has the advantage of not solidifying even at very low temperatures.

**Dry and Wet bulb thermometer** : These are ordinary mercury thermometers, which measure the air temperature. The wet bulb is the same as dry bulb thermometer except that its bulb is kept wet by a muslin cloth fed by water from a bottle through a wick. The evaporation of water from the muslin cloth lowers temperature of the mercury. The wet bulb thermometer therefore shows a lower temperature than the dry bulb thermometer. In case both the thermometers record similar readings, then it is presumed that the air is completely saturated with moisture as happens during rains.

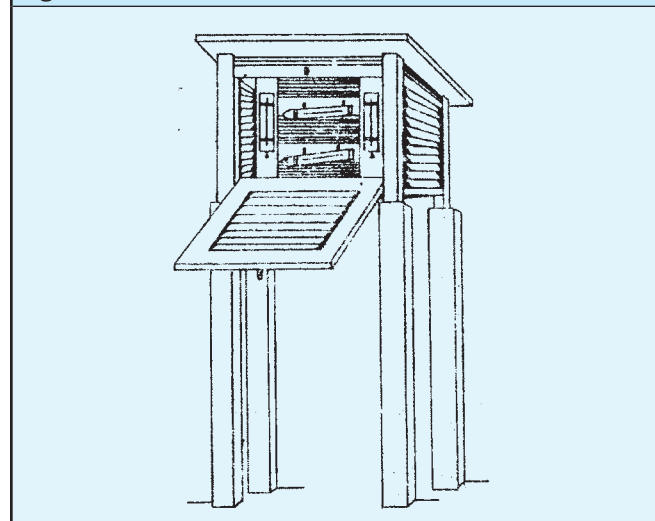
**Maximum thermometer** : This is a mercury thermometer with a very fine constriction near the neck of the bulb. It is hung up almost horizontally with the bulb end slightly lower than the other end. The capillary stem of the thermometer has a small metal indicator, which is pushed along by the mercury and fits tightly enough to remain behind when the mercury recedes. With the rise in temperature, the mercury expands and rushes across the constriction pushing the indicator. Once the temperature falls and the mercury recedes, the indicator, which fits tightly in the capillary, is measured at its lower end to give the maximum temperature reached. The thermometer is reset each time by pulling down the indicator with a magnet until it comes in contact with the mercury.

**Minimum thermometer**: Minimum thermometer has alcohol inside, in which a dumb-bell shaped index is immersed. When the temperature falls the spirit drags the index down towards the bulb end, but when the temperature rises the spirit expands and runs past the index. At the end of any period of observation, the position at the end of the index farthest from the bulb is considered as the minimum temperature recorded. The maximum and minimum thermometer are installed on a wooden base which is placed inside a box such as the Stevenson's screen described below, for accurate recording of temperature.

**Maximum and minimum thermometer** : Here the two thermometers are conjoined and made as a glass tube with three limbs, which combines the principles of maximum and minimum thermometers. The commonest such instrument is the Six's thermometer, which is not considered accurate for meteorological measurements and is not used by Indian Meteorological department.

**Stevenson's screen** : To ensure an accuracy of measurement of air temperature, the thermometers are mounted in a box of approved pattern called as the 'Stevenson's screen'. It is a double louvered box whose internal dimensions are 76 cms length, 45 cms width and 48 cms height. It has a double roof, the upper one projecting 5 cms beyond the sides of the box and sloping from front to back, and has an open base. At the front is a hinged door opening downwards. The box is mounted on four posts with its door opening to the North or South depending on whether it is placed in a region in the Northern or Southern hemisphere respectively. The bulbs of thermometers are placed at a height of 120 to 180 cms from the ground, and at least 6 m away from the nearby buildings or large structures to provide unobstructed flow of air around the equipment. The thermometers are hung inside the box such that no bulb comes within 8 cms of roof or sides of the box. They can be easily read in this position without being disturbed or touched (Fig. - 1).

**Fig. - 1 : Stevenson's screen**



**Temperature recordings** : The mean daily temperature is obtained by adding twenty-four hourly observations and dividing this by twenty-four. The temperature of a month is

the mean of those thirty days, and the temperature of a year is the mean of those of twelve months. The temperature of the air varies at different parts of the day. It is increased by the absorption of solar radiation during the day. The variation of temperature with a maximum and a minimum, dividing the day into periods of eight and sixteen hours, is the diurnal variation with the difference called as the diurnal range.

Some simple precautions are also necessary in taking the readings in these instruments. Sufficient time should be allowed for the mercury to come to thermal equilibrium with the surrounding air. Nearness of the instruments to surfaces much hotter or cooler than the air will also give a false reading.

### Measurement of Solar Radiation

The Sun's rays warm up the atmosphere, which is measured by the instruments described above. Another factor, which contributes to rise in environmental temperature is the heat given out by hot objects on the earth's surface, after they have absorbed heat. This heat given out is known as radiant heat and is in the infrared range of spectrum. These objects record higher temperatures than that of the surrounding atmosphere. To measure the warmth of an atmospheric condition, it is thus essential to measure the radiant heat also.

**Campbell - Stokes Sunshine Recorder** : The number of hours of sunshine are recorded by the Campbell-Stokes Sunshine Recorder. This comprises of a charted paper placed on a concave surface of the recorder. A solid glass globe brings to focus the sun's rays on to this paper, which chars the paper at the point of focus. With the movement of sun throughout the day, a charred line is created on the paper, which when measured gives the number of hours of sunshine in the day (Fig. - 2).

**Fig. - 2 : Campbell-Stokes sunshine recorder**



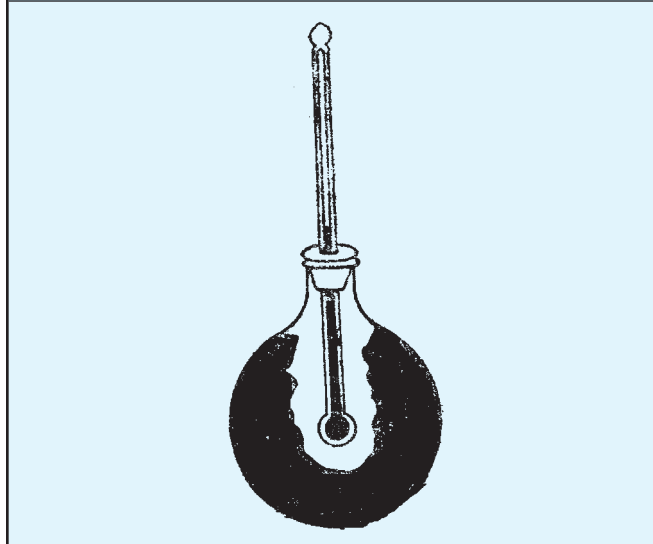
**Solar radiation thermometer** : This instrument measures the intensity of solar radiation on a given day. It comprises of a black bulb thermometer enclosed inside a glass shield. The glass shield is devoid of air to avoid any aberrance in measurements. Black colour being absorbent of heat, the thermometer records a higher temperature than ambient air temperature, when it is exposed to sun rays. The difference in the maximum thermometer reading taken inside the Stevenson screen and the Solar radiation thermometer denotes the intensity of solar radiation.

**Black Globe thermometer** : The Black Globe thermometer measures the radiant heat directly. It comprises of a hollow copper globe of about 15 cms diameter, with an opening at a

side. Through this opening is inserted a calibrated mercury thermometer such that its bulb is placed in the centre of the globe. The globe is painted with matt-black paint and the equipment is suspended outside on a stand. The matt-black paint absorbs radiant heat from the surrounding objects. If the surrounding environment is windy, a black globe with 20 cms should be used. The instrument should be placed in the environment for about 20 minutes by which time it reaches equilibrium. The temperature is recorded thereafter. The globe thermometer records a higher temperature than the ordinary air temperature thermometer, since it is affected both by the air temperature and the radiant heat.

Various modifications have been made in the standard black globe thermometer such as the wet globe thermometer, which has a wet black cloth covering the sphere or the modified globe developed by Hellon & Crockford, which reaches equilibrium in 8 to 10 minutes and is made of a lighter gauge material and has an internal air stirring mechanism (Fig. - 3).

**Fig. - 3 : Black Globe thermometer**



### Measurement of Atmospheric Pressure

The atmospheric pressure close to sea level on the earth's surface is measured as 760 mm of mercury (Hg) and is called as 1 atmosphere of pressure. This pressure falls as the altitude increases and rises as the altitude decreases at the rate of 1 atmosphere for each 33 feet depth below sea level.

Atmospheric pressure is measured with the help of an instrument called as a barometer. These could be the aneroid or mercury barometer, of which the latter are more accurate. Some of the well-known barometers are Fortin's barometer, Kew Pattern station barometer, commonly used by the Indian Meteorological Department. The barograph is a continuous measurement of the atmospheric pressure over a 24 hour period. The instrument is a circular box, the walls of which collapse or distend when the atmospheric pressure rises or falls and are supplied with the recording device and spare charts. More sensitive barographs recording very minimal fluctuations of pressure are called as 'Microbarographs'. The fluctuations



seen in a barometer are considered to be of importance in determining the pattern of weather conditions. Ordinarily the barometric readings during field studies are recorded on the aneroid barometer, which needs regular calibration with the mercury barometer.

### Measurement of Atmospheric Humidity

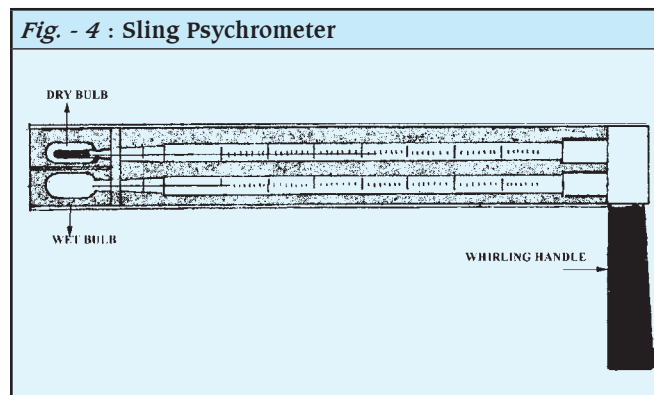
Atmospheric humidity or the moisture content of air is generated from large watery surfaces, which are exposed to atmosphere. Moisture is also added to air by living animals and plants due to their constant discharge of water vapour from the lungs or leaves. The moisture content of air can be expressed in two different manners as Absolute humidity and Relative Humidity (RH). Absolute humidity is the amount of water vapour per unit weight or volume of air expressed as grams per litre or grams per cubic metre of air and is measured by absorption hygrometers. Relative humidity describes the moisture content of air at any given temperature as a percentage of the maximum possible moisture content i.e. the ratio of amount of water vapour actually present in the air to the amount that would be present where the air saturated with moisture expressed as a percentage out of 100.

The amount of water vapour necessary to cause saturation of air varies directly with the temperature, the higher the temperature of air, more the water vapour it can hold before saturation point is reached. When the air becomes completely saturated, evaporation from any surface in that area ceases altogether. If the air is cooled, the excessive moisture precipitates for the particular temperature. This is called 'Dew Point'. Humidity has an effect on the comfort levels, though not directly on the physical health of a person. At relative humidity levels above 65 percent the air inside a room feels sticky, while air at RH below 30 percent is unpleasant.

**Mason's Hygrometer** : This is the most widely used instrument for measuring humidity at the permanent meteorological stations. It consists of two similar thermometers mounted side by side on a Stevenson screen. One of them is a dry bulb thermometer, which measures the ambient air temperature. The other thermometer is the wet bulb thermometer, which is similar to the dry bulb thermometer but has its bulb covered with a muslin cloth kept moist by a cotton wick, which dips in a reservoir of distilled water. This thermometer records air temperature as influenced by the rate of evaporation from the muslin cloth. The drier the air the greater the rate of evaporation and lower would be the readings on the wet bulb. In a saturated atmosphere, the readings of dry and wet bulb coincide. The difference in the reading is called as 'Depressions of the wet bulb' and is inversely proportional to the atmospheric moisture. The readings recorded on the hygrometer could be used to determine the relative humidity, the vapour and the dew point with the help of hygrometric tables.

A stationary wet bulb creates a zone of higher humidity immediately surrounding it when the air movement is sluggish due to continuous evaporation of water. This may give rise to falsely higher readings on the instrument and is obviated by providing an air velocity artificially by mechanically moving the two thermometers, as is carried out in the Sling Psychrometer described below.

**Whirling or Sling Psychrometer** : This instrument has a dry and a wet bulb thermometer mounted side by side on a metal strip, which is fixed on a wooden frame. The frame has a handle on a side, which acts as a pivot on which the wooden frame can be rotated. The wet bulb thermometer is kept wet by a piece of wick which soaks water from a small cylindrical water container. The instrument, once ready, is whirled standing with the back to the sun at the rate of 4 rotations per second. The readings on the thermometer show a dip due to evaporation of water brought about by the air movement created due to the rotation. Successive readings are noted on the wet bulb thermometer till they do not show any further change i.e. two successive readings on the wet bulb thermometer are the same and this reading is recorded. The reading on the dry bulb thermometer is also recorded at this point of time. The two thermometer readings are used to determine the relative humidity of the air using suitable tables and charts. The rotation could also be carried out using a motorised device or a modification carried out on the psychrometer called as the 'Assmann Psychrometer' which draws air at the rate of 5 metres per second onto the thermometers using clockwork fan. These devices give more accurate measurements (Fig. - 4).



### Measurement of Air Movement

Air movement determines the cooling power of air and it influences the comfort levels in an environment. The equipment used to measure air movement are Kata thermometer and anemometers. The latter could be of propeller type, thermoanemometers or the hot wire anemometers.

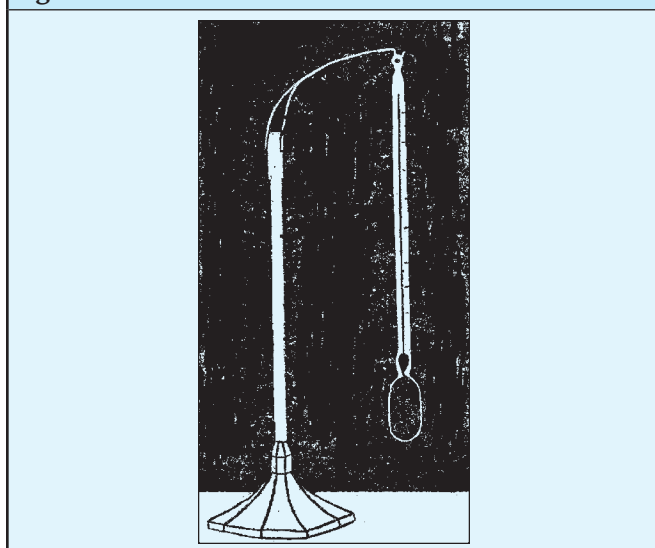
**Kata Thermometer** : The Kata thermometer is useful in measuring air velocities as low as 10 feet per minute. 'Kata' is a Greek word meaning 'down' and the Kata thermometer is an alcohol thermometer with a glass bulb 4 cm long and 1.8 cm in diameter. The bulbs are silvered to reduce the errors due to radiation. These thermometers are available to cover the following cooling ranges :

- Standard Kata (Red coloured alcohol) with a cooling range between 100°F to 95°F.
- High temperature Kata (Dark Blue coloured alcohol) with a cooling range between 130°F to 125°F.
- Extra High temperature Kata (Magenta coloured alcohol) with a cooling range between 150°F to 145°F.

Each Kata thermometer has a given kata factor determined by the manufacturers and is provided with standard charts with

instructions for use. Two thermometers are used to record air movement, the bulb of one is covered with a wet muslin cloth, called as the wet kata and the other is the dry kata. The two thermometers are set prior to taking readings by immersing them in hot water to warm them slightly above 130°F, when the alcohol rises to a small reservoir at the top of the instruments. The bulb of dry kata is wiped dry. Then both the instruments are suspended in air at the point of observation about 60 cms away from the observer. The time in seconds is recorded using a stop watch for the alcohol to drop across the cooling range for example, from 100°F to 95°F for the standard kata. The observations are repeated four times and after discarding the first, an average of the other three are taken and an average length of time is arrived at. The kata factor for the instrument divided by the average length of time gives the wind velocity in millicalories per square centimetre per second. Kata charts can also be used for this purpose. A dry kata reading of 6 and above and a wet kata reading of 20 and above were regarded as indices of thermal comfort (Fig. - 5).

**Fig. - 5 : Kata thermometer**



**Anemometer** : These are used to measure the unidirectional wind velocity and are of the rotating vane or the propeller type. The propeller comprises of two short metallic arms joined rigidly in the middle at right angles to each other. At each of the four free ends of these two arms is attached a half-hemispherical hollow cup with its rim in a vertical plane and the hollows of all the four looking in the same direction. This is mounted on a vertical spindle such that the arms can move free in a horizontal plane. When this is mounted on the top of tower unobstructed by trees and buildings and the wind blows from a direction, it catches one or more of these cups and sends them whirling at a speed equal or proportional to the wind velocity. The spindle is further attached to the anemometer box and there is a counter inside the box called 'cyclometer' to measure the wind speeds.

**Thermo-anemometer and Hot Wire anemometer** : A thermo-anemometer is a mercury anemometer with an electrically heated metallic coil around its bulb. A rheostat regulated the

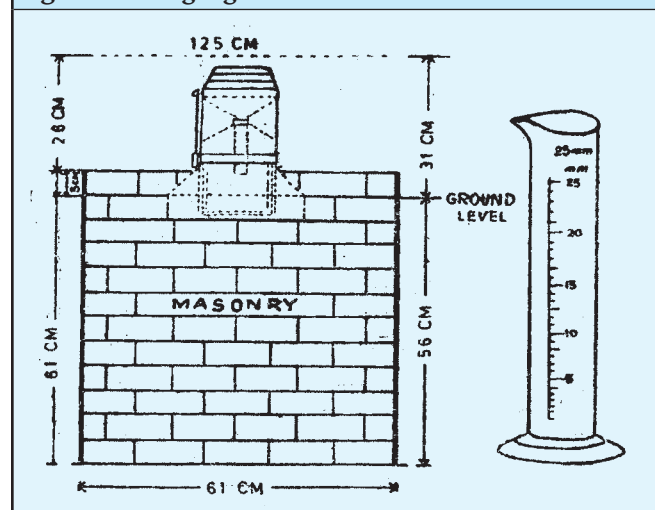
voltage in this coil. The velocity of air can be measured upto 5000 cms per seconds or more using suitable voltage in the coil and the calibration charts.

A hot wire anemometer is made up of three pieces of electrically heated fine platinum wires. The change in resistance produced by the cooling effect of air current is measured by a potentiometer or a galvanometer. This instrument can measure very low air speeds below 100 centimetres per seconds.

### Measurement of Precipitation

Precipitation is a collective term used for all forms of water precipitated from the atmosphere such as rain, snow, hail, dew and frost. Rainfall is measured by rain-gauges in inches or millimetres per time unit (day or month). The Indian Meteorological Department uses the Symon's rain-gauge at its rainfall measuring stations. The rain-gauge consists of a funnel for collecting rainfall, a receiving vessel and a measuring glass (Fig. - 6).

**Fig. - 6 : Rain gauge**



The funnel is made of copper and is cylindrical in its upper part with a diameter of 20.3 cm. The receiving vessel is a small copper can, which fits inside an outer casing. The measuring glass is calibrated and specific to a particular rain-gauge. The outer casing of the instrument along with the receiving vessel and collecting funnel is sunk in an open level ground in a masonry or concrete foundation. The top of the receiving funnel should be placed exactly horizontal one foot above the ground level. It should be ensured that there are no obstructions such as trees or buildings nearby. After the desired time has elapsed, the collecting funnel is removed, the receiving vessel lifted out and the contained water poured carefully into the measuring glass and read off. Similar instrument could also be used to measure snowfall.

### Summary

Meteorology is the science concerned with the phenomena occurring in the atmosphere. The elements, which comprise the meteorological environment, are atmospheric pressure, air temperature, humidity, rainfall, direction and speed of wind and movement of clouds and weather. Climate and weather

have marked effects on health and diseases. Early information about the weather conditions is essential to take preventive measures against its adverse effects. This method is termed as Weather forecasting and it also helps in planning for the prevention and control of diseases, predicts the level of human efficiency and forecast the dangers of climatic extremes and vagaries on human life.

Atmospheric temperature is recorded by a thermometer, which is exposed in open sheds to allow free circulation of air and protected from direct rays of the sun by a thick roof. Both mercury and alcohol thermometers are used for this measurement. The various instruments available for its measurement are Dry and Wet bulb thermometer, Maximum thermometer, Minimum thermometer, Maximum and minimum thermometer and Stevenson's screen. A rise in environmental temperature is due to radiant heat and sun's rays hence to measure the warmth of an atmospheric condition, it is essential to measure the radiant heat also. It is measured by Campbell - Stokes Sunshine Recorder, Solar radiation thermometer and Black Globe thermometer. The difference in the maximum thermometer reading taken inside the Stevenson screen and the Solar radiation thermometer denotes the intensity of solar radiation.

Atmospheric pressure is measured with the help of an instrument called as a barometer. These could be the aneroid or mercury barometer of which the latter are more accurate. Some of the well-known barometers are Fortin's barometer, Kew Pattern station barometer commonly used by the Indian Meteorological Department and the Barograph. The barograph is a continuous measurement of the atmospheric pressure over a 24 hour period. The fluctuations seen in a barometer are considered to be of importance in determining the pattern of weather conditions.

Atmospheric humidity or the moisture content of air can be expressed in two different manners as Absolute humidity and Relative Humidity (RH). At relative humidity levels above 65 percent, the air inside a room feels sticky, while air at RH below

30 percent is unpleasant. Mason's Hygrometer is the most widely used instrument for measuring humidity at the permanent meteorological stations. Whirling or Sling Psychrometer and Assmann Psychrometer give more accurate measurements.

Air movement determines the cooling power of air and it influences the comfort levels in an environment. The equipment used to measure air movement are Kata thermometer and anemometers. The latter could be of propeller type, thermoanemometers or the hot wire anemometers.

Precipitation is a collective term used for all forms of water precipitated from the atmosphere such as rain, snow, hail, dew and frost. Rainfall is measured by rain-gauges in inches or millimetres per time unit (day or month). The Indian Meteorological Department uses the Symon's rain-gauge at its rainfall measuring stations.

## Study Exercises

**Short Notes :** (1) Kata thermometer (2) Psychrometer.

### MCQs

1. Stevenson screen is used for measuring (a) Air Temp (b) Cooling power of Air (c) Humidity (d) Air movement.
2. Globe thermometer is used to measure (a) Air Temp (b) Cooling power of Air (c) Humidity (d) Mean Radiant Temp.
3. The measuring liquid of kata thermometer is (a) Alcohol (b) Mercury (c) Water (d) None.
4. Kata thermometer was devised to measure (a) Air Temp (b) Cooling power of Air (c) Humidity (d) Air movement.
5. The speed with which the air should pass over the bulb in a wet bulb thermometer is (in m/Sec) (a)5 (b)10 (c)50 (d)100.
6. Air velocity is measured by (a) Anemometer (b) Psychrometer (c) Globe thermometer (d) Stevenson screen.
7. Kata thermometer can record air velocities as low as (in ft/min) (a)10 (b)2 (c)20 (d)1.

**Answers :** (1) a; (2) d; (3) a; (4) d; (5) a; (6) a; (7) a.

The term "heat stress" is applied to any degree of environmental heat that causes physiological thermoregulatory mechanisms to get activated. Human beings are homoeothermic creatures whose physiology attempts to maintain a constant core body

temperature of 37°C (range 36 to 38°C). Obviously, this requires balancing of the body heat production with heat loss which is achieved by a combination of physiological mechanisms (as peripheral vasodilatation or vasoconstriction, changes in heart rate, sweating or shivering) and behavioral mechanisms (increase or decrease in voluntary physical activity, seeking appropriate shelter etc). In addition, environmental conditions viz., temperature, humidity and speed of air also greatly determine whether a person will be subjected to thermal stress. Prevention and management of thermal stress disorders therefore requires an understanding of these physiological, behavioral and environmental mechanisms and manipulating

them appropriately. For the purpose of thermoregulation, the human body can be conceived of having two “layers” - an outer periphery or “shell” consisting of skin, subcutaneous tissue and muscles, and an inner “core” consisting of brain, heart and viscera.

## Epidemiology

Adverse effects of heat stress are an important cause of morbidity and mortality not only in developing countries, but in the developed countries as well. In India, 3,194 deaths due to heat-stroke have been recorded over the 5-year period - 1999 to 2003; the actual magnitude may be much more. The central and northern plains, western deserts and tropical forest areas of North - East have environmental conditions causing heat stress during the months of April to September. In India, more than 1600 heat related deaths were reported during the year 2003 (1).

### Human (Host) Factors

A wide array of host factors have been implicated in increasing the risk of heat illnesses, as shown in Box - 1.

<b>Box - 1 : Persons at high risk of heat stress</b>
Extremes of age (<5 years or >65 years)
Pregnancy
Occupation : military, agricultural, construction & industrial settings, labourers, sports-persons and miners
Low level of physical fitness
Lack of acclimatization to environmental heat
Obesity
High ambient temperature, high atmospheric humidity, low air velocity
Alcohol use - acute and chronic
Skin diseases : Extensive prickly heat, psoriasis, pyoderma
Sleep deprivation
Co-existing febrile illness, renal, thyroid, cardio-vascular and metabolic diseases
Previous history of heat-illness
Use of drugs or habit forming substances : Phenothiazines, anti-cholinergics, ACE-inhibitors, MAO-inhibitors, cocaine, amphetamines
Residence on floors higher than ground floor, especially top floors, and urban areas
High population density as occurs during social and religious conglomerations
(Sources : References 2 - 13)

**Physical activity and adverse effects of hot environment:** Physical activity in a hot/humid environment is a major determinant of heat illness. With the broad group of physical activity, certain variables determine the occurrence and severity as follows :

**(i) Nature of physical activity :** The nature of physical activity and its strenuousness, at a given time is one of the

most important determinants, since it directly determines the metabolic heat being produced by the body which, in turn, reflects the intrinsic heat load of the body. It also needs to be noted that running or jogging at fast pace leads to very high metabolic heat production and may be particularly hazardous during hot weather.

**(ii) The amount of load being carried :** This could be either external load (as baggage) or as a part of body weight itself (e.g. an obese persons). For every additional kilogram of such “load”, an additional 2 kcal/hour of additional heat will be produced, when walking at ordinary pace. This would further increase as the pace increases.

**(iii) The type of terrain :** As compared to walking on an ordinary black topped road, the metabolic heat production will progressively increase when walking (at the same speed), on a cross country track, on recently ploughed fields, on snow or on over heavy sand, in which case the heat production may be almost two times when compared to walking on road. (The hot environmental conditions associated with sandy terrain are, in any case, additional).

**(iv) The Inclination (Gradient) :** Heat production increases, at a given pace, as the gradient increases. Even a 10% increase in the gradient may substantially increase metabolic heat production.

**(v) The duration of physical activity :** In harsh, hot & humid environment even well trained persons may suffer from adverse effect of hard physical activity if continued for more than half an hour unless adequate rest pauses are interspersed.

**The type of clothing and adverse effects :** There are three aspects, in relation to clothing, which determine the dissipation of metabolic heat, being produced in the body.

- The *insulation*, measured in Clo units (8). The insulation should be, ideally, as low as possible in a hot environment.
- The *permeability to moisture* which should be as high as possible.
- Absorption of “*radiant energy*” which is quite high for dark clothing.

Synthetic material has poor permeability and should be avoided. Similarly multilayered clothing, which ‘trap’ layers of still air between them tend to increase the insulation even if they have good permeability. Thus the correct approach would be to use light coloured loose fitting clothing, in one or two layers, and made of ‘breathable’ material as cotton.

### Environmental Factors

While various attributes of the human host, as described earlier, play an important role in determining who will and will not ultimately get affected by heat illness, a major role in these health issues is played by the physical environment - the air temperature, humidity, air movement, and radiant heat from sun or other hot objects.

From the physical environment point of view, the major factor which emerge as determinants of heat illness are, the temperature of ambient air (usually determined by Dry Bulb Thermometer (DBT), the relative humidity (usually determined by using psychrometric charts, using the reading of both the



DBT and the Wet Bulb Thermometer (WBT), the Mean Radiant Temperature (MRT) whose main source is either solar radiation or radiations from hot objects as furnaces, and which is usually determined by the Globe Thermometer (GT), and the speed of the air (usually determined by anemometers or specialized thermometer). Based on the permutation and combination of these parameters, certain indices of environmental heat illness have been developed. A brief description of these “*thermal stress indices*” is as follows :

**(a) Effective Temperature :** ET is defined as the subjective feeling of warmth (or cold) at a given temperature of air (DBT), when RH is 100%, the air is almost still (minimal air movement) and the subjects are ordinarily clothed. In general, when a person is at rest with a body metabolic heat production of 100 kcal/ hour, in an environment of 100% RH and minimal air movements, an air temperature (DBT) of 36°C is the ET and marks the upper limit of 4 hourly tolerance. If heat production increases, by strenuous activity to about 425 kcal/hour, under the same environmental conditions, a DBT of 31°C is the upper limit of ET for 4 hourly tolerance (14). For the outdoor setting, the preferred index is ‘Corrected Effective Temperature (CET)’, where Globe thermometer temperature (GT) is used in place of DBT.

**(b) Oxford (syn - Wet-Dry - WD) Index :** The Oxford Index is a simple and quite effective Index, based on DBT and WBT :  $WD\ Index = 0.85\ WBT + 0.15\ DBT$ .

**(c) Wet Bulb Globe Temperature (WBGT) :** WBGT index is the most commonly used index of thermal stress. It takes into account the effect of MRT (as measured through Globe Thermometer (GT) in addition to WBT and DBT as follows :

Outdoor WBGT =  $0.7\ WBT + 0.2\ GT + 0.1\ DBT$

Indoor WBGT =  $0.7\ WBT + 0.3\ GT$

WBGT levels of 30°C and above indicate definite thermal stress and care needs to be exercised (15). From May to August, most of the Indian subcontinent (except the northern hilly areas) tends to have WBGT values of more than 30°C.

## Prevention of Heat Related Illness

Governmental as well as the public health functionaries cannot afford to ignore the potential dangers of sustained heat wave and should develop a contingency plan. Although heat stroke is amenable to medical treatment, control can best be achieved by applying the principles of public health surveillance, public education, outreach to vulnerable persons, availability of life saving first aid and enlistment of the help of the entire community can save lives (16). A structured approach towards prevention and control of Heat illnesses in communities consist of :

- Public Health measures directed towards communities and large population groups
- Specific preventive measures directed towards individuals/ small groups identified to be at high risk of heat illnesses due to certain occupational characteristics
- Early detection and first aid.

**Public Health Measures Directed Towards Communities and Large Population Groups :** In tropical countries like India, millions of people among the general population are at

risk during the hot/humid months, especially when spells of heat wave strike. In such settings, heat related casualties may occur in large numbers in short duration, creating almost a disaster like situation and hence the need for public education, provision of preventive amenities at vantage points, and quick first aid. From the public health angle, the following aspects need to be addressed :

**(i) Public education regarding preventive measures :** Creating public awareness should be high on the list for the public health administrators. Full use of audio-visual and print mass media must be made during the onset of hot weather and also well before the expected heat wave. The *messages* should include the following aspects :

- Do not venture out in the sun, especially between 10 am to 4 pm unless the same is necessary.
- Avoid strenuous physical exertion between 10 am to 4 pm during the hot weather unless the same is necessary for reasons of occupation.
- Drink at least 4 to 5 litres of cool water in a day even if not feeling thirsty. If undertaking strenuous physical activities, drink a quarter to half litre of water after every half an hour, as long as strenuous activity continues.
- Do not wait for ‘thirst’ to develop. Keep drinking water regularly even if not thirsty.
- If exposure to sun is necessary, place a wet hand towel around your neck.
- Put on a wide - brimmed hat of light colour when going out. Simple caps as golf cap may not give enough protection.
- Put on sunglasses when going out in the sun.
- Apply a sun screen ointment with a Sun-Protection-Factor (SPF) of at least 15, which should be able to protect against both UVA and UVB rays, when going out in the sun.
- Avoid alcohol consumption during hot humid months. If consumption becomes necessary, keep the same within limits of less than 2 small drinks of hard liquor or one bottle of light beer per day.
- Keep children less than 5 years and elderly (aged 65 years and above) away from sun as far as possible.
- Never leave children (or pets) in a closed, parked car. Try and park your car in cool, shaded place.
- Use a car-sun visor to minimize the effect of direct radiant heat produced by the sun, to enter inside the parked car.
- Dress for hot, humid weather should be ‘breathable’ i.e. Loose fitting, light weight, light colored, preferably of cotton material and in one or two layers only.
- Carry a water bottle with cool drinking water whenever you go out in summer months.
- If you feel exhausted, confused or running out of memory/ consciousness, move to a shaded place, sit/lie down, drink cool water and seek help.

**(ii) Provisions of basic preventive amenities at vantage points on a large scale basis, during high risk periods :** There are four basic amenities which all public health managers must strive to provide to the general public during the hot weather or else, if some high risk activity as sports events or religious/ social gatherings are likely. They are :

- Cool drinking water at vantage points.
- Covered/shaded areas for taking rest pauses.

- Facilities for first aid in a way that they are early accessible to all, particularly the high risk groups.
- Public information system to make all aware about the facilities and the telephone numbers/addresses of key persons and first-aid facilities, who may be contacted during need.

**(iii) Identification of high risk groups and enlistment of community support :** Studies have revealed, there are certain high risk groups like agricultural workers, manual labourers, young children, old people those who are unable to care for themselves and those who form part of large social or religious gatherings/ festivals, are more vulnerable to the effects of heat. And enlistment of community support as part of voluntary services with outreach efforts towards these high groups can be of much utility in minimizing the public health impact of heat.

**Public Health Surveillance, Early Warning Systems and Disaster Plan :** The need to have a good epidemiological surveillance system for heat illnesses as well as various environment conditions that determine those illnesses need not be over emphasized. This should be established not only for specialized groups like Armed forces or industries but also for the general community as well. It is only through ongoing collection of data and monitoring of trends of occurrence of illness and environmental factors, that proper policy decisions on public health aspects of heat illnesses can be taken (3, 17, 18). An effective heat illness surveillance system must include reporting of all heat illness cases according to diagnostic categories, both for indoor and outdoor cases separately. It should have at the minimum, data related to time and place of exposure, as well as basic clinical data, besides including the antecedent/precipitating factors and personal risk factors. It should also have the essential meteorological data (WBT, DBT, GT) for various locations. The data should be analyzed in an ongoing manner and a 'Heat and Health Early Warning System' should be developed to issue early warnings and use of public health/preventive measures to the physician as well as to the general community. Simple warning criteria based on WBGT for outdoor exercises as running and cycling, for general public can be that, at the place where and time when an outdoor exercise or sports event is being planned, if WBGT index is more than 28°C, or else the WBT recording is more than 26.5°C, the event should not be held (17). If both, the Dry Bulb (DBT) readings and Relative Humidity (RH) levels are known, a rough guidance for outdoor physical exercise can be as shown in Table - 1. Note that these meteorological parameters should be recorded as near the place of outdoor exercise as possible.

**Specific Preventive Measures Directed Towards Individuals and Small Groups :** Specific preventive measures directed towards individuals or specific high risk groups as industrial workers, military personnel, sports persons etc., are undertaken to achieve the following objectives :

- Proper protective measures in the industries as isolation of furnaces, and spray of cold aerosols.
- Seeking shade and wind to the extent possible.
- Frequent rest pauses interspersed between phases of physical activity.

<b>Table - 1</b>		
<b>Dry Bulbs Temp. (DBT)°C</b>	<b>Relative Humidity (RH) levels (%)</b>	
	<b>Moderate risk</b>	<b>High risk</b>
29.5°C	100%	-
32.2°C	70-99%	-
35.0°C	50-70%	>80%
37.8°C	40-50%	60-80%
40.6°C	20-40%	50-60%
43.3°C	10-30%	40-50%
46.1°C	10-20%	30-40%
48.9°C	1-10%	20-30%
<i>(The interpretation of Table - 1 is as follows : for example if the outdoor DBT is 37°C and the RH is 48%, there is moderate risk of developing heat illness; if the RH at the same temperature is 65%, there is high risk.)</i>		

- Putting on proper clothing of low insulation, low energy absorption and high permeability.
- Reducing the amount of exercise in terms of duration or intensity or both.
- Avoiding carrying of load or reducing the load.
- Acclimatization to heat and proper hydration.
- Avoidance of obesity, alcohol and other habit forming agents as cocaine, cannabis and caffeine.
- Avoidance of self medication.
- Avoiding physical activity and exposure to hot environment during febrile illness, until fully recovered.
- Ensuring proper sleep of 7 to 8 hours in the night and cooler parts of early morning. An afternoon rest in a shaded place may be of further protective value.
- Maintenance of general hygiene and sanitation, regular bath and care of skin, proper immunization and hygiene of food & water, to avoid GIT infections.
- Nutritious and palatable meals with plenty of drinking water.
- Treatment of skin conditions as prickly heat, psoriasis, sun burns etc.

**Acclimatization to heat :** Acclimatization to heat is a process of undertaking gradually increasing physical exercises in gradually increasing hot environment with a view to develop physiological changes, so that the individual, so acclimatized, is able to perform physical activities in the hot environment for which he/she has been acclimatized, with much less risk of suffering adverse effects of heat. The individuals to be acclimatized are subjected to physical exercise in a hot environment in which they are ultimately required to work. The schedule should be in a graded manner, starting with lower intensity of physical exercise for lesser duration (about an hour) in less hot environment. This is gradually increased, both in intensity and duration (about 90 -120 minutes) and to the required hot environment, by the 6th or 7th day and continuing thereafter for another 7 days. It takes about 10 to 14 days for status of acclimatization to be achieved. During the

process of acclimatization, individuals should be encouraged to drink plenty of water/oral fluids and additional salt may be given with meals (not as salt tablets).

**Maintenance of Hydration :** During the process of acclimatization and also after acclimatization, it is imperative that adequate hydration be maintained, otherwise the entire process of acclimatization will be negated. It needs to be noted, and explained that there is no substitute to adequate hydration even after full acclimatization since acclimatization itself works on the principle of increasing the sweating. One can acclimatize to physical work in heat but there is nothing like acclimatization to dehydration.

Persons should be encouraged (even, at times, forced or ordered) to keep drinking water regularly while working in hot environment, even when not thirsty. It must be explained clearly that thirst is quite a poor index of dehydration and should not be relied upon. Drinking only when thirsty will result in inadequate replacement of water losses and result in dehydration of more than 2% of body weight, which may be dangerous. The best fluid for drinking is cool, hygienic water. It would be worthwhile to drink half a litre of water, about an hour before starting physical activities in hot weather, as a 'prehydration' method and to negate any pre-existing water deficit. Thereafter every person should drink 300 to 350 ml water (equal to the usual steel tumbler) every half hourly, during the exercise, without waiting for thirst. In-fact, more frequent intakes of smaller amounts (250 ml i.e. one ordinary size glass tumbler every 20 minutes) may be even better. At the same time, care should be taken not to drink so much that it leads to abdominal distension.

#### Adverse Effects of Environmental Heat & their Emergency Management

**Heat Stroke (HS) :** The classical clinical description of HS is the triad of hyperpyrexia (rectal temperature >40°C), CNS dysfunction and anhidrosis. Anhidrosis, however, is not a diagnostic requirement, since it may appear later when volume depletion is severe. Moreover, in cases which initially start as HE or cases of HS which occur among young people who have been exerting physically, the skin may be moist. Brain dysfunction is usually severe (coma, stupor or delirium), but may sometimes be subtle, manifesting as inappropriate behaviour or impaired judgment. In fact, any person who develops irrational or confused behavior following exposure to heat stress either with or without a history of physical exertion, should be treated as a potential HS patient. Other clinical features include evidence of dehydration, shock, convulsions and, sometimes, mild icterus. Two forms of HS are recognized, viz. the classical (CHS) and the exertional (EHS) form. It is important to recognize the clinical differences between the two forms (Box - 2).

Heat stroke should be considered as a possibility in any patient who presents with elevated body temperature and altered mental functions. Important and common diseases which need to be excluded are tropical infectious diseases like cerebral malaria, encephalitis and meningitis. The diagnosis of HS is usually one of exclusion and the typical history of exposure to hot environment during the immediate past is an indication towards heat stress hyperthermia. HS must be treated as a serious medical emergency. Delay in institution

<b>Box - 2</b>		
	<b>CHS</b>	<b>EHS</b>
Age group	Elderly	15 to 45 years
Previous health status	Usually compromised	Healthy
Concurrent activity	Sedentary	Strenuous activity
H/o drug use	Often present	Usually present
Sweating	Often absent	Often present
Skin	Dry	Moist
Rhabdomyolysis	Unusual	May be severe

of appropriate therapy by even few minutes may make all the difference between life and death. The treatment objectives are, firstly, rapid cooling to bring down the core temperature to below 39°C, reducing it by approximately 0.2°C per minute; secondly, rehydration and care of comatose patient; and, thirdly to support the organ system function. Cooling measures should be stopped once core temp falls below 39°C. The steps in management at first aid level, and at primary care/solo physician level are shown in Box - 3 and 4 respectively.

**Heat Exhaustion (HE) :** The features which differentiate HE from HS are that core temp is less than 40°C and there is no evidence of CNS dysfunction, though some patients may be anxious or irritable. The main features are feeling of exhaustion, nausea, headache or light headedness, features of dehydration, hypovolaemia (tachycardia, loss of skin turgor, dry mucous membranes and thirst) and syncope. Sweating is usually profuse and skin is moist. Rectal temperature is usually between 39°C to 40°C, though some patients may have a normal temperature. Urinary output is reduced and urine may be light to dark yellow in colour. Depending on how energetically the patient has been replacing either water or salt, two subtypes, viz. Water Depletion HE and Salt Depletion HE may occur. In water Depletion HE, as compared to Salt Depletion HE, vomiting and muscle cramps are not a prominent feature, while thirst is prominent, and serum Na<sup>+</sup> is normal or raised. However, mostly a mixed picture, as described earlier is seen.

Treatment consists of shifting the patient to a cool, shaded and ventilated place. The clothing should be loosened, patient placed in recumbent position and feet should be elevated. If patient can drink, give one litre of water (or, preferably, "Oral Rehydration Solution" 1 packet dissolved in one litre water or else a solution of 2.5g common salt and 2.5g baking soda in 1 litre water) orally in about 30 min. Give a total of 2 litres in about one to one-and-a-half hours. Simultaneously, measures for cooling, as described under heat stroke, should be initiated. Keep monitoring rectal temp; if rectal temp goes beyond 39°C, the patient may be passing on to heat stroke and should be shifted to a medical facility for appropriate management.

#### Other Adverse Effects of Hot Environment

**Heat Cramps :** These manifest as spasms of muscles, especially lower extremity and shoulder, following heavy muscular exertion in hot environment, with associated intake of hypotonic oral fluids. Treatment consists of oral administration of 0.1% to 0.2% salt solution.



**Box - 3 : Heat Stroke : First Aid**

Record rectal temperature. If it is not possible to record rectal temp, record oral temp and add 0.5°C.

Try and move patient to a cooler, shaded place.

Remove the clothes.

Spray skin with water at 25 to 30°C or wrap the patient with a sheet soaked in water at 25-30°C.

Continue fanning manually or with an electrical fan.

Keep vigorously massaging the skin to prevent cutaneous vasoconstriction during cooling.

If available, place ice packs or towel soaked in cold water around the neck, axillae and groin.

Nurse in the comatose position; clear oral secretions.

Transport to the medical facility as an emergency.

**Box - 4 : Heat Stroke Management at the Level of Solo-Physician or at Primary Health Care Level**

Initiate measures outlined under first aid if not already initiated

Establish IV-line; take blood sample for investigations.

Start normal saline (or Ringer lactate) drip at 20-25°C. Give a challenge of 1 litre fluid in 15 to 30 minutes. Add other electrolytes such as K<sup>+</sup>, as guided by subsequent investigations.

If any evidence of seizures, give IV Diazepam 5-10mg over 10mts

If facilities are available, intubate the patient and initiate ventilatory support.

If rectal temp is not coming down or there is evidence of cerebral, hepatic or renal complications consider transferring the patient to a hospital with adequate facilities.

**Heat Tetany** : Symptoms include carpopedal spasms and paraesthesiae following short exposures to excessively hot environment, leading to hyperventilation and respiratory alkalosis. Treatment consists of removing the patient to a cool environment and asking him to slow down the respiration.

**Heat Syncope** : This manifests as syncope following exposure to heat stress as a result of peripheral vasodilatation. One should exclude other serious causes of syncope. Treatment consists of removal of patient to cool environment and oral rehydration.

**Heat Oedema** : This presents with pitting oedema of hands and feet, usually in the elderly, following exposure to heat stress. Other causes of oedema should be excluded. Treatment consists of reassurance, elevation of affected limbs and, if required, compression bandage.

**Prickly Heat (Lichen Tropicus, Malaria Rubra)** : It manifests as erythematous, pruritic, maculopapular rash. If the condition is allowed to progress, extensive prickly heat that can progress to chronic dermatitis and superinfection can occur. Prevention consists of regular baths with cool water after gently scrubbing the skin and wearing loose, light weight clothing. Local application of calamine lotion or chlorhexidine lotion alongwith oral antihistamines is helpful.

## Summary

The term “heat stress” is applied to any degree of environmental heat that causes physiological thermoregulatory mechanisms to get activated. Humans are homoeothermic creatures whose physiology attempts to maintain a constant core body temperature of 37°C (range 36 to 38°C). For the purpose of thermoregulation, the human body can be conceived of having two “layers” - an outer periphery or “shell” consisting of skin, subcutaneous tissue and muscles, and an inner “core” consisting of brain, heart and viscera.

Adverse effects of heat stress are an important cause of morbidity and mortality. In India, the central and northern plains, western deserts and tropical forest of North - East have environmental conditions causing heat stress during April to September. The high risk conditions include extremes of

age (<5 years or >65 years), pregnancy, workers in military, agricultural, construction & industrial settings, labourers, sports-persons and miners, those having poor physical fitness, lack of heat acclimatization, obesity, alcohol use, skin diseases, sleep deprivation, co-existing febrile illness, renal, thyroid, cardio-vascular and metabolic diseases, previous history of heat-illness & use of drugs or habit forming substances e.g. Phenothiazines, anti-cholinergics. Besides the factors mentioned, certain other Human (Host) Factors are implicated in causation of heat stress as gender, racial and genetic factors, physical activity, type of clothing, lack of concurrent hydration, floor of the residential building, urban rural differences & social and religious conglomeration. Environmental factors involved are temperature of ambient air, relative humidity, Mean Radiant Temperature (MRT) & air speed. Certain indices of environmental heat illness based on the permutation and combination of these parameters are Effective Temperature, Oxford (syn : Wet-Dry : WD) Index & Wet Bulb Globe Temperature (WBGT) index.

A structured approach towards prevention and control of heat illnesses in the community consist of Public Health measures directed towards communities and large populations groups, specific preventive measures directed towards high risk individuals/small groups & early detection and first aid.

In Public health measures directed towards communities and large population groups, the aspects that need to be addressed are public education on various preventive measures such as not venturing out in the sun, especially between 10 am to 4 pm during the hot weather, drinking at least 4 to 5 liters of cool water in a day even if not feeling thirsty; provisions of basic preventive amenities at vantage points on a large scale basis, during high risk periods; identification of high risk groups and enlistment of community support; and development of Public Health Surveillance, early warning systems and disaster plan.

Specific preventive measures directed towards individuals and small groups should be directed to high risk groups as industrial workers, military personnel, sports persons etc., to achieve the objectives of proper protective measures in the industries,



seeking shade and wind to the extent possible, frequent rest pauses, proper clothing of low insulation, low energy absorption and high permeability, reduced physical exercise, avoiding carrying/reducing the load, heat acclimatization and proper hydration, avoidance of obesity, alcohol, habit forming agents, self medication, physical activity and exposure to hot environment during febrile illness; ensuring proper sleep of 7 to 8 hours in the night and cooler parts of early morning with an afternoon rest in a shaded place; maintenance of general hygiene and sanitation, regular bath and care of skin, proper immunization and hygiene of food & water, nutritious and palatable meals with plenty of drinking water, treatment of skin conditions.

Acclimatization to heat is the process of undertaking gradually increasing physical exercises in gradually increasing hot environment with a view to develop physiological changes, so that the individual is able to perform physical activities in the hot environment for which he/she has been acclimatized, with much less risk of suffering adverse effects of heat. It is in a graded manner, starting with lower intensity of physical exercise for lesser duration in less hot environment which is gradually increased, both in intensity and duration. The physiological changes consequent to acclimatization are increased sweating in response to exercise, lowered threshold for exercise induced sweating, lesser rise in heart rate and lesser rise of skin and rectal temperature in response to exercise, decreased amount of salt excretion in sweat, increased ability to sustain sweat production during prolonged exercise and redistribution of sweating from truncal region to the extremities.

Maintenance of hydration by drinking water regularly while working in hot environment, even when not thirsty is extremely important. Advise should be to drink 300 to 350 ml water (equal to the usual steel tumbler) every half hourly, during the exercise, without waiting for thirst.

Adverse effects of hot environment include Heat Stroke (HS) which is a triad of hyperpyrexia (rectal temperature  $>40^{\circ}\text{C}$ ), CNS dysfunction (usually severe) and anhidrosis. Other features include evidence of dehydration, shock, convulsions and mild icterus. Two forms of HS are recognized, viz. the Classical (CHS) and the Exertional (EHS) form. The treatment objectives are, firstly, rapid cooling to bring down the core temperature to below  $39^{\circ}\text{C}$ , reducing it by approx  $0.2^{\circ}\text{C}/\text{min}$ ; secondly, rehydration and care of comatose; and, thirdly to support the organ system function. Heat Exhaustion (HE occurs when the core temp is less than  $40^{\circ}\text{C}$  with no evidence of CNS dysfunction. The main features are feeling of exhaustion, nausea, headache or light headedness, dehydration, hypovolaemia, syncope, profuse sweating and moist skin. Treatment consists of shifting the patient to a cool, shaded and ventilated place, loosening the clothing, recumbent position and feet elevation. If patient can drink, give one litre of water (or, preferably ORS) orally in about 30 min. Give a total of 2 litres in 1-1½ hours. Simultaneously, measures for cooling as under heat stroke, initiated. Other adverse effects of hot environment include heat cramps, heat tetany, heat syncope, heat oedema & prickly Heat.

## Study Exercises

**Long Question :** Discuss the public health and community based preventive actions that you will adopt, as the District

health officer, for dealing with an expected heat wave that is likely to last for about 3 to 4 weeks, in the state of Punjab.

**Short Notes :** (1) Heat stroke versus heat exhaustion (2) Risk factors for adverse effects of hot environment (3) Thermal stress indices (4) Acclimatization to heat.

## MCQs & Exercises

- For every additional kilogram of load being carried, how much of additional heat will be produced, when walking at ordinary pace : (a) 1 kcal/hour (b) 2 kcal/hour (c) 3 kcal/hour (d) 4 kcal/hour.
- All the following are important aspects which determine the dissipation of metabolic heat, in terms of the clothing being worn except : (a) Insulation (b) Radiance (c) Permeability (d) Absorption.
- The commonest skin disease which interferes with sweat function thereby reducing heat tolerance is \_\_\_\_\_.
- Febrile illness, as a consequence of infection or following immunization, increases the \_\_\_\_\_ of the body, as well as the heart rate.
- During heat-wave conditions, the morbidity and mortality in urban areas tends to be higher as compared to rural areas due to \_\_\_\_\_ effect.
- Globe Thermometer is used to measure : (a) Relative humidity (b) Ambient temp (c) Radiant heat (d) Air velocity.
- Oxford Index is dependent on (a) DBT (b) WBT (c) DBT & WBT (d) None of the above.
- Which is the most commonly used index of thermal stress (a) DBT (b) WBGT (c) WBT (d) Oxford.
- A good sun screen ointment should have a Sun-Protection-Factor (SPF) of at least, to be able protect against both UVA and UVB rays, when going out in the sun : (a) 10 (b) 15 (c) 20 (d) 25.
- Acclimatization to heat takes how many days? : (a) 2 - 6 days (b) 6 - 10 days (c) 10 - 14 days (d) 14 - 18 days.
- Unit of measurement of insulation of clothing is \_\_\_\_\_.
- Anemometers are used to measure : (a) Relative humidity (b) Ambient temp (c) Radiant heat (d) Air velocity.
- Which WBGT levels indicate definite thermal stress and that care needs to be exercised : (a)  $10^{\circ}\text{C}$  -  $20^{\circ}\text{C}$  (b)  $20^{\circ}\text{C}$  -  $30^{\circ}\text{C}$  (c)  $30^{\circ}\text{C}$  & above (d) All are correct.
- Drinking only when thirsty will result in inadequate replacement of water losses and dehydration due to loss of how much water as percentage of body weight : (a)  $<1\%$  (b)  $1\%$  (c)  $2\%$  (d)  $>2\%$ .
- Heat stroke is a triad of hyperpyrexia (rectal temperature  $>40^{\circ}\text{C}$ ), CNS dysfunction and \_\_\_\_\_.

**Answers :** (1) b; (2) b; (3) Prickly heat (Malaria Rubra); (4) Heat load; (5) Heat Island; (6) c; (7) c; (8) b; (9) b; (10) c; (11) Clo units; (12) d; (13) c; (14) d; (15) Anhidrosis.

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Adverse effects of extremes of cold environment have been an important public health issue in the history of mankind (1, 2). Deleterious effects of extreme cold are inherent in the atmospheric environment at high altitude, but they also occur at low altitudes as in the Polar Regions. Even sub tropical areas like the plains of Northern India experience severe winters, where such illnesses do occur. Extreme cold conditions occur in India in the Himalayan, Sub - Himalayan and the northern Indian plains with cold waves and deaths being recorded every year. Over the 5-year period - 1999 to 2003, a total of 3,524 deaths due to cold exposure have been reported; the actual magnitude may be higher.

Human exposure to extreme cold produces significant physiologic and psychological challenges. Cold is considered as an important environmental stressor, in view of its serious consequences (3). The human body becomes even more susceptible to the adverse effects of cold when chronic exertional fatigue, sleep loss, and inadequate nutrition are also co-existent (4). Groups at particularly high risk include military personnel, agriculturists, mountaineers and persons engaging in adventure or winter sports. From socio - economic aspect, persons with low income, poor housing and inadequate clothing are at particularly high risk especially during the cold wave conditions. Extremes of age (<5yrs or >65yrs), physical exhaustion, pre - existent malnutrition or starvation, use of alcohol and underlying diseases (hypothyroidism, hypoadrenalism, diabetes and CV Disease) increase the risk.

#### Adverse Health Effects of Cold

Adverse effects of cold environment can manifest as either

generalized effects (hypothermia) or local "tissue-freezing" effects as frost bite, or Non-Freezing Cold Injuries (NFCI) as trench foot and chilblains.

**Generalised Hypothermia** : The normal core (rectal) temperature of normal healthy human beings is 37 to 37.5°C. Early symptoms of generalised adverse effects of cold become apparent as the "core" (rectal) temp. drops below 36°C and are clearly evident once it is below 35°C. Depending on the core temp, hypothermia may be classified as borderline (36 to 35°C), mild (35 to 32°C), moderate (32 to 28°C) and severe (<28°C). One of the earliest symptoms of hypothermia is change in behaviour but, unfortunately, the victim is the last person to notice such changes himself. There are mild mood changes, lack of affect, apathy, uncoordinated movements, ataxia, confusion and decreased ability to sense cold.

Initially, there is tachycardia, tachypnoea & shivering which can be voluntarily controlled. However, as hypothermia becomes more severe, (32 to 35°C) there is bradycardia and decrease in respiratory rate. Higher reasoning becomes impaired; shivering becomes violent and cannot be stopped voluntarily. As the core temp falls below 32°C, shivering stops. Skin becomes blue and puffy. Patient becomes semiconscious and muscles start becoming rigid. Trismus is often present. There is marked bradycardia and lowering of respiratory rate. Cardiac dysrhythmias are very common, especially atrial/ventricular fibrillation.

Once the core temp drops to 28°C or less, the patient is completely unconscious with severe bradycardia. Radial pulse may not be palpable and carotid pulse may reveal as low as 2 to 3 beats per mt. Respiratory rate is also reduced to 1 to 2 per min. Muscles become rigid and pupils dilated. *At this stage the patient may appear dead but may not be so. Carotid pulse must be carefully palpated in all such cases.*

*Hypothermia should be treated as a medical emergency.* Early recognition and institution of therapy may make all the difference between life and death. The basic principle of

management is quick warming of the “core” without causing simultaneous vasodilation of the periphery, from the level of first aid till the most elaborately equipped critical care facility. The steps in management at the first aid level and at the primary care/ solo physician level are shown in Box - 1 & 2, respectively.

#### Localized Effects of Cold

**Frost Nip and Frostbite :** Frost nip involves freezing of top layers of skin tissue. It is generally reversible and manifests as numbness and white, waxy or rubbery feeling of the affected skin but the deeper tissue is still soft. Frostbite is the more severe form and affects all layers of the skin and often the deeper tissue also. Frostbite is of four degrees, depending on the depth of the tissue involved. As an urgent first aid measure, remove any constrictive clothing or bands. Start local warming by placing the affected part in a warm water bath at 40-42°C. If nothing is available, place the affected part in the axillae or on the stomach of another healthy person. Analgesics and sedatives should be given for relief of pain. Initiate immunisation with tetanus toxoid and evacuate to a surgical facility at the earliest opportunity. If generalised hypothermia and local frost bite both are present, first treat the patient for generalized hypothermia. Local rewarming for frostbite should be undertaken only after core temp has returned to normal.

**Non - Freezing Cold Injuries :** These include chilblains and trench (immersion) foot, occurring due to prolonged exposure to cold environment with wet conditions. Chilblains manifest with initial pallor of affected area (usually fingers, toes, cheeks or earlobes) followed by erythema, pruritus and intense pain. Prevention by way of avoidance of exposure to cold and wet conditions among susceptible persons is the most important.

#### Box - 1: Management At First Aid Level

Remove wet clothing only when patient has reached a warm, dry and sheltered environment and not in the open.
Immediately wrap the patient all around, including head, with warm clothes, blankets, quilts, sleeping bags - whatever insulatory material is available, even news papers or rags. Make an “insulatory wrap” of about 4 inches thickness all around the patient. Provide a wind and water proof outer most layer, as polythene sheets.
Make hot packs with warm water bottles covered with a cloth, or warm pads, at 42°C to 45°C, and apply them to axillae, groin and neck.
Do not warm the extremities at this juncture. Place arms and hands on the sides and not on the abdomen or in axillae.
Do not let patient do any physical activity. Treat as a “stretcher case”.
If patient can take orally give warm, sweetened tea or milk to provide “fuel”.
Do not massage the limbs.
Do not give alcohol or tobacco
Evacuate to a sheltered place preferably to a medical facility at the earliest.

Otherwise, there is no specific treatment, though symptoms may be ameliorated by oral Nifedipine in some cases.

Trench foot is caused by prolonged exposure of feet to cold and wet conditions. The skin is reddened with tingling pain and itching. Gradually the skin becomes pale, mottled and finally dark purple, gray or blue. If the circulation remains impaired for more than a few hours, permanent damage to the affected part can occur. Treatment consists of gentle drying, elevation of the affected limb and keeping it at an environmental temperature of 18 to 22°C while keeping rest of the body warm. NSAIDS may be given for relief of pain. The patient should not walk on the affected limb till fully cured. Prevention is, once again, very important and consists of keeping the feet clean and dry, dabbing the feet with aluminium hydroxide powder thrice daily, and changing into dry socks and shoes at the earliest .

#### Epidemiology

**Environmental Factors :** The following are the major environmental factors which determine the severity of cold induced diseases :

**Severity of Cold :** Severity of atmospheric cold and its abrupt occurrence increases the liability of incidence of cold injuries among non-acclimatised, non-resident individuals.

**Duration of Exposure :** It is an important factor determining the final injury. About 10 hours of exposure to minus 10°C is needed to cause the cold injury, but may occur in shorter period of time, in intense cold.

**Wind Movements :** These hasten tissue cooling. The combination of ambient low temperature and wind movement is termed as the ‘Wind-chill factor’. The probability of cold climate to cause cold injuries is directly proportionate to the

#### Box - 2 : Management at Solo Physician/Primary Care Level

Check rectal temp and other vital parameters.
Quickly open up the insulatory layer, remove wet clothing (if not already removed at first aid level). Change patient to dry clothing.
Apply warm packs at axillae, groin and neck. Reapply the “insulatory layer” around the patient, as described under first aid.
Establish IV line and start 5% dextrose (or any other crystalloid) preferably warmed to 37 to 41°C. Initial fluid challenge should be 500 ml to 1 litre in half to 1 hour.
Start oxygen inhalations with face mask, 4 litres/min, preferably warm and humidified oxygen, if equipment is available.
<i>If facility exists</i> , pass an indwelling bladder catheter. Start monitoring urinary output.
Keep monitoring core temperature. The rectal thermometer should be inserted to at least 15 cm into rectum. If there is no increase in core temp despite rewarming efforts in more than an hour or else if patient is not shivering and unresponsive, consider evacuation to a well-equipped hospital. Evacuate as a stretcher case.
Institute CPR if carotid pulsations are absent.



'wind-chill' factor rather than its temperature alone. Increased wind velocity, by increasing the 'wind-chill' factor, increases chances of generalised and localized injuries due to cold. For example, at 0°C ambient temperature, the conditions become equal to minus 18°C, if the wind is blowing at a speed of 40 km per hour.

**Moisture** : Moisture is a good thermal conductor and its presence in contact with the skin interferes with the natural insulating action of the sebaceous material on the skin. Wet clothing, either due to external wetting or internal wetting due to sweat, is therefore dangerous.

**Hypoxia** : High altitude hypoxia deprives the cardiac muscle of oxygen and thereby decreases the cardiac output, lowering the peripheral blood and oxygen tension and reducing the tissue oxygen saturation. Hypoxia also devitalises the capillary endothelium and increases exudation into tissues. All these increase the proneness of the extremities to get cold injuries; skin, being the least vital organ, suffers the most.

**Clothing and shelter** : An extremely important determinant of cold illnesses and their prevention is the adequacy of clothing and shelter in such weather. Clothing insulates the body from its surroundings. It can also cause radiant heat gain (mainly from solar radiations) as well as retard conductive and convective heat loss in cold climate. The index of thermal resistance of clothing is measured in 'Clo' units. To maintain a person in comfort, clothing with higher clo units will be required if metabolic heat production decreases, or ambient temperature decreases, or RH decreases, or air movement increases. At 0°C, persons undertaking light work or else complete rest, will need clothing 2.6 and 5.4 clo units respectively; at - 20°C these requirements will be 4 and 8.3 clo respectively. As a rough guideline, without wind penetration or air movement around the clothing, the Clo values for a given weight of clothes equals 35% of the clothing's weight in Kg; e.g. wearing of total of 10 Kg clothing will produce Clo value of 3.5 Clo units, and will be reasonably good enough for a person doing very light work (1.5 MET) at an ambient air temperature of 0 degrees C, in a still air environment.

#### Human (Host) Factors in cold illnesses

**Age and Sex** : People at extremes of age (less than 5 years or more than 65 years) are known to be more susceptible. Women seem to be protected possibly due to the increased subcutaneous fat. There is preliminary evidence from laboratory studies that dark skinned people may be more susceptible to adverse effects of cold as compared to whites.

**Circulatory Stagnation** : Local circulatory stagnation allows local temperature to be lowered, increases liability of exudation through the already damaged vascular endothelium and also deprives the tissues of nutrition and oxygen, thereby increasing devitalisation. This may be caused by forced immobility due to being pinned down in shelters or vehicles, or during conditions of prolonged bad weather. Tight fitting clothes, boots or socks may also cause constriction.

**Physical Inactivity** : It increases risk of cold injuries. Activity increases the metabolic heat production and is an important prophylaxis against cold injuries.

**Nutrition** : Adequate, or even increased, calorie intake is necessary to sustain the increased heat production and the increased work required to function in a cold environment (5). Vitamin A deficiency increases liability to infections especially of mucous membranes. Vitamin C deficiency increases capillary permeability and decreases healing power of tissues. The presence of adequate subcutaneous fat definitely increases the insulation and hence protects against cold (6, 7).

**Poor Physical Health** : Intercurrent /chronic diseases, convalescence and physical exhaustion decrease the general tissue vitality, physical activity and also power of acclimatisation, and hence increase the liability to cold injuries.

**Poor Mental Health** : Mental apathy, fatigue, fear and anxiety which are common in a cold climate, especially under hypoxic conditions at high altitude, cause neglect of precautions and increase in physical inertia, thereby increasing liability to cold injuries.

**Local diseases** : Local injury or skin infection predisposes the particular part to cold injuries.

**Tobacco** : Use of tobacco increases the risk of frost bite due to severe vasospasm induced by it and definitely aggravates the injury itself when once established.

**Alcohol** : Alcohol has been universally regarded as a very important and avoidable risk factor in cold illnesses. Its consumption, especially if followed by exposure to cold, or excessive physical activity or lethargy after alcohol consumption, increases risk of general hypothermia and also local cold injuries.

**Cold Adaptation** : Adaptation to cold, although not as good as acclimatisation to heat or high altitude, is nevertheless an important factor determining individual vulnerability to cold injuries.

#### Prevention of Cold Illnesses

**Clothing** : Special attention should be given to clothing in cold weather, in a scientific manner. In providing insulation from the cold, the mesh of the cloth fibres traps air that then becomes warm. Several layers of light clothing or garments lined with wool, fur, feathers or synthetic fabrics provide better insulation than a single, bulky layer. The clothing layer in contact with the skin should effectively "wick" moisture away from the body's surface to the next insulating clothing layer for subsequent evaporation. Wool or synthetic (e.g. polypropylene) that insulate well, as well as dry quickly, serve this purpose. A woollen cap very effectively contributes to heat conservation since nearly a third (33%) of all body heat loss is from the head region alone. If clothing becomes wet either due to external moisture (snow or rains) or due to condensation from sweating, it loses as much as 90% of its insulating properties; this may actually start facilitating heat loss from the body rather than conserving heat. Hence, wet clothing should be changed at the earliest opportunity in cold environment.

Secondly, it must be ensured that while the clothing should provide adequate insulation (by way of adequate material and layers, as described above), it should, at the same time, allow for water vapour to escape through the clothing, if sweating occurs. If this does not happen and sweat accumulates near the



skin layer, its condensation may become another hazardous situation, which was faced by the expeditions to Polar Regions. Hence, scope must be left to allow some layers to be removed if required, without exposing the body to cold. The basic rules for dressing in a cold climate are :

- Keep the clothing clean otherwise the wicking / moisture repelling action will be compromised.
- Do not sweat unnecessarily; undertake activities in a way that sweating is kept to the minimum.
- Keep the clothing dry; wet clothing will grossly reduce the insulatory power.
- Dress in layers (as explained above).

It must be noted that clothing must be worn in sequence, with undergarments and thermal inners being the innermost layer, followed by shirt, trouser, sweaters, and finally the jackets/thermal or feather coveralls. The fit of each item is very important; each item should be tried in its correct sequence. If clothing is too tight, it will restrict the blood flow and increase the predisposition to cold injury.

**Boots** : In cold weather when two pairs of socks are worn, boots become tight and this may compel the individual to discard them. Therefore, boots should be a loose fit, kept soft and water proof and every person should have an extra dry pair of socks and boots to change into, if feet get wet. One must remember never to sleep with boots on; before going to sleep, boots should be removed and dried.

**Socks** : A pair of thin nylon / polypropylene socks should form the inner layer, being worn next to the skin and the next layer should be the heavy woollen socks to absorb moisture. These should not be tight. Every person exposed to intense cold should wear extra pairs of woollen socks. Damp socks should be changed immediately.

**Shelters** : Shelter used in cold environment should be designed on the same basic principles of layering as for cold weather clothing. The tents should have a strong, tightly woven outer shell, which should be impervious to rain and snow. The inside liner is a lighter weight fabric and is hung to provide an air space along the outer shell. Ideally the tent should have a floor made of impervious material. If ever a stove is burnt inside the tent for heating purposes, the potential dangers of Carbon Monoxide (CO) poisoning and fire hazards is to be kept in mind. Arrangements for ventilation must be ensured in such circumstances.

**Nutrition** : Energy requirement in the cold environment is more due to higher metabolism. In general, for civilian population, who are also likely to be indulging in some sort of winter or mountain sports activities, the energy requirement may be 3000 to 3500 Kcal for women and 3500 to 4000 Kcal for men. Provision of adequate hot and appetising meals should be ensured. Vitamin C is also necessary for the cellular reformation, vascular endothelial integrity and as a steroid sparer. It may be given in the form of multivitamin tablets.

**Exercise** : Regular moderate exercise to keep up the circulation without causing any exhaustion or excessive sweating should be undertaken frequently. When climatic conditions do not permit movement in the open, static physical activity by frequent vigorous movements of limbs, movements of neck

and back, wriggling of toes and moving of fingers should be continuously practised. Face muscles should be wrinkled to keep up the circulation.

**Venous Congestion** : People should not sit for long periods cramped up in enclosed places or upon the railing with feet hanging down and especially over the edge of seats as this leads to venous congestion. Too tight clothing also causes venous stagnation.

**Alcohol** : Alcohol is best avoided when confronted with harsh, cold environment. In any case, it should never be consumed in excess over a short duration and none at all when one is likely to go out into cold environment.

**Smoking** : It is advisable not to smoke at all. Those who cannot avoid smoking should do so only in moderation. It should be definitely prohibited once the cold injury occurs.

**Buddy System** : For small parties on adventures / expeditions, it is always a good practice to have a “buddy system”, i.e. to pair up people and make them responsible to look after each other, by watching each other's face and feet for observing any early tissue damage. Buddies also watch out for each other's personal hygiene, nutrition, and behaviour so that any aberration is identified at the earliest and first aid is given.

**General Personal hygiene** : It should be maintained at the highest level. Besides ensuring local cleanliness and preventing infections, it will enhance the general feeling of well being, so essential in tough, cold environment. Proper bathing is preferred; however, even a basin of water for a sponge bath will help. When no water is available, simply rubbing the body, preferably with a wool rag, is worth the effort. It is recommended that such a procedure be followed weekly. Changing to clean or even airing of soiled socks and underwear periodically will help to maintain body cleanliness. At least two or three hot baths in a week in snowbound and cold environs are necessary. Bathing places should be sheltered from wind and snowfall. However, too frequent use of too much soap is not good as it removes the greasy sebaceous material and decreases insulation.

**Foot Hygiene** : The feet should be inspected before going to bed every night, for any swelling, ulcer or numbness. Wriggling the feet and toes before going to sleep and even within the boots, while walking, should be an inculcated habit. It is much better to make two partners responsible for inspecting each other's feet. Feet must be washed with warm water, thoroughly dried and smeared with a little Vaseline, before sleeping. This helps prevent frost bite. An individual with ulcers and abrasions on the foot should not move around until they are healed. Talcum powder should be used before wearing socks in the morning to decrease dampness during exertion and reduce friction with socks.

**Oral Hygiene** : By daily cleaning the teeth with a piece of gauge or other cloth wrapped around a finger is an effective practice in the absence of toothbrush.

**“Feel Good”** : Keeping well is especially important when one is stranded. While physical fitness of the body decides survival, yet a positive mental attitude is just as important. Personal cleanliness, dry clothing, ventilated shelter without drought, a warm bed, and adequate recreational activities are helpful.

**Re-exposure** : Persons who have once suffered from cold injury should be very careful when getting exposed to cold environment again.

**Adaptation to Cold** : Systematic acclimatisation to cold can be carried out by exposing newly inducted people to the atmospheric temperature of 0°C to 5°C for three or four hours a day for three consecutive weeks. During the first week people should be dressed in vest cotton, full sleeves flannel shirt, pullover, woollen trousers, woollen cap, gloves and boots with only one pair of woollen socks. Outside the exposure hours, people can put on the additional clothing as jackets, coveralls, etc. During the next two weeks, pullover is also removed, so that people stay in flannel shirt and trousers for 3 to 4 hours. The site selected for exposure should be sheltered from wind. If there is any wind or breeze, people should wear a thin nylon wind-cheater. Since physical exercise warms the body and hence impedes the acclimatisation process, during the hours of exposure, therefore, physical exercise should not be allowed; however, normal sedentary recreational work as reading, knitting, playing cards etc., which do not involve much physical activity, may be carried out. People should be assured that exposure to cold for cold acclimatisation will cause no harm. If any complaints like rhinitis, pharyngitis, fever, excessive shivering or cramps are noticed; the exposure should be discontinued for the day or until cured. It can be restarted and gradually increased day by day when the individual has recovered.

**High Altitude Acclimatization** : Often, cold environment co-exists with high altitude environment. Adverse effects of high altitude will worsen the physical and psychological adversities due to cold and vice-versa. Proper acclimatization to high altitude should be therefore undertaken, as described in the chapter on high altitude.

**Early diagnosis, first aid and prompt treatment** : These are aimed at prevention and arrest of tissue damage. Early detection and first aid would go a long way in prevention of further damage, in both generalised as well as local cold injury. The details have already been discussed earlier in this chapter.

**Protection against Snow Blindness** : Humans can make no natural adjustments to the reflection of bright sun from snow, ice, and water, even with an overcast sky. Dark glasses are, therefore, a must. One must not wait until eyes start hurting. If the glasses are lost, improvised eye protection, by either wearing a muffler or stockings over one eye through which one can barely see. Treat snow blindness by getting the victim to a dark place. Apply eye shades to both eyes. Cool compresses may help to relieve the pain. Time is the only cure for temporary snow blindness.

**Protection against Sunburns** : Sunburn can occur even at temperatures below freezing point especially at higher elevations. Sunlight reflected upwards from bright surfaces may rapidly burn the most tender spots, viz., lips, nostrils, upper portion of ears and eyelids. Sunburn also may occur on cloudy days. A strong wind makes the burn even more severe. Sunburn cream should be applied frequently to all exposed skin surfaces.

## Summary

Extreme cold conditions occur in India in the Himalayan, Sub - Himalayan and the northern Indian plains with cold waves and deaths being recorded every year. Human exposure to extreme cold produces significant physiologic and psychological challenges. Groups at particularly high risk include military personnel, agriculturists, mountaineers and persons engaging in adventure or winter sports, low income groups with poor housing and inadequate clothing, extremes of age (<5yrs or >65yrs), physical exhaustion, pre - existent malnutrition or starvation, sleep loss, use of alcohol and underlying diseases. Environmental Factors as Severity of cold, duration of exposure, wind movements, moisture, hypoxia, clothing and shelter also play a significant role.

Adverse effects of cold environment manifests as either generalized effects (hypothermia) or local "tissue-freezing" effects as frost bite, or Non-Freezing Cold Injuries (NFCI) as trench foot and chilblains. Generalised Hypothermia, depending on the core temp, may be classified as borderline (36 to 35°C), mild (35 to 32°C), moderate (32 to 28°C) and severe (<28°C). Earliest symptoms are change in behaviour, mood, and lack of affect, apathy, uncoordinated movements, ataxia, confusion and decreased ability to sense cold. Tachycardia, tachypnoea & shivering occur initially followed by bradycardia, decreased respiratory rate, impaired reasoning & violent shivering, paradoxical undressing with stuporous gait as hypothermia becomes more severe (32 to 35°C). Below 32°C, shivering stops with blue, puffy skin, semiconsciousness, muscle rigidity, trismus, marked bradycardia, lowered respiratory rate & cardiac dysrhythmias, especially atrial/ventricular fibrillation occurs. At 28°C or less, complete unconsciousness with severe bradycardia, reduced respiratory rate, muscle rigidity with dilated pupils is seen. Hypothermia should be treated as a medical emergency. Basic principle of management is quick warming of the "core" without causing simultaneous vasodilation of the periphery.

Frost nip involves freezing of top layers of skin tissue, is reversible and manifests as numbness and white, waxy or rubbery feeling of the affected skin. Frostbite is the more severe form affecting all layers of the skin involving the deeper tissue. It is of four degrees, depending on the depth of the tissue involved. As an urgent first aid measure, remove any constrictive clothing or bands, local warming by placing the affected part in a warm water bath at 40-42°C, analgesics, sedatives & Tetanus toxoid are to be administered. Evacuate to a surgical facility at the earliest. Non - Freezing Cold Injuries in the form of chilblains manifest with initial pallor of affected area followed by erythema, pruritus and intense pain. Prevention comprises of avoidance of exposure to cold and wet conditions. Trench foot is caused by prolonged exposure of feet to cold and wet conditions manifesting as reddened skin, tingling pain and itching. Gentle drying, elevation of the affected limb and keeping it at an environmental temperature of 18 to 22°C while keeping rest of the body warm along with NSAIDs is the treatment. Prevention consists of keeping the feet clean and dry, dabbing the feet with aluminium hydroxide powder thrice daily, and changing into dry socks and shoes at the earliest.

Prevention of Cold Illnesses involves clean, dry & layered clothing; loose fit, soft & water proof boots, an extra dry pair of socks, inner thin nylon / polypropylene socks and outer heavy woollen socks with at least four pairs of woollen socks; strong, tightly woven impervious tents; provision of adequate hot and appetising meals ; regular moderate exercise, static physical activity by frequent vigorous movements of limbs, movements of neck and back, wriggling of toes and moving of fingers; not sitting for long periods cramped up in enclosed places or upon the railing with feet hanging down; avoiding smoking & alcohol; practice “buddy system”; personal hygiene including oral & foot hygiene; precautions on re-exposure; cold adaptation; high altitude acclimatization; early diagnosis, first aid and prompt treatment. In harsh, extreme cold climate, in the face of an emergency, survival techniques in the form of skills pertaining to shelter construction, first aid, map and chart orientation and sanitation should be a major element of preparation. Protection against Snow Blindness involves use of dark glasses. Treatment is by getting the victim to a dark place; apply eye shades to both eyes & cool compresses to relieve pain. Protection against sunburns should be practised by applying sunburn cream frequently to all exposed skin surfaces.

## Study Exercises

**Long Question :** Forward a detailed plan of advise on preventive aspects as well as emergency first aid which you will give to a group of approximately 40 mountaineers who will be taking part in a national expedition to climb a mountain peak located at height of 25,000 feet.

**Short Notes :** (1) Acclimatization to cold (2) Principles of dressing for prevention of cold (3) First aid in hypothermia (4) First aid in frost bite.

## MCQs & Exercises

- Age group which is most vulnerable to effects of cold is (a) <5 yrs (b) 5-65 yrs (c) >65 yrs (d) a & b (e) a & c.
- Which of the following is a Non-Freezing Cold Injury (NFCI) (a) Frost bite (b) Trench Foot (c) Hypothermia (d) Frost nip.
- What is the Core body temp in Severe Hypothermia (a) <28°C (b) <29°C (c) <30°C (d) <31°C.
- The normal core (rectal) temperature of normal healthy humans is : (a) 36 to 36.5°C (b) 36.5 to 37°C (c) 37 to 37.5°C (d) 37.5 to 38°C.
- In \_\_\_\_\_, a person with hypothermia starts removing the clothes rather than putting on more clothes.
- ECG shows \_\_\_\_\_ wave at the junction of QRS complex in Hypothermia.
- The basic principle of management in Hypothermia is : (a) Quick warming of the “core” without causing simultaneous vasodilation of the periphery (b) Quick warming of the “periphery” (c) Quick warming of the “core” with simultaneous vasodilation of the periphery (d) None of the above.
- In Frost bite, local warming is done by placing the affected part in a warm water bath at (a) 36 to 38°C (b) 38 to 40°C (c) 40 to 42°C (d) 42 to 44°C.

- Treatment in Trench foot consists of keeping the affected part at what environmental temperature, while keeping rest of the body warm : (a) 14 to 18°C (b) 18 to 22°C (c) 22 to 26°C (d) 26 to 30°C.
- About \_\_\_\_\_ hours of exposure to \_\_\_\_\_ °C is needed to cause cold injury. (a) 5 hours, minus 10°C (b) 10 hours, minus 10°C (c) 10 hours, to minus 5°C (d) 5 hours, minus 5°C.
- The probability of cold climate to cause cold injuries is directly proportionate to the \_\_\_\_\_ rather than its temperature alone.
- The index of thermal resistance of clothing is measured in \_\_\_\_\_.
- A woollen cap very effectively contributes to heat conservation since nearly \_\_\_\_\_ % of all body heat loss is from the head region alone : (a) 13% (b) 23% (c) 33% (d) 43%.
- If clothing becomes wet either due to external moisture (snow or rains) or due to condensation from sweating, it loses what % of its insulating properties : (a) 60% (b) 70% (c) 80% (d) 90%.
- Energy requirement in the cold environment is \_\_\_\_\_ Kcal for women and \_\_\_\_\_ Kcal for men : (a) 2000 to 2500 , 2500 to 3000 (b) 2500 to 3000 , 3000 to 3500 (c) 3000 to 3500 , 3500 to 4000 (d) 3500 to 4000 , 4000 to 4500.

**Answers :** (1) e; (2) b; (3) a; (4) c; (5) Paradoxical undressing; (6) ‘J’ (Osborn); (7) a; (8) c; (9) b; (10) b; (11) ‘wind-chill’ factor; (12) ‘Clo’ units; (13) c; (14) d; (15) c.

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High Altitude illness is a collective term for the syndromes that can affect unacclimatised travellers, shortly after ascent to high altitude (1). The term “unacclimatised travellers” also includes the native highlanders who are re-inducted into high altitude after a sojourn to lower altitude or if they move to a still higher altitude from the normal place of stay in high altitude. The term “high altitude illness” encompasses the syndromes of Acute Mountain Sickness (AMS), High Altitude Cerebral Oedema (HACO) and High Altitude Pulmonary Oedema (HAPO) (1).

With the present body of knowledge, there does not seem to be any clear cut demarcation as to the height above sea level that constitutes “High Altitude (HA)”. The general opinion varies and is dependant on the altitude at which definite manifestation of high altitude illness are likely to occur in a noteworthy proportion of the subjects. Generally, an altitude of 2700 m (9000 feet) and above defines high altitude, with increasing grades of high altitude as 2700 to 3600 m, 3601 to 4500m and 4501 to 5400m. Altitudes above 5400 m in are often referred to as “extreme high altitude” wherein permanent successful acclimatization becomes very difficult. However, the above levels cannot be sacrosanct boundaries; in fact high altitude illness is being increasingly recognised at “moderate” altitudes of 2200 to 2500m (2)

Around 140 million people over the globe live permanently at altitudes of over 2500 m (3) and approximately another 40 million enter high altitude area every year for reasons of occupation, sporting or recreation. Miners in South America go for work to altitudes as high as 6000 m, while Indian soldiers are deployed at even higher altitudes. Persons who are at a definitely increased risk of being affected by high altitude illness include Native highlanders who re-enter high altitude after stay at lower altitudes; Mountaineers; Soldiers; Trekkers; Adventurers; Miners at high altitude; and, Pilgrims and porters (4, 5).

### The High Altitude Environment

Effects of high altitude are encountered among visitors to high altitude terrestrial environments and in high altitude aviation. The environmental conditions at high altitudes which influence physiological processes are : the lowered atmospheric pressure and partial pressure of oxygen, lowered temperature and humidity, increased intensity of sunshine and cosmic electrical conditions and the isolation under monotonous mountain conditions. The chief hazards on health, however arise from the low atmospheric pressure, coupled with low partial pressure of  $O_2$  in the alveolar air leading to low oxygen tension in the blood and low ambient temperature, all of which worsen as the altitude increases. The main problem with high altitude terrestrial environment is, in fact, the declining atmospheric pressure. For instance, the atmospheric pressure which is 760

mm Hg at sea level drops down to only approx. 500 mm Hg at around 11000 feet above Mean Sea Level (MSL). Now, as we know from a very basic law of physics (Boyle's Law) that the partial pressure of a mixture of gasses is equal to the sum of the partial pressure (pp) of these gasses; and the partial pressure of these individual gasses is proportional to their concentration in the gaseous mixture. For all practical purposes, air is mainly a mixture of Nitrogen (N) and Oxygen (O) in the proportion of 80% and 20% respectively. Thus the pp of N will be four fifth and that of O will be one-fifth that of the atmospheric pressure at a given location. Hence, at sea level, where the atmospheric pressure is 760 mm Hg, the partial pressure of 'N' is 4/5 of 760 i.e. approx 608 and that of 'O' is approx. 152 mmHg.

Now as the atmospheric pressure drops with ascent from sea level (by very roughly, 25 mm Hg for every 1,000 feet ascent), hence at 11,000 feet it would be approx. 500 mm Hg; and, by Boyle's law, at this height, the partial pressure of Nitrogen would be (4/5 of 500) i.e. 400 mm and that of Oxygen will be 100 mm Hg. It is this progressive decline in partial pressure of oxygen in ambient air (commonly referred to as “thinning or air” or, “rarefied air”) that results in reduction of alveolar oxygen pressure, with all the resultant pathological issues of high altitude. Thus, though the concentration of oxygen in atmospheric air at high altitude is still one-fifth, the net result because of such reduction of partial pressure of oxygen is as if there was a lack of Oxygen in the air. Thus, at around 11,000 feet, the effect is as if oxygen in the air were 13.8% instead of 21% normally seen at sea level. The details are depicted in the Table - 1. This is the basic environmental issue that triggers a massive cascade of physiological responses, intended to be protective, once a human being is inducted into high altitude.

**Table - 1 : Altitude, pressure, temperature, oxygen partial pressure and percentage**

Altitude		Pressure (mm Hg)	Oxygen Partial pressure (mm Hg)	Equivalent Oxygen percentage
Feet	Meters (mm Hg)			
0	0	760.0	159.2	20.96
9,000	2,743	543.2	113.8	14.96
12,000	3,658	483.2	101.2	13.31
15,000	4,572	428.8	90.5	11.81
18,000	5,486	379.4	79.5	10.45
20,000	6,096	349.2	73.1	9.61

**Physiological Adaptation** : The lowered atmospheric oxygen partial pressure at high altitude causes alveolar and arterial hypoxia leading to tissue hypoxia. As described earlier, the oxygen partial pressure in alveoli is decreased at high altitude and hence, to compensate for this, circulatory and haemopoietic adjustments are made by the body physiology. There is increased frequency of respiratory and cardiac rhythm. Finally the increased amplitude of respiratory and cardiac movements gradually occurs. Interstitial fluid is diverted to the vascular compartment which alters the haemodynamics and cause hypervolaemia, thereby overloading the pulmonary circulatory system and cardiac function. These mechanisms are usually



uneventful and insensible up to about 2500 to 3000 m; however, above that height when pronounced physiological mechanisms are called to action, the symptoms of 'early mountain sickness' which in reality are the symptoms of 'rapid acclimatization', become manifest. If acclimatization is inadequate, or if it breaks down, or if the ascent to higher altitude is too rapid, the essentially beneficial adaptive responses become aberrant and the disease processes occur.

The common acute high altitude syndromes are Acute Mountain Sickness (AMS) and High Altitude Pulmonary Oedema (HAPO). Less commonly, High Altitude Cerebral Oedema (HACO), a cerebral syndrome may occur at sudden induction into very high altitudes of 4500 mtrs and above. Chronic Pulmonary Hypertension is a rare syndrome occurring after prolonged residence at high altitude areas.

**Acute Mountain Sickness (AMS)** : The latent period of AMS (time elapsing from entry into high altitude to onset of first symptom) is usually 6 to 12 hours. Sojourns to high altitude which last for less than 6 hours are not likely to be associated with AMS. AMS is quite uncommon below the altitudes of 2000 m. The incidence of AMS has been quite variable in different studies and primarily depends on the altitude reached, the rate (speed) of ascent to high altitude and physical exertion after entry into high altitude, besides other variables. Various workers have observed incidence of as low as 6% to as high as more than 60% (6 - 11).

**High Altitude Pulmonary Oedema (HAPO)** : The incidence of HAPO has been found to be quite variable, between 0.5% to 5%, as reported by various workers. Any person irrespective of age, gender or race, who enters into a high altitude terrestrial environment, is at risk of HAPO, including native highlanders who enter into high altitude after a stay at lowlands. However, certain groups seem to be at a higher risk due to Socio-behavioral or occupational reasons. These include soldiers, mountaineers, trekkers, adventurers, mountain-sports persons, miners working at high altitude, porters, and land pilgrims to high altitude shrines. Most of the epidemiological studies indicate that the 'latent period' or 'induction time' (period elapsing from entry into high altitude to the onset of first manifestation of HAPO) is usually between 6 to 96 hours, though rare cases can occur as late as ten days also. Onset beyond this range is quite uncommon (12 - 16). Therefore, it is logical to conclude that the period of first 72 hours following induction into high altitude seems to be important, with the initial 48 hours being most crucial for enforcing preventive measures regarding acclimatization, especially avoidance of any physical activity (except for self-care activities of a routine nature).

**Risk Factors for AMS and HAPO** : The major risk factors for both, AMS and HAPO are :

**Physical exercise soon after induction into high altitude:** Physical exercise even of moderate intensity, undertaken within 72 hours of arrival into high altitude is an important determinant and is almost universally upheld by all experts. The risk has been observed in nearly all the studies, at various places in the world, and the estimates show a strong and significant association. Thus, the association fulfils the required epidemiological parameters of strength of association,

temporality, consistency, dose response and plausibility. However, it is noteworthy that physical exercise is not an 'essential' determinant, since the condition can occur even among persons who have not exerted/are asleep/are at rest, especially if ascent to high altitude has been rapid, as by air.

**Lack of Acclimatization** : AMS and HAPO commonly affect subjects who have not properly acclimatized themselves to high altitude environment soon after arrival. Acclimatization is a gradual process by which the body physiology gets adjusted to high altitude environment.

**Altitude of ascent** : The "critical altitude" at which the risk of developing AMS or HAPO is very high has been reported as 3000 m in the Himalayas, 3600 m in the Andes and somewhat lower (2600m) in the Rocky mountains. This is not to be confused with the definition of "high altitude" which is generally taken as > 2500 mtrs. AMS can however, occur even at lower altitudes of 2500 mtrs.

**Rate of ascent** : Epidemiological studies have clearly shown that the speed with which an individual reaches high altitude, especially into a crucial altitude of 3000m and above, seem to be an important determinant in causing high altitude illness. Observations have shown that both among soldiers as well as tourists who move to high altitude areas by air, ascending almost 3000m (or even more) within less than an hour, the incidence rates are much higher when compared to the same location being reached by road transport over 3 to 4 days. The slow ascent by road over a few days may allow some acclimatization.

## Prevention of Adverse Effects of High Altitude

Individual tolerance to hypoxia varies and has no correlation with physical fitness in its ordinary sense. Complacency or bravado which in itself is one of the symptoms of hypoxia, encourages excessive physical activities without proper and adequate acclimatization. Rapid ascent without acclimatization followed by physical activity increases the risk of effects of hypoxia.

**Acclimatization** : In general, acclimatization should be undertaken whenever a person reaches an altitude of 2500 metres or above, though a night spent at moderate altitude of 1500 to 2500 m before ascent to high altitude, is likely to further aid in acclimatization process.

Acclimatization is undertaken by 1 to 2 days of complete rest (allowing for only daily activities of living), followed by gradually increasing physical effort for next 2 to 4 days at a particular level of high altitude. This process should be repeated for every 1000 mtrs gain in altitude, i.e. after the person reaches another stage of stay in high altitude which is 1000 metres higher than the previous level at which he / she had acclimatised, another similar round of acclimatization (of 2 days of complete rest followed by 3 to 4 days of gradually increasing physical activity) should be undertaken for each such 1000 metres gain in altitude.

While negotiating high altitude areas, *gradual ascent*, thereby giving time for acclimatization to develop, is the key strategy in prevention. In general, at altitude greater than 3000 m, each

night should be spent at an altitude of not more than 300 m above the previous night, with a rest day after every 2 to 3 days (i.e. after every 1000 m of ascent). In certain situations, as tourists coming for mountaineering, this rate of ascent may be considered to be slow and unrealistic and may be modified so that the altitude difference between two consecutive “sleeping sites” should not be more than 600 m per day.

All recommendations emphasise “*sleeping altitude*” which means that it is permissible to ascend more than the recommended daily rate as long as descent is made for sleeping, i.e. the time tested maxim of “climb/work high but sleep low”.

Visitors to high altitude areas also need to be educated that the actual pathophysiological changes at high altitude take 6 to 24 hours to gradually develop and hence they may not get any symptom during initial 6 to 8 hours or even during first day; however, they should not take this as an immunity from adverse effects of high altitude. Many serious cases have occurred because tourists started exerting on the first or second day because they did not have any symptoms.

**Chemoprophylaxis** : Acetazolamide orally, for three days before induction into high altitude areas has been recommended by some authorities as it may help in reducing the occurrence or severity of AMS / HAPO, but evidence from RCTs is still not available.

**Other Measures** : Environmental cold is generally present at high altitude areas and care should be taken to adopt preventive measures, as explained in the previous chapter. Ensuring adequate intake of fluids by mouth and avoidance of tobacco and alcohol is also desirable.

**Physical performance at High altitude** : It needs to be noted that even after complete and successful acclimatization, the capability to perform any given exercise or physical task will be reduced at high altitude in comparison to lower altitudes. This was clearly evident during Mexico Olympics of 1968, held at an altitude of 2300m wherein most of the world class athletes experienced as much as 13% reduction in their performance. Leaving aside the world class sports persons, evidence suggests that for normal, healthy and properly acclimatized subjects, the physical capability will be just about 70 to 75% at an altitude of 3100 m (Compared to capability at sea level altitude) and would be about 50 to 60 % at 4000 m. Care should be taken, therefore, by all persons moving to high altitude, to make realistic readjustment in their expectations regarding task performance.

## Summary

High Altitude illness is a collective term for the syndromes that can affect unacclimatised travellers, shortly after ascent & encompasses the syndromes of Acute Mountain Sickness (AMS), High Altitude Cerebral Oedema (HACO) and High Altitude Pulmonary Oedema (HAPO). High altitude (HA) is defined as an altitude of 2700 m (9000 feet) and above, with increasing grades. Altitudes above 5400 m are referred to as “extreme high altitude”. High risk groups are the native highlanders who re-enter HA after stay at lower altitudes, mountaineers, soldiers, trekkers, adventurers, miners, pilgrims and porters.

Health hazards in HA arise from the low atmospheric pressure,

with low partial pressure of O<sub>2</sub> in the alveolar air leading to low oxygen tension in the blood and low ambient temperature. Progressive decline in partial pressure of oxygen results in reduction of alveolar oxygen pressure. Physiological Adaptation at HA involves lowered atmospheric oxygen partial pressure causing alveolar and arterial hypoxia leading to tissue hypoxia which is uneventful and insensible up to 2500 to 3000 m & above that height, symptoms of ‘early mountain sickness’ which are the symptoms of ‘rapid acclimatization’ appear. The common acute high altitude syndromes are AMS with a latent period of 6 -12 hours & uncommon at <2000 m, incidence varies between 6% - 60% & depends on the altitude reached, rate of ascent and physical exertion after entry into HA; HAPO with an incidence between 0.5% - 5% with certain groups at a higher risk due to socio-behavioural or occupational reasons, latent period being 6 - 96 hours, with the initial 48 hrs being most crucial for enforcing preventive measures regarding acclimatization.

Risk Factors for AMS & HAPO include physical exercise soon after induction, lack of acclimatization, altitude (higher the altitude more the risk) & fast speed of ascent. Prevention of adverse effects requires avoidance of complacency or bravado, acclimatization as per the recommendations with gradual ascent being the key strategy in prevention, not having an altitude difference of more than 600 m / day between two consecutive “sleeping sites”, chemoprophylaxis with Acetazolamide orally X 3 days before induction & other measures such as ensuring adequate intake of oral fluids, avoidance of tobacco & alcohol and precautions against environmental cold. Physical performance at HA is reduced. Care should be taken to make realistic readjustment in the expectations regarding task performance.

## Study Exercises

**Short Notes** : (1) Acclimatization to high altitude (2) Acute mountain sickness (3) High altitude pulmonary oedema (4) Lake Louise criteria

### MCQs & Exercises

1. The term “unacclimatised travellers” also includes the native highlanders who are re-inducted into high altitude after a sojourn to lower altitude (True/false)
2. “High altitude illness” encompasses the syndromes of all except : (a) Acute Mountain Sickness (AMS) (b) High Altitude Cerebral Oedema (HACO) (c) High Altitude Pulmonary Oedema (HAPO) (d) Cold stroke.
3. Altitude of \_\_\_\_\_ defines high altitude & Altitudes of \_\_\_\_\_ are often referred to as “extreme high altitude.
4. Globally, how many people live permanently at altitudes of over 2500 m : (a) 10 million (b) 40 million (c) 100 million (d) 140 million.
5. The environmental conditions at high altitudes which influence physiological processes are all except : (a) Lowered atmospheric pressure (b) High partial pressure of oxygen (c) lowered temperature and humidity (d) increased intensity of sunshine.
6. The adverse effects of environmental cold occurring at high altitude, as compared to when they occur at plains are not aggravated due to atmospheric and tissue hypoxia (True/false)

7. Progressive decline in partial pressure of oxygen in ambient air is commonly referred to as \_\_\_\_\_.
8. What is the partial pressure of oxygen (in mm Hg) at an alt of 3600m, where atmospheric pressure is about 485 mm Hg & equivalent O<sub>2</sub>% being 13.5% ? (a) 91.2 (b) 101.2 (c) 201.2 (d) 301.2.
9. What is the latent period of AMS (time elapsing from entry into high altitude to onset of first symptom) : (a) 3 to 6 hours (b) 6 to 12 hours (c) 12 to 18 hours (d) 18 to 24 hours.
10. What is the usual incidence of HAPO ? : (a) 0.5% to 1% (b) 0.5% to 3% (c) 0.5% to 4% (d) 0.5% to 5%.
11. Which period is most crucial for enforcing preventive measures regarding acclimatization? (a) Initial 4 hours (b) Initial 14 hours (c) Initial 24hours (d) Initial 48 hours.
12. The "critical altitude" above which the risk of developing AMS or HAPO is very high in the Himalayas is (a)1000 m (b) 2000 m (c) 3000 m (d) 4000 m.
13. The process of Acclimatization should be repeated for every \_\_\_\_\_ mtrs gain in altitude : (a) 100 (b) 500 (c) 1000 (d) 1500.
14. Altitude difference between two consecutive "sleeping sites" should not be more than : (a) 200 m per day (b) 400 m per day (c) 600 m per day (d) 800 m per day.
15. Which drug is recommended for Chemoprophylaxis three days before induction into high altitude areas (a) Acetazolamide (b) Furosamde (c) Doxycycline (d) Paracetamol.

**Answers :** (1) True; (2) d; (3) 2700 m (9000 feet), above 5400 m; (4) d; (5) b; (6) False; (7) Thinning of air" or "rarefied air"; (8) b; (9) b; (10) d; (11) d; (12) c; (13) c; (14) c; (15) a.

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## Water Supply

*Sunil Agrawal*

Water constitutes one of the important physical environments of man and has a direct bearing on his health. Water is a prime natural resource, a basic human need and a precious national asset. Water is important to man and therefore, WHO refers to "control of water supplies to ensure that they are pure and wholesome as one of the primary objectives of environmental sanitation". Water is essential for drinking, cooking, bathing and washing, laundering, ablution, domestic sanitation, domestic animals and industries.

**Safe and Wholesome water :** Drinking water should be safe as well as wholesome. Water is termed safe when it does not harm

the consumer even when ingested over prolonged periods. Safe and wholesome water thus, must be

- (a) Free of pathogenic organisms
- (b) Free from harmful chemical substances
- (c) Acceptable to taste and appearance
- (d) Usable for domestic purposes

**Water Requirements :** The supply of water must be satisfactory in quality and adequate in quantity, readily available to the user, relatively cheap, and easily disposed after it has served its purposes. The Environmental Hygiene Committee in the code of basic requirements of water supply, drainage and sanitation along with National Building Code recommends minimum of 135 lit per capita per day (lpcd) for residences with full flush system for excreta disposal. The recommended values for domestic and non domestic purpose are given in Table-1.



**Table - 1 : Recommended Per Capita Water Supply Levels For Designing Schemes (1)**

S No	Classification of towns/cities	Recommended maximum water supply levels (lpcd)
1	Communities where water is provided through public stand posts	40
2	Towns provided with piped water supply but without sewerage system	70
3	Cities provided with piped water supply where sewerage system is existing	135
4	Metropolitan and mega cities provided with piped water supply where sewerage system is existing	150

### Sources of Water

**Rain Water** : Rainwater is used as a direct source on islands, such as Bermuda, where the rain is collected and led into cisterns to serve as the only available water supply. Catchment areas for direct capture of rainwater are also useful for individual households as in South West USA or small communities as in Gibraltar where paved catchments are used. Rain water is usually soft, plumbosolvent and mildly acidic due to its reaction with carbon dioxide in the atmosphere to form carbonic acid. Physically it is clear, bright and sparkling. Bacteriologically, rain water from clean surroundings is free from pathogenic agents.

**Surface water** : It usually originates from rain water. It includes rivers, streams, upland reservoirs and lakes. Surface water is moderately soft and prone to contamination from human and animal sources. The extent of contamination at a particular time and place will depend upon the proportion of pollution to the amount of water available, from the feeding streams, upstreams or springs, the extent of stagnation or outflow over a given time and the extent of natural self purification. Surface water sources include Lakes and ponds; Impounding reservoirs; Rivers; irrigation canals; Sea water; and, Waste water reclamation.

**a) Lakes and ponds** : The water is more uniform in quality than water from flowing streams. Lakes are increasingly becoming vulnerable to pollution as they are quite accessible for human activities. Long storage permits self purification, sedimentation, oxidation of organic matter, and a tremendous drop in bacterial count. If there is proper cleanliness and sanitation in catchment area, then the stored water may not require any treatment other than disinfection. The concentration of pollution increases as water evaporates. The degree of self purification is negligible and the amount of pollution added to it each day is unpredictable. Therefore, water from fresh water lakes, which are properly protected, fenced and patrolled is generally pure and can be made potable whereas that from a pond is never recommended for human consumption. Unfortunately, it constitutes one of the main sources of water supply in the rural areas of this country. The improvement can be achieved

by applying the basic techniques of modifying a part of the pond into a filter bed. The filtered water is then drawn into gravity fed well and finally chlorinated before supply.

**b) Impounding Reservoirs** : These are the collections of water harnessed in the impounding reservoirs by constructing earth, concrete or masonry dams across at convenient places in the valleys in the mountainous regions. These collections are relatively pure in general but may get polluted due to grazing of animals and human activity. Impounding reservoirs are subject to same conditions as natural lakes and ponds. While top layers of water are prone to develop algae, the bottom layers of water may be high in turbidity, carbon dioxide, iron, manganese and, on occasions, hydrogen sulphide.

**c) Rivers and Streams** : These are natural drainage channels of the land. The quality of river water depends upon the geological strata through which it has travelled, the seasons of the year, and the amount of pollution that has occurred during its course. Generally, it is moderately hard but some river waters are brackish and may get contaminated while traversing long distances from sewage and other waste discharge from habitations located along their course. Other sources of pollution are the industrial effluents, carcasses and human dead bodies. The inadequacy of traditional methods of water treatment to tackle gross river water pollution may be indicated by the outbreaks of viral hepatitis in New Delhi in 1955-56, when there were 30,000 cases. In wet periods, the water in rivers and streams may be low in dissolved solids content but often of a high turbidity. In dry periods, river flows are low and the load of dissolved solids is less diluted.

**d) Sea Water** : Sea water is huge and plentiful source of water but it is difficult to economically extract water of potable quality because it contains 3.5% of salts in solution. Offshore waters of the oceans and seas have a very high salt concentration and hence are unfit for consumption. Desalting or demineralising process involves separation of salt and water from saline waters. The most appropriate method for desalination of sea water is thermal distillation as done in Middle East and the West Indies. Several different processes, including electrodialysis, reverse osmosis, and direct-freeze evaporation, have been developed for this purpose.

**Underground water** : Rain water percolating in the ground and reaching permeable layers in the zone of saturation constitutes ground water source. Underground Water (Fig. - 1) is of major importance to civilization, because it is the largest reserve of drinkable water in regions where humans can live. Underground reservoirs have the following major advantages:

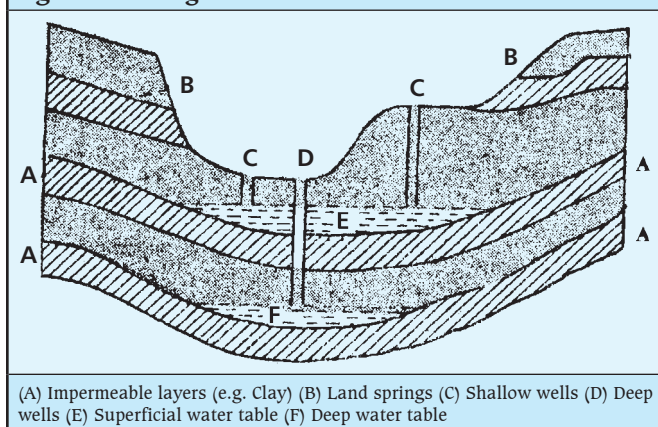
- Bacterially, groundwater is much better than surface waters
- They do not lose water through evaporation
- Their quality is not so likely to be affected by natural, urban or industrial pollution as surface water.
- They do not require expropriation of large areas of land.
- They may be located nearer to the points of use than are surface impoundments.

Generally, ground waters are clear and colourless but are harder than the surface waters of the region in which they occur. Although groundwater is a renewable resource, reserves are replenished relatively slowly. Because groundwater is recharged



and flows so slowly, once polluted it will remain contaminated for extended periods. Contamination arises from leaking underground storage tanks, poorly designed industrial waste ponds, and seepage from the deep-well injection of hazardous wastes into underground geologic formations. Almost all highly industrialized areas in our country have contaminated their groundwater due to industrial wastes and agricultural run-offs (CPCB, 1994). Even all the villages too, do not have access to safe water. A “problem village” is defined as one where no source of safe water is available within a distance of 1.6 km or where water is available at a depth of more than 15 meters or where water source has excess salinity, iron, fluorides and other toxic elements or where water is exposed to the risk of cholera and guinea worm.

**Fig. - 1 : Underground Water**



**Springs** : Springs are due to the emergence of groundwater to the surface. Springs can be ‘shallow springs’ and ‘deep springs’ depending upon whether the water comes from the superficial or the deep water tables. Deep springs can be turned into well like reservoirs by building parapets around them.

**Wells** : The subsurface sources include springs, wells and galleries. Wells can be classified according to construction process as Dug wells, Bored wells, and step wells. Alternatively, they can be classified depending on the depth and the layer of water table as shallow wells, deep wells and artesian wells.

**Shallow Wells** : These tap the ‘superficial water table’ i. e. the water table above the first impervious layer of the earth. They are of utility in abstracting limited quantity of water which usually goes dry in summers. The quality of water depends upon the geological formation and the degree of pollution by seepage from the adjacent area, which is unpredictable. Shallow wells are, therefore, inferior to deep wells as sources of water for human consumption as they are prone for contamination. The Cholera outbreaks in Delhi in 1988 were due to contamination of shallow wells.

Shallow well can be made sanitary by deepening the bottom, installing a handpump with screen and then filling the well with coarse sand upto water level; clay is then put over sand till it reaches a little above the surface level and then left for consolidation. When the material used for filling is consolidated a platform and drainage may be constructed.

**Deep Wells** : These tap the deep water table lying between the two impermeable strata and their yield is constant. Because of longer travel of groundwater to reach previous layers below the top impermeable layers, deep wells yield a safer supply than shallow wells. An ideal deep well is the one which is sunk to a sufficient depth below the first impermeable geological stratum, well stained with stones or bricks set in cement concrete provided with a covered parapet with a coping or sloped platform around and fitted with a pump. The depth of water should be sufficient to ensure an adequate quantity and sedimentation. The differences between shallow and deep wells is given in Table - 2.

Table - 2 : Difference between Shallow and deep well			
S No		Shallow well	Deep well
1	Definition	Water from above first impermeable strata	Water from above second impermeable strata or impervious layer
2	Chemical quality	Moderately hard	Much hard
3	Bacteriological quality	Fair but prone for contamination	Good
4	Yield	1 gpm	100 gpm

**Artesian wells** : Artesian groundwater is groundwater, that is, by an overlying impervious layer, prevented from rising to its free water table level, and therefore is under pressure. The name is derived from French Artesian of Artois, a province where such wells were first drilled in modern times. Artesian wells are not common in India.

**Sanitary Well** : A properly located, well constructed and protected against contamination, yielding safe water supply is known as Sanitary Well. Sanitary well can be constructed as :

**a) Location** : located at least 50 ft away from likely source of contamination on the higher ground but not more than 100 mt from consumers.

**b) Lining** : lining of the well is built by bricks or stones in cement upto a depth of about 20 ft. This lining is carried 2-3 ft above the ground level inside the parapet.

**c) Parapet** : Wall around well upto a height of 60-90 cm above the ground with lining inside.

**d) Platform** : There should be 2-3 ft wide cemented platform around parapet with sloping outwards.

**e) Drain** : A cemented drain is made around platform to drain storm water and spilled water to the main drain or soakage pit which should be constructed away from cone of filtration of well.

**f) Covering** : The top of the well should be covered with some gap for aeration and ventilation. The gaps should be such that impurities cannot go inside.

**g) Handpump** : A manual or electric pump should be connected to draw water hygienically.

**h) Consumer Responsibility** : Strict cleanliness should be enforced in the near vicinity of the well, personal ablutions, animal droppings, washing of clothes and animals, bathing etc should be prohibited.

**i) Water stagnation** : Water should not be allowed to stagnate near well to prevent breeding of mosquitoes.

**j) Quality** : The physical, chemical and bacteriological quality of water should conform to the acceptable standards of quality of safe and wholesome water in rural settings.

**Water Sources - Selection and Protection** : In order to expect a safe and wholesome water for human consumption, the proper source and site should be selected keeping in view the liability and degree of pollution and its dilution, power of self purification, daily yield, duration for which available, wholesomeness of water, and the approach to the area. The area all around the source and delivery point should then be protected against pollution by fencing and prohibiting entry of animals and unauthorized persons. The activities like defecation, bathing and washing should not be allowed even in near vicinity of the area (catchment area). Water from streams and lakes should be drawn from the upstream side of the township and as far from the banks as possible and pumped into the treatment tanks. Personnel attending to the water treatment/distribution should be protected against typhoid and other infectious diseases and medically inspected.

#### Health Hazards Due to Impure Water

Health may be affected either directly by consuming contaminated water or indirectly through food chain and also by use of water for recreational, agricultural, trade and other purposes. The health hazards of water pollution may be classified as Biological, Chemical and Radiological. The diseases related to water supply and caused by biological agents of disease are summarised in Table - 3.

#### Water Purification

Comprehensive details of water treatment processes in settings of small scale communities, as well as large scale community supplies are laid down in standard publications (1, 4-6). Reference No. 1 is generally accepted as a standard reference by various Public / civil engineering agencies in our country.

Medical Officers dealing with water supply systems are advised to refer to these manuals.

#### Purification of Water on a Large Scale

The aim of water purification is to produce and maintain water that is hygienically safe, aesthetically attractive and palatable, in an economical manner. The testing of water quality should not be restricted to treatment facilities but to be extended to the point of consumer use.

Conventional treatment of water includes prechlorination, aeration, flocculation (rapid and slow mixing) and sedimentation, rapid gravity filtration and post chlorination to render water safe for consumption. First few steps of water treatment are also called as Clarification which removes suspended matter and later disinfection kills pathogenic organisms. Disinfection without clarification may be practiced if water is beyond any doubt free of pollution and is visibly clear, or under extreme urgency. For example, ground water may need no treatment, other than disinfection. Surface water which tends to be turbid and polluted requires extensive treatment. The components of a typical water purification system comprise one or all of the following measures, viz., (a) Pretreatment, (b) Filtration and (c) Disinfection

**Pretreatment** : The sub-steps included in pre-treatment are Storage, Coagulation, Rapid Mixing, Flocculation, and Sedimentation. The details are described as follows.

**(a) Storage** : Even when water appears very clear, clarification should be insisted upon particularly for surface water. Minute particles of suspended organic matter which usually give lodgment to microbes particularly the viruses are not usually destroyed by the usual dosage of chlorine. Efficient clarification, therefore, eliminates besides the suspended matter, harmful organisms, cysts, ova, mollusc and Cyclops, and thus reduces the chlorine demand of water. The two methods available for clarification are sedimentation and filtration. Filtration is superior to sedimentation provided that the suspended matter is not too dense. Sedimentation requires more time (several hours) than filtration and the amount of water that can be dealt with is limited by the size of tanks available. Sedimentation less efficiently eliminates ova and cysts than filtration. However, efficient sedimentation prior to filtration definitely results in

Table - 3 : Classification of Water related diseases (3)	
Category	Diseases
<i>Water borne diseases</i> : Caused by the ingestion of water contaminated by human or animal faeces or urine containing pathogenic bacteria or viruses.	Cholera, typhoid, amoebic and bacillary dysentery, viral hepatitis, leptospirosis, giardiasis.
<i>Water washed diseases</i> : Diseases due to lack of water. Poor personal hygiene favours spread.	Scabies, skin sepsis & ulcers, yaws, trachoma, conjunctivitis, flea-, lice-, and tick- borne diseases, in addition to the majority of water borne diseases which are also water washed
<i>Water based diseases</i> : Caused by parasites found in intermediate organisms living in water. Infecting agents spread by contact or ingestion of water. An essential part of life cycle of agent takes place in aquatic animal eg snails, Cyclops etc	Schistosomiasis, dracunculiasis and some other helminths
<i>Water related diseases</i> : Transmitted by insect vectors which breed in water	Yellow fever, dengue, encephalitides, filariasis, malaria, onchocerciasis, trypanosomiasis, sleeping sickness

a better final clarity of water, and relieves the filters of the clogging debris.

Sedimentation is carried out by allowing water to stand in concrete, masonry or canvas tanks over a variable period from 2 to 6 hours for settling the coarse suspended matter. This process can be hastened and improved in quality by coagulation and flocculation, which precipitates particulate and colloidal matter. The coagulation and flocculation are greatly influenced by physical and chemical forces such as electrical charges on particles, exchange capacity, particle size and concentration, pH and water temperature, electrolyte concentration and mixing.

**(b) Coagulation :** Coagulation describes the effect produced by the addition of a chemical to a colloidal dispersion, resulting in particle destabilisation. Operationally, this is achieved by the addition of alum and its rapid mixing for obtaining uniform dispersion of the chemical. The chemical coagulants employed are pure aluminium sulphate  $\text{Al}_2(\text{SO}_4)_3$  (alum) or more commonly aluminoferric, which is an impure form of alum containing about 1 percent of ferric sulphate. Both salts are readily soluble in water and forms aluminium hydroxide which engulfs and precipitates with it the minute particles of suspended matter. The optimum reaction for rapid and efficient sedimentation is at pH 7, at which the addition of 35 g of alum or aluminoferric per 1000 l will rapidly clarify any turbid water. If water is exceptionally turbid, as much as 70 g per 1000 l may have to be used. Finely divided clay, fuller's earth, bentonites and activated carbon are commonly used materials used as Coagulant aids which improves or accelerates the quick forming, dense and rapid settling flocs.

**(c) Rapid Mixing :** Rapid mixing is an operation by which the coagulant is rapidly and uniformly dispersed throughout the volume of water, to create a more or less homogenous system. Water is agitated violently and the chemical is injected in the most turbulent zone. Generally large sludge volumes are produced with alum which requires frequent desludging operations at the treatment plants causing increased wastage of water. There is also the possibility of aluminium carry over in water treated with alum. High levels of aluminium in potable water are reported to cause Alzheimer's disease, a form of senility. However at present there is no clear evidence to suggest a link between aluminium and Alzheimer's disease (Cole, 1990). Poly aluminium chloride (PAC) has been developed as an alternative coagulant for alum by an Indian manufacturer. PAC hydrolyzes with great ease as compared to alum, emitting polyhydroxides with long molecular chains and greater electrical charge in the solution, thus contributing to maximize the physical action of the flocculation. Better coagulation is obtained with PAC as compared to alum at medium and high turbidity waters. Floc formation with PAC is quite rapid. The sludge produced by PAC is more compact than that produced by alum.

**(d) Flocculation :** Flocculation is the process of gentle and prolonged stirring of coagulated water in the flocculation chamber for the purpose of forming settle able particles (flocs) from destabilised colloidal sized particles through the aggregation of the minute particles. After coagulation, the individual floc particles are easily observed by the naked eye, being of the order of 1-2 mm in diameter. In practice, the velocities in flocculation tanks vary from 1 m/s at the entrance,

decreasing to about 0.2 m/s near the outlet, with a retention time of 30 minutes. Slow mixing is the hydrodynamic process which brings the particles to collide and then agglomerate resulting in the formation of large and readily settle able flocs of aluminium hydroxide. These can be subsequently removed in settling tanks and filters. The mechanical type of flocculator is widely used in which paddles rotate at 2 to 4 rpm. In actual practice this quantity of alum or aluminoferric brings the natural alkalinity of the vast majority of waters down to a pH of 7 and no other treatment is required.

**(e) Sedimentation :** Sedimentation is the separation of suspended particles from water by gravitational settling down. The coagulated water is now led into sedimentation tanks where it is detained for periods ranging from 2-6 hrs, where the flocculant precipitate settles down in the tank together with impurities and bacteria. The precipitate or sludge which settles at the bottom is removed from time to time without disturbing the operation of the tank. For very turbid water sedimentation may be better carried out in two stages; initial settling of the bulk of the coarse debris followed by chemical flocculation. Leading the flow of water through long tortuous broad channels at slow velocity and storage in large reservoirs before its entry into the sedimentation tanks helps to achieve better sedimentation. This also exposes water to the natural purifying effects of the sun's rays and fresh air, and the biological effect of minute aquatic fauna and flora. These processes render the water highly suitable for filtration and bring down the bacterial content of water considerably.

### Filtration

Filtration is a process for separating suspended and colloidal impurities from water by passage through a porous media. Filtration, with or without pre-treatment, has been employed for treatment of water to effectively remove turbidity. It is almost universally adopted in a large scale purifying process of water in municipal, cantonment, garrison or base areas where permanent water works exist. Storage and sedimentation, with or without flocculation depending upon the quality of water, almost always precede the process of filtration. Filters are slow and rapid sand filters and mechanical filters. Mechanical filters are used in small, more sophisticated water plants and also in the water tank trucks and trailers. Sand, coal, crushed coconut shell, diatomaceous earth and powdered or granular activated carbon have been used as filter media but sand filters have been most widely used as sand is widely available, cheap and effective in removing impurities. The driving force to overcome the fractional resistance encountered by the flowing water can be either the force of gravity or applied pressure force. The filters are accordingly referred to as gravity filters (Paterson's filter) and pressure filters (Candys filter). Depending on flow rates the filters are classified as : (i) Biological or slow sand filters, and (ii) Mechanical or rapid sand filters

### Slow Sand or Biological Filters

Slow sand filters were first used for treatment of water in 1804 in Scotland and subsequently in London. Then their use spread out throughout the world. These are large masonry tanks 2.5 m - 4 m deep rectangular or circular, containing sand supported on gravel and the water is passed through them slowly from above downwards. As the filter plants need extensive tracts



of land these are usually situated on the outskirts of town located on the bank of a river. To avoid choking of the media preliminary sedimentation and clarification is necessary.

**Filter Bed :** The filter beds are usually rectangular in shape, arranged side by side in rows and may be either open on top or covered. Each bed usually covers an area from one tenth of an acre to one acre land. The filter bed consists of

- (a) Supernatant water layer - 1-1.5 mt
- (b) A bed of filter medium - sand bed 1-1.2 mt.; graded gravel 0.3-0.5 mt.
- (c) An underdrainage system - 0.16 mt
- (d) Set of control valves and appurtenances

The supernatant provides the driving force or constant head for the water to overcome the resistance of filter bed and provides waiting period of some hours for the raw water to undergo sedimentation, oxidation and particle agglomeration. A layer of graded gravel of about 30 - 50 cm thickness is placed over the perforated pipes. Above the gravel is the sand bed having a thickness of about 1-1.2 m. The sand grains have an effective diameter between 0.2-0.3 mm. The underdrainage system which is about 16 cm in depth, consists of porous or perforated pipes which serves the dual purpose of providing an outlet for filtered water as well as supporting the filter media above. A system of control valves facilitates the regulation of filter rate and adjustment of water level in the filter. An important component of the regulation system is the "V-notch" or "venturimeter" which measures the flow of water or bed resistance or loss of head.

In a slow sand filter, water is subject to various purifying influences as it percolates through the sand bed. Impurities are removed by combination of straining, sedimentation, bio-chemical and biological processes. Shortly after the start of filtration, slow sand filter acts primarily biologically by forming a slimy 'zoogeal' layer also known as 'Vital Layer' or '*Schumutzdecke*' on the sand bed. This layer is slimy and gelatinous and consist of thread like algae and biological organisms like plankton, diatoms and other minute plants and protozoa. They feed on the organic matter and convert it into simple harmless substances. The vital layer which is also the heart of the filter removes organic matter, holds back bacteria & oxidises ammonical nitrogen into nitrates & helps in yielding, bacteria free water. Till the vital layer of the filter bed is fully formed (called ripening of bed), the filtrate is run to waste.

**Filter cleaning :** After several months of running of the filter, the bed resistance increases necessitating cleaning. When the filter has attained the maximum permissible head-loss, it is taken out for service for cleaning. The inlet is closed and the supernatant is drained out, then water level is lowered 10-15 cm below the top of sand bed by opening the valves. Without allowing the bed to dry up, the filter is cleaned manually by removing the top layer of 2-3 cm of sand along with the filter skin. This is done manually by scraping the vital layer. After several years of operation when the thickness of the sand bed reduces to about 0.4 to 0.8 m, it is necessary to make up the sand depth to the original level. The plant is to be closed down and a new bed is to be constructed.

**Mechanism of Action of Slow Sand Filters :** In a slow sand

filter, due to the fine grain size, the pores of the filter-bed are small. The filter is capable of reducing the *Esch. Coli* content and the total bacteria count. It will remove protozoa such as *E. histolytica* and helminths such as *S. haematobium* and *A. lumbricoides*. Trouble free operation is only possible when the average turbidity of the raw water is less than 5 nephelometric turbidity units (NTU) with occasional peak values below 20 NTU permissible. Removal of impurities is brought about by different processes such as :

- (a) Straining
- (b) Sedimentation
- (c) Adsorption
- (d) Biochemical and microbial actions

In straining, suspended particles that are too large to pass through the pores are retained at the surface or top layer of the filter. In the upper part of the filter-bed, sedimentation of fine suspended solids also takes place. Settling efficiency is very high due to the large surface area (10,000 to 20,000 sq. m per cu. m of the filter sand) and slow rate of filtration. The rate of filtration of water lies between 0.1 to 0.4 m<sup>3</sup>/hour/sq mt of sand bed surface.

Advantages of slow sand filter	
1.	Simple to construct and operate.
2.	The cost of construction is cheap.
3.	The quality of filtered water is very high.
4.	Preferred for rural or small community water supplies.

Performance standards for slow sand filter	
1.	The filtrate should be clear with a turbidity of 1 NTU or less.
2.	The filtrate should be free from colour.
3.	When raw water turbidity is around 30 NTU, the filter runs should normally be not less then 6 to 8 weeks, with the filter head not exceeding 0.6 mt.
4.	The initial loss of head should not exceed 5 cm.

### Rapid Sand Filters

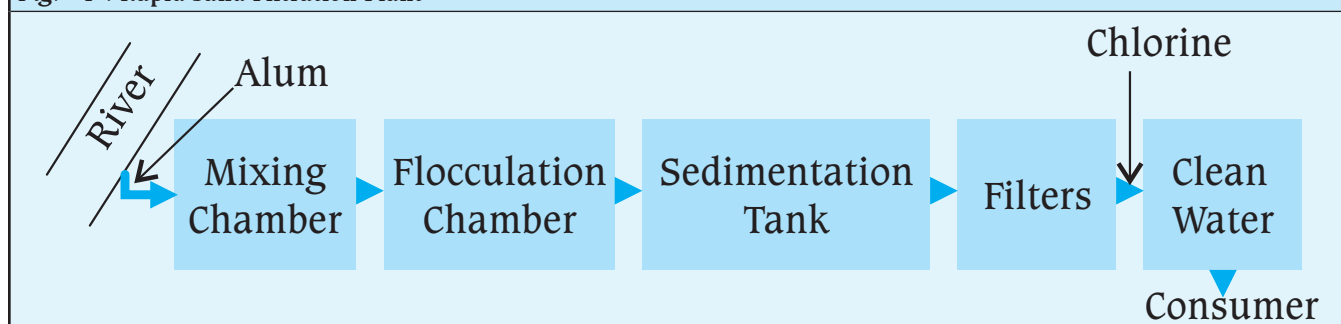
In 1885, the first rapid sand filter was installed in USA, and since then they are popular worldwide. These are of two types 'gravity type' (Paterson's filter) and the 'pressure type' (Candy's filter). While the former is usually used in large installations, the latter is used in smaller installations such as swimming pools. The various steps in the working of a gravity type rapid sand filter are shown in Fig. - 1.

**Filter Bed :** The filter bed is a watertight rectangular chamber with a surface area of about 90 m<sup>2</sup>. The depth of the sand bed is usually one meter having sand particles whose sizes are bigger than the ones used in slow sand filters. The filter bed consists of :

- (a) Supernatant water layer - 1-1.5 mt
- (b) A bed of filter medium - sand bed 1-1.2 mt.; graded gravel 0.3-0.5 mt.
- (c) An underdrainage system - 0.16 mt
- (d) Set of control valves and appurtenances



Fig. - 1 : Rapid sand Filtration Plant



Below the sand bed is a layer of graded gravel of about 40 cm thickness. The 'effective size' of the sand particles is between 0.4-0.7 mm. The under drainage is below the graded gravel layer which collects the filtered water.

**Filtration :** The alum floc makes a tough slimy layer (chemical) over the sand bed, which acts mechanically. Oxidation of ammonia also takes place during the passage of water through the filters. In this system there is no time wasted for ripening of the bed. The rate of filtration in a rapid sand filter is about 100 times faster than of slow sand filter. The rate of filtration is 5-15 m<sup>3</sup>/m<sup>2</sup>/hour. When the bed gets clogged after use for a day or so, it is cleaned by back washing by reversing the flow of filtered water.

**Filter Cleaning :** Rapid sand filters need frequent washing daily or weekly, depending upon the loss of head. The process of cleaning the filter bed is called Backwashing, in which water or compressed air is passed in the reverse direction or below upwards to dislodge the impurities and loosen the sand bed. The backwash rates of 42-54 m<sup>3</sup>/m<sup>2</sup>/hour is used to clean filters. The washing is stopped when clear sand is visible or wash water is clear. After backwashing, the filter bed is put to use immediately and not after 24 hours or so as is required for the formation of biological film in a slow sand filter.

Advantages of rapid sand Filter	
1.	Rapid sand filter can deal with raw water directly.
2.	The filter beds occupy less space.
3.	Filtration is rapid, 40-50 times that of slow sand filter.
4.	The washing of filter bed is easy.

Performance standards for rapid sand filters	
1.	The filtrate should be clear with a turbidity of 1NTU or less.
2.	The filtrate should be free from colour.
3.	The filter runs should normally be not less than 24 hours, with the loss of filter head not exceeding 2 mt.
4.	The wash water consumption should not exceed 2% of the quantity filtered in between washing.

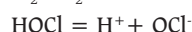
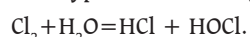
### Disinfection

For purification of water after pre-treatment and filtration, the disinfection of water is carried out. The need for disinfection

to prevent water borne diseases and its inclusion as one of the water treatment processes is considered necessary. Disinfection of water means making it fit for drinking by destroying all pathogenic organisms that may be present in it. Broadly, modern disinfection processes include :

1. *Physical methods* such as thermal treatment and ultrasonic waves.
2. *Chemicals* including oxidising chemicals such as chlorine and its compounds, bromine, iodine, ozone, metals like silver etc
3. *Radiation*.

**Chlorination :** In water treatment or purification practise, the term disinfection is synonymous with chlorination. Disinfection of water is therefore, usually carried out by the use of chlorine who fulfils all the criteria's of good disinfectant. Gaseous chlorine is greenish yellow in colour and is 2.5 times heavier than air. Under pressure, it is a liquid with an amber colour, oily nature and approximately 15 times as heavy as water. Chlorine gas is powerful irritant to lungs and eyes with odour threshold of 3.5 ppm by volume. The safety limit for a working environment is 1 ppm of chlorine in air by volume for an exposure period of 8 hours. When chlorine is added to water it forms hydrochloric acid and hypochlorous acid. Hypochlorous acid further dissociates into hydrogen ions (H<sup>+</sup>) and hypochlorite ions (OCl<sup>-</sup>).



The reaction is reversible. The disinfection action of chlorine is mainly by hypochlorous acid and partly by hypochlorite ion. Chlorine acts best when pH of water is around 7 because of predominance of hypochlorous acid. Fortunately most waters in India have a pH between 6 to 7.5. However sporing organisms, protozoal cysts, helminth ova, molluscs, cyclops and cercariae are not affected by the usual dosage. Organic matter or reducing salts deviate chlorine which results in uncertainty of its action.

**Chlorine Demand :** Chlorine and chlorine compounds by virtue of their oxidising power can be consumed by a variety of inorganic and organic materials present in water before any disinfection is achieved. It is therefore, essential to provide sufficient time and dose of chlorine to satisfy the various chemical reactions and leave some amount of unreacted chlorine as residual either in the form of free or combined chlorine adequate for killing the pathogenic organisms. The recommended concentration of free

chlorine is 0.5 mg/L for one hour. The difference between the amount of chlorine added to water and the amount of residual chlorine after a specified contact period (usually 60 minutes), at a given temperature and pH of water is defined as 'chlorine demand'.

**Breakpoint chlorination** : The point at which the free residual chlorine appears after the entire combined chlorine residual has been completely destroyed is referred to as breakpoint and the corresponding dosage is the breakpoint dosage. The point at which chlorine demand of water is met is called 'breakpoint chlorination'. If chlorine is added further, it only increases free chlorine. Breakpoint chlorination achieves the same results as superchlorination in a rational manner and can therefore be construed as controlled superchlorination.

A high chlorine dose creates unpleasant chlorinous taste in water. Initial high dose of chlorine application or the uncertain chlorine content of the unstable bleaching powder used may result in excessive chlorine application. Free chlorine in the strength of 0.5 ppm in water is imperceptible; but over 0.5 ppm the chlorine taste becomes faintly noticeable; whilst above 1 ppm a definite chlorine odour and taste are apparent.

**Dosage of Chlorine** : Under conditions assuring efficient clarity of water, 30 min of contact with the 'disinfecting dose', freedom from chlorinous taste and presence of 0.2 to 0.5 ppm of free chlorine is considered adequate to achieve health safety.

**Superchlorination** : Under worse conditions or in the presence of actual or potential danger of outbreak of intestinal infections or when water is heavily polluted or fluctuate rapidly in quality, large doses of chlorine is added to the water called 'Superchlorination'. The dose of chlorine may be as high as 10-15 mg/L with contact periods of 10-30 minutes. Decolourisation should be carried out before consumption of water. The sporing organisms like the welchii group, the protozoal cysts like those of *E. histolytica*, helminth ova, molluscs, cercariae and viruses of infectious hepatitis and poliomyelitis in water require a higher concentration of chlorine maintained over a long time for disinfection.

**Methods of Chlorine Application** : Chlorine can be applied to water by three methods :

- 1) By the addition of a weak solution prepared from bleaching powder, HTH etc. for disinfecting small to medium quantities of water. It is simple, does not require electricity and relatively safe but instability of bleaching powder, its hygroscopic nature and low percentage of available chlorine makes it difficult to reach desired levels of free chlorine.
- 2) By the addition of weak solution of chlorine prepared by electrolysis of a solution of brine which requires deployment of electrochlorinators which is still an emerging technology.
- 3) By the addition of chlorine, either in gaseous form or in form of solution made by dissolving gaseous chlorine in small auxiliary flow of water, the chlorine gas being obtained from pressurised chlorine containers.

**Chlorine Gas** : In the modern water works application of gaseous or liquid chlorine with the help of mechanical injector called 'Chloronomes' is the method of choice. Since chlorine

gas is an irritant to the eyes and poisonous, it should be applied only through chlorinating equipment called Patersons Chloronome. In this process the charging of the water supply with chlorine, ascertaining persistence of free chlorine content are all carried out automatically. By ensuring 0.5 ppm of free chlorine at the treatment plant and if the delivery of water is not delayed for more than 6 hours, generally results in 0.2 ppm of free chlorine at consumers end. If quantity of water to be treated is more than 500,000 litres per day, chlorine gas has been found to be the most economical.

**Chloramination** : Chloramines are loose compounds of chlorine with ammonia. They impart less chlorinous taste in water and give a more persistent type of residual chlorine. This prolonged residuum confers the power of long resistance to contamination during the flow of water through the pipe system and hence may be advantageously used in large urban water plants where the pipeline runs for several million meters. Their drawback is that they have slower and inferior action than chlorine.

**Bleaching Powder** : Bleaching powder is used for disinfection of water in small water supplies having capacity upto 0.5 mld and rural areas. Bleaching powder is a variable mixture of calcium hydroxide, calcium chloride and calcium hypochlorite also known as chlorinated lime ( $\text{CaOCl}_2$ ). It was first introduced for sterilization of water by Horrocks in 1914. When it is mixed with water, the calcium hypochlorite decomposes into calcium chloride and chlorine. It is a white amorphous powder with pungent smell of chlorine. When freshly made it contains about 33 percent of available chlorine. It is, however, very unstable and its chlorine is readily set free by the action of moisture,  $\text{CO}_2$ , heat, light, and possibly even by continued vibration sustained during long journeys. Bleaching powder is also difficult to introduce in accurate doses into large quantities of water, leading to further error in the dosage and finally to taste trouble. Bleaching powder is stored in corrosion free air tight containers made of wood, ceramic or plastics and kept away from sunlight. Bleaching powder is generally made into a thin slurry with the water and the supernatant is applied to water.

**Water Sterilising Powder (WSP)** : Bleaching powder is considerably improved in its keeping quality by the addition to quicklime in the proportion of 80 : 20 when it is known as water sterilising powder. Its available chlorine should not be less than 25 percent. WSP is usually used for disinfection of water under field service conditions. It is supplied in packs of 50 g, 100g,  $\frac{1}{4}$  kg,  $\frac{1}{2}$  kg, 1 kg and 25 kg. WSP is soluble in about twenty times its weight of water, yielding an insoluble precipitate consisting mostly of Calcium Hydroxide  $\text{Ca}(\text{OH})_2$ , silica etc. This settles quickly, if too thick a paste is not made; otherwise a gelatinizing action takes place and great difficulty in settling is encountered. It is not necessary or desirable to grind or break up the lumps thoroughly and too much agitation is detrimental to prompt settling. 500 g of WSP mixed with 5 : 1 water contains approximately 2.5 percent available chlorine if the powder is of 25 percent strength. Chlorine solution can maintain its strength for weeks if properly corked in brown bottles.

**Hypochlorites** : The chemicals used are Sodium Hypochlorite and Calcium Hypochlorite which can have 60-70% available chlorine. Calcium hypochlorite can be fed either in the dry or

solution form, while sodium hypochlorite is fed as solution. Corrosion resistant materials such as ceramics, glass, plastic or special rubber should be used while handling hypochlorite solutions.

**Agents Other than Chlorine** : Broadly there are three main types of disinfectants other than chlorine :

1. Physical agents including heat
2. Chemical agents such as ozone, halogens
3. Radiations of various types such as Ultraviolet rays, Gamma rays and X-rays.

**Heat** : Boiling of water can disinfect it but it cannot be used to disinfect large scale supplies. It can be used in emergency for individual or household drinking water.

**Ozone** : It is a powerful oxidizing agent. It removes undesirable odour, taste, colour and organic matter. It even inactivates viruses in a few seconds and hence can be used most advantageously for destruction of enteropathogenic viruses. Since ozone decomposes and disappears within short time there is no residual germicidal effect. Hence, a minimal dose of chlorine may be added to the ozonised water before distribution. In this combined treatment, the two methods complement each other. The ozone dosage required for potable water treatment varies from 0.2 to 1.5 mg per litre. Ozonisation of water is presently practiced in the advanced countries. The combination of ozone for pretreatment while providing some disinfection, to be followed by chlorination, has become a popular sequence in Europe and is beginning to be used in USA to reduce the level of trihalomethanes in finished water. Some disadvantages of ozone treatment are :

1. Its high cost of production.
2. Inability to provide residual protection against recontamination.
3. Its onsite generation due to instability.

**Ultraviolet Irradiation** : UV radiation may kill a cell, retard its growth, change its heredity by gene mutation. Wavelength region from 2500-2650 Angstrom units is recommended for maximum destruction of cells.

A mercury vapour arc lamp emitting invisible light of 2537 Angstrom units applied to water by a low pressure mercury lamp constructed of quartz or special glass which is transparent and produces a narrow band of radiation energy, is a useful method of disinfection used in the Soviet Union. The advantages of UV radiation are that exposure is for short periods, no foreign matter is actually introduced and no taste and odour produced. Overexposure does not result in harmful effects.

**Other Halogens** : Halogens are oxidising agents and agents like fluorine, iodine, bromine can also be used for disinfection. In view of the formation of organochlorine compounds by chlorine which are either known or suspected carcinogens, many chlorine alternatives such as bromine and iodine substances are receiving renewed interest. These substances for the present, however, do not seem to be a viable alternative to chlorine.

**Tests for Chlorination** : Before disinfecting any source of water the chlorine demand of the water source should be calculated, this will give adequate disinfection and a desired level of free chlorine. The test used for calculation of chlorine

demand of water is called Horrock's Test. The object of this test is to determine the quantity of the particular sample of WSP required to sterilize any particular sample of water. The test is carried out by means of the 'case water testing sterilization' (Horrock's Box). The Horrock's box contains :

- six white cups of 200 ml capacity each
- one black cup of 240 ml capacity;
- two metal scoops, each of which holds 2 g of WSP when filled level with the brim;
- a bottle of stock cadmium iodide-starch solution;
- a bottle containing 85 ml of 50 percent glacial acetic acid;
- 25 sodium thiosulphate tablets 100 mg each;
- seven glass stirring rods.
- one pipette
- two droppers

The test should be carried out while the water receptacle is being filled with clarified water (7).

**Procedure** : A standard solution of the particular sample of WSP is prepared in the black cup. First a thin paste with one level scoopful of the WSP and a little clarified water is made and then gradually more water is added up to the mark on the inside of the cup and the mixture is stirred with a clean glass rod. The lime in suspension gradually settles down. This is known as stock solution or mother solution. The six white cups are then filled with clarified water to within half a centimetre from its top. Drops of the standard WSP stock solution from the black cup are added to each of the white cups by the pipette, so that the first cup receives one drop; the second cup receives two drops and so on serially increasing until finally the sixth cup receives six drops. One drop represents one part of chlorine in a million parts of water when added to the white cupful of water. The pipette must be held vertical when delivering the drops. The contents of each cup are stirred with a clean stirring separate rod, starting at the first cup, and allowed to stand for half an hour, shading them from sunlight. After that time three drops of the starch-cadmium iodide indicator solution are added to each cup from the drop bottle/dropper and stirred with a clean stirring separate rod. Some of the cups will show a blue colour. This indicates the presence of free residual chlorine.

The serial number of the cup showing definite blue colour indicates the number of scoopfuls of the particular sample of water sterilizing powder required to sterilize 455 L of water and to leave 1 ppm of free chlorine after chlorine demand of that sample of water is satisfied during half an hour contact with chlorine.

For example, if cups 3, 4, 5 and 6 show a definite blue colour, then three scoopfuls of WSP are required to sterilize 455-500 L of the particular water sample and leave 1 ppm residual free chlorine after half an hour contact. If superchlorination is indicated one more scoopful of WSP per 500 L of water is required to be added. This will give 2 ppm of free chlorine in water after 15 min contact. In the example given above a total of 4 scoopfuls of WSP per 500L will be needed for superchlorination. The WSP used for chlorination or superchlorination should be from the same tin from which the WSP for Horrock's test was used.

An indicator solution can be made by preparing a uniform paste of 1.5 g of starch in 25 ml of distilled water and then adding



it slowly to 75 ml of boiling distilled water while continually stirring it, and boiling for subsequent 15 min. After cooling, 7.5 g of cadmium iodide is added to the mixture and dissolved by shaking. In an emergency potassium iodide may be used if cadmium iodide is not available. The solution should be stored in a well-corked dark brown bottle in a dark and cool place. The keeping quality of the solution is enhanced by the addition of 1ml formalin to this solution.

**Tests for Adequacy of Chlorination :** Adequate control must be kept on chlorination by a regular examination of the treated water to make sure that the requisite amount of free chlorine has persisted in the water for the requisite time. This can be done by means of starch-iodide, thiosulphate with starch-iodide, orthotoluidine, orthotoluidine arsenite or neutral red.

**Orthotoluidine (OT) Test :** This is the most commonly used test in public health practice. It is carried out with the 'Comparator type of apparatus' (Lovibond Comparator) indicates chlorine below 1 ppm. The test was developed in 1918 and it uses analytical grade O-tolidine, dissolved in 10% solution of hydrochloric acid. 0.1 ml of orthotoluidine solution is added to 1 ml of water in a standard glass cell or tube. The yellow colour, which develops, is matched against tinted glass discs. The immediate (flash) reading within 10 seconds shows the free chlorine and that taken after 5 min (delayed) gives the combined content of chloramines and free chlorine. OT reacts with free chlorine instantaneously but reacts more slowly with combined chlorine. In the absence of the Comparator, the appearance of intensity of yellow colour can give rough estimate of amount of free chlorine present.

**Orthotoluidine Arsenite Test (OTA) :** It is a modification of OT test. Certain interfering substances such as nitrates, iron, manganese etc which when present in water also gives yellow colour with orthotoluidine. The OTA reagent overcomes this drawback and hence gives better determination of free and combined chlorine separately.

**Colour Test :** Fill a white cup with chlorinated water to be tested and stir into it 10 drops of fresh cadmium-iodide-starch indicator solution. If there is one or more parts of free chlorine in million parts of water a blue colour will appear. In this test the residual chlorine replaces iodine and combines with cadmium radical; iodine so released combines with starch and turns it blue.

**Determination of Chlorine Content in WSP :** A rough and ready field test can be carried out by the use of the Horrock's Box. A WSP solution is made by mixing one level scoopful of the WSP powder to be tested in the black cupful of clarified water. One scoopful of this solution is mixed with a scoopful of cadmium-iodide indicator solution in a white cup and a tablet of acid sodium bisulphate is added to it. The 0.05 percent neutralising reagent is prepared by dissolving a 100 mg tablet of sodium thiosulphate in a white cupful of water. Scoopfuls of this solution are added to the blue mixture of indicator-WSP solution and stirred. The number of scoopful of the thiosulphate solution added until the blue colour first disappears indicates the percentage of chlorine in the WSP under test.

**Purification of Water on a Small Scale (Households and small groups of people)**

**Boiling :** It is very effective and kills all bacteria, viruses, spores, cysts and ova when the water is boiled for 5 to 10 min called "rolling boil". It also removes temporary hardness by driving off  $\text{CO}_2$  and precipitating the calcium carbonate. The taste of water is, however, altered. Boiled water has also no residual protection against subsequent contamination and hence care to be taken to avoid contamination during storage.

**Chemical Disinfection :** It may be carried out with either chlorine solution, bleaching powder, WSP, perchloron, chlorine tablets, high test hypochlorite or iodine solution. The chlorine tablets manufactured by the National Environmental Engineering and Research Institute, Nagpur (NEERI) are about 15 times more potent than ordinary halogen tablets and are available in the market. A single tablet of 0.5 g is sufficient to disinfect 20 l of water. The tablets are mostly used while travelling or by soldiers during march or field areas. Potassium permanganate is no longer recommended, as it is not a satisfactory water disinfecting agent although it is a powerful oxidizing agent. It has other drawbacks such as alteration of colour, smell and taste of water.

**Filtration :** It is done through ceramic filters such as Pasteur Chamberland, Berkefeld and Katadyn filters. The essential part of a filter is the candle, which is made of unglazed porcelain in Pasteur Chamberland type, and of Kieselgurh in Berkefeld type. The surface of the candle in Katadyn filter is coated with a silver catalyst. The bacteria coming in contact with filter candle get killed by the oligodynamic action of silver ions. Filter candles are liable to be clogged. These are to be cleaned by scrubbing with a hard brush under running water. The candles should be boiled at least once a week. Relatively clean water should be used with ceramic filters. Filter candles, however, removes bacteria but do not remove filter-passing viruses. Most of the household filters available in market work on electricity on principles of disinfection by UV radiation.

**Disinfection of Wells :** It is sometimes necessary on a large scale during epidemics of cholera and other gastro-intestinal infections. Chlorination with bleaching powder is the most effective and cheapest method for this purpose. The quantum of water in the well is first worked out and the amount of WSP required is then estimated by Horrock's test. The required quantity of WSP is then made into a thin paste with little water in a bucket. The bucket is filled three-fourth with water stirring all the time. About 5 to 10 min time is allowed for the chalk to settle down. The supernatant clear solution is then transferred to another bucket and the chalk is discarded. The bucket containing the clear chlorine solution is lowered into the well and the well water agitated by lowering and drawing the bucket several times. After half an hour's contact, orthotoluidine test is carried out. If fresh residual chlorine is less than 0.5 mg/l, additional quantities of WSP will have to be added. During epidemics, wells should be disinfected every day. Steps in well disinfection are :

a) Find the volume of water in a well by formula

$$(3.14 \times d^2 \times h \times 1000) \div 4$$

(Where d = diameter of well, h = depth of water column)

Or, find out by following formula (measurements of depth and diameter are in metres)



**Circular well** : Depth of water x square of diameter x 785 = liters of water in the well.

**Rectangular** : Depth of water x length x breadth x 1000 = liters of water in the well.

- b) Find the amount of bleaching powder required for disinfection by Horrock's test.
- c) Dissolve bleaching powder in water
- d) Delivery of chlorine solution into the well.
- e) Contact period
- f) OTA test

## Water Quality Standards and Criteria

The WHO has published in 1993 vol 1 and in 1996 vol 2 of second edition of Guidelines for Drinking water quality on various parameters for drinking water quality to be used by different countries in making their own standards. They are laid down in standard references (8, 9, 10, 11) and should be referred to as and when required. The methods of examination of water are also given in details in the publications of ICMR (12). In brief the standards are as follows

1. Acceptability Aspects.
2. Microbiological Aspects
3. Chemical Aspects.
4. Radiological Aspects.

### Acceptability Aspects

The drinking water should not only be safe but also pleasing in appearance, taste and colour. Wholesomeness and acceptability of drinking water is determined by the following factors :

**Turbidity** : Turbidity should be less than 5 NTU and before chlorination should be < 1 NTU. Turbidity above 5 NTU, becomes unacceptable to the consumer. Turbidity indicates incomplete treatment of water and also interferes with disinfection of the water.

**Colour** : The acceptable limit for colour in drinking water is 15 true colour units (TCU). Colouration of water may be due to presence of organic matter such as peat, metals like iron and manganese or due to industrial wastes.

**Taste and Odour** : Even though no guideline limit values have been laid down, any water with significant degree of taste and odour is unacceptable to the user. Taste and odour may be due to mineral matter, presence of organic matter and occasionally due to excessive residual chlorine in treated waters.

**Total Dissolved Solids (TDS)** : The amount of TDS in water has an important effect on its taste. Water with very low concentrations of TDS, such as the rain water is not relished by the consumer because of the flat, insipid taste. The palatability of waters with TDS levels below 600 mg/litre is considered to be good and those above 1200 mg/litre become unpalatable and objectionable due to scale formation in pipes, heaters and household appliances. The guideline value for TDS is to be below 1000 mg/litre.

**pH** : The guideline value for pH of water is 6.5 to 8.5. Water with pH levels below this range may corrode pipelines, resulting in increased levels of certain chemical substances, such as lead, in water. At pH levels above this range, the efficiency of the disinfectant action of chlorine is reduced.

**Hardness** : Depending on the interaction of other factors, such as pH, water with hardness above 200 mg/litre may cause scale deposition in the distribution system and may result in excessive soap consumption. On the other hand, water with a hardness of less than 100 mg/litre has a low buffer capacity and is corrosive for water pipes. For domestic use the amount of hardness of water should not be more than 300 ppm. For laundries and boilers the softer the water the better it is.

**Dissolved Oxygen** : Even though no health based guideline value has been laid down, depletion of dissolved oxygen content in water encourages microbial reduction of nitrates and sulphates to nitrites and sulphides respectively, with consequent odour problems.

**Ammonia** : Ammonia in water is an indicator of possible bacterial, sewage and animal waste pollution. It may be present in a non-ionised or ionised form. The guideline value is 1.5 mg/litre. Ammonia may be free (F), saline(S), or Albuminoid (Alb). If both types of ammonia are low i.e. F and S are 0.05 ppm or less and Alb. 0.1 ppm or less, the water is probably good. If both types of ammonia are higher than the above figures then the water is bad.

**Chlorides** : The guideline value for chloride is 250 mg/litre even though the maximum permissible level is kept at 600 mg/litre. Other indications of pollution will also help in arriving at conclusions.

**Iron** : A trace of iron is almost always present in water. Iron upto 0.3 mg/L is acceptable. Above that it causes constipation, colic and results in the colouration of vegetables while cooking and staining of linen.

### Microbiological Aspects

**a. Standards of Bacterial Quality** : The primary bacterial indicator recommended are coliform group of organisms, whereas supplementary indicator organisms are faecal streptococci, sulphite reducing clostridia etc.

**Coliform Organisms** : It includes all aerobic and facultative anaerobic, gram negative, non sporing, motile and non motile rods capable of fermenting lactose at 35-37 deg. C in less than 48 hrs. The coliform group includes both faecal and non faecal organisms. e.g. Faecal group is *E Coli* and non faecal group is *Klebsiella aerogenes*. The coliform organisms are chosen as indicators of faecal pollution in water because :

- a. Coliform organisms are present constantly in the human intestines but they are foreign to potable waters and hence their presence in water indicates faecal contamination.
- b. They are easily detected by culture methods.
- c. They survive longer than other pathogens.
- d. The coliform organisms have greater resistance to the forces of natural purification.

**Faecal Streptococci** : In doubtful cases, the finding of faecal streptococci is regarded as important confirmatory evidence of recent faecal pollution of water. Streptococci are highly resistant to drying and may be valuable for routine control testing after laying new mains or repairs in distribution systems or for detecting pollution by surface run off to ground or surface waters.

**Cl perfringes** : The spores of *Cl perfringes* survive longer time and resist chlorination at the doses normally used for disinfection. Their presence in water, in absence of other organisms indicates the faecal contamination occurred at some remote time.

**Bacteriological Standards - Treated Water** : Ideally, all samples taken from the distribution system should be free from coliform organisms. In practice this standard is not always attainable and the following standard for water collected in the distribution system is therefore recommended throughout any year : *95 percent of samples should not contain E Coli coliform organisms in 100 ml water sample taken during that 12 month period; no consecutive samples should contain coliform organisms in 100 ml of water samples.*

**Bacteriological Standards - Individual or Small Community Supplies** : The standards outlined above may not be attainable in the case of waters from wells and springs. In these waters, the coliform count should be less than 10 per 100 ml. Persistent failure to achieve this particularly if *E Coli* is repeatedly found calls for rejection of water supply.

**b. Standards of Viral Quality** : As stated earlier, water free of faecal coliform need not necessarily be free of viruses. Enteroviruses, reoviruses and adeno-virus have all been detected in water. As per WHO standards not more than one plaque forming unit (PFU) per liter of water is considered potable. There should also be complete absence of enteropathogenic viruses and faecal bacteriophages. Ozone has been shown to be most effective viral disinfectant.

**Table - 4 : Inorganic chemicals of health significance in drinking water**

Constituents	Recommended maximum limit of concentration (mg/lit)
Antimony	0.005
Arsenic	0.01
Barium	0.7
Boron	0.3
Cadmium	0.003
Chromium	0.05
Copper	2
Cyanide	0.07
Fluoride	1.5
Lead	0.01
Manganese	0.5
Mercury	0.001
Molybdenum	0.07
Nickel	0.02
Nitrate	50
Nitrite	3
Selenium	0.01

## Chemical Aspects

These indicators are of two types, viz., inorganic constituents and organic constituents.

**a. Inorganic Constituents** : The details are shown in Table-4.

### b. Organic Constituents

**Polynuclear Aromatic Hydrocarbons (PAHs)** : Most of the PAHs identified in the environment are from combustion and pyrolysis processes. The main source of human exposure to poly aromatic hydrocarbons is via food with drinking water contributing only minor amounts. Some of these are known to be carcinogenic. Their concentration, in general should not exceed 0.2 g / L.

**Pesticides** : Chlorinated hydrocarbons and their derivatives, herbicides, soil insecticides and pesticides that leach out from the soil are of importance in connection with water quality. The recommended guideline value for human beings are given in Table - 5.

Table - 5 : Guidelines for Chlorinated Hydrocarbons for Humans	
Pesticides	Upper limit of concentration (microgram/lit)
Aldrin/dieldrin	0.03
Chlordane	0.2
DDT	2
Hexachlorobenzene	1
Lindane	2
Methoxychlor	20
Pentachlorophenol	9

## Radioactive Substances

The effects of radiation exposure are called 'Somatic' if they manifest in exposed individual, and called 'Hereditary' if they affect the descendants. There is an increasing hazard of pollution of water supplies by radioactive substances. Malignant diseases are the most important delayed somatic effect. The radioactivity of water is measured in picocuries per liter (pCi/l). The WHO has proposed the following limits of radioactivity as acceptable :

- Gross alpha activity 3 pCi/l.
- Gross beta activity 30 pCi/l.

## Surveillance of Drinking Water Quality

Drinking-water supply surveillance is "the continuous and vigilant public health assessment and review of the safety and acceptability of drinking-water supplies" (WHO, 1976). This surveillance contributes to the protection of public health by promoting improvement of the quality, quantity, accessibility, coverage, affordability and continuity of water supplies (known as service indicators) and is complementary to the quality control function of the drinking-water supplier. The following are the component steps for establishing a water quality surveillance system :

### a. Sanitary Survey

A sanitary survey is an on-site inspection and evaluation by a qualified person of all the conditions, devices, and practices in the water supply system which pose a danger to the health and well being of the water consumer. The hygiene inspection of the source, surroundings and site of water supply is carried out by making a plan and following it systematically. The site for obtaining water for human consumption from the selected source should also be properly examined before final selection. No bacteriological or chemical examination can take the place of a sanitary survey as the pollution is often intermittent and may escape the laboratory testing.

#### Sanitary Surveys should be undertaken when :

- A new source is contemplated
- Laboratory analysis indicates hazard to health
- An outbreak of waterborne disease occurs in the area
- To interpret bacteriological, chemical and physical analyses of samples
- When any change takes place that can affect the water system, e.g. industries coming up in watershed and
- Also on a regular basis depending on size and available staff and resources and population / area under coverage. Majority of samples should be from problem areas, i.e. those with poor results in the past, low pressure zones, areas with high leakage, densely populated areas with inadequate sewerage, dead ends on pipelines, areas far away from waterworks etc.

### b. Sampling

Sampling of water should be done with strict aseptic precautions. It should be carried out by competent and trained personnel in accordance with the methods and frequency of sampling prescribed in the WHO guidelines for drinking water quality.

### c. Bacteriological Surveillance

The World Health Organization (WHO) recommends the measurement of *E Coli* in drinking water samples as the best indicator of water quality. The WHO guideline for potable water is less than one *E Coli* per 100 ml of drinking water (World Health Organization 1998). The following tests are conducted for bacteriological surveillance of drinking water :

**Presumptive Coliform Test** : The available methods are

**Multiple Tube Method** : This test is based on estimating the Most Probable Number (MPN) of coliform organisms in 100 ml of water. The test is carried out by inoculating measured quantities of the sample water (0.1, 1.0, 10, 50 ml) into tubes of McConkey's Lactose Bile salt Broth with bromocresol purple as an indicator. If the samples can't be inoculated on the spot then, they should be packed in ice and sent expeditiously to the laboratory. Bottles containing McConkey's broth, the sample of water and a small inverted tube are incubated for 24 to 48 h at 37°C. The multiplication of the faecal organisms present in water under test produces acid and gas. From the number of tubes showing acid (as shown by the pink colour of the mixture) and gas, as seen in the inverted tubes, an estimate of the MPN of coliform group of organisms per 100 ml water

is ascertained from the standard tables. The estimates are therefore 'presumptive' and not actually existing. Details of the procedure are given by Cheesbrough (13).

**Membrane Filtration Technique** : In some countries membrane filter technique is used as a standard procedure to test for the presence of coliform organisms. A measured value of the water sample is filtered through a membrane made of cellulose ester. Bacteria present in water are retained on the surface of the membrane. The membrane is then directly inoculated face upwards on suitable media at appropriate temperature. Within 20 h the colonies grow and can be counted (13).

**Faecal Streptococci and *Cl. perfringens* Detection** : The significance of these two tests have been discussed earlier. Their presence provides useful confirmatory evidence of the faecal pollution of water.

**Colony Count** : The colony count on nutrient agar at 37°C and 22°C provide an estimate of the general bacterial content of water. A single count is of little value, but counts from the same source at frequent intervals are of considerable value. A sudden increase in the count serves as the earliest indicator of contamination and hence this test is gainfully used in the public water works. The recommended plate counts are given in Table - 6.

Table - 6		
Water at consumer end	Plate count after 2 days at 37°C	Plate count after 3 days at 22°C
Disinfected	0	20
Not disinfected	10	100

Plate count on yeast extract agar at 22°C for 7 days is even a better indicator due to the absence of chlorine residue when there is uninhibited bacterial growth.

**Colilert Method** : Colilert is a recently available method to determine the MPN of coliforms. Colilert uses defined substrate technology to detect and quantify total coliforms and *E Coli* from water samples. Colilert is simpler to use, allows greater output and requires less time to standardize than standard methods. Colilert is an acceptable method to measure the presence and quantity of coliforms in water samples in a developing country setting (14).

### Organic matter

Data on the level of organic matter in treated water provide an indication of the potential for the regrowth of heterotrophic bacteria (including pseudomonads and aeromonads) in reservoirs and distribution systems. Organic matter can be measured as Total Organic Carbon (TOC), Biochemical Oxygen Demand (BOD) or Chemical Oxygen Demand (COD). BOD is primarily used with wastewaters and polluted surface waters, and TOC is the only parameter applicable to drinking water. Measurement of these three parameters requires basic laboratory facilities and adequately trained personnel.

### Hardness of Water

Hardness of water may be defined as its soap destroying power. Hardness is undesirable because it wastes soap, retards washing, causes encrustation of the water carrying system and



heating utensils resulting in wastage of fuel and even explosion of boilers (1, 4 - 7). Vegetables cooked in very hard water may be less digestible. It reduces the life of fabrics also. Hardness is of two types :

- *Temporary or carbonate Hardness* : It is due to Calcium bicarbonate or Magnesium bicarbonate
- *Permanent or non carbonate Hardness* : It is due to Calcium sulphate, Magnesium sulphate, Chlorides and nitrates of calcium and magnesium or else Iron, manganese and aluminium compounds

Hardness is expressed in terms of milli-equivalents per litre (mEq/L). One mEq/L of hardness producing ion is equal to 50 mg ( $\text{CaCO}_3$ ) (50 ppm) in one litre of water. The four grades of describing hardness are : Soft water : <1 mEq / L (<50 mg/L); Moderately Hard : 1-3 (50 - 150 mg/L); Hard Water : 3-6 (150-300 mg/L); Very Hard Water : >6 (>300 mg/L). Softening of water is recommended when hardness exceeds 3 m Eq/L.

Drinking water should be moderately hard. It has been observed that in some localities supplied with soft drinking water showed a significantly higher prevalence of either arteriosclerotic heart disease, degenerative heart disease, hypertension, sudden death of cardiovascular origin, or a combination of these. However, it is based on purely circumstantial evidence and further studies are in progress to establish the association.

The methods of removal of hardness are briefly stated as below:

**Temporary Hardness** : This can be removed by boiling, addition of lime, addition of sodium carbonate or by permutit process.

**Permanent Hardness** : This can be removed by addition of sodium carbonate or by base exchange process.

## Fluoridation of Water

Fluorine is naturally present in water supplies. Its removal is necessary when the concentration in drinking water is more than 1.5 ppm. The optimum concentration in countries like India where people consume a lot of water should be between 0.5 to 0.8 ppm. Fluoride concentration over 1.5 ppm causes dental fluorosis. A still higher concentration causes skeletal fluorosis. People in the States of Rajasthan and Punjab are presently facing this problem of water supply. The excess quantity of fluoride in water may be removed by 'Nalgonda technique'. On the other hand if fluoride content of water is less than 0.5 ppm then it is associated with dental caries. The term 'Flouridation' has been given to the process of supplementing the natural fluoride content of potable waters to the point of optimum concentration.

## Detection of Poisons in Water

Water is the most vital source of all kinds of life on this planet. There is every possibility of sabotage of the drinking water source by the enemy/militants. It must be ensured that water is free from poisons before it is declared potable. Testing of poison in drinking water requires elaborate laboratory facilities, which are not possible in remote areas. A set of Kit has been developed by DRDE Gwalior and marketed by Hindustan Metal Industries, Nai Sarak, Gwalior-1(MP) keeping in view the above requirement and facilitated testing of most commonly present poisons, sulphur mustard, nerve agent and microbial

contaminations. The kit is housed in aluminium container having shoulder strap to carry for field use. The kit is provided with the reagents/material, sufficient for testing poisons 50 times.

## Sanitation of Swimming Pool

A swimming pool is an artificial structure where water volume per swimmer is relatively small. The recommended area is 2.2 sq m (24 sq ft) per swimmer. The water is thus exposed to contamination by ammoniacal and other organic substances as well as organisms from skin, nasopharynx and other orifices of the swimmer. The health hazards associated with swimming in these pools are usually fungal, viral and bacterial infections of the skin, eye, ear, nose, throat and upper respiratory tract, intestinal tract and so on. Proper maintenance of pools is, therefore, of vital importance. General guidelines on sanitation of swimming pool are being given in subsequent paragraphs. Further details are available in standard texts (15).

A continuous inflow or a daily change of water, though ideal, is usually not feasible. The modern pools are equipped with continuous filtration and chlorination system. The "fill and empty" system is also encountered. Considerable attention is thus necessary to ensure that water is maintained continuously in a pure state in such pools. If the water is turbid provision for sedimentation in a separate settling tank may become inescapable. The water must be renewed at least once a week and 10-15 percent of the water should be replaced by a fresh daily inflow. When the pool is emptied, the floor and the sides should be thoroughly scrubbed and lime washed. Addition of copper sulphate 2g per 1000 l once a week will prevent algal growth and accumulation of slime.

Chlorination is carried out by injecting gaseous chlorine by the use of chloronome. Continuous maintenance of 1 ppm of free residual chlorine provides adequate protection against bacterial and viral agents. When chloronomes are not installed or not functioning, the required amount of WSP as calculated by Horrock's test is first made into a thin mixture and distributed evenly over the surface of water. The water is then stirred with paddles. Subsequently, each day until the next filling, half that amount of WSP should be added half an hour before the swimming time. Tests for free residual chlorine is to be carried out daily half an hour after adding WSP. It will be ideal to keep the pH of water between 7.4 to 7.8 as irritation of eyes due to chloramine formation will be minimum. In a swimming pool the process of chlorination preferred is 'breakpoint' chlorination. When chlorine is added to water it immediately forms chloramines with ammonia, which is always present. The process continues till all the ammonia present is used up and the concentration of chloramines reaches its peak. Chloramines are, however unstable and react with excess free chlorine present in water and get oxidized completely to nitrogen and thus water contains no longer any free chlorine. Break point is said to have been reached when water no longer gives 'flash' reaction of free chlorine. Any further addition of chlorine hereafter causes a proportionate rise in the residual free chlorine, which acts as efficient germicidal agent. The bacteriological quality of swimming pool water should reach as nearly as possible the standard of drinking water. The test should be carried out weekly.



## Water Supply in Emergencies and Disasters

The following is a list of hygiene practices that protect health in disasters and emergencies.

People's ability to achieve these protective actions depends on the availability of material resources, such as adequate clean water, soap, toilets, etc. and personal resources, such as time and energy. The details are shown in Table - 7.

## The International Drinking Water Supply and Sanitation Decade 1981-1990 (16, 17)

The 'Decade' was launched at a special meeting of the United Nations General Assembly on 10 November 1980 following the recommendation of the UN Water Conference at Mardel Plata in 1977. The priority given by the above conference to the provision of safe water supply and sanitation was influenced by the joint report of WHO and World Bank which showed that in 1975 some 1230 million people were still without safe water supplies and 1350 million people had lack of adequate sanitation facilities. Among the rural populations of developing countries, only 22 percent had access to reasonable safe water and only 15 per cent had facilities for excreta disposal. The Mardel Plata action plan also urged the individual countries to establish goals for 1990, which match the global target of the Decade. In India, under the International Drinking Water Supply and Sanitation Program the laid down target was 100 percent safe water supply, in both urban and rural areas. As per available reports, till 1994-95, 85 percent of the target has been achieved.

**Targets of the Decade (1991-2000)** : The targets were fixed by the Indian Government for the decade as

- 100% urban and rural supply
- 50% urban sanitation
- 25% rural sanitation

The Guinea worm eradication programme was linked with this decade. In 1986 the National drinking water Mission (NDWM) popularly unknown as Technical Mission was launched in order to provide scientific and cost effective content to the centrally sponsored Accelerate Rural water supply programme. In 1987 the National Water Policy was announced that has given high priority to drinking water.

## Eleventh Five Year Plan (2005-2012) in Relation to Safe Water Supply

**Past Programmes and Outlays** : Government of India's major intervention in water sector started in 1972-73 through *Accelerated Rural Water Supply Programme* (ARWSP) for assisting States/UTs to accelerate the coverage of drinking water supply. In 1986, the entire programme was given a mission approach with the launch of the Technology Mission on Drinking Water and Related Water Management. This Technology Mission was later renamed as *Rajiv Gandhi National Drinking Water Mission* (RGNDWM) in 1991-92. In 1999, Department of Drinking Water Supply (DDWS) was formed under the Ministry of Rural Development (MoRD) to give emphasis on rural water supply as well as on sanitation. In the same year, new initiatives in water sector had been initiated through Sector Reform Project, later scaled up as *Swajaldhara* in 2002.

An investment of about Rs.72,600 crores has been made (under both State and Central Plans) from the beginning of the planned era of development in rural water supply sector. This investment has helped to create assets of hand pumps, public stand posts, mini-piped water supply schemes and multi village schemes in the country under the Rural Water Supply Programme.

The *Swajaldhara* programme was launched in 2002-03. The programme involves a community contribution of 10% of the

**Table - 7 : Water Safety**

At the source	Water for drinking is collected from the cleanest possible source. If necessary, a distinction is made between water for drinking and water for other uses, such as bathing, laundry, watering animals.
	Water sources are protected from faecal contamination by fencing (to keep animals away), and by siting latrines or defecation fields at least 10 - 30 metres away, depending on ground conditions.
Collection, storage and use of water at household level	Water is collected and stored in clean, covered containers. Water is taken from the storage container with a clean, long-handled dipper or through a tap placed slightly above the bottom container.
	Efforts are made not to waste water.
Use of water	If there is a risk that water is not safe, it is filtered and/or chlorinated or boiled.
	Water for making food or drinks for young children is boiled.
Personal Hygiene	
Water for washing	If possible, plenty of water is used for washing. Clothing is laundered regularly.
	The most readily-available water is used for personal and domestic hygiene.
Hand-washing	All family members wash their hands regularly : after defecating; after cleaning a child who has defecated and disposing of the stool; before preparing food; before eating; before feeding a child.
	Adults or older children wash the hands of young children.
Note : To make water safe for drinking, it should be brought to a vigorous rolling boil. If boiling or chlorination are not possible at household level, then low-turbidity water may be disinfected by exposing it to bright sunlight for at least one day (Reed 1997).	

project cost to instill a sense of owner ship among the people and also to take over the O&M of the schemes constructed under the programme. The Centre provides 90% of the project cost as grant. The proportion of population covered till now is shown in Table - 8.

<b>Table - 8 : Percentage of population covered with Water Supply Facilities</b>		
<b>Year</b>	<b>Urban Population (million)</b>	<b>Percentage of Population Covered with Water Supply</b>
1981	152	78
1991	217	84
2001	285	89
2004	308 (Projected)	91

**Eleventh Five Year Plan Targets for Rural Water Supply :** To “Provide clean drinking water for all by 2009 and ensure that there are no slip-backs by the end of the Eleventh Plan” is one of the monitorable targets of Eleventh Five Year Plan. Under *Bharat Nirman Programme* it is proposed to provide safe drinking water to all habitations. The Government is also committed to provide 100% coverage of water supply to rural schools. The ARWSP includes school water supply also. Accelerated Rural Water Supply Programme has provision of water supply to existing schools; the new schools are covered under other programmes like Sarva Shiksha Abhiyan of Ministry of Human Resources Development.

**Strategies during the Eleventh Five Year Plan :** In order to achieve 100 per cent coverage of clean water and sanitation in rural areas, rural sanitation programme will be linked with the National Rural Health Mission. Efforts will be made to launch a Sarva Swasthya Abhiyan in the county that will cover the primary health care, safe drinking water and sanitation in urban areas. The strategies include :

- Convergence of health care, hygiene, sanitation and drinking water at the village level
- Participation of stake holders at all levels, from planning, design and location to implementation and management of the projects
- Institution water quality monitoring and surveillance systems by involving PRIs, community, NGOs and other civil society organizations
- Increased attention to IEC campaign

#### **Local Participation**

Involvement of the community in the monitoring of the water supply works is recommended. Department of Drinking Water Supply has initiated monitoring of the water quality under the National Rural Drinking Water Quality Monitoring and Surveillance Programme under which the Gram Panchayat/Village Water and Sanitation Committee provided with user friendly field test kits for testing both bacteriological and chemical contaminants followed by testing of the samples at district and state level laboratories. Such initiatives need to be extended to the other regular programmes under the Accelerated Rural Water Supply Programme also.

**Recommended Outlays for Eleventh Five Year Plan :** The full coverage of rural drinking water supply is to be achieved by March 2009 and 100 % sanitation coverage by the end of Eleventh Plan (2012) with mass awareness and Nirmal Gram Puraskar. The Eleventh Plan Central sector GBS is Rs.41,826 crore (at 2006-07 prices) and Rs.47,306 crore (at current prices) and this provision will draw matching provision in the State Plan to the tune of Rs. 49,000 crore. Thus the total outlays in the Eleventh Five Year Plan for Rural Water Supply & Sanitation sector would be close to Rs. 1,00,000 crore. The total outlay for Urban Water Supply and Sanitation sector would be Rs. 75,000 crore.

#### **Summary**

For drinking water to be wholesome it should not present a risk of infection, or contain unacceptable concentrations of chemicals hazardous to health and should be aesthetically acceptable to the consumer. The infectious risks associated with drinking water are primarily those posed by faecal pollution, and their control depends on being able to assess the risks from any water source and to apply suitable treatment to eliminate the identified risks. Rather than trying to detect the presence of pathogens, at which time the consumer is being exposed to possible infection, it is practice to look for organisms, while not pathogens themselves, that show the presence of faecal pollution and therefore the potential for the presence of pathogens.

It is also important to be able to check on the effectiveness of treatment processes at eliminating any pathogens that might have been present in the untreated source, and ‘indicator’ organisms fulfil that role. Treatment should be able to eliminate all non-sporeing bacteria and enteric viruses and the less restricted the parameter chosen the more suitable it should be. Water quality can deteriorate in distribution due to ingress or regrowth and measures of regrowth potential are described.

#### **Study Exercises**

##### **MCQs**

1. Which of the following is considered an adequate water supply/head/day in urban areas (a) 50-100 L (b) 100-150 L (c) 150-200 L (d) 200-250 L
2. Purest water in nature is from (a) Lakes (b) Springs (c) Rains (d) Ponds.
3. Salt concentration in sea water is (a) 1.5% (b) 2% (c) 3.5% (d) 5%.
4. Ground water has the following advantages : (a) Likely to be free from pathogenic organisms (b) Usually requires no treatment (c) Supply is likely to be certain even during dry season (d) Likely to be hard.
5. Guinea worm disease was a health problem where there were : (a) Dug wells (b) Artesian wells (c) Tube wells (d) Step wells.
6. Which one of the following is not a waterborne disease : (a) Kala azar (b) Poliomyelitis (c) Giardiasis (d) Roundworm
7. The vital layer of the slow sand filter is also known as : (a) Superficial layer (b) Sand bed layer (c) Schmutzdecke (d) Chemical layer.

8. The disinfecting action of chlorine is mainly due to (a) Chloride atom (b) Hypochlorous acid (c) Chloride ion (d) Hypochlorite ion.
9. Action of chlorine is maximum when water pH is around (a) 3 (b) 5 (c) 7 (d) 9.
10. Chlorination does not affect in normal doses (a) Salmonella (b) Polio (c) Shigella (d) HIV.

**Answers :** (1) b; (2) c; (3) c; (4) d; (5) d; (6) a; (7) c; (8) b; (9) c; (10) b.

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## Excreta Disposal

*Rajul K Gupta*

Disposal of human excreta assumes greater importance than any other waste. The methods of disposal can be classified as follows :

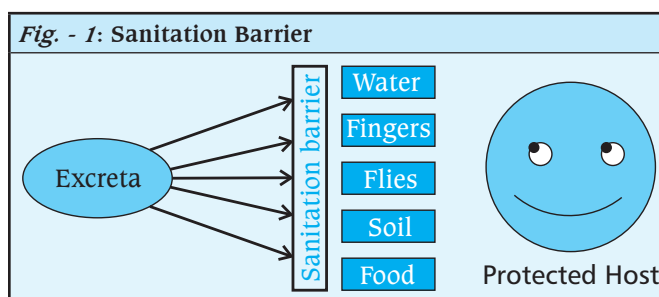
**(a) Insanitary Methods :** These include open defecation and conservancy system.

**(b) Sanitary Methods :** These are further subdivided into two methods, depending whether sewerage (water carriage system) is available or not, as follows :

- Unsewered Areas : The methods include trench latrine, dug well or bore hole latrine, water seal latrines, septic tanks, aqua privies and chemical closets.
- Sewered areas : The system in these areas includes the standard sewerage system.

**Sanitation Barrier :** The sanitation control which aims at interruption of transmission of the disease agent from the reservoir to the new host can be achieved at several levels such as segregation of excreta and wastes, protection of water supply, protection of food and drinks, control of flies and the

practice of personal hygiene. The most effective measure out of all these would be segregation of excreta and arrangement for its proper disposal so that the disease agents do not get a chance to reach the new host. The sanitation barrier (Fig. 1) in the simplest way can be provided by a sanitary latrine and a disposal pit.



## Excreta Disposal in Non-Sewered Areas

### Open defecation fields

In some cultures, defecating in the open is preferred to using a latrine. Open defecation can never be accepted as a satisfactory system of excreta disposal but it might be inevitable in certain circumstances. In these situations, open defecation areas

should be clearly demarcated rather than littering the entire area. The principles of hygiene must be kept in mind (as discussed below) and the method must be followed for as short a period as possible. Open defecation may be the only option (for a displaced population in disaster) in the initial phase and might work well for 24 to 48 hrs, provided appropriate facilities of open defecation areas are set up and the following aspects are carefully considered. The community must be encouraged to use better alternatives as soon as the latrines are ready for use.

#### Location

- It should be located as centrally as possible to the people who are going to use it (within 50-100 m or 1 minute walking distance, of shelters if possible) but away from public buildings or roads.
- It has to be located at least 30m, preferably 50m from water sources or food storage/preparation areas. The fields where crops are grown should not be used for this purpose.
- It is preferable to have adequate space and vegetation to allow people to find an appropriate defecation space so that there is enough privacy.
- The field should be surrounded by a drain so that surface water cannot enter it and to prevent any runoff from the field contaminating other areas.
- The field should be on land sloping away from the camp and surface water sources and downhill of settlements. Consideration should be given to the direction of prevailing winds, to reduce the nuisance caused by odour. Areas subject to flooding or containing running water should be avoided. The soil should be easy to dig so that faeces can be buried.

**Setting up** : As a first measure, it may be necessary to make temporary open defecation fields by just marking off areas with tape. Defecation areas or fields may be surrounded by screening/ plastic /canvas sheeting. Segregated sites for each sex are desirable.

#### Usage

- Attendants will need to be recruited and provided with training to encourage correct use and hand-washing.
- Users need to be encouraged to use one strip of land at a time and the strip furthest away from the entrance. Used areas must be clearly marked.
- Users should cover the faeces with soil.
- Provide anal-cleansing materials (water in small pots / mugs) and methods for their safe disposal.
- People must wash their hands afterwards. A 200 lit plastic barrel or a large bucket fitted with tap can be situated at the entrance of the area for hand-washing. Soap or ash should also be provided for effective hand washing. If soap or ash is not available, a barrel can be filled with 0.05% chlorine solution. This can be made by adding half a tablespoon (7.5g) of High Test Hypochlorite HTH (70% active chlorine) granules, or 15g of bleaching powder (approx 35% active chlorine), to 10lit of water.

#### Service Type Latrines (Conservancy System)

In the conservancy system, night soil is removed by a human agency using a bucket. Night soil is transported in buckets

on the head or in night soil carts manually to a disposal site. Disposal may be done through dumping, composting or burial by shallow trenching. This is totally unacceptable not only considering human dignity but is not acceptable through hygiene point of view either. It is filthy and insanitary. Night soil lying at home awaiting disposal stinks and attracts flies. The collection, transport and disposal of night soil, all perpetuate the infection cycle. Absence of manpower for this job puts the system to a halt.

It was recommended by the Environmental Hygiene Committee, in 1949, that service areas must be replaced by sanitary latrines. The founder of Sulabh International, Dr B Dubey, also took up the issue in a big way. He showed the way forward by almost revolutionizing the sewage disposal to eliminate human carriage of night soil and installing low cost sanitary latrines instead.

#### Shallow Trench Latrines

Shallow trench latrines are trenches 20-30cm (about a foot) wide and 15-30cm (about ½ -1 foot) deep. The dimensions can however vary. The trench field can be divided into strips 1.5m wide with access paths. Trenches are dug in parallel with an interval of at least 60 cm in between two trenches. The earth removed should be neatly piled at its head end which could be used to cover the excreta by each user, and subsequently to fill the trench. The issue of privacy is also important. Plastic sheeting, bamboo-mat etc. can be used to make 'walls' (Fig.-2). The trench is used by squatting astride it, with a foot on either side and not both feet on the same side. After defecation the excreta must be covered by earth with a scoop.

**Advantages** : It is rapid to implement. Faeces can be covered easily with soil.

**Constraints** : Limited privacy, short life and requirement of considerable space are some of the constraints. Fly breeding occurs if excreta is not covered with earth.

#### Deep Trench Latrines

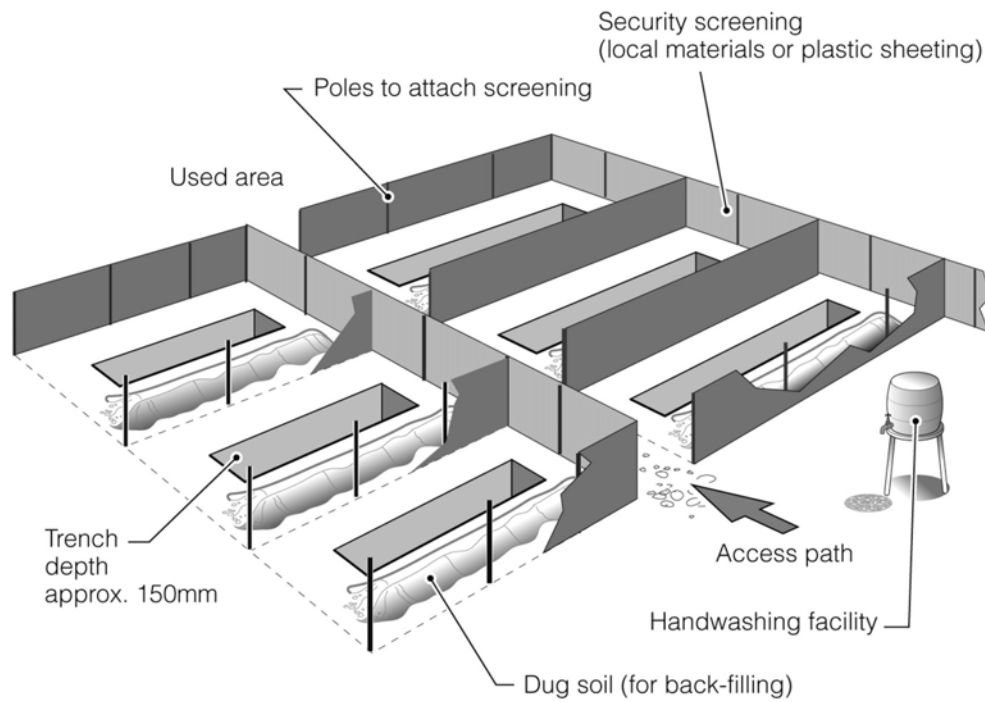
Deep trench latrines could be an appropriate short term solution to the immediate requirements of a displaced community or for camps of a longer duration(1, 2). While they are much more hygienic than the Shallow Trenches and can be used for a relatively prolonged period but at the same time more manpower, tools and materials are required to set them up. The recommended maximum length of trench is 6m, providing six cubicles. Trenches should be 0.8m -1m wide and 2m - 2.75m deep. (Fig. - 3). A deep trench latrine of the above dimensions (80 cm to 100 cm wide by 2 m to 2.75 m deep) which is 3.75 m long can be used by 100 people for few months. One must work on a minimum standard of at least one 'toilet seat' for every 20 persons (1,3).

**Advantages** : It is cheap and quick to construct; no water is needed for operation. It is easily understood by the community.

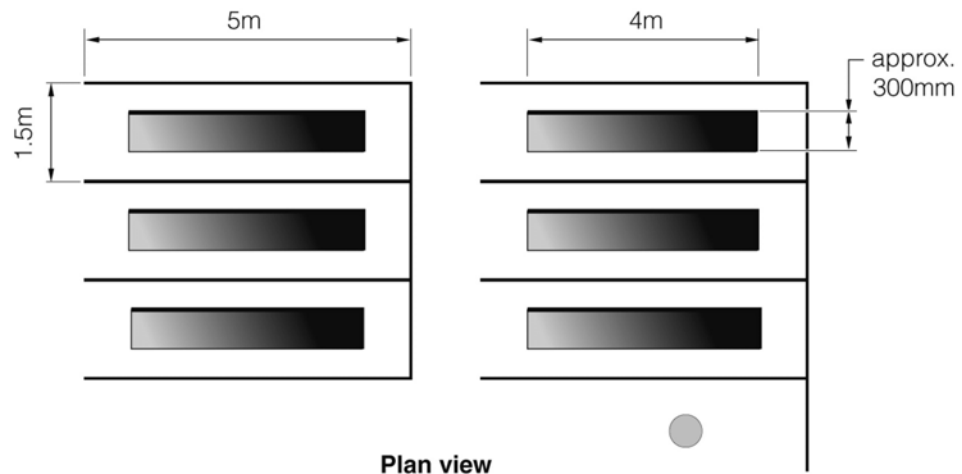
**Constraints** : Unsuitable where water-table is high, soil is too unstable to dig or ground is very rocky; often odour problems; cleaning and maintenance of communal trench latrines are often poorly done by users.



**Fig. - 2 : Shallow trench latrines (1)**



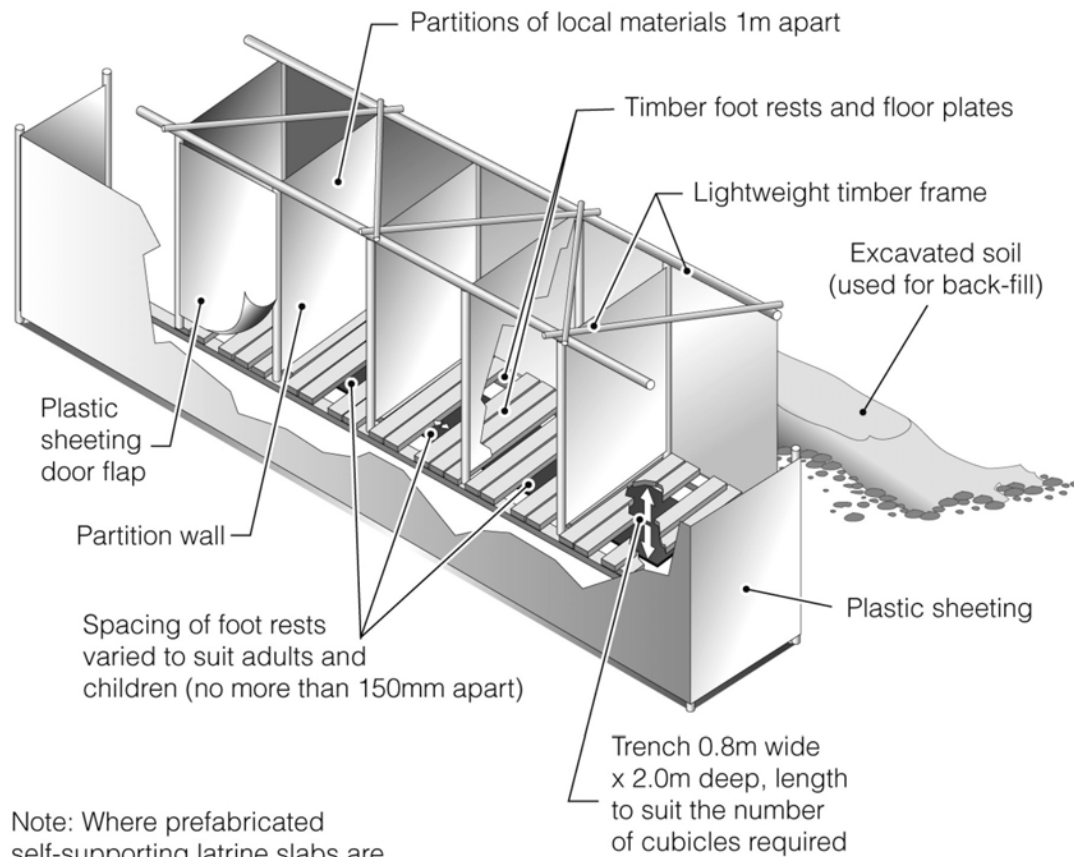
**Superstructure**



**Plan view**

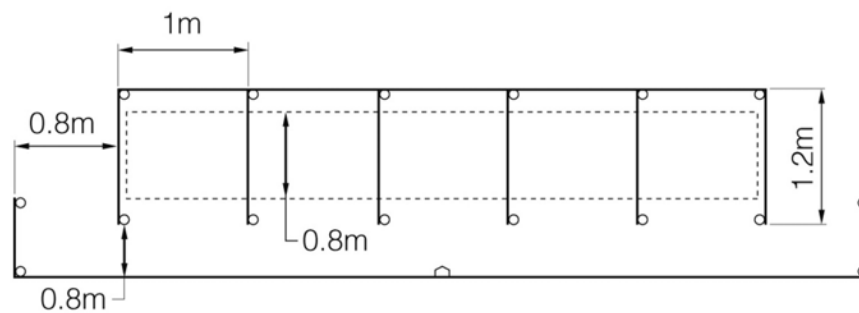
Image courtesy of WEDC. © Ken Chatterton

**Fig. - 3 : Deep Trench Latrine (1)**



Note: Where prefabricated self-supporting latrine slabs are to be used in place of timber cubicle sizes may need to be adjusted to fit slab width (e.g. 0.8m)

### Superstructure



### Plan view

Image courtesy of WEDC. © Ken Chatterton

### Improved Deep Trench Latrine

An improvisation of Deep Trench Latrine may be carried out by placing the seats fitted with modified water closets, 1.5m in front of the long edge of the trench. As many as 3 to 5 Indian type water closet seats of plastic / fiber glass / chinaware are fitted to enable maximum number of people use it simultaneously. The seats are fitted with a water seal (bend pipe) which is connected to a pipe leading into the trench. Small quantity of water (2.5 to 3 liters) is sufficient to flush the seats after each use. The excreta is flushed through sewage pipes into the trench. This type of latrine, therefore, is more hygienic and acceptable. It is similar in principle to the hand flushed water seal latrine. The water seal prevents access to flies by sealing off the night soil and escape of foul gases (4). A storm water drain dug all around prevents rainwater from entering the trenches.

### Simple Pit Latrines (Dug Well Latrine)

Simple pit latrines are simple and quick to construct and generally inexpensive. The pit should be as deep as possible (at least 2m in depth) and covered by a latrine slab. If the soil is loose, at least the top 1m of the pit should be lined to prevent collapse. This should be firmly supported on all sides and raised above the surrounding ground level to prevent surface water entering the pit. A squat or drop-hole is provided in the slab which allows excreta to fall directly into the pit-this can be covered with a removable lid to minimize flies and odour. The

superstructure can be made from materials available locally.

The advantages are that it is cheap; quick to construct; no water needed for operation. However, the constraints are that it is unsuitable where water-table is high, soil is too unstable to dig or ground is very rocky; often odour problems (Fig. - 4).

### Improved Pit Latrine (The Ventilated Improved Pit Latrine)

This latrine is an improved pit latrine designed to minimize odour and flies. A vent pipe covered with a gauze mesh or fly-proof netting extending at least 0.5m above the superstructure roof is incorporated into the design to remove odorous gases and prevent flies entering and trap any flies trying to leave. Air should be able to flow freely through the squat hole and vent pipe; therefore no drop-hole cover is required. The superstructure interior is kept reasonably dark to deter flies, but there should be a gap, usually above the door, to allow air to enter (Fig. - 5).

**Advantages :** Reduced odour & flies and good results.

**Constraints :** Difficult and expensive and time consuming to construct properly; dark interior may deter young children from use; does not deter mosquitoes.

### Borehole Latrines

Emergency demands quick work. A borehole latrine fulfills this requirement. It can be constructed very rapidly if an auger or

a drilling rig is available. Borehole latrines are most appropriate in situations where a large number of latrines must be constructed rapidly, and where pits are difficult to excavate, either because of ground conditions or the lack of a labour force.

**Dimensions :** The borehole has a typical diameter of 400mm and a depth of 5-10m. At least the top 0.5m should be lined (Fig. - 6).

**Advantages :** The borehole can be excavated quickly; suitable in hard ground conditions and appropriate where only a small workforce is available.

**Constraints :** Drilling equipment is required; there is a greater risk of groundwater pollution due to greater depth than pit latrines; lifespan is short; sides are liable to be fouled, causing odour and attracting flies; and there is a high likelihood of blockages. This option should only be considered in extreme

Fig. - 4 : Simple pit latrine (1)

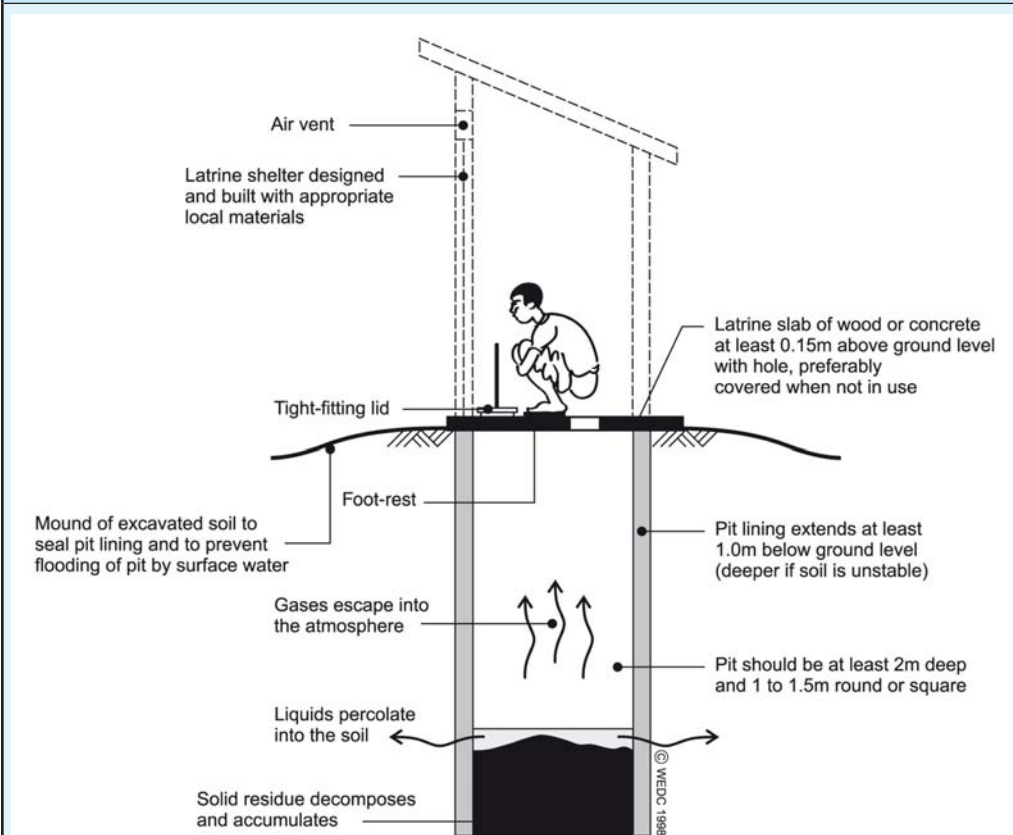


Image courtesy of WEDC. © Rod Shaw

**Fig. - 5 : Ventilated Improved Pit (VIP) Latrine (1)**

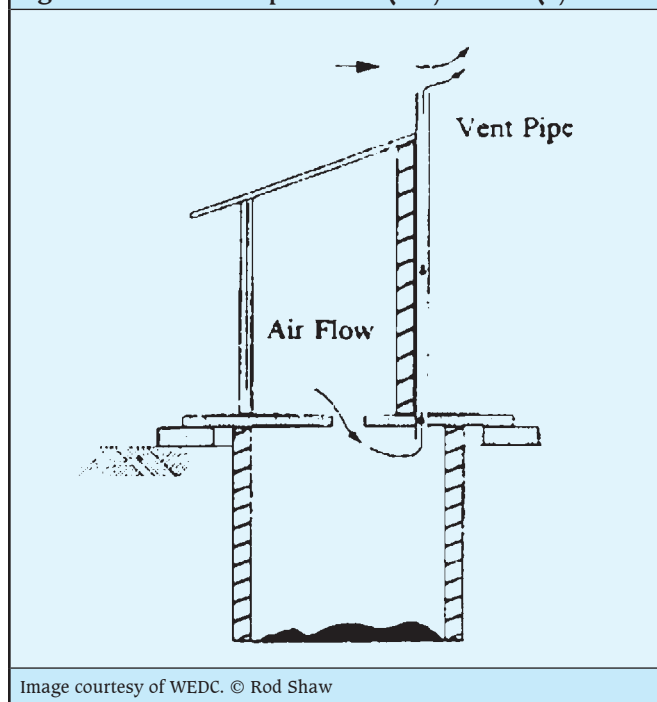


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conditions when pit excavation is not possible. A hole 300mm (1 foot) in diameter and 5 metres deep should last for (a family of) five people for two years.

#### **Pour-Flush Latrines (Water Seal Latrines)**

Pour-flush (hand flush or water seal) latrine is a very hygienic mode of excreta disposal. It functions on the principle of a 'water seal'. Water acts as a hygienic seal and helps remove excreta to a wet or dry disposal system. The simplest pour-flush latrines use a latrine pan incorporating a shallow U-bend which retains the water (water seal). After defecation, a few litres of water must be thrown into the bowl in order to flush the excreta into the pit or sewerage system below. Pour-flush latrines may be constructed directly above a pit or may be offset whereby the waste travels through a discharge pipe to a pit or septic-tank (Fig. - 7).

**Dimensions :** The amount of water required to flush the system will depend on the type and size of the water-seal construction. A 90mm (3") U-bend normally requires 2-3 litres to flush effectively, while a 120mm (4") U-bend generally requires 4-5 litres to flush. These quantities are significantly less than the amount required to flush most western water-closet toilets which may use as much as 15 litres per flush.

**Advantages :** Lack of odour; relatively less water is used up. It is ideal where water is used for anal-cleansing; easy to clean; off-set design does not require a self-supporting latrine slab.

**Constraints :** Solid anal-cleansing materials may cause blockages; more expensive than simple pit latrines.

**Variants :** Several designs have been tried and are in use. Noteworthy of these are those made by Planning Research and Action Institute (PRAI), Lucknow and by Research cum Action Project (RCA), Ministry of Health. The RCA latrine is widely in

**Fig. - 6 : Borehole latrine (1)**

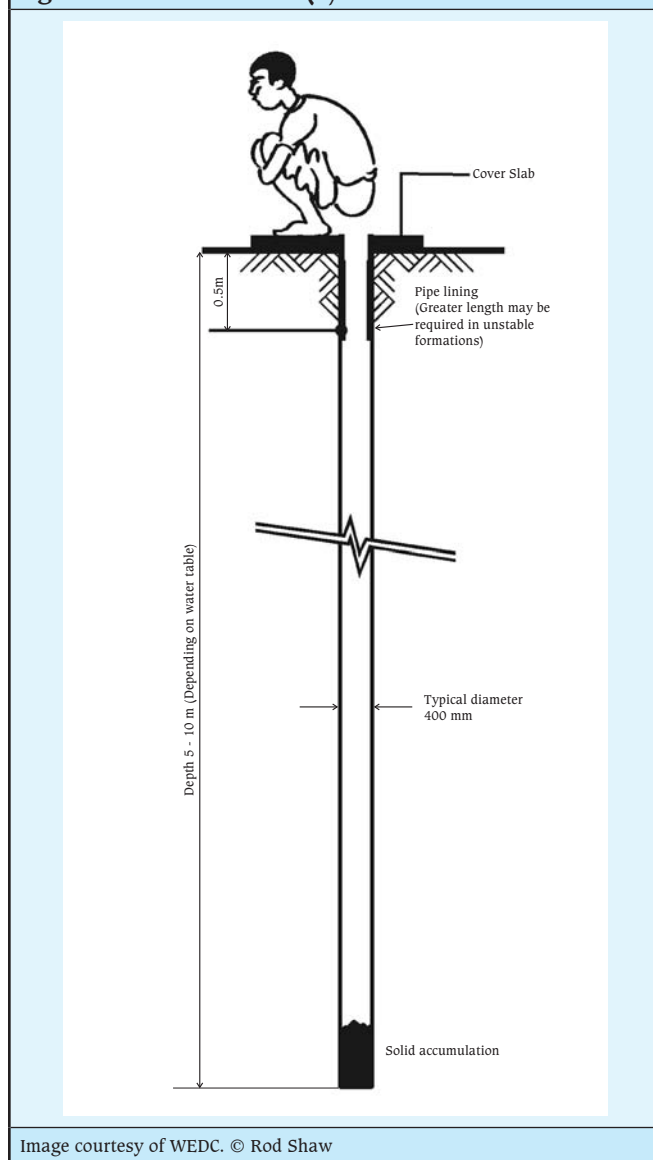


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use.

**Design of a RCA Latrine :** The RCA latrine comprises of a squatting plate, made of an impervious material like cement-concrete. This is easy to clean and maintain. Raised footsteps are included in the squatting plate. There is a pan directly underneath the squatting plate. The pan receives the night soil. Pan is connected to the trap, which is a bent pipe. The trap holds water and serves as a water seal. The depth of the water seal is 2 cm (Fig. - 7C). It prevents access to flies and avoids release of odour. The trap is connected to the pit (which could be a dug well), through a connecting pipe. When the pit fills up another one can be dug up and pipe may be accordingly shifted. The pit can also be made directly underneath the pan; in that case there is no requirement of the connecting pipe. An appropriate superstructure can be made.

It is easy to maintain the latrine. Latrine is hand flushed by



Fig. - 7 : Pour-flush latrines (1)

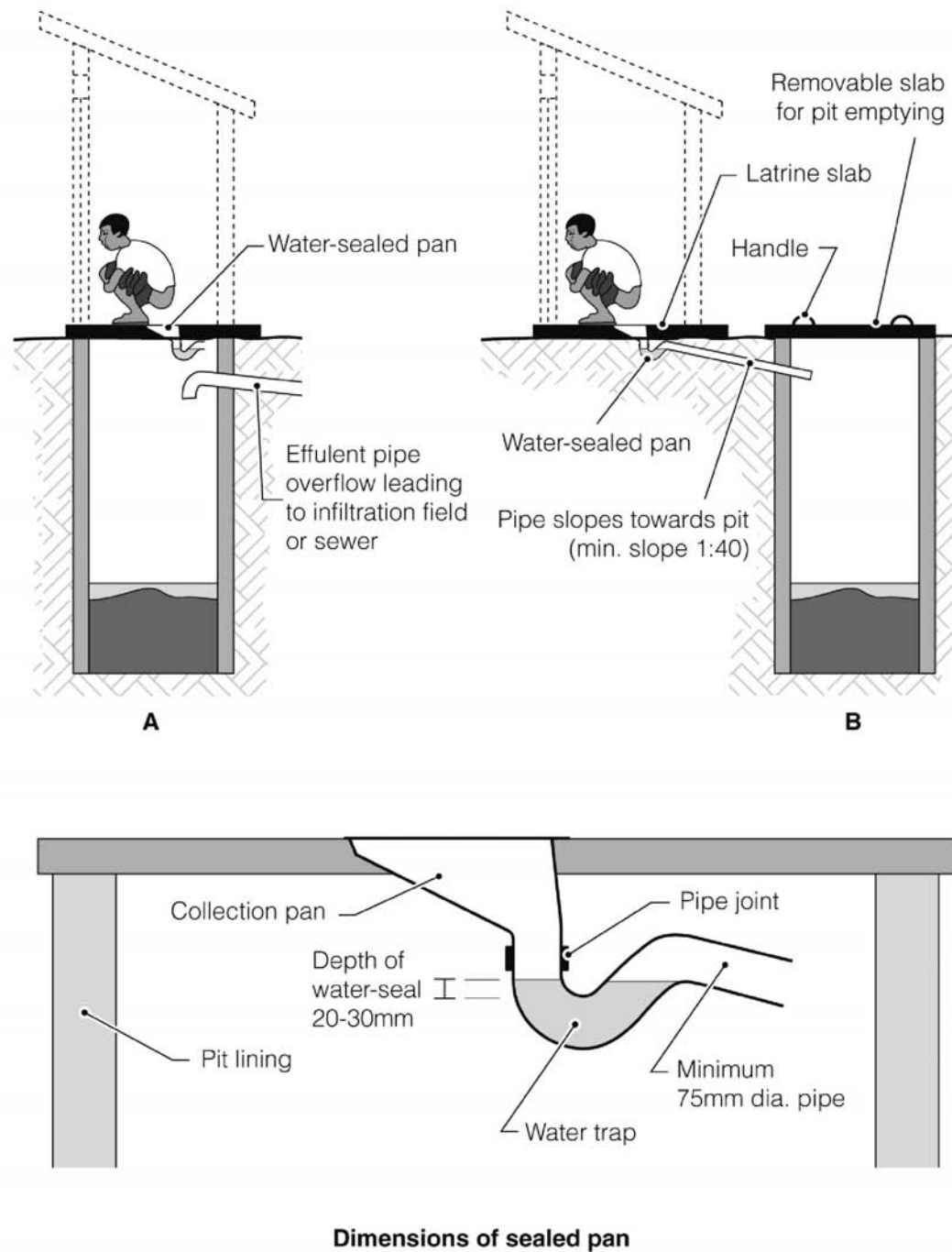


Image courtesy of WEDC. © Rod Shaw

pouring 1 to 2 lit of water every time the latrine is used. The squatting plate should also be washed clean every day.

Certain modifications can be undertaken for more efficient functioning. A pre-fabricated Indian type of commercially available squatting plate made of china clay can be used instead of a concrete one. This would be most hygienic. Secondly, rather than using a 'dug-pit' for disposal of night soil, a septic tank can be built. One will have to incur extra cost on these modifications but these would make the latrine close to an ideal system.

### Septic Tank

Septic tank is an ideal system for hygienic final disposal of excreta in the absence of a central sewerage system. Excreta from many pour-flush latrines can be discharged into a septic-tank. A septic-tank is designed to collect and treat excreta and toilet wastewater. Its use is likely to be appropriate where the volume of wastewater produced is too large for disposal in pit latrines, and water-borne sewerage is uneconomic or unaffordable. Septic-tanks are, therefore, particularly suited to systems involving high water use, especially where water is used for flushing and anal-cleansing. However, they are difficult to manage for very large populations and are best suited to single households or a group of households or institutions such as hospitals or schools. The efficiency of a septic tank system is inferior to the sewage works but is much cheaper, quicker and easier to provide and maintain than sewage works.

**Design and Construction** : Septic tank consists of an underground concrete tank usually double chambered. A tank with more than two chambers is expensive and has no additional advantage. Even a single chambered tank has been found satisfactory for a small installation. The latrines should preferably be grouped together with one or more tanks placed close to a group. The sewers leading from the latrines to the tanks should have manholes at every 100m and at every change of direction. Two or more medium sized tanks arranged in parallel instead of one large tank are preferable as these facilitate removal of sludge without disturbing the functioning of the system.

The capacity of the tank should be at the scale of 20-30 gallons per user with a minimum size of 3mx3m (500 gallons). It may be 1.5 to 2m deep. The entire length of the tank should provide a minimum air space of 30 cm above the liquid level. The septic tank is covered by a concrete slab with a manhole in it. The aeration chamber should be ventilated by one or more shafts, the opening of which should be screened with wire-gauze. The inlet and exit pipes to the tank should be trapped. The effluent may be disposed into a soak-well (Fig. - 8).

**Functioning** : The septic tank functions by the biological process of anaerobic and aerobic digestion. The crude sewage on entry to the anaerobic chamber is allowed to stand for 2 to 3 days and is acted upon by the anaerobic microorganisms. A colloidal solution is formed which is only partially digested and hence has an offensive smell. The complete oxidation and mineralization of the colloidal matter is carried out by the aerobic micro-organisms in the aerobic chamber. Though most of the pathogens, after having undergone aerobic treatment, die but the cysts and ova of the intestinal parasites survive.

The effluent loses most of its offensive smell. The minerals are absorbed from the soil by the plants. The use of ordinary household soap in normal amounts is unlikely to affect the digestion process of a septic tank.

**Maintenance** : The operation and maintenance of a septic tank is simple. To commission a septic tank it has to be first filled with water and then seeded with a bucketful of sludge from another tank. Not less than 25 lit of water per day per user must enter the tank. Use of soap water and chemicals should be avoided. Sludge from the tank is to be bailed out once in a year or two. The tank cover or roof, which usually consists of one or more concrete slabs, must be strong enough to withstand any load that will be imposed. Removable cover slabs should be provided over the inlet and outlet. Circular covers, rather than rectangular ones, have the advantage that they cannot fall into the tank when removed.

Routine inspection is necessary to check whether desludging is needed, and to ensure that there are no blockages at the inlet or outlet. A simple rule is to desludge when solids occupy between one-half and two-thirds of the total depth between the water level and bottom of the water tank. The most satisfactory method of sludge removal is by vacuum cleaner.

### Communal Aqua-Privies

An aqua-privy is a latrine constructed directly above a septic-tank. Aqua-privies are appropriate where pit latrines are unacceptable. The amount of water required for flushing is much smaller than for a septic-tank due to the location of the tank. It helps to exclude odours from the superstructure.

**Advantages** : Reduced odour; ideal where water is used for anal-cleansing; easy to clean.

**Constraints** : Increased quantity of water required; solid anal-cleansing materials may cause blockages; more expensive and difficult to construct than simple pit latrines.

**Minimum standards** : Not more than four families per latrine.

### Sulabh Shauchalaya

The concept of Sulabh Shauchalaya was introduced by Dr B Dubey. He modified the standard hand flush latrine to suit rural Indian community. It consists of a specially designed pan and a water seal trap. It is connected to a pit 3x3x3 feet. Minimal water is needed in the process. The excreta gets decomposed to manure in the pit. Sulabh International also maintains a chain of Sulabh Shauchalayas, community latrine, across the country. This provides clean and sanitary toilets to the users at a minimal cost. These are also maintained by the Sulabh International society.

### Chemical Toilets

Chemical toilets are sanitation units that consist of a squatting pan placed above a water-tight excreta-holding tank, which usually contains a chemical solution (formaldehyde, etc) to aid digestion and reduce odour. This is contained in a single prefabricated plastic unit with a lockable door. These can be adopted as temporary solutions where pit latrines or septic-tanks are unsuitable or unacceptable, as in aircrafts or trains. The initial charge of chemical is adequate for 40 to 160 uses.

**Fig. - 8 : Septic tank (1)**

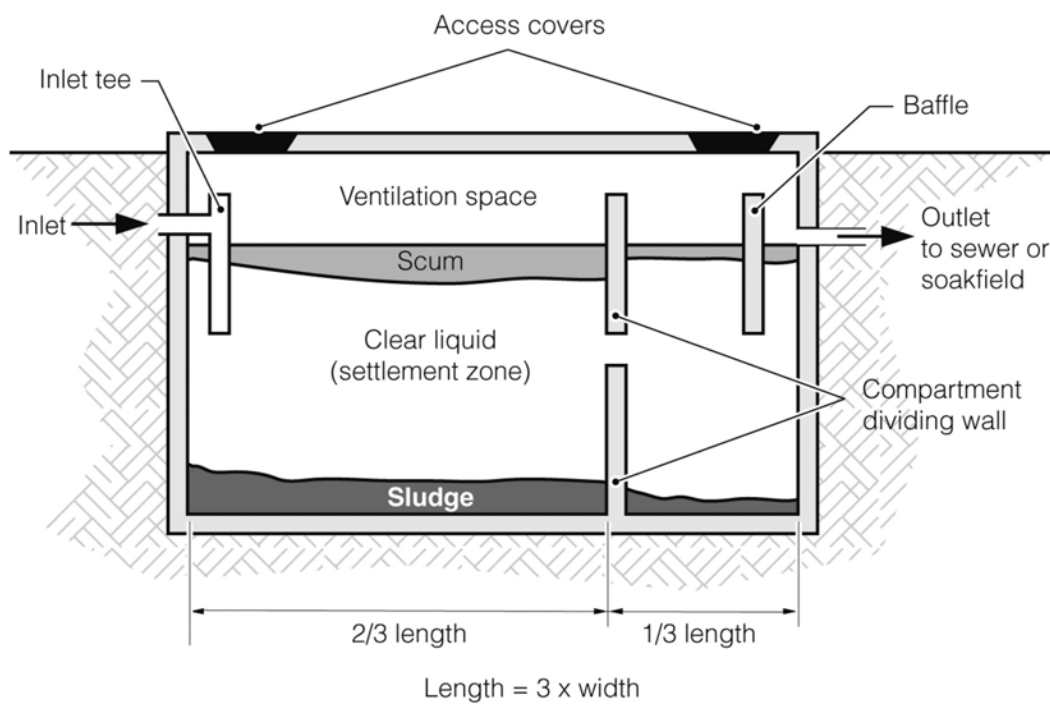
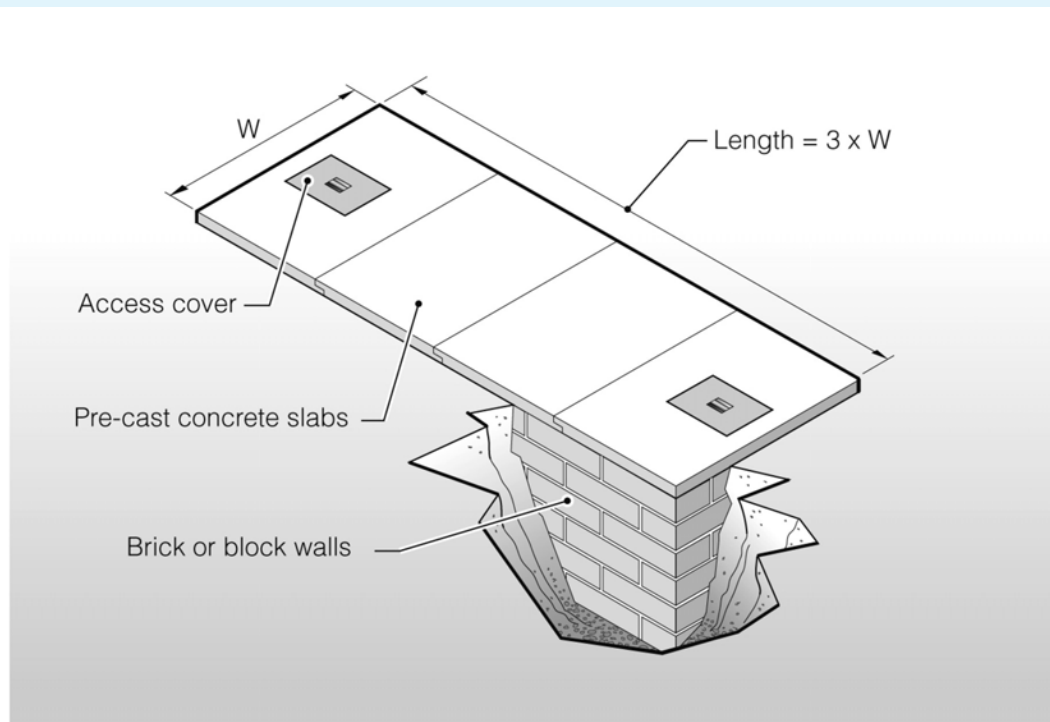


Image courtesy of WEDC. © Ken Chatterton

**Uses :** These are used in aircrafts and as a short term measure in disasters, etc.

**Advantages :** Portable; hygienic; minimized odour; can be mobilized rapidly.

**Constraints :** High cost; unsustainable for long periods; regular servicing and emptying required.

## Water carriage system

The water carriage system is useful for large residential and commercial. The human excreta and waste water are carried away by a network of underground pipes called sewers to the ultimate disposal site. Obviously this is the method of choice for urban areas having piped water supply (5). In India the water carriage system was used for the first time in Calcutta in 1867. But even today, unfortunately not more than 20 percent of the urban areas in India can boast of this method of sewage disposal. In large cities this is the ideal system of sewage disposal.

Laying down such a system is infrastructure and capital intensive. It amounts to digging up lanes and by-lanes. Skilled manpower is a must to establish the system. Piped water supply is mandatory to run the system. On - going maintenance has to be done to keep the pipes going. Importance of sewerage system was realized during floods at Mumbai in the year 2005 when heavy rains lashed Mumbai. The water carriage system being inadequate, ill maintained and choked, couldn't cope up with the excessive rain water and caused flash floods. This had drastically disrupted life in the commercial capital of India leading to heavy economic losses and outbreak of Leptospirosis.

### Classification

There could be two types of sewerage systems, the combined and the separate systems. The combined system carries both sewage and storm water in the same sewage line. In the separate system, however, the surface water is not admitted into the sewers. The latter is the system of choice.

### Components

The water carriage system consists of household sanitary fittings, house sewers, street sewers and sewer appurtenances.

**(a) Household Sanitary Fittings :** These include water closets, urinals, washbasins, bathtubs along with their plumbing systems.

**(b) Soil Pipes :** These are pipelines, which carry excreta from the water closets to the house drain. They are fitted with outlet ventilators for the escape of foul gases and hence are placed outside along rear walls of the houses and are carried above the roof tops.

**(c) House Drains :** It is an underground iron or stoneware pipe usually of 10 cm diameter and is laid in the courtyard 15 cm below the ground level on a bed of cement concrete mix with sufficient gradient towards the public sewer. It carries away the discharges from the household sanitary fittings to the street sewers.

**(d) Public Sewer :** It is a network of underground pipelines varying in diameter from 22 cm to 3 m for carriage of sewage from domestic, industrial and commercial areas to the place

of final disposal. While laying the pipelines sufficient gradient is to be ensured for self-cleansing velocity of sewage. This velocity varies from 60 cm to 90 cm per second.

**(e) Sewer Appurtenances :** These are manholes and traps installed in the sewerage system :

**(i) Manholes :** Manholes are the openings built in sewers for the purposes of repairs and cleaning. They are placed wherever there is change in the direction of sewers, at the junction of two or more sewers and at a distance of 100 meters in the long, straight run of the sewers. Workers entering manholes are at a risk of gas poisoning and asphyxiation; so due precautions must be taken while entering them.

**(ii) Traps :** Traps are devices designed to prevent entry of foul gases inside the house and to remove sand, grit, grease etc. from sewage. Traps are placed at three points (1) under the water closet, (2) at the junction of the house drain and the street sewer and (3) where the surface water enters the sewers. There are several designs of traps. The simplest one is a bent pipe containing water as a seal (Fig. - 7C). The water seal in a trap is the distance between the highest level of water in the trap and the lowest point of the trap's concave upper surface.

## Composition of Sewage

Sewage contains 99.9 percent water and 0.1 percent solids, which are partly organic and partly inorganic. Sewage teems with living organisms, some of which may be pathogenic. The strength of the sewage may be expressed in terms of biochemical oxygen demand, chemical oxygen demand and suspended solids.

### Biochemical Oxygen Demand (BOD)

It is defined as the amount of oxygen absorbed by a sample of sewage during a specified period, generally 5 days at a specified temperature, usually 20°C for aerobic digestion. This is the most important test carried out on sewage. Sewage with a BOD value of 300 mg/l (300 ppm) or above is termed as strong while that of 100 mg/l (100 ppm) or below is termed weak.

### Chemical Oxygen Demand (COD)

Chemical oxygen demand is the amount of oxygen required to oxidize the organic matter by use of dichromate in an acid solution and to convert it to carbon dioxide and water. The value of COD is always higher than the BOD because many organic substances can be oxidized chemically but not biologically. Commonly, BOD is used to test the strength of untreated and treated municipal and biodegradable industrial waste waters. COD is used to test the strength of wastewater that is either non biodegradable or contains compounds that inhibit activities of microorganisms.

### Suspended solids

If the suspended solids are 100 mg/l or more, it is termed strong.

## Sewage Purification

The aim of sewage treatment is to convert an offensive and potentially dangerous mixture into an inoffensive effluent and sludge which can be disposed off safely and without causing nuisance into river, sea or on land. The conversion of complex organic matter in the sewage to simpler substances takes



place by two processes, viz aerobic and anaerobic. The aerobic method requires a continuous supply of free dissolved oxygen for the aerobic microorganisms to break the organic matter into simpler substances such as carbon dioxide, ammonia, water, nitrite, nitrate, sulphate etc. The anaerobic process is more effective where the sewage is highly concentrated and contains plenty of solids. Hence, this method is usually gainfully utilized for digestion of sludge in sewage works. The end products of anaerobic decomposition are methane, ammonia, carbon dioxide, hydrogen etc.

**Sewage Treatment Plant** : The sewage treatment undergoes through many stages. These can be conveniently divided into Primary, secondary and tertiary treatment stages.

- **Primary treatment** : The first stage is the physical treatment to remove solids (from the liquid). This physical treatment is often referred to as primary treatment.
- **Secondary treatment** : The primary treatment is followed by biological treatment brought about by aerobic and anaerobic bacteria.
- **Tertiary treatment** : Treatment rendered in addition to the conventional secondary treatment for improving further the quality of effluent is termed 'tertiary treatment' or advanced waste treatment process. The sludge is also given treatment for stabilization and dewatering. Chemical treatment by the addition of coagulants may be used to assist sedimentation and sludge treatment. Flow diagram of a modern sewage treatment plant is shown in (Fig. - 9).

#### Primary Treatment

**(a) Screening** : It is the first step in the sewage treatment for removing the larger solids. The raw sewage is passed through bar-screens with openings of 8 to 10 cm between the bars placed across the inflow channels. The screenings can be manually raked from the screens and buried.

**(b) Grit Removal** : Combined sewerage systems carry grit from roads or other debris from general sullage and fine granular

inorganic material. This material which otherwise causes heavy wear in pumps and tends to settle out and cause difficulty in later treatment processes must be removed in grit chambers and channels. The sewage is allowed to flow in a channel at a controlled velocity of about 30 cm/s, which is slow enough for the heavy non-organic solids to settle down but fast enough to carry the lighter organic solids forward. The grit is removed periodically, washed free of organic matter and dumped on waste land for reclamation or to fill excavations and quarries without causing nuisance.

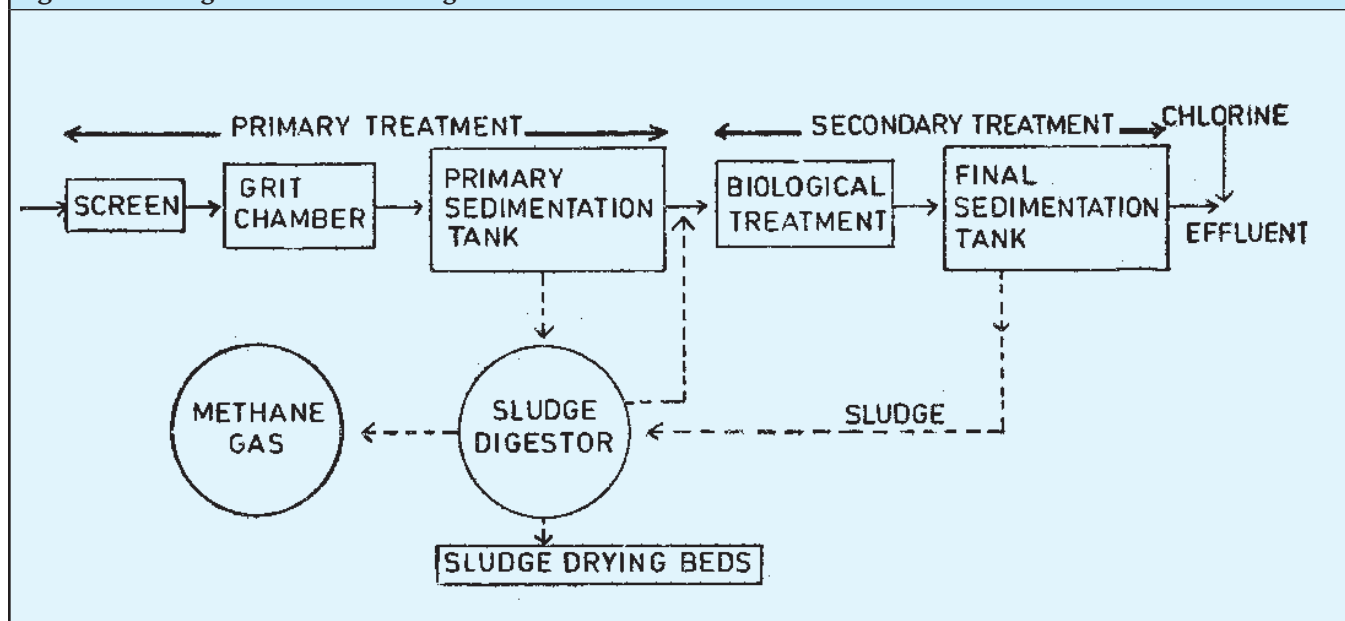
**(c) Primary Sedimentation** : It is the third step to remove as much of the organic solids as possible from the liquid sewage. The same principles as those for the treatment of water are employed. Sedimentation tanks may be rectangular with a horizontal flow, hopper-shaped with vertical flow, or circular with radial centrifugal flow. Slow moving paddles to encourage flocculation of solids and increased settling velocities may be incorporated. The sewage is retained in sedimentation tanks for 4 to 12 hours. The process removes 50-60 percent of the suspended solids and about 40 percent of the BOD of the sewage. The settled sludge is removed by mechanical scrapers to hoppers from which it is drawn off either continuously or at frequent intervals to prevent it from becoming septic. The sewage is then treated biologically.

#### Secondary Treatment

The secondary or biological treatment of sewage essentially involves the oxidation of suspended and dissolved organic matter by aerobic bacteria. Carbonaceous matter is converted to carbon dioxide and water, and nitrogenous material to ammonia, nitrites, and nitrates. Fungi, algae, ciliate protozoa, insects and worms supplement the bacterial digestion. The main processes employed for biological treatment are as under:

**(a) Percolating or Trickling Filters** : The effluent from the primary sedimentation tanks is brought into the percolating filter through a central pipe. The effluent is sprinkled uniformly

Fig. 9 : Flow Diagram of Modern Sewage Treatment Plant.



on the surface of the bed by a revolving device. This device is nothing but an assembly of pipes with rows of multiple holes in them (spraying nozzles). The rotating pipes sprinkle a thin layer of effluent on the surface of the filter. This effluent then trickles down the filter. The percolating filter consists of beds 1.5 to 2 m in depth, made of stone, cinders, slag, brick pieces or other impervious material generally from 3 to 8 cm in size. The beds are usually circular. A slimy 'zooglean' film of aerobic bacteria and other organisms develops on the surface of the stones. In trickling downward through the bed, the sewage donates its organic content to the vital zooglean film for its nutrition and in return receives soluble organic salts produced by oxidation. Access of air through the filter is essential for the zooglean fauna to oxidize the organic matter. A competent percolating filter plant reduces the BOD of the raw sewage by 85 to 95 percent. Percolation is followed by final settling into secondary sedimentation or humus tanks to remove the particles of the zooglean matter and innocuous debris (Fig. - 10).

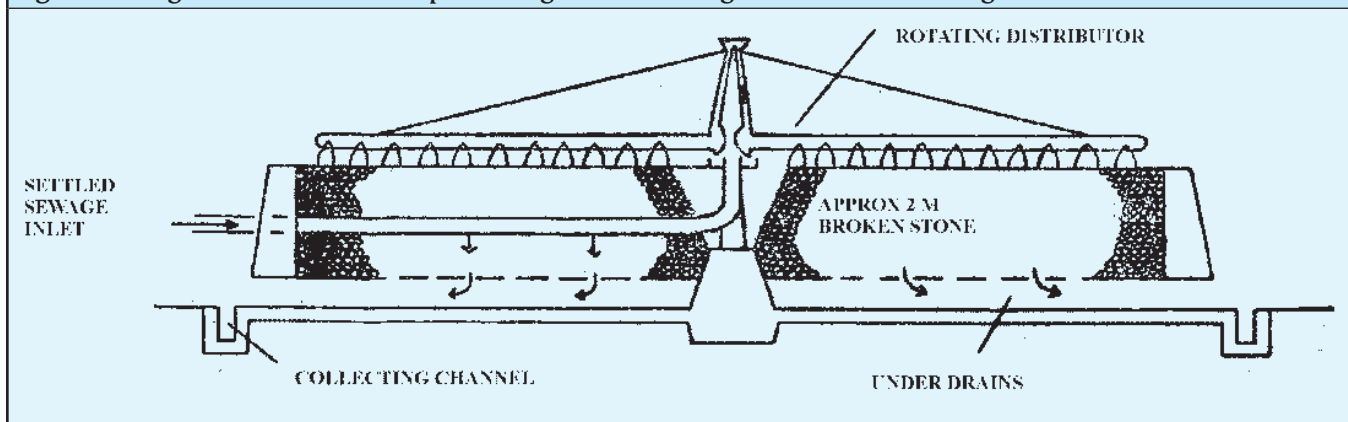
**b) Activated Sludge Process** : Activated sludge process is an alternative to the percolating or trickling filter method described above.

**Principle** : The principle is to add sufficient quantity of sludge obtained from the final settlement tank (called 'activated sludge' or return sludge) to sewage that is to be treated (the effluent from the primary sedimentation tank). Activated sludge contains active aerobic bacteria vital for decomposition of sewage. This mixture (called the 'mixed liquor') is mechanically aerated in an aeration tank to facilitate bacterial decomposition. In the presence of ample oxygen the aerobic bacteria utilize the raw sewage and convert it into stabilized, odourless compounds.

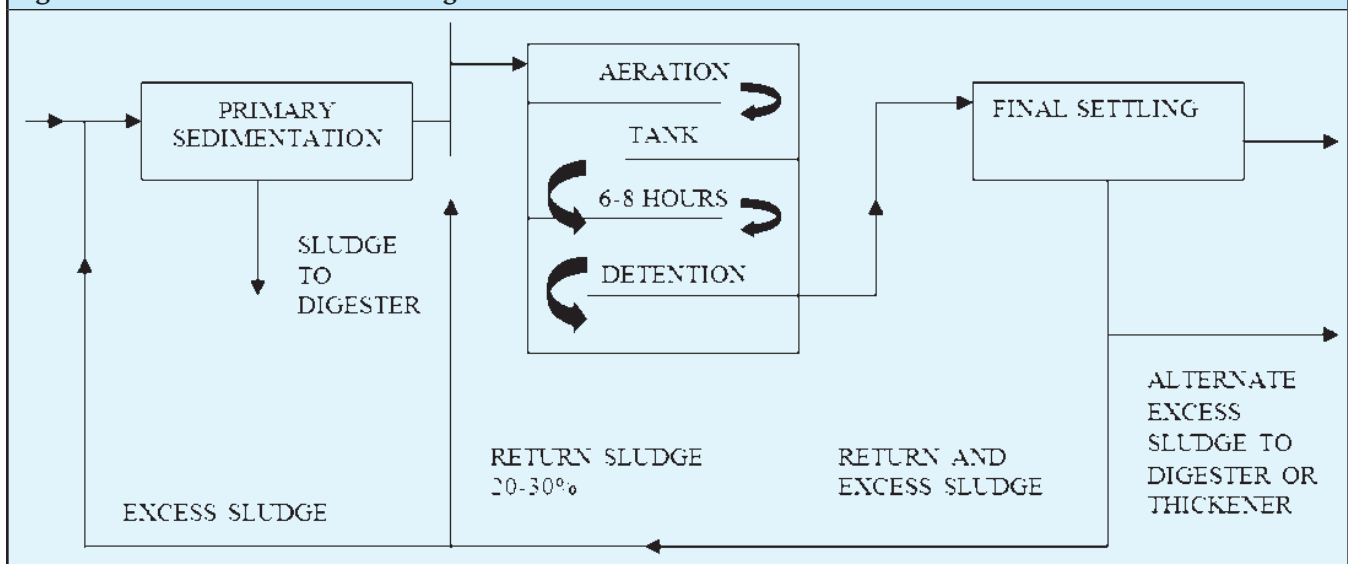
**Process** : The process requires air supply and thorough mixing which brings about an intimate contact of the organic solids with oxygen and aerobic bacteria. First the effluent from the primary sedimentation tank is mixed for an hour or two with the activated sludge returned from the final sedimentation tank to form the 'mixed liquor'. Now the oxygenation of this mixed liquor is carried out for 4 to 6 hours by one or more of these methods :

- (i) Diffused Air System : Compressed air is blown through porous plates, domes or pipes fixed at the bottom of aeration channels (Fig. - 11).
- (ii) Simplex Surface Aeration : Motor driven propellers are used

**Fig. - 10 : Diagrammatic section of a percolating Filter for biological treatment of sewage**



**Fig. - 11 : Conventional Activated Sludge Process**



to mix and break up the sewage into fine spray, bring it in contact with air and induce circulation in hopper bottomed chambers.

**The plant :** The plant consists of a long channel or a series of chambers through which the sewage passes while aeration process proceeds. The aeration is followed by settling in tanks. The sludge is removed and the clear purified final effluent flows out for safe discharge. Most of this activated sludge is returned to be mixed with the sewage from the primary settling tanks as described above. Thus there is a continuous circulation of activated sludge within the system.

The activated sludge method is a more efficient than trickling filter method. Activated sludge plant occupies one tenth of the space occupied by a trickling filter and is also faster. This however is costlier to install and run. It is best suited for large towns.

Following secondary treatment, there are two types of substances that are left, viz., the semisolid sludge and the watery effluent. These two products are dealt in the following ways :

### Sludge Treatment

The sludge from primary or final sedimentation tanks contains 90 to 95 percent water. This high water content needs to be reduced for converting the sludge to a solid condition in which it may be used or disposed off harmlessly. Anaerobic digestion is the most preferred sludge treatment method. The sludge is pumped daily into enclosed digestion tanks. With anaerobic fermentation a gas comprising of about 70 percent methane and 30 percent carbon dioxide is produced. This sludge gas is a valuable fuel. It can be used to generate the entire power needed for running the activated sludge plant. Power is used for pumping, air compression, electricity generation, and heating on the plant. The surplus gas may be compressed and used as vehicle fuel or cooking.

For most effective digestion and gas production, the digesters are heated to about 32°C. Digestion converts much of the organic solids to gas and soluble matter, and so reduces the quantity of solids to be handled eventually. Digested sludge is a black liquid with a tarry odour and is more amenable to subsequent dewatering than undigested sludge. Apart from digestion, the main object of sludge treatment is to de-water it so that it can be handled as relatively compact, moist solid rather than as a much greater volume of liquid with a low solid content. The following processes are used for dewatering the sludge and may be applied to either raw or digested sludge.

**a) Air drying :** Liquid sludge, after digestion, is placed on sand beds for air drying. Percolation into the sand and evaporation are the chief processes involved in the dewatering process. Air drying requires dry, relatively warm weather for greatest efficiency, and some plants have a green-house like structure to shelter the sand beds. The semisolid sludge, which is left, is lifted manually or mechanically. Dried sludge in most cases is used as a soil conditioner; sometimes it is used as a fertilizer.

**b) Lagooning :** Sludge is stored in open basin, a few meters deep to allow settlement of solids. Clarified liquid may be drawn off, and the solids are eventually dug out.

Sewage sludge contains useful nitrogen and phosphorus, and although rather deficient in potassium, it forms a moderately good fertilizer. Undigested primary sludge and undigested activated sludge are easier to apply to land, and their humus content improves the soil. In suitable circumstances sewage sludge may be composted with municipal refuse. Where sludge cannot be used either as a fertilizer or for composting, or, in a few cases, for recovery of by-products, it is usually tipped for land reclamation, dumped at sea, or incinerated.

### Disposal of Effluent

The effluent after treatment is usually discharged on land or into water bodies.

**a) Disposal on Land :** If suitable land is available the effluent can be used gainfully for irrigation purposes. Over the past few decades, there has been a considerable revival of interest in the use of wastewater for crop irrigation in arid and semiarid regions owing to the scarcity of alternative water supply and the need to increase food production. Reuse of treated effluent for the irrigation of crops and urban 'green spaces' (such as parks and golf courses) has expanded significantly in many countries.

**Risks in sewage farming :** Enteric viruses appear to be particularly persistent in sewage, under natural conditions. Sewage farming or spread of treated effluent on farms is still used in many countries, particularly those having low rainfall and high temperatures. Enteric viruses have been found in raw sewage in concentrations of 1-10 per ml in various countries. Thus the risk of transmission of infections through sewage farming remains alive. The risk increases if the sewage had not been treated adequately, prior to its discharge for sewage farming.

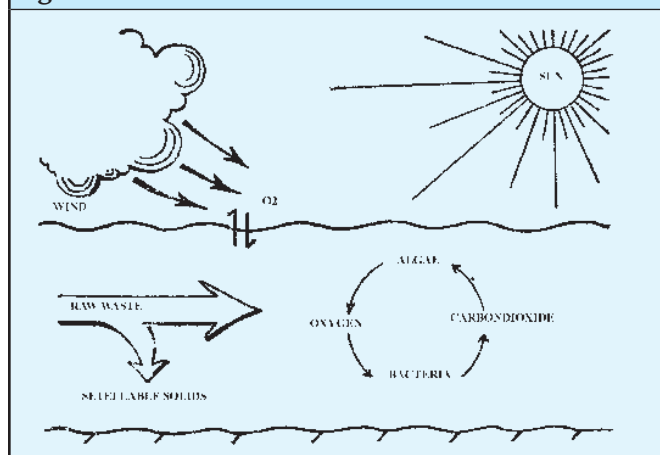
**(b) Disposal by Dilution :** Discharging the effluent into bodies of water such as rivers, streams, lakes and sea for the purpose of dilution and oxidation of the impurities by the dissolved oxygen in water is termed as "disposal by dilution". The BOD content of the effluent and diluting capacity of the bodies of water are the important considerations before discharging effluent into the water body. Since river water is used for drinking, effluent must be adequately treated before discharging. Lately industrial waste and chemicals are being dumped into the sewage, which poses a threat to people's health, when the effluent is eventually discharged into rivers. The aquatic flora and fauna is also adversely affected.

### Oxidation pond

Oxidation pond is also known as the "Redox Pond, Sewage Lagoon and Waste Stabilization Pond". It is probably the cheapest method of satisfactory sewage disposal. It is an open shallow pool up to 5 feet deep with an inlet and outlet. The presence of algae, bacteria decomposing organic matter and sunlight are mandatory for the functioning of oxidation pond. Bacteria oxidize sewage to carbon dioxide, ammonia and water. The algae, with the help of sunlight utilize carbon dioxide, water and other organic substances for its growth. Algae releases oxygen during photosynthesis, which is used by bacteria. So the pond works as an aerobic system during the sunlight hours, and anaerobically during the dark (night) hours, especially in the lower layers (Fig. - 12). The effluent can be used for farming

or can be discharged into rivers after suitable treatment. If the pond runs well, it is an accepted method for sewage disposal in small communities.

**Fig. - 12 : Oxidation Pond**



### Oxidation Ditch/Aerated Lagoon (6)

This process used in oxidation ditch or aerated lagoon utilizes mechanical rotors for extended aeration and thus minimizes the requirement of land area. The land requirement in this method is barely one tenth of oxidation pond. During primary sedimentation itself, a reduction of 30-40% in the number of coliforms is obtained (as against 90% and 95% in other biological treatment processes). On stabilization with a 30-day retention, coliforms reduce to 99 - 99.9%. Most other vegetative bacterial pathogens also appear to be removed in the same proportion as coliforms. Certain helminthic eggs may be effectively removed by primary sedimentation and even more effectively by stabilization pond treatment of 5-7 days duration; viruses are less effectively removed. Coagulation and filtration remove 98 to 99.9% of viruses.

Ponds have the advantage of providing a fairly high degree of treatment at relatively low cost, with minimal requirement of equipment or skilled operators.

### Biolatrine (Biogas plant)

The biolatrine is an example of 'appropriate technology'. It not only takes care of the sewage in an efficient manner, the gas obtained as a by-product is utilized for cooking. Moreover the digested substrate may be utilized as fertilizer (18 - 20). It functions on the principle of anaerobic degradation of excreta. The main focus is however mostly on sanitary aspects, i.e. clean toilets with low maintenance demand, rather than high gas productivity.

**Design :** Biolatrine is designed as integrated fixed-dome biogas plants, where up to 6 latrines can be installed around a dome. The main advantage of biolatrine is that they are generally run without water (except for the start-up phase) thus substantially reducing water demand and related costs. The urine will provide sufficient liquid for the substrate to be able to flow. The toilet chamber is connected to a vent pipe corresponding to those of the VIP latrine. The soil conditions is a consideration and should allow effluent and slurry

absorption.

**Usage :** A biolatrine may only be an appropriate if at least 25 people are connected to its use. The excreta of 25 people will produce an average of about 1 m<sup>3</sup> of biogas per day (40 l per person a day), representing the approximate cooking energy demand of one household. For institutions with 500 or more people, the produced biogas may supply sufficient energy for a canteen. Application may occur for institutions like schools, prisons, religious centres, or for public facilities like markets. In Ralegaon Siddhi (Dist. Ahmednagar), Maharashtra community latrines have been connected to biogas plants. Biogas produced is being distributed to houses for cooking purposes.

### Disposal of Animal Excreta

Animal excreta is also required to be disposed off in a sanitary manner. It might not directly cause disease but it carries enormous potential for fly breeding. It can be managed by disposing it in biogas plants, sanitary land fill or composting (disposal along with biodegradable solid waste).

**a) Disposal in Biogas Plant (Gobar Gas Plant) :** In view of the increasing energy crisis, this method is gaining rapid popularity, particularly in countries having large cattle population. In this method the dung gets anaerobically converted into good quality manure under hygienic conditions and there is also generous liberation of biogas energy.

The digester is partly an underground masonry tank with an incomplete partition in the middle. It has an inlet and an outlet pipe. Dung mixed with water in equal proportion is put inside through the inlet. In the plant, excreta is often mixed with straw or other vegetable waste, and equal quantity of water is added to make slurry which is fed to the inlet side of the chamber. Effluent slurry is removed after retention time of 30-50 days. Biogas production is greater at higher temperatures. This gas can be used as fuel in the kitchen, for running engines, lighting and other purposes. A biogas plant is inexpensive, simple in construction, easy to handle and can be made locally from indigenous materials.

**(b) Composting :** It is often carried out in conjunction with solid waste and night soil. Chapter on solid waste disposal can be referred to for details.

### Summary

Effective and hygienic disposal of excreta is called for not only as a social need but as a health need as well. Many diseases like cholera, typhoid, dysentery, diarrhoea, hookworm, roundworms, poliomyelitis, hepatitis etc can be transmitted through fingers, flies, food, fomites and water contaminated by excreta.

There are various methods of sewage disposal. While open defecation might still be a preferred method in many rural areas, it remains the most unsatisfactory one. It can only be resorted to in the eventuality of a disaster when the population is displaced and has to be accommodated in a relief camp for a short duration. The conservancy system (carrying excreta manually to the disposal site), is also a detesting method and is fortunately waning. In the areas where there is no sewage system, simple pit latrines (dug well latrine), bore hole can be used. But the pour flush latrine is the ideal one as it contains



an eater seal. PRI and RCA types are its modifications that are in use.

Septic tank is a suitable method of final disposal of night soil. Trench latrines (deep and shallow) can be used for camps for short durations. Chemical closets are also used for short duration use.

Water carriage system is the ideal system of sewage disposal and is used in large cities. Networks of pipes from households connect to a labyrinth of underground sewage pipes to the final disposal site, i.e. the sewage treatment plant. Biological and mechanical processes break down the sewage into innocuous products that can be discharged safely into land or water bodies.

Other methods of sewage disposal are the oxidation pond and oxidation ditch. Biogas plant is also one method. Animal excreta can be disposed off through a *Gobar* gas plant or composting.

## Study Exercises

**Long Questions :** (1) Enumerate the diseases that can be caused by poor disposal of sewage. Describe one method for the disposal of sewage in a village at a family level (2) What do you mean by secondary treatment of sewage ? Describe the activated sludge process in detail.

**Short Notes :** (a) Oxidation pond (b) Sanitation barrier (c) Water seal (d) Trickling filter (e) *Gobar* gas

### MCQs

- The depth of the water seal is : (a) 2 cm (b) 2" inches (c) 20 inches (d) 20 cm
- Septic tank uses (a) Aerobic digestion (b) Anaerobic digestion (c) Both (d) None
- Which is not a method of secondary treatment of sewage (a) Trickling filter method (b) Activated sludge method (c) Screening (d) Sludge treatment

- In immediate aftermath of disaster, displaced population can use this method (a) Open defecation (b) Water carriage system (c) Biogas method (d) Communal aqua privy.
- Oxidation pond works on : (a) Aerobic principle during night and anaerobic during day (b) Aerobic principle during day and anaerobic during night (c) Aerobic in both day and night (d) Anaerobic in both day and night

Match the following

Population group with most suitable method of sewage disposal	Population group Most suitable method of sewage disposal
6. Joint family in a village	(a) Trench latrine
7. Large city	(b) Septic tank
8. Group of 20 households	(c) Water carriage system
9. Temporary camp	(d) Pour flush latrine
10. Family in a town	(e) Biogas plant

**Answers :** (1) a; (2) c; (3) c; (4) a; (5) b; (6) e; (7) c ; (8) b; (9) a; (10) d.

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Solid wastes include rubbish or materials that are not economically useful, present in solid, liquid or gaseous form, which originate from a wide range of human operations, such as industry, commerce, transport, agriculture, medicine and domestic activities. It contains food waste, demolition products, dead animals, manure and other discarded material but should not contain nightsoil.

Waste produced by human activities is increasing in most parts of the World. The output depends on the degree of urbanisation, dietary habits, lifestyles and living standards. In most of the countries the per capita daily solid waste produced is between 0.25 to 2.5 Kg. Majority of this waste is diverted towards recycling in developing countries, while in the developed countries sophisticated methods are used to dispose the ever increasing waste generated (Solid wastes disposal in all the countries is done through landfill). With the rise in urbanisation, land areas available for filling are getting lesser and lesser. The alternate methods of disposal such as burning or incineration are neither cost effective nor environment friendly. Toxic products from wastes disposed in

landfill sites increasingly leach into groundwater or cause the generation of explosive methane gas. These waste materials are also attractive to cockroaches, flies and rodents and hence need early and effective disposal.

**Environmental impact of solid waste disposal** : Solid wastes, if allowed to accumulate and not disposed off properly have a tendency to cause the following impacts :

- Contamination of ground water by leachate generated by waste dump
- Surface water contamination by run-off from the dump
- Waste decomposes and favours fly breeding, attracts rodents and pests
- It is aesthetically unpleasant and generates foul odour
- Generation of inflammable gas such methane and green house gases inside the waste dump
- Bird menace on the dump, which affect the flight of aircraft
- Transmission of disease through pests, stray animals and cattle

**Classification of Solid wastes** : A thorough knowledge of quantity, composition and type of waste is essential to plan effective disposal. Solid wastes could be of different types such as :

(a) **Refuse** could be generated from street sweepings, markets, stable litter comprising of animal droppings and left-over feeds, industrial refuse ranging from inert to toxic and explosive compounds and commercial refuse from retail stores, hotels, warehouses and offices.

(b) **Rubbish** a general term applied to solid wastes originating in houses, commercial establishments and institutions, excluding garbage and ash. It includes paper, clothing, bits of wood, metal, glass, dust and dirt.

(c) **Ash** is the residue from burning of wood, coal, charcoal, coke and other combustible materials used for cooking and heating purposes in domestic, commercial and industrial establishments. Ashes consist of a fine powdery residue, cinders often mixed with small pieces of metal and glass.

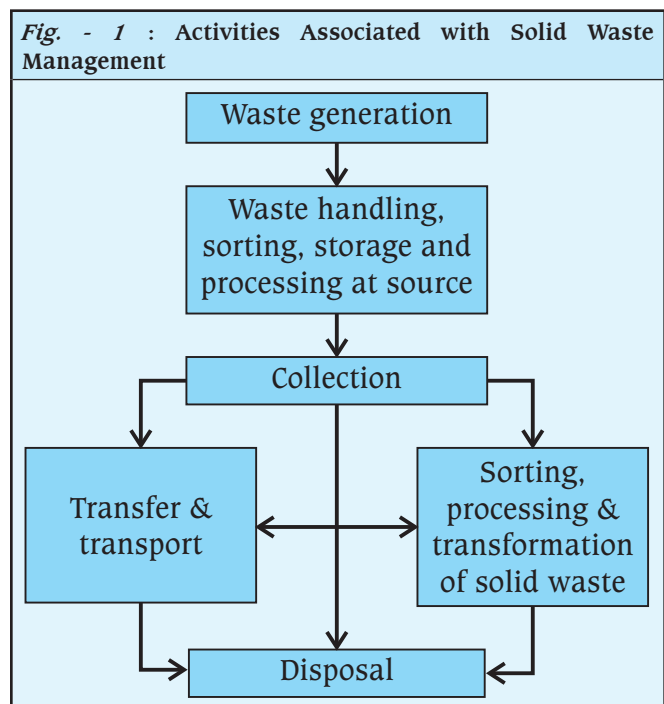
(d) **Garbage** is a term used to describe animal and vegetable wastes resulting from the handling, storage, sale, preparation, cooking and serving of food. It contains organic matter, which decomposes to emit foul odour and hence requires urgent disposal.

**Plastics and their role in waste disposal**: Plastics are organic polymeric materials that can be transformed into desired shapes by different industrial processes. These may contain natural elements such as natural rubber, cellulose or synthetic elements such as polythene or nylon. Plastics have excellent thermal and electrical insulation properties and good resistance to acids, alkalis and solvents. Plastics are widely used in commercial and industrial sectors such as packaging industry, building, motor manufacturing and consumer goods industry. However these plastics are not easily destroyed during waste management processes and are poorly biodegradable. Moreover the chlorinated plastics emit toxic gases when thermally treated. Plastics are known to clog or choke water lines, sewers or storm water drainage systems. They are easily blown by wind and litter the areas near waste dumps thereby

being aesthetically unappealing

## Solid Waste Management

The activities associated with the management of solid wastes in a community from the point of generation to its disposal revolves around the following functional elements (a) waste generation (b) waste handling (c) sorting, storage and processing at source (d) collection (e) sorting, processing and transformation and (f) disposal (Fig. - 1). These elements are relevant to all manner of solid waste disposal be it from urban localities, slums, rural areas or after any calamitous event in an area. In the latter event the urgency to dispose off the waste material is extreme. The waste material in a post disaster situation depends on the type of disaster, which has occurred. It could range from household goods to building material and in extreme situations include human and/or animal bodies.



## Solid Waste Disposal in an Urban Area

Urban areas include cities and towns and have a higher density of population by virtue of which the quantity of solid wastes generated is very high. Besides this there are people from different professions, socio-economic status, ethnic and cultural backgrounds living in varied accommodations in these areas. They thus produce equally diverse kinds of waste material from their domestic, commercial and industrial professions/establishments. Composition of solid wastes changes from place to place even in the same country due to this heterogeneity.

Major constituent of waste is putrescible organic matter with the balance of the content comprising of metal, glass, ceramics, plastics, textiles, dirt and wood in proportions depending on the local factors. Studies have shown that while the quantity of paper waste increases with the rise in income of the countries, the density, moisture content and proportion of food waste is

more in the waste generated in low income countries.

Studies conducted by National Environmental Engineering Research Institute, Nagpur have shown that in India out of the wastes generated, the biodegradable fraction is very high due to the habit of using plenty of fresh vegetables in food preparation. It demands frequent removal of waste from the collection points. The proportion of ash and fine earth content in the waste are also high due to the inclusion of the street sweepings, drain silt and construction and demolition debris in it. The most ideal arrangement for collection of solid waste in an urban area would be door-to-door collection of waste material by a team of waste handlers. However this is not practicable in all places in the cities especially in the urban slums.

### Waste Management Plan

**(a) Sorting** : This indicates 'separation and storage of individual constituents of the waste materials'. Sorting helps in removing the material, which needs to be recycled and ensures that the hazardous wastes are handled separately. It assists in minimising the waste and ensures reduction in landfill space for final disposal. Sorting could be carried out at household level, at the municipal bin, central sorting facility, waste processing site or the landfill site. At the household level sorting is carried out by the inmates. Traditionally, items such as newspapers, used bottles, jars, old clothes, strong plastic bags are not mixed with everyday household wastes. These are reused or sold at a later date to informal recycling trade middlemen or the '*kabariwallah*'. Garden wastes from houses gets mixed with the municipal waste, there being no separate mechanism for its disposal. At the next stage of sorting at the municipal bin the ragpickers take over and collect waste material of use to them such as plastics mostly water bottles, paper, rags, metal cans and rubber items to resell or recycle them. This business continues at the landfill site where the pickings include small metal pieces, plastic bags or any item considered to be of economic value. Thus at the primary level an intensive sorting is carried out. The recovered material thereafter reaches the next level of sorting where the informal recycling trade middlemen sort out all metals, plastics and all types of paper. The salvaged items out of the waste is purchased by the wholesale dealer, who does more sorting, since he is the final link in the chain before the recycling factory. The balance of waste material is disposed off in the landfill. After sorting the waste is divided into the following streams :

- Dry recyclables
- Construction and demolition waste
- Biodegradable waste
- Bulky waste
- Hazardous waste
- Mixed wastes

Sorting could be carried out manually or by semi-mechanised or fully mechanised systems. The manual system employs handpicking of waste for reuse, which is followed in most cities in developing countries, by the ragpickers and the informal recycling trade middlemen, while in the semi-mechanised system the waste material is placed on a conveyor belt and then hand-picked off the belt, for reuse. The mechanised system involves size reduction of waste through shredders and crushers followed by screening, density and magnetic

separation of waste followed by its compaction by balers and crushers.

**(b) Storage** : This is the first essential step in management of solid wastes. Every household, shop, industry, commercial centre or establishment generates waste that it needs to be stored safely prior to giving it for collection. Presently such establishments and institutions do not maintain receptacles of adequate size for storage of waste as a result of which the solid waste lies overflowing the bins or littering the streets causing public nuisance. In some instances the waste generated is simply thrown out to the streets for the municipal sweeper to sweep it up. Wastes of the recyclable variety are mixed with organic waste and not sorted out or at worst the wastes may be thrown into the municipal sewers or drains, which end up blocking them and obstructing the flow of water in them.

It is therefore essential at first to educate the people to store waste at source, dispose waste as per directions of the local bodies and effectively participate in the activities of local authorities to keep the cities clean. The type and size of waste bins need to be described to households, shops, offices, institutions, hotels, vegetable & fish/meat markets, street vendors, marriage halls, construction sites and health care establishments. It needs to be emphasised that the recyclable wastes should be kept separate from the organic matter capable of decomposition. The food/ biodegradable waste should be stored in a non-corrosive container with lid. Building associations, communities and commercial complexes must keep central waste storage bins of adequate capacity to ensure that they hold the wastes generated till the time they are cleared by the waste lorries. Construction and demolition wastes should not be dumped on the streets, public spaces, footpaths and pavements.

**(c) Collection of waste** : The next essential step in waste management is primary collection of waste matter. This ensures that the waste from the source is collected regularly such that it is not disposed in the streets, drains or water bodies.

Doorstep collection of waste from households, shops and establishments is insignificant in the urban areas and wherever it is introduced through private sweepers or departmentally, the system does not synchronise further with the facility of waste storage depots and transportation of waste. This results in its indiscriminate disposal in public places.

**Waste collection measures** : A daily waste collection service should be provided to all sources of generation for collection of putrescible organic waste from the doorstep because of the hot climatic conditions of the country. Recyclable material can be collected at longer intervals as this waste does not normally decay and need not be collected daily. Domestic hazardous waste is produced occasionally hence needs to be collected less frequently and could be disposed off by the community in central bins kept for the purpose.

Collections could be made from doorstep or at the community level by hand carts/ tricycles or motorised vehicles. The hand carts or tricycles should have detachable containers of 30 to 40 litres capacity, made of sturdy material, with a handle at the top and a rim at the bottom for easy handling. Similarly the community bin carrier or the bin lorry should have the capacity to carry 40 containers from a central point in the communities



or slums to the place of final disposal.

**Waste storage depots (secondary)** : Wastes collected from the source could be temporarily stored at depots till the time they are taken to the final disposal site. At present most municipal areas have cement-concrete-cylindrical bins, masonry bins, metal rings or open sites for storage of wastes. Improper storage at the bins or littering of waste gives an unsightly appearance and also attracts rodents, pests and animals that further spread the litter or could carry diseases from the decomposing matter.

Temporary waste storage depots, which synchronize with primary collection and transportation system, are required to be located at suitable sites in a municipal area. Large metal containers, which are covered, could be placed at specific points. These places should have concrete or asphalt flooring. The waste material could thereafter be transported at regular intervals by Lorries having mechanised equipment to lift and load the bins to take them to the final disposal sites.

**(d) Disposal of solid waste** : Solid waste disposal in developing countries is mostly carried out by filling up land sites. In India this nature of disposal accounts for most of the municipal refuse. This is followed by incineration and to a very minimal extent by composting. The choice of disposal method depends on the economic considerations, availability of land, local labour and circumstances. Some of the technologies in use in these countries include sanitary landfill, incineration, composting, biogas plant, Effective Microorganisms technology and salvaging.

**Dumping** : The refuse collected from the cities and municipal areas are dumped in the low-lying areas or open tracts of lands, usually by the roadside. This process, though not a correct method of disposal of solid waste, is nevertheless practised in many cities in the country and in certain locations in a particular municipal area limit. The city of Kolkata in India practises the method of dumping of municipal solid wastes after its sorting. Some of the reclaimed lands, where refuse is dumped, are also given thereafter for cultivation.

This method has the disadvantage of lying in the open ground thereby being dispersed by the wind to nearby places, attracting rodents, insects and birds causing a risk of transmission of diseases and encouraging breeding of flies. Besides this the

open waste dump lying on the roadside emits foul odours and is an aesthetic nuisance. The urban areas thereafter resort to burn these wastes to reduce their bulk, thereby causing air pollution. The malodorous fumes and the toxic gases, which are emitted due to burning of wastes such as plastics and other materials, are spread in the direction of wind movement. Besides, these dumps are accessible to animals and scavengers or ragpickers since these areas are usually not made secure from ingress of these elements. The drainage from these dumps contributes to the pollution of surface and ground and the soil around.

Dumping of waste disposal should be outrightly discouraged as an unsanitary practice. Only dumping of demolition materials could be permitted in low lying areas outside the cities or municipalities (Fig. - 2).

**Landfill** : Landfill (Controlled tipping) is a method of selecting depressed areas or creating artificial trenches where waste matter is thrown and compacted with a layer of earth on top of it. This method is suitable if adequate land is available, within the economic range of the waste source. The modern day landfill is utilised for disposal of wastes two to three times a week and differs from dumping in that if properly carried out it reduces the nuisance of foul odour, menace of flies, rodents and animals. It also prevents any dispersal of the waste matter and is protected from scavengers. Soil, water and air pollution is avoided and the reclaimed land could be utilised for growth of vegetation or parks after a period of time (Fig. - 3).

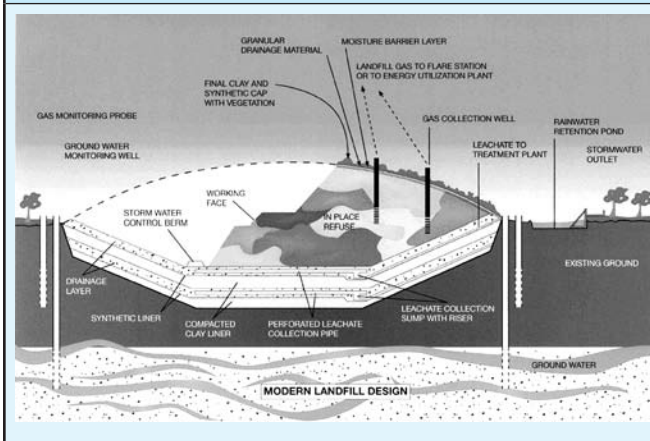
**Site selection** : The site selection for a landfill is carried out away from habitation. A hollow low lying area is usually selected such as an abandoned quarry, depression in land or swampy area, which is not a source of rain water harvesting or natural aquifer for a municipal area. If such land area is not available, as an alternative to this, trenches are dug in an open and flat area with the help of dozers. Some of the points which should be remembered while selecting a site for landfill are :

- Waste site should not be subject to flooding easily
- Deep sands with shallow water tables should be avoided, to prevent seepage of toxic wastes into the drinking water
- Fractured limestone soils, humid areas or wetlands with easy percolation should be avoided.
- Soil with pH 6.5 or above should be chosen such that the

Fig. - 2 : Dumping



Fig. - 3 : Landfill





metals such as cadmium, mercury, lead, chromium and copper are less soluble in the subsoil water and reduce the chance of pollution.

#### **Sites**

(a) Trenches - where long trenches of 2 to 3 m depth and 4 to 12 m width are dug and the refuse is compacted and covered with excavated earth. It is estimated that an acre of flat land area would be required for ten thousand population.

(b) Ramps or slopes - where moderately sloping lands are selected and soil is excavated for compacting purposes. The waste dump should be prevented from damage by rain water and thus upland drainage should be diverted.

(c) Unused areas - such as disused quarries, pits and land depressions wherein the solid waste is packed and consolidated in uniform layers using mechanised equipment.

**Process of disposal :** The refuse or solid waste is collected and deposited in these sites using bulldozers or crawler type tractor. In trenches the filling takes place from the farthest end. Each layer is upto 2 to 2.5 m deep. At the end of the day or as per the desired frequency the top of the refuse is layered with earth of at least 30 cms thick using mechanised equipment and evenly levelled. The mass is covered with clinkers and fast growing shrubs. Over a period of time due to physical, chemical and biological processes in the buried waste matter, heat is generated and anaerobic decomposition of the organic matter takes place, which also destroys pathogens. Thereafter the process cools down and the waste is converted into an innocuous mass by the end of six months of burial. The land could thereafter be used as a green belt or parks could be developed on it.

**Notable features:** The trenches could also be lined and the filled could be contoured to minimise pollution of soil nearby. Methane gas is generated during the decomposition of solid waste, which is explosive in nature. This land should therefore not be used for construction purposes. Vents could be created in the topsoil cover to release this gas. Dumping of bulky goods such as household equipment should be avoided. These goods could be recycled or incinerated. The method has a drawback that it requires soil cover, which has to be made available at all landfill sites.

**Composting :** It is a method where in the combined disposal of solid waste is carried out alongwith stable litter, night soil and sludge. Compost is humus like material, which is generated due to the breakdown of organic matter under bacterial action, and is rich manure. Thus the final product of degradation in composting has a recyclable component and the compost could be sold at a price to agriculturists. Composting uses aerobic method of digestion (Fig. - 4).

**Pre-treatment :** The refuse or solid waste is pre-sorted to remove materials that could be recycled or have salvage value or those ones, which cannot be composted. It is thereafter ground to reduce the waste particle size and this improves the efficiency of decomposition process.

#### **Methods**

(a) **Bangalore method :** It was evolved under the auspices of Indian Council of Agricultural Research at the Indian Institute of Science, Bangalore. It is also known as the hot fermentation

process due to the generation of heat in the process to decompose the waste.

In this method long trenches are dug each with a depth of 1 m and width of 1.5-2.5 m. Greater depths is not recommended since they delay the process of decomposition and therefore decrease its effectiveness. The refuse is then placed in the trench at the bottom making a layer of about 15 cms thick. Over this a layer of nightsoil is put to a depth of 5 cms. In this manner alternate layers of solid waste and nightsoil are layered one above the other till the heap rises 30 cms above the ground level. The top layer is recommended to be of refuse of about 25 cms thickness. Thereafter the heap is covered with excavated earth firm enough to not allow a person's legs to sink in the heap while walking.

**Fig. - 4 : Composting**



**Process :** The fermentation process begins in a week's time with generation of considerable amount of heat, which stays for 2 to 3 weeks. The organic mass is decomposed and pathogenic microorganisms are destroyed in the process, which is completed in 4 to 6 months. Gases such as ammonia, methane, carbon dioxide and nitrogen produced in the process are released into the atmosphere. The resultant manure is well-decomposed, odourless, innocuous material of high manurial value. The soluble material produced may leach into the underlying or surrounding soil or ground water.

(b) **Mechanical composting :** It is a process in which the compost is manufactured in a short period of time with use of waste materials and night soil. A sorting is done in the initial stages and items such as rags, bone and metal pieces and glass, which are likely to interfere with grinding operation, are removed. The waste matter is then pulverised by mechanised equipment and thereafter mixed with night soil or sludge in a rotating machine. This mixture is then incubated under controlled conditions of pH, temperature and aeration. The compost is ready in 4 to 6 weeks time as humus like material with a total nitrogen, phosphorus and potassium content of 1 to 3 percent. The product thereafter is cured, blended with additives, bagged and marketed.

(c) **Vermicomposting :** It is a method of disposal of kitchen and

plate wastes, which serves the dual purpose of disposing off the garbage as well as proving eco-friendly. Here a suitable area is chosen which is bound by a 2 to 3 feet high brick wall and few hundred earthworms are introduced in it. The waste is dumped in this area and water is sprinkled daily on this dump. The waste matter is broken down by the worms and compost, which could be used as bio-fertiliser, is produced in 2 to 3 months.

The process does not generate any explosive gases or leachate and can be used in agriculture and organic farming. It enriches the soil due to the deep burrowing worms and bacteria in the organic matter. The process could generate green areas and is used in small scale disposal of waste matter.

**Notable features :** The process of vermicomposting has the advantage of dual disposal of nightsoil and solid waste in a manner that the end product could be reused as organically rich manure. However the process needs training of manpower who are required to handle the mixing and incubation of night soil with refuse and may generate hesitation on their part to be involved in the process.

**Effective Microorganisms (EM) Technology :** This is a modern eco-friendly technology consisting of use of friendly microorganisms such as phototropic bacteria, lactic acid bacteria, Actinomyces and yeasts. These microorganisms are added to kitchen wastes in specially designed drums. The wastes are converted into compost, which can thereafter be utilised as manure. The EM solutions available commercially are classified into EM 1 and EM 2 categories depending on their shelf life, which varies from 30 days in the latter to 6 months in the former. EM technology also has the advantage of keeping the drains clean by decomposing the sewage and suppressing its bacterial content.

**Incineration :** This is a process of disposal of solid waste material by thermal technology and has gained popularity in several developed countries. The incinerators use heat recovery process and also have air pollution controls. Incineration is also chosen in those places where suitable land mass is not available. Many industrialised countries are practising this method under strictly controlled environment, with appropriate training to the waste handlers. Waste generated in hospital premises is disposed off in this manner in most countries.

Incineration of waste material is not a useful method for India because of the fair proportion of ash, which is contained in it. The ash contained in the refuse makes its combustion difficult. Hence pre-treatment of the waste material is required, which is expensive and requires heavy infrastructural outlay. Besides this incineration involves wastage of precious bio-fuels and deprives the communities of much needed manure.

## Solid Waste Disposal in an Urban Slum

Urban slums comprise a congregation of temporary or semi-permanent structures, which are constructed by the new settlers in an urban area, due to lack of proper housing facilities and in most instances by illegal occupation of land. These settlements usually house people from low socio-economic strata, who are poorly educated and as a consequence show a lack of awareness regarding the hygiene and sanitation issues especially related to solid waste management.

The houses in slums are constructed in rows with a narrow path in between them. The storm drainage system is usually rudimentary and temporarily constructed. The slum dwellers use common toilets and bathing facilities, where the waste water or night soil is connected to the sewers or in certain instances to the larger storm water drains. Disposal of solid wastes in the slums has the following peculiarities :

- Quantity of waste generated is lesser as compared to other areas in the urban locality.
- Solid wastes mostly comprise of used bottles, tins, plastics and ashes, since most of the salvageable items are recycled.
- Animal manure and feeds are a significant part of solid wastes from slums since small farm animals co-habit with humans.
- Vegetable peels and kitchen wastes are discarded in large quantities while the food product packages are not usually a part of the waste matter.
- Slums localities in the various cities also have small-scale or cottage industries, which generate waste materials. Sometimes these industries give rise to hazardous or toxic chemicals such as from the dyeing and tanning industries. Some industries are also engaged in recycling of goods salvaged from the refuse bins. Hence the wastes from these places need to be disposed off properly.
- There is no existing system of door-to-door collection of waste items. The people in the slum community deposit their garbage in the public bins located centrally.
- The roads/paths in the slums are narrow, hence the refuse lorries are unable to negotiate the paths and therefore the waste bins are placed at fewer points.
- The wastes from these bins require more frequent emptying to prevent waste matter to spill over in the ground below and create nuisance.
- Adequate sorting of the wastes take place in the bins located in the slum localities, hence the remaining waste meant for final disposal is non-recyclable matter.

## Waste Disposal

Waste disposal in slums is carried out in the same manner as the solid waste, which is disposed from the rest of the municipal locality. The waste bins are placed at the pre-determined points and the community is made aware of the place. The wastes are collected at these sites from the households and these are thereafter taken to the disposal area. Sorting of the wastes is carried out by the rag-pickers at the municipal bins and the recyclable material salvaged by them is sold to informal middlemen. The second stage of sorting by the rag-pickers is carried out at the municipal waste disposal area. The remaining wastes comprise of non-recyclable material, which is easily decomposed by the processes such as sanitary landfill, composting or incineration or any modern day technology discussed in the previous paragraphs.

## Solid Waste Disposal in Rural Areas

Rural areas comprise of villages and some temporary nomadic settlements or camps. In the last census conducted in 2001 the rural population in India comprised more than 70% of the total population of the country. The rural economy is primarily

agrarian with the population engaged in cultivating crops or vegetables for selling in the market and for consumption, depending on the nature of farming practised in the area or economic need. Some rural areas also practise poultry farming, fish farming or apiculture. The farm work is steadily becoming mechanised in most parts of the country with machines sowing and harvesting crops throughout the year. As a result of this large amounts of unused parts of the crops or vegetables are generated as wastes, which require regular disposal. Some of the rural areas also have small-scale industries, which produce solid wastes or liquid chemical wastes. These also require disposal in an appropriate manner.

The community residing in the villages comprise of a large population who belong to the lower socio-economic strata. The levels of literacy are lower compared to cities and the health status indicators of morbidity, mortality and natality compare unfavourably with the urban areas. The density of population is lesser in villages, while more number of families live jointly, with all of its members contributing to the family occupation.

Waste generated in the rural areas is lesser in quantity compared to urban wastes. It consists primarily of organic matter from the households or the rural industry such as vegetable peels, crop wastes, manure, fodder, animal feeds, ash and lesser quantities of tins, bottles or paper unless there is a particular industry located in the rural area. Majority of the recyclable wastes are salvaged before disposal to be used in households.

**Current disposal methods :** In the rural areas at present there is no system of organised collection and disposal of refuse, which is temporarily deposited in a pit or a bin to be disposed later by burning or dumping outside the village or is thrown around indiscriminately. The waste ends up polluting the nearby soil, water and air and at times hazardous wastes from small industries could be harmful to the human life. The local self-governing bodies or the Panchayati Raj Institutions are responsible for maintenance of hygiene and sanitation in the rural areas and they influence the methods of waste disposal.

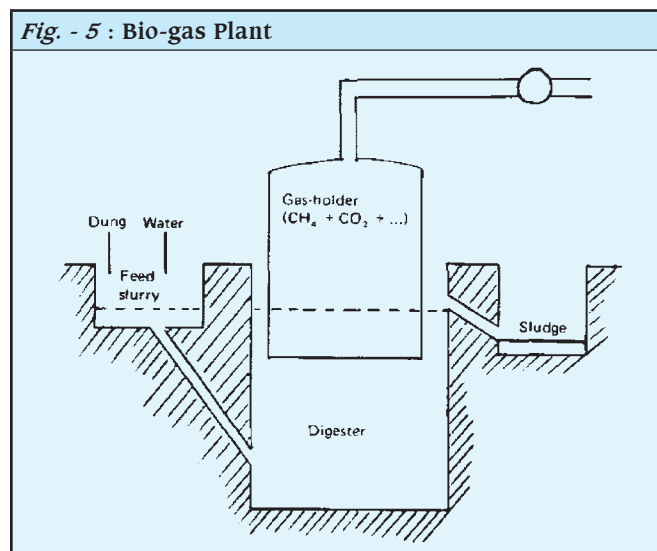
### Methods of disposal

**(a) Manure pits :** This method of waste disposal could be practised by the individual households in the rural areas. Pits could be dug near the house and the wastes such as kitchen wastes, cattle dung, fodder or animal feeds, leaves could be thrown into them. The wastes should be covered by earth at the end of each day and reused the next day. Two such pits could be dug simultaneously of 1 to 1.5 m and used one at a time. When one pit is filled up it is covered with a top layer of soil and compacted. In 5 to 6 months time, the wastes are decomposed and converted into manure, which could be returned to the fields.

**(b) Burial :** Burial method of disposal is suitable for disposal of refuse of the village or small settlements. This could be undertaken in an area if sufficient land is available. The method is similar to sanitary landfill and the involves digging a trench 2 m deep and 1.5 m wide in which the refuse from the village or camp is deposited and at the end of the day the refuse is covered with 20 to 30 cms of earth. The disposal continues in this manner till the time the level in the trench is 40 cms from ground level, when the trench is filled and compacted and

a new trench is dug out. The waste matter is decomposed in 4 to 6 months time when it can be taken out and used as manure in the fields. A trench of this size and 1 m long would suffice for 200 persons for a week. The length of the trench could be varied depending on the requirements of the rural area. The method of burial needs to be practised in the correct manner to avoid any rodent or pest nuisance.

**(c) Biogas plant :** The animal excreta generated in the rural areas are fairly large in quantity and could be utilised to generate bio-fuels and thus be recycled (Fig. - 5). In the rural areas this excreta is mixed with straw to make dung cakes which are used as fuel for cooking purposes.



Animal excreta also carry an enormous potential of fly breeding and thus its sanitary disposal is required. This could be achieved by disposing them in bio-gas plants or through landfills or by composting. Details of biogas plant have already been discussed in the chapter on excreta disposal.

### Solid Waste Disposal in Post Disaster Situations

Disasters produce solid wastes in large amounts. Natural or man-made disasters produce debris comprising of soil, building material and green waste such as trees and shrubs. The type and quantity of the waste depends upon the type and magnitude of the disaster. Most of the times the destruction created in the wake of the disasters are of such magnitude that it overwhelms the capacity of the affected community to dispose off the debris.

#### Solid Wastes during Disasters

These wastes are mostly in the form of debris, which stands for 'the remains of anything that is broken down or destroyed'. Hurricanes leave behind debris made of construction materials, damaged buildings, sediments, green waste and personal property. Earthquakes generate sediment from landslides besides building materials and personal property; the waste material due to fires and explosions may increase the ash and toxic waste contents in the debris. Floods notoriously produce



mud, sediment and sandbags beside the rubble of dismantled houses. The household goods damaged due to inundations are disposed off by the communities. Fire debris also includes charred remains of vehicles, wood, ash and metal objects. In addition to all this, there could be bio-hazardous and radiation wastes due to manmade disasters, which need specialised disposal techniques. Disasters also tend to take a heavy toll of human and animal lives and thus disposal of dead bodies or animal carcasses has to be carried out on priority after identification of the bodies. Post disaster wastes also include the wastes from relief material, which arrives in bulk at the disaster affected sites and have a potential to cause aesthetic nuisance.

### Managing Disaster Debris or Solid Wastes

The management of solid wastes after disaster situations must be based on the existing regulations in a community and it must be consulted on all occasions. The cycle of waste management comprising of collection, storage, staging, recycling, disposal, hazardous waste identification and handling, administration and dissemination of information to the public needs to be adhered to ensure efficient disposal of waste matter.

**Planning for disposal** : Post disaster situations require additional quantity of specialised equipment and supplies such as saws, portable generators, vehicle repair equipment and water storage arrangements. It is important to pre-select temporary debris storage and processing sites at a convenient place to allow the collection crews to reduce travel time when transferring debris to processing or disposal facilities. These sites should be accessible to heavy equipment with low impact on the environment and adjacent housing areas.

**Waste management** : After the disposal of the dead bodies and the carcasses in a hygienic manner, the task that needs to be carried out next on priority is to dispose off organic matter first. This comprises food wastes, animal feeds, plants and trees, soil, decomposable household goods, waste from the relief materials and manure. The existing methods of sanitary landfill, composting or incineration could be used for this purpose. Equipment are needed to quickly prepare the area for disposal of refuse. Incinerators, which are not damaged, could serve as the best method of early disposal of solid waste in a post-disaster situation.

Large bulk of disaster generated waste matter comprises of building rubble and damaged infrastructure. This could first be removed to a temporary storage site and thereafter be disposed off by landfill, filling up land depressions or for road construction or levelling, after suitable grinding and breaking down to pieces of desirable size. Care should be taken to ensure that no hazardous waste matter is included in this waste bulk. Broken trees, poles, metal roofs, sandbags, cables, packing material from relief goods, which are salvaged, could thereafter be disposed off by selling or reusing them to construct the infrastructure in the affected area.

The local authorities should establish communication strategies to coordinate with the affected communities in implementing disaster plans. Staffing patterns should be improved and they should be trained to handle increased number of telephone calls and requests concerning waste removal. Additional staff would

be required to train and monitor debris collection contractors, enforce disposal restrictions and help solve implementation problems.

**Legal Framework** : The following acts and rules govern the disposal of solid wastes in India, published by the Ministry of Environment and Forests, which is the nodal Central Govt ministry responsible for the proper disposal of solid wastes :

- (a) Environment (Protection) Act 1986
- (b) Bio-Medical Waste (Management and Handling) Rules 1998
- (c) Municipal Wastes (Management & Handling) Rules 1999

### Summary

Solid wastes include rubbish or materials that are not economically useful, present in solid, liquid or gaseous form, which originate from a wide range of human operations, such as industry, commerce, transport, agriculture, medicine and domestic activities. It contains food waste, demolition products, dead animals, manure and other discarded material but should not contain nightsoil. The output depends on the degree of urbanisation, dietary habits, lifestyles and living standards. In most of the countries the per capita daily solid waste produced is between 0.25 to 2.5 kg.

Solid wastes, if allowed to accumulate and not disposed off properly have a tendency to contaminate drinking water sources, favour fly breeding, attract rodents and pests, generate foul odour and inflammable gases and transmit various diseases. Solid wastes could be of different types such as Refuse generated from street sweepings and markets, Rubbish originating in households excluding garbage and ash, Ash which is residue from burning of wood or coal and Garbage including animal and vegetable wastes

The management of solid wastes in a community include (a) waste generation (b) waste handling (c) sorting, storage and processing at source (d) collection (e) sorting, processing and transformation and (f) disposal.

Urban areas produce diverse kinds of waste material from their domestic, commercial and industrial professions/establishments. Sorting could be carried out at household level, at the community refuse collection site or the landfill site. It segregates the different types of wastes. Collection of wastes could be made by waste handlers at household level, shops and small establishments, while at the community level it could be carried out by hand carts/ tricycles or motorised vehicles equipped with detachable containers of 30 to 40 litres capacity. Wastes collected from the source could be temporarily stored in cement-concrete-cylindrical bins or masonry bins till the time they are taken for final disposal. The waste material could thereafter be transported at regular intervals by Lorries having mechanised equipment to lift and load the bins to take them to the final disposal sites. Final disposal of solid waste is carried out by sanitary landfill, incineration, composting, biogas plant or Effective Microorganisms technology.

Waste disposal in urban slums, is carried out in the same manner as the rest of the municipal locality though the type and quantity of waste generated is slightly different. Waste generated in the rural areas is lesser in quantity and



consists primarily of organic matter from the households or rural industry. The local self-governing bodies or Panchayati Raj Institutions are responsible for maintenance of hygiene and sanitation in the rural areas. The main methods of waste disposal here are manure pits, burial, biogas plants and other technologies such as composting and incineration. Solid wastes during disasters are mostly produced in the form of debris, dead bodies or animal carcasses and wastes from relief material. The management of solid wastes after disaster situations must be based on the existing requirements of the affected community. Additional quantity of specialised equipment and supplies such as saws, portable generators, vehicle repair equipment and water storage arrangements are required in these situations.

Community participation is the key to ensure success in the implementation of solid waste disposal. To ensure that community participation is optimum, strong and sustained Information, Education and Communication programme needs to be adopted. The acts and rules governing the disposal of solid wastes in India, published by the Ministry of Environment and Forests are Environment (Protection) Act 1986, Bio-Medical Waste (Management and Handling) Rules 1998 and Municipal Wastes (Management & Handling) Rules 1999.

### Study Exercises :

**Long Questions :** Enumerate the health hazards due to improper Solid waste disposal and describe the methods for solid waste disposal in an Urban area.

**Short notes :** (1) Solid waste disposal in an Urban Slum (2) Solid waste disposal in a rural area (3) Sanitary landfill (4) Incineration (5) Composting

#### MCQs :

1. Waste paper is an example of (a) Refuse (b) Rubbish (c) Garbage (d) none
2. A method of selecting depressed areas or creating artificial trenches where waste matter is thrown and compacted with a layer of earth on top of it is (a) Manure pit (b) Controlled tipping (c) Burial (d) Dumping
3. Bangalore method of Composting is a type of (a) Aerobic (b) Anaerobic (c) both (d) none
4. Bangalore method of refuse disposal is not recommended for population above (a) 100,000 (b) 200,000 (c) 300,000 (d) 400,000
5. Dual disposal of nightsoil and solid waste is seen in (a) Manure pit (b) Controlled tipping (c) Composting (d) Sanitary landfill
6. The method of solid waste disposal which is not ideal/feasible for rural setup is (a) Manure pit (b) Biogas plant (c) Burial (d) Mechanical composting

**Answers :** (1) b; (2) b; (3) b; (4) a; (5) c; (6) d.

*Kunal Chatterjee*

Biomedical waste could be defined as “any solid, fluid or liquid waste, including its container and any intermediate product, which is generated during the diagnosis, treatment or immunisation of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals and the animal waste from slaughter houses or any other like establishments”. As per the Biomedical waste (management and handling) rules 1998, under the Environment Protection Act of India, proper management of biomedical waste is a statutory requirement and these rules have been elaborated in the Gazette notification of the Ministry of Environment and Forests, Govt of India dated 20 Jul 1998.

Majority of the waste generated in a health care establishment is non-hazardous waste of general nature. It is comparable to domestic waste and is produced due to administrative and house-keeping functions of these establishments. Almost four-

fifths of hospital wastes comprise this category of general waste. The rest 20 percent of health-care waste is hazardous and could be infectious, toxic or radioactive and cause significant risk to the health of community members.

#### How do we Classify Biomedical Waste?

The Ministry of Environment and Forests of the Govt of India, in exercise of its powers conferred under the Environment Protection Act 1986, have categorised these biomedical wastes for the purpose of safe disposal, as given in the Table -1.

#### Quantity of Biomedical Waste Generated in Health Care Settings

The quantity of waste generated in a hospital would direct its waste management policy and is dependent upon the type of hospital and the health problems, hospital policies and practices followed and the nature of patient care provided in them. The reports available from developed countries indicate that this quantity is equal to 1 to 5 kg/bed/day with variations among countries, hospitals and specialities. In India, from the data available from regional or local studies, it is presumed that most hospitals generate roughly upto 1 to 2 kg/bed/day of biomedical waste. This quantity varies between Government

**Table - 1 : Classification of Biomedical Wastes**

Waste category	Waste Class
Cat. No. 1	Human Anatomical Wastes
Cat. No. 2	Animal Wastes
Cat. No. 3	Microbiology and Biotechnology wastes
Cat. No. 4	Waste Sharps
Cat. No. 5	Discarded medicines and Cytotoxic drugs
Cat. No. 6	Soiled wastes include items contaminated with blood, body fluids such as cotton, dressings, linen, beddings etc.
Cat. No. 7	Solid wastes i.e. waste generated from disposable items other than sharps such as tubings, catheters, IV sets.
Cat. No. 8	Liquid wastes
Cat. No. 9	Incineration ash is generated of any biomedical waste.
Cat. No. 10	Chemical wastes

and private health care establishments. Most studies in India also inform that the waste generated contains less disposable material like rubber tubes, plastics etc. Most of the waste generated in a hospital (around 85%) is non-hazardous, while 10% are infective including sharps and pathological waste and the remaining 5% are non-infectious but hazardous such as chemical, pharmaceutical or radioactive wastes.

### Principles of Control of Hazards of Biomedical Waste in Health Care Establishments

The biomedical wastes generated in a health care setting could be rendered safe by following certain principles of infection control as described :

- Each institution should develop its own *biowaste management policy* and ensure that the health care workers are adequately trained to handle biological waste.
- Measures such as *universal safety precautions*, *hand washing* and *proper segregation* of waste material should be encouraged.
- Rational *patient management policy* should be followed and admissions restricted to those for whom it is felt absolutely necessary, to reduce incidence of hospital acquired infections.
- Proper *house-keeping* is essential and the hospital premises should be kept clean and well-ventilated.
- Use of *disinfectants* should be rationalised.

### Steps in the Management of Biomedical Waste

The biomedical waste generated in a health care establishment is required to be disposed in an appropriate manner to prevent health hazard to the health care providers and the general community. As a pre-requisite to a good hospital waste management plan, it is essential to ensure the availability of safe and reliable supply of water, sanitation facilities, maintenance of cleanliness and demarcation of vital areas that need stricter sterility norms. After ensuring the availability of these basic facilities, the steps discussed below should be followed for management of biomedical waste :

**(a) Survey of waste generated** : A survey of waste generated in a health care establishment determines the quantity, type and source of waste generation inside the premises. It also

finds out the level of disinfection in a hospital and gives an insight to the disposal practices being followed by the hospital staff. In this manner proper attention could be given to dispose of all categories of waste safely with least harm to the environment and also provide specific training to providers to correct improper waste disposal practices.

**(b) Segregation of hospital waste** : Segregation could be defined as 'separation of different types of wastes by sorting'. It denotes the process where wastes of different types, hazardous nature and consistency are separated such that special attention could be given to their disposal. This ensures that the associated risks and the costs of handling the relatively smaller quantities of infectious and hazardous wastes are kept minimal. Accordingly, the non-hazardous waste, which is of general nature and disposed off with municipal garbage, could be dealt with less harm to health care providers and waste handlers. Therefore the best course of action is to segregate the wastes into various categories at the source/point of generation itself. This activity is best undertaken by the 'generator' of the biowaste that is the health care provider himself. The waste categories need to be segregated as per the categories described earlier. This categorisation should be displayed at such locations that most of the people i.e. patients, providers and attendants benefit from it. It would be of more benefit to prepare these instructions in the local languages.

**(c) Collection & Categorisation of waste** : This step in the waste management integrates into segregation of biomedical wastes. The wastes generated need to be collected in proper containers such as sputum mugs, urinals, plastic containers for sharps and so on. It is a good practice to colour code the containers holding different types of hospital waste (Table-2).

In such instances where the detailed colour coding system is not feasible on account of low level of training among the waste handlers it is preferred to use at least three colour codes for ease of understanding. These are -

- Green for general waste (non infectious)
- Red for infectious waste (microbiological, anatomical, pathological and soiled linen)
- Yellow for sharps, plastics and disposables

**Table - 2 : Colour coding and type of containers for disposal of Biomedical waste**

Waste category	Type of Containers	Colour code
Category 1	Plastic bags	Yellow
Category 2	Plastic bags	Yellow
Category 3	Plastic bags/ disinfected container	Yellow/Red
Category 4	Puncture proof plastic containers	Blue
Category 5	Plastic bags	Black
Category 6	Plastic bags/ disinfected containers	Yellow/Red
Category 7	Disinfected containers/ puncture proof containers	Red/Blue/White
Category 8	Not applicable	Not applicable
Category 9	Plastic bags	Black
Category 10	Plastic bags (for solids)	Black

Besides this colour coding, the categories of waste to be disposed should also be mentioned on the containers. If reusable bins/containers are used then they should be cleaned/disinfected properly before being used again. The containers should be of the correct size to hold the desired quantity of waste and devoid of sharp edges for ease of handling. The colour coded containers need to be located at the point of generation of wastes to ensure proper segregation at the source itself.

**(d) Storage of waste :** It means the 'holding of biomedical waste for such period of time, at the end of which waste is treated and disposed of.' The wastes, which are generated in a health care establishment, should ideally be disposed off immediately. However if there is a chance that the waste needs to be stored at some place as per hospital policy, then the place should be safe from tampering and access to rag-pickers. In most instances it is seen that the wastes are stored near the municipal dump pending final disposal and generally the hospitals shake their responsibility off it. This happens more often when the waste disposal is outsourced to a contractor and creates a potentially hazardous situation, due to unscrupulous elements picking up these wastes and recycling them. It is thus absolutely essential that no biomedical waste is stored at any place where it is generated, beyond a period of 48 hours. During the storage period the waste must not be allowed to decay or putrefy.

**The storage containers should have the following characteristics -**

- They should be made of sturdy, hard plastic or metal and should be leak proof and puncture proof.
- They should be of adequate size to avoid overflow with a secure lid and handle and should be colour coded.
- They should not be easily destroyable by rodents & should have smooth, rounded surfaces to hold plastic bags.
- Plastic bags should be large, sturdy and leak proof with no tears. They should line the complete storage bin from

inside and some portion should be outside.

- In case the wastes need to be incinerated along with plastic bag then the bags should be made of non-chlorinated plastics, to avoid environmental pollution.
- Bags should be colour coded, labelled and marked with a biohazard symbol (Fig. -1).
- The storage containers holding sharps, besides being leak proof, should also contain appropriate disinfectants such as sodium hypochlorite solution.

#### **Storage area**

- The storage area should be earmarked and protected from all sides. It should have a clear warning sign and accessible to only authorised persons.
- The facility should have adequate storage space for at least two days with a robust construction and proper drainage system.
- Radioactive wastes should be disposed off separately, in a demarcated area and labelled properly.
- The timings of waste collection should be fixed for specific areas and all the containers should be regularly cleaned and disinfected before reuse.

**Biohazard symbol should be used as label on all containers and vehicles meant for storage and transportation of waste.**

**(e) Transportation of waste :** Transportation is the vital link between the site of waste generation and the final disposal point. It involves movement of the waste generated from the source to interim storage site and its final disposal as per its category. While being transported, it should be secured from the public as well as waste handlers, who have inadequate knowledge of the waste and could be exposed to unnecessary risks. The vehicle used for transportation should be able to achieve the task with minimal effort, spillage or disturbance to the waste. Usually the health care establishments utilise push carts, waste trolleys and wheelbarrows to transport waste inside the hospital premises. Outside the hospital cycle rickshaw or waste van/lorry is used to transport the biomedical waste to its final site of disposal. It should be ensured that the transport used is of robust construction, has adequate space, is leak proof and covered. It should also not allow the mixing of hazardous and non-hazardous waste materials and the frequency and timings of transport should be informed to all sites of generation of waste in a health care establishment. The hospital authorities should keep proper documentation of the frequency of waste transportation.

**(f) Technologies for waste treatment :** Biomedical waste is treated before its final disposal to reduce its bulk and make it free from pathogenic organisms. Treatment changes the physical, chemical or biological characteristics or composition to render the waste non-hazardous to health and environment. The different types of waste treatment technologies are chemical

**Fig. - 1 : Biohazard symbol**



disinfection technology, thermal technology, mechanical technologies and irradiation technology. These are described as follows :

**(i) Chemical disinfection Technology :** It uses chemicals to destroy pathogenic organisms from any inanimate object. Generally the infectious wastes generated in a health care establishment are treated with this method. This method is used to treat the following wastes (Table - 3).

- Sharps contaminated with blood and body fluids
- Instruments, equipment that are used to cut, pierce or enter the natural orifices like needles, syringes and endoscopes
- Contaminated floors, surfaces, clothes, beds, beddings, enamel, crockery and bed pans
- Wet mopping of intensive care units, operation theatres, wards and patient waiting areas.

**Table - 3 : Recommended concentration/dilution of Chemical disinfectants**

Disinfectants	Contaminated condition	Grossly contaminated condition
Sodium hypochlorite 5% available chlorine as liquid bleach	20 ml/L	200 ml/L
Calcium hypochlorite 70% available chlorine	1.4 gm/L	7.0 gm/L
Sodium dichloro- isocyanurate powder	1.7 gm/L	8.5 gm/L
Chloramine 20% available chlorine	20 gm/L	20 gm/L
Tincture of Iodine/ Povidone Iodine	2.5%	2.5%
Ethyl alcohol	70%	70%
Isopropyl alcohol	70%	70%
Glutaraldehyde 2%	2.5%	2.5%
Formaldehyde 40%	5%	10%
Savlon	5%	10%
Dettol 4.8% v/v	4%	10%
Cresol	2.5%	5%

Notes : The choice of disinfectants would depend on factors such as effectiveness, availability and the cost considerations. A contact period of 30 minutes is required for effective disinfection by the disinfectants. Plastics, rubbers and metals could be treated by chemical disinfection, but not all instruments/ waste should be treated in this manner. Some of the waste materials require further disposal after chemical disinfection such as blood, secretions, excreta and body fluids, which have been spilled. It should also be ensured that the wastes, which are to be incinerated, are cleaned of chemical disinfectants, especially halogen compounds to avoid environmental pollution.

**(ii) Thermal technology :** It uses heat to decontaminate instruments and equipment and the temperatures in this process may rise to extremely high levels. Most of the microbes are destroyed at temperatures below 100°C. Thermal technologies could be broadly classified into two groups depending upon the range of temperatures used in the process. There are the low heat systems operating at temperatures below 150°C and high heat systems where temperatures could go upto 5000°C. The

former uses steam or hot water while the latter uses plasma torches or combustion pyrolysis to destroy the waste material. Thermal technologies include autoclave, hydroclave, microwave and incinerators.

**Autoclave :** This is a low heat process in steam at high temperatures is brought into contact with microorganisms for a specified period of time, to disinfect the waste matter completely. Autoclaves are used for sterilisation of reusable medical instruments, microbiology cultures and stock solutions (Fig. -2). The autoclaves used for biomedical waste management are of the following types :

- Gravity displacement type - where air is pushed out of the autoclave by steam under pressure. This system operates at temperatures of 121°C and has a cycle time of approximately 60 - 90 minutes. The material to be sterilised is packed inside and the steam needs to penetrate into the waste wads to ensure effective sterilisation. The system has its disadvantage that there may be pockets of air left within the waste layers, which may reduce the temperatures attained inside thus reducing efficiency of the system.
- Prevacuum type - here vacuum pumps are utilised to evacuate the air in the chamber of autoclave and steam under pressure is pushed in, which is able to penetrate the waste material more thoroughly. This technology thus reduces the cycle time to approximately 30 - 60 minutes and the temperatures attained are upto 132°C.

**Fig. - 2 : Autoclave**





Infectious wastes and bags are placed in the sealed chamber and exposed to the steam at required temperature and for a specified holding time. The wastes are reduced in volume minimally and the contaminating organisms are destroyed after the holding time period. The treatment process is monitored by placing spores of *Bacillus stearothermophilus* at the centre of waste load and checked.

**Notes :** The process has the advantage of having low operating costs, with minimal or non-toxic liquid or air emissions. However the waste volume is not completely reduced and certain categories of wastes such as cytotoxic or pathological wastes cannot be treated through this method. Moreover at times malodorous fumes are generated which need to be controlled. This method could be combined with shredding, grinding or compacting to reduce the volume of the waste material substantially.

**Hydroclave :** This is a steam sterilisation technology in which the steam is used as an indirect heating source thus allowing total dehydration of waste material.

**Fig. - 3 : Hydroclave**

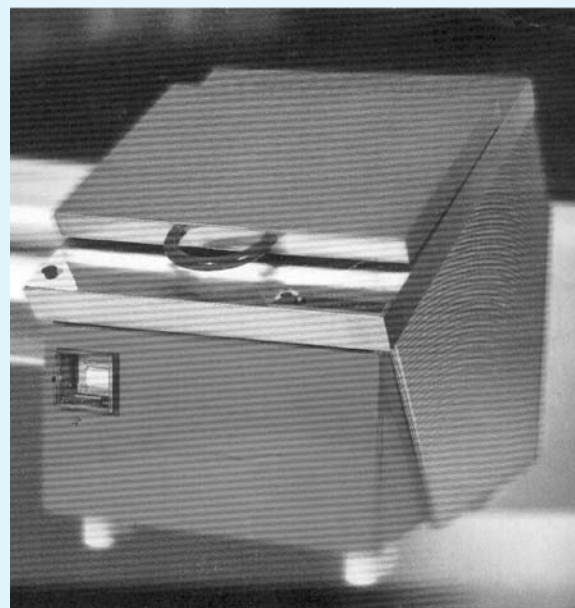


The hydroclave (Fig. - 3) essentially comprises of a double-walled cylindrical container, which is horizontally mounted and has doors at the top and bottom for loading and unloading waste matter. In addition it has mixing arms inside the container that rotate to fragment the waste material. When steam is introduced into the outer jacket/wall it transmits heat rapidly into the wet waste inside the inner chamber. The waste matter is continuously subjected to tumbling motion by the motor mounted mixing arms whereby it produces its own steam and the pressure inside the chamber begins to rise. More steam is introduced from without to achieve the desired temperature and pressure. The holding time for waste is 15 minutes at 132°C or 30 minutes at 121°C. This continuous mixing ensures dehydration of the waste material and almost total dryness can be achieved inside the chamber. The organic components of the waste are hydrolysed and the waste matter is reduced by weight and volume. It has a mechanism of self-unloading after the treatment cycle, by opening the bottom door and reversing the rotation of the mixing arms. The mechanism has the advantage

of not requiring any pre-treatment of waste and complete dehydration of waste is achieved. The reduction in volume and weight makes it easy for final disposal of biomedical waste and the capital costs are low. However this mechanism also gives out malodorous fumes and certain pathological and cytotoxic wastes cannot be treated with this method.

**Microwave :** This low heat system uses microwaves to heat up the waste material from inside, unlike the external heat given in autoclave and hydroclave. Microwaves are electromagnetic waves that lie between the 300 to 300,000 mega hertz range in the electromagnetic radiation spectrum. They are able to penetrate materials and create vibrations in all the dipole molecules such as water in the waste materials. This vibration generates friction, which in turn produces heat to disinfect the waste material (Fig. - 4).

**Fig. - 4 : Microwave**



The waste matter is loaded manually on to a bucket hoist, which loads it into a sealed unit with a shredder, where the waste alongwith its bag is shredded and thereafter moistened with steam. This is then moved continuously by a screw auger, which is heated by series of microwave generators. The heat produced at 95 - 100°C for a holding period of 25 minutes kills all microorganisms without decomposing the material. Emissions are thus reduced and the air inside the microwave is passed through filter to eliminate potentially hazardous airborne pathogens. Wastes such as tubings, needles, syringes are rendered harmless and reduced in volume by 80%. These could then be used as landfill.

**Notes :** The process of microwave treatment renders waste matter acceptable for landfill. The water emissions are negligible; however air emissions are somewhat odorous. It requires a shredder for pre-treatment of waste and the microwaves are unable to penetrate large objects such as amputated limbs and specimens, which are part of anatomical wastes. The operational costs are high and skilled operators

are required.

**Incinerator** : Incineration is a high heat system process of burning combustible solids at a very high temperature in a furnace. It employs combustion of waste material in stages, followed by cleaning of the flue gas through a number of pollution control devices. The end product is devoid of infectious organisms and organic compounds of waste, which is aesthetically acceptable (Fig. - 5).

**Fig. - 5 : Incinerator**



**Classification** : Incinerators are classified into different types depending on the type of fuel consumed, stages of incineration process and mechanism of action. Based on the type of fuel consumed the division could be -

- Conventional incinerator using wood/charcoal
- Electrical incinerator
- Oil fired incinerator using some electricity and diesel oil

Currently the incinerators used are mostly of oil fired variety. This is almost maintenance free, quick to operate and almost smoke free. The incinerators could also be divided into stage I, II & III depending on the incineration process. Stage I involves thermally combusting the waste at temperatures above 800°C in a refractory lined heated chamber. This stage of combustion generates some volatile chemicals. The stage II incinerator is made of special refractory material and uses excess additional air to raise the temperature inside it to 1050 - 1100°C. This destroys the pathogenic organisms alongwith all chemicals/volatiles produced during stage I including harmful gaseous by products like dioxins and furans. Stage III incinerator uses venturi scrubbers, fabric filters, activated carbon and packed bed towers to eliminate polluting gases such as carbon monoxide, HCl, oxides of nitrogen and heavy metals such as mercury.

The hospital wastes that can be incinerated are :

- Surgical, autopsy and obstetrical wastes containing human or animal tissues.
- Dialysis, contaminated ward waste and isolation room waste.
- Blood and its products and microbiological wastes.

**Notes** : All materials of infectious nature are destroyed by incineration. The volume and mass of the waste material is reduced upto 80 - 95% thus ensuring safe final disposal. No pre-treatment such as shredding is required. However incineration process could give rise to air emissions of toxic materials such as particulate matter, acid gases, dioxins and furans. High operational costs and level of skill to operate the system is required. Certain radioactive wastes and aerosols containers cannot be incinerated.

(iii) **Mechanical Technology** : This technology is generally used to change the physical form and characteristic to enable ease of handling of the waste. This technology involves pulverising, compacting or shredding of waste matter to reduce its volume and weight. However this technology cannot be used of its own as final means of waste treatment, but has to be combined with other technologies especially thermal technology. Typically, these processes are carried out either before or after the waste has been decontaminated and are as under :

**Compaction** : Compacting is carried out by a hydraulic ram against a hard surface. Infectious content of waste is not reduced, while the possibility of formation of aerosols of infected matter and spillage of liquids does exist. Also, the process destroys the integrity of containers and requires skills to operate and maintain machines.

**Grinding and shredding** : Waste material is broken down into smaller particles under negative pressure to avoid any spillage outside the chamber. This method is used as a pre-treatment before technologies such as microwave and reduces the waste volume and renders it unrecognisable.

**Pulverisation** : This method consists of putting the waste in a hopper and mixed with large volume of water and bleach solution. The waste is torn to shreds and then fed to an ultra high speed hammer mill with large spin blades which pulverise the matter into small, safe particles. The solids and liquids are then separated and disposed off.

(iv) **Irradiation technology** : This involves exposing the waste matter to ultraviolet or ionising radiation in an enclosed chamber. Decontamination occurs when nucleic acids in the living cells are irradiated. The time of exposure, directness and level of relative humidity in the waste matter determines the efficiency of the procedure. The wastes are reduced by 20% in volume and the disinfected remains could thereafter be mechanically broken down and disposed off in landfill sites. The advantage with this technology is that energy input is minimal and it is used to treat items, which cannot be heated. The emissions are low however trained operators are required for this operation. The wastes need further treatment by another technology prior to disposal. Source of radiation also needs to be properly disposed off after its decay.

**How to select a treatment technology :** The health care establishments have to establish a fine balance between optimum use of consumable material/ disposables and selection of appropriate waste treatment technology. This selection would depend on the categories of waste generated, type of equipment/technologies available on-site and off-site and the appropriateness of the selected technology for a particular waste matter. Disinfection efficiency, automated system, reduction of waste volume/ weight and recovery of recyclable products should be primarily considered. The selected technologies should have minimal polluting effect, discharges and emissions should be low and operational and fuel costs must be low. Usually incineration and autoclaving are the most widely used technologies, the former for anatomical wastes and latter for other infectious wastes, which are not incinerable.

#### (g) Final disposal methods

**General non hazardous wastes :** These could be disposed off by landfilling at sites away from water sources and dwelling units and covered with suitable cover material. The site should be delimited with secure fences and sign postings. The sites could be trenches, sloping terrains or abandoned quarries. Mechanised equipment could be used for spreading the waste and trimming the top soil. Composting using night soil along with the biowaste could be used in trenches and vermiculture methods for garbage from kitchen and cafeteria could also be used. Large quantities of general wastes could be disposed using technologies, which convert the biodegradable wastes into fuel pellets, incinerable matter or biogas.

**Liquid wastes :** Liquid wastes from kitchens, cafeteria and laundry should be treated with a chemical disinfectant followed by neutralisation with reagent. The waste should thereafter be discharged into the sewerage system. In places with no sewerage system, the treated liquid wastes could be drained into soakage pits or waste stabilisation ponds.

**Human anatomical wastes :** These should be incinerated and thereafter the ash can be sent to landfill sites.

**Sharps :** These have the maximum chances of causing injuries due to mishandling and hence need precaution and care during disposal. They are stored in puncture proof containers in disinfectant solutions (e.g. plastic bread boxes), at the site of generation. Major portion of the sharps are needles, which can be cut by needle cutter and contained in 1% bleach solution or destroyed by needle destroyer. Some of the precautions in handling sharps are :

- The health workers employed in the hospital should be vaccinated against Hepatitis B
- Infectious waste handlers should wear heavy duty gloves while dealing with waste matter
- Recapping of needles should be discouraged. Sharps should not be carelessly put at place of work.

After this treatment the residual waste could be sent to a landfill for disposal.

**Microbiology waste :** This is disposed by autoclave, hydroclave, microwave or incineration. The residue could be used in specialised landfills.

**Infectious solid waste :** This is treated by an appropriate thermal technology method and disposed off as general waste.

**Chemical waste :** Chemical waste of non hazardous nature could be disposed off as general wastes or recycled/ reused. Hazardous waste should be treated and discharged into sewers after dilution or incineration.

**Radioactive waste :** These are generated in the Nuclear medicine, Radiotherapy or Radiology departments need to be disposed according to guidelines laid down by the Bhabha Atomic Research Centre, India. Checks also need to be carried out in these establishments for radiation emission, use of protective gears and maintenance of equipment. The solid wastes are disposed by concentration and storage, while liquids by dilution and dispersal.

**Pressurised containers :** These should be disposed off alongwith general waste, in special landfills.

### Administrative issues

Effective hospital waste management is possible when all the components of an organisation are well trained, aware and actively supportive of the programme.

#### Waste Management Policy

All health care establishments should have a comprehensive waste care management policy. The hospital administrators, safety and infection control committees and departments such as nursing, housekeeping, laboratories and maintenance need to be more involved in the waste management activity. The general hospital waste management policy should serve as a mission statement, to inform regulatory and other agencies how the hospital's waste is managed. It should give an overview of the programme while the different departments need to prepare their specific procedures.

The hospital/health care establishment waste management policy should be in consonance with the existing guidelines on the subject by the regulating authority, i.e. the Biomedical Waste (Management and Handling) Rules, 1998 of the Ministry of Environment and Forests, Govt of India and should cover the following aspects :

- (a) A background survey and evaluation of waste generated should be conducted prior to implementation of waste management policy guidelines. Suitable places for placement of equipment should be identified and equipment, materials and supplies procured based on the requirement.
- (b) A Hospital Waste Management Committee could be created, especially in large hospitals. Its members could be Head of hospital, Infection Control committee members/ their representatives, Heads of certain Departments, Chief of nursing staff and representatives from ancillary and support services.
- (c) In smaller hospitals a nodal officer could be identified as in-charge hospital waste management. Key members from the hospital could be designated to assist the nodal officer in discharge of his/her duties.
- (d) The role and functions of each of the member of the hospital waste management committee should be clearly and lucidly defined. Periodic meetings could be held of the functionaries to ascertain the progress of implementation of policy, hear suggestions and discuss any change of plans.



- (e) The steps of waste management for the hospital/ health care establishment alongwith the actions of the various departments should be clearly described in the policy.
- (f) Training of staff on the issues related to hospital wastes and generating awareness regarding the vision and mission of the establishment are critical to the success of the programme.
- (g) Supervision of waste handlers and periodic reinforcement of training is required for efficient and safe management of hospital wastes.

## Summary

Biomedical waste is defined as “any solid, fluid or liquid waste, including its container and any intermediate product, which is generated during the diagnosis, treatment or immunisation of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals and the animal waste from slaughter houses or any other like establishments”. If it is not handled or disposed with proper care, it could be potentially hazardous and have significant public health consequences. Most of the wastes generated in a hospital (around 85%) are non-hazardous, while 10% are infective including sharps and pathological waste and the remaining 5% are non-infectious but hazardous such as chemical, pharmaceutical or radioactive wastes. The quantity of waste generated in a hospital in developed countries is 1 to 5 kg/bed/day with variations among countries, hospitals and specialities and in India; it is upto 1 to 2 kg/bed/day. As per the Biomedical waste (Management and Handling) rules 1998, under the Environment Protection Act of India, proper management of biomedical waste is a statutory requirement and these rules have been elaborated in the Gazette notification of the Ministry of Environment and Forests, Govt of India dated 20 Jul 1998.

As per WHO, the biomedical wastes could be classified into eight categories on the basis of the type of waste and the risk of transmission of infectious material in them. They are General waste (domestic), Pathological, radioactive, Chemical, Infectious, Pharmaceutical wastes, Sharps and pressurised containers.

The biomedical wastes generated in a health care setting could be rendered safe by following certain principles of infection control like developing policies for bio-waste management as well as rationale patient management; by taking measures such as universal safety precautions, hand washing and use

of disinfectants and most importantly by reduction and proper segregation of wastes. The important steps to be followed for management of biomedical waste are survey of wastes generated; segregation of the hospital wastes at the source itself; collection & categorisation of waste into colour coded containers; storage of wastes for short period of time till the time of transportation in proper containers and in earmarked areas, displaying the biohazard symbol; transportation of waste to the final disposal point in proper vehicles by earmarked staff with protective gear; treatment of waste before its final disposal to reduce its bulk and make it free from pathogenic organisms by chemical disinfection, thermal technology (like autoclave, microwave, UV, IR and incinerators), mechanical technology or by irradiation and final disposal of the waste by incineration or by disposing off in a secured landfill.

## Study Exercises

**Long Question :** Describe the procedure of Biomedical waste management in a 100 bedded hospital / health care setting.

**Short Notes :** (1) Biomedical waste categorisation (2) Segregation of Waste (3) Final Disposal of Biomedical wastes (4) Incineration (5) Hazards of Biomedical waste

### MCQs

- The percentage of Biomedical waste generated in a hospital which is non-hazardous is (a) 85% (b) 50% (c) 25% (d) 15%
- The quantity of waste generated in a hospital in developed countries is (in kg/bed/day) (a) 10-15 (b) 5-10 (c) 1-5 (d) >30
- According to the categories of bio-medical waste, waste sharps come under which category? (a) 3 (b) 4 (c) 5 (d) 6
- According to the categories of bio-medical waste liquid waste comes under which category? (a) 8 (b) 7 (c) 5 (d) 6
- According to the categories of bio-medical waste incineration ash comes under which category? (a) 8 (b) 7 (c) 9 (d) 10
- The recommended treatment option for disposal of bio-med wastes with colour-coding of Black is (a) Secured Landfill (b) Incineration (c) Chemical Disinfection (d) None
- Category of bio-med wastes that is not colour-coded as Black (a) 5 (b) 8 (c) 9 (d) 10

**Answers :** (1)a; (2)c; (3)b; (4)a; (5)c; (6)a; (7)b.



Kunal Chatterjee

*House*, as per the New Oxford Dictionary, is defined as a building for human habitation, especially one that is lived in by a family or a small group of people and consists of a ground floor and one or more upper storeys. Housing is described as houses and flats considered collectively. For the purpose of public health aspects, housing would also include adjacent walks, paths, streets, open space, shops, utilities, health centres, schools and administrative services. The density of population in an area, number of persons per room and physical condition of the dwellings are also considered when the effect of housing on the health of a community is taken.

The last two centuries have seen a rapid rise in industrial economies in the World with consequent changes in the distribution of population resulting from migrations, movements, establishment of new settlements and temporary camps in different countries. The increase in number of people results in increase in demands on the local civic amenities. Public health infrastructure in cities is unable to cope with this rise alongside the natural rise in the population residing in it. Population movements thus result in overcrowding, uncontrolled settlements and poor environmental conditions in the urban areas.

### Housing Conditions in the World

**Developing Countries** : Most of the developing countries have a problem of overcrowding and the living conditions are inadequate, forcing the urban dwellers into periurban slums. Cities in Southern and south-eastern Asia, African continent and Latin America variously have deplorable living conditions in these slums, which lack the basic housing and sanitation facilities. As a result of these conditions compounded by malnutrition, lack of education and inadequate medical and social services, communicable diseases become the predominant cause of morbidity. The plight of the vulnerable groups in these slums such as the children, elderly and women is terrible with the health care indicators grossly unsatisfactory. Infant mortality rates are high, high crime rates and other malevolent behaviour are often seen in the community and children may be abandoned by the parents due to poverty. These places are also the ideal grounds for breeding social unrest.

**Developed Nations** : In the recent decades the numbers of people without adequate shelter have increased even in the developed or relatively affluent countries. Rising economic costs of living, unemployment, inflation of commodity prices have created hard times for people in these countries and forced them out of their homes. The developed countries and their public health departments have to increasingly spend on the creating shelters and provide for such people. When these social safety nets are broken or wilt under pressure of increasing destitute population, the vulnerable people suffer the most and are turned homeless. These nations also have a problem of migrants or refugees pouring in from neighbouring

countries thereby affecting the already groaning public health infrastructure. As a consequence to this, a rise in mental health problems, substance abuse, alcoholism and crimes is noticed. Rising land prices and the need to provide accommodation for all its dwellers have also seen a proliferation of high-rise, high-density apartments. These create problems such as tensions attributable to living too close to neighbours, inadequate playing space for children and poor civic services in these areas.

**Displaced Populations** : The refugee population and the internally displaced people live in temporary settlements in developing countries. They depend on civic services of the nearby areas, which are themselves below par. Countries in Asia, Latin America and Africa are home to millions of refugees who have arrived due to displacement resulting from natural calamities, civil strife or wars. Their housing conditions are worse than periurban slums with inadequate health services, precarious supplies and poor record of safety and security of these people. The refugee population are often threatened by hostilities and suffer from various communicable diseases prevalent in poor camp living conditions. The children and vulnerable people exhibit signs of malnutrition and stress disorders due to trauma of displacement.

### Housing Standards

Housing standards vary from country to country and are not confined to merely calculating the per capita space and floor space. Socio-economic characteristics such as family income, family size, composition, living standards, and cultural factors are also taken into consideration in determining housing standards. The Environmental Hygiene Committee has established minimum standards required to be maintained by building regulations in India, of which the important ones are:

**Site** - elevated, not subject to flooding, away from vector breeding places and nuisance, soil should be dry and safe for founding the structure. Subsoil water should be below 10 feet.

**Set back** - as open space around house with no obstruction to lighting and ventilation

**Floor** - pucca, impermeable, easily washable, smooth and free of cracks and crevices and damp-proof.

**Walls** - reasonably strong, low heat capacity, not easily damaged and should not harbour rats or vermin

**Roof** - height not less than 10 feet with low heat transmittance coefficient

**Rooms** - at least two with the number increasing according to family size

**Floor area** - should be 100 sq. ft for one person and at least 120 sq ft for more than one person

**Cubic space** - at least 500 c.ft per capita; optimum is 1000 c.ft.

**Windows** - at least 2 windows per living room if the room is not provided mechanical ventilation and artificial lighting, placed at a height of not more than 3 feet above ground, window area should be 1/5<sup>th</sup> of floor area.

**Lighting** - daylight factor exceeding 1% over half floor area.

**Kitchen** - should be separate for every dwelling, protected against dust and smoke, provided with storage space, water supply, drainage and adequately lighted.

**Sanitary privy** - in every house and readily accessible.

**Garbage and refuse** - should be removed daily and sanitarily disposed.

**Bathing and washing facilities** - should be exclusive to the house.

**Water supply** - should be safe and adequate.

**Rural Housing Standards** : At least two living rooms, ample verandah space, built up area should not exceed one-third total area, separate kitchen with paved sink or platform for washing utensils, sanitary latrine in the house, sanitary well or tube well within quarter mile of house, cattle sheds at least 25 feet from dwelling houses and adequate arrangement for disposal of waste water, refuse and garbage.

**Housing Standards for Displaced Populations** : Temporary shelter in existing buildings should be provided to people as per the following guidelines :

- People living on beds or mats should have minimum of 3.5 sq. m of floor area or 10 cu m of air space.
- Beds or mats separated by a minimum distance of 0.75 m.
- Buildings should have emergency exits and fire escapes and people educated in fire safety drills.
- One wash basin provided for every 10 people, separate benches for men and women.
- One shower head is needed for every 50 people in temperate climates and one for every 30 people in hot climates.
- Water flushed toilets may be made available in existing buildings. Outside latrines should be located within 50 m of the building, but at least 20 m away from kitchen, dining hall and water supply.
- One refuse bin of capacity 50-100 litres with tightly fitting lid should be provided for every 12-15 people.

The guidelines for those people who are housed in tents or makeshift shelters are as below :

- Site should be located above flood level and away from excessive vegetation
- Camps should not hold more than 10000-12000 people.
- Drainage ditches should be constructed to drain rain water away from shelters and storage areas. Stagnant water collections should be drained or filled up.
- Shelters should be arranged in rows of 10-12 on both sides of road, at least 2 m away from road edges. The road should be at least 10 m wide for easy access of vehicles and distance between tent pegs should be 8 m.
- Tents or prefabricated units could be used as shelters. Where plastic sheets are used, one piece 4 metres by 6-7 metres should be provided to one household.
- No one should have to walk more than 500 m to water point and there should be at least one water point for every 250 people.
- At least one toilet should be provided per 20 people with separate provisions for men and women. Requirement of children and elderly should be accordingly catered for suitably.

- Accommodation arrangements should be separately catered for children, with provision for adults to stay with them. These children may be disoriented and frightened and may have special nutritional needs, which should be adequately looked after. Feeding and nutrition rehabilitation units for special needs should be provided with up to 15-30 litres of potable water per bed per day.

**Housing and the Governmental policy** : In India the National Family Health Survey (NFHS) collects data on housing condition of people. The data from NFHS 3 shows that only about 26% of rural India lives in pucca houses, with only 28% having access to piped drinking water and 26% have access to toilet facilities. While housing is a state subject but the Union Govt formulates policy for housing especially pertaining to weaker sections, and the schemes are implemented at the state level. A separate Ministry of Works and Housing has been created as early as 1952 to implement the Government Housing Programmes. These programmes comprise of the public sector housing for governmental employees and social housing schemes for low and middle income groups.

States have established statutory housing boards for promoting various housing schemes. The National Housing Policy is enunciated in the national five year plans and the eighth and subsequent plans consist of creating an enabling environment for housing activity by eliminating various constraints and providing special assistance to the disadvantaged groups including the rural and the urban poor, the scheduled castes and tribes, physically handicapped, widows and single women.

## Ventilation

The ability of an individual to comfortably accommodate himself in a house depends upon numerous factors in the physical environment of which an important one is the ventilation provided in his living and working area. The dictionary meaning of ventilation is 'intentional movement of air from outside a building to inside'. Adequate ventilation improves comfort levels of an inhabitant. However an excess of ventilation may result in discomfort due to cooling of the indoor air temperature, which is a not desirable, particularly in cold and dry or damp area in the country. Ventilation is one of the most important factors for maintaining acceptable indoor air quality in a building.

Ventilation does not merely mean flow of air in a room or replacement of vitiated air inside the room by fresh air being blown from the windows, doors or ventilators. It also implies control of the quality of air flowing inside the room by modifying the temperature, humidity and purity to provide an environment, which is thermally controlled and comfortable, gives a sense of well-being and reduces the risk of transmission of airborne diseases.

**Ventilation air** : The air used to provide acceptable indoor air quality is called as ventilation air. It removes the bad odours from inside building spaces due to presence of humans/ animals. This air is delivered either naturally or by means of mechanical ventilation and these means could increase or decrease the temperature of air or change its moisture content depending on the requirement inside the building. The rate at which outdoor air replaces indoor air is described as 'air

exchange rate'. When this rate is low, the pollutant levels in an environment increase.

**Ventilation standards** : These standards have largely been fixed on the area and amount of ventilation air required to achieve a sense of freshness in a room and remove body odours. These standards are described as :

**(a) Floor space** : This describes the product of the length and breadth of the room and is considered an important parameter for ventilation. The optimum floor space requirements per person vary from 50 to 100 feet.

**(b) Cubic space of area** : This has been used in the past and earlier prescriptions were of a fresh air supply of 3000 cu feet of air per person per hour. Since the products of respiration tend to accumulate in the lower levels, hence higher heights of rooms, beyond 12 feet, are ineffective from the point of view of ventilation and are not taken into account for establishing these standards. Current standards consider 1000 to 1200 cu feet per person per hour to be sufficient for generating comfort.

**(c) Air change** : It is a better standard for ventilation than cubic space requirement. If the cooling power of air arising out of adequate air changes is satisfactory, then even with a dip in the oxygen content of air upto 18 percent no deleterious effects would occur on human physiology. The recommended number of air changes in living room should be 2 to 3 in an hour, while in work rooms and assemblies the air changes could be 4 to 6 per hour. Higher changes could result in creation of air drought, which could reduce the comfort levels and hence should be avoided.

#### Types of ventilation

**Infiltration** : In infiltration the outdoor air flows into the house through openings, joints and cracks in walls, floors, ceilings and around windows and doors. Commercial buildings and sometimes residential areas are kept under slightly positive pressure relative to the outdoors to reduce infiltration. This helps in moisture management and humidity control inside the rooms.

**Natural ventilation** : This occurs when the air in a space is changed with outdoor air without the use of mechanical systems such as fans or circulators. Natural ventilation is mostly achieved through operable windows but could also be achieved through temperature and pressure difference between spaces. In this method of ventilation reliance is placed on the forces of nature such as wind, ambient temperature and air pressure. These are best utilised by proper location of windows, doors, ventilators and skylights. There are two types of natural ventilation occurring in buildings as described below :

**(a) Wind driven ventilation** : Pressures generated by wind are usually high and majority of the buildings rely mostly on this method. When wind blows through a room it is termed as 'perflation' and on its tail end it generates a suction effect known as 'aspiration'. These phenomena are seen when the doors and windows face each other and provide cross ventilation. The air has a capability to diffuse through narrow openings and spaces and thus may ventilate the rooms in addition to passage through the doors and windows.

The impact of wind on a building affects ventilation and

infiltration rates through it and the associated heat losses and gains. It creates areas of positive pressure on the windward side of the building and negative pressure on the leeward side and the sides of the building. Thus the shape of the building is crucial in creating wind pressures that will drive air flow through its apertures. Simple building shapes improve the ventilation while complex shapes create more turbulent air flows.

Wind driven ventilation has several benefits. Being a naturally occurring force it is readily available, economic to implement, could be controlled by users and achieves great magnitude and effectiveness. However it is limited by its unpredictability in speed and directions, which vary constantly; the air quality is not controlled and could introduce pollutants inside a room and may create draughts and discomfort.

**(b) Stack driven ventilation** : When there is temperature difference between two adjoining volumes of air, the warmer air will have lower density and be more buoyant and thus will rise above the cold air, creating an upward stream. In a house, such kind of effect, known as 'stack effect' happens in a fire place in a forced/active manner, while it occurs passively in spaces without direct access to outdoors. To have optimum ventilation due to stack effect in a building, the inside and outside air temperatures must be different, such that the warmer indoor air rises and escapes the building through the higher apertures, while colder, denser air from the exterior enters the buildings through lower level openings. The greater this temperature difference the greater the stack effect.

This kind of ventilation does not rely on wind but can take place in hot, summer days also; the air flow is relatively stable with a greater control in choosing the areas of air intake. However it is limited due to lower magnitude of ventilation, reliance on temperature differences, restrictions to the ventilation due to building designs and possibility of introducing polluted external air inside the room. Such type of ventilation is generally used in mills, boiler rooms, warehouses and industrial plants.

Natural ventilation can be an effective means when both the wind driven and stack ventilation can be used to augment each other's effect in an optimal manner. However its chief drawback is that it is not possible to regulate the velocity of incoming air or adjust its temperature and humidity.

**Mechanical ventilation** : This kind of ventilation is used where natural ventilation does not improve the indoor air quality or increases the chance of bringing contaminants inside the building. Such ventilation systems are usually established in places with high humidity to remove the excess moisture from ventilation air. Commonest forms of mechanical ventilation are:

**(a) Ceiling fans, table or floor fans** : These are used to circulate air within a room for the purpose of reducing the perceived temperature, because of evaporation of perspiration from the skin of occupants. These fans do not introduce outside air inside the room, hence do not provide ventilation in the strictest sense. Air-coolers are used in hot & dry conditions in the developing countries and are quite popular in India. They comprise of a chamber whose walls are made of straw, which is kept cool by pouring water on to the walls and evaporation



of water due to the warm air outside. A cool environment is thus created inside the chamber and a fan kept in this chamber blows cool air inside the room.

**(b) Use of exhausts** : Here the indoor air is extracted out with the help of mechanically driven fans. These are used in combination with the doors and windows since exhaustion of air outside the room creates a vacuum and this needs to be replaced by fresh air, which enters the room through windows, doors and other inlets. Exhausts are useful in industries especially where excess heat is generated. In residential areas they are placed in kitchens and bathrooms for extricating smoke or odours. Usually exhausts are placed near the roof to extricate hot air, which rises up in a room. The exhaust blades should be cleaned & well maintained to ensure their long life.

**(c) Plenum ventilation** : This is a process where air is blown inside a room by the use of fans and it enters through ducts. This kind of ventilation creates a positive air pressure inside the room. When this mechanism is combined with exhaust mechanism it creates 'balanced ventilation'. Such kind of plenum ventilation is also being used, alongwith air-conditioners, to supply air inside the building such that fresh air is circulated to leave out the odours and pollutants.

**(d) Air conditioning** : It is a system, which provides a combination of cooling, ventilation and control of humidity for a building where it is installed. The system has a refrigerant providing cooling through a 'refrigeration cycle'. This cycle comprises of four elements to provide the cooling effect. A *compressor* provides compression for the system. This causes the cooling refrigerant vapour to heat up. Next a condenser cools the vapour by exchanging its heat with outside air and the vapour condenses into a fluid. The condensed fluid enters the next element called as *evaporator-dehumidifier* where in the pressure drops and fluid evaporates and in the process draws heat from the surroundings, thus cooling it. The vapour is then returned to the compressor and pushed inside the room by a fan. Since the evaporator operates at a temperature below dew-point, moisture is collected at this end, which falls into a pan and is removed by a pipe outside.

Air conditioners are installed inside the residential areas or commercial complexes as either stand-alone systems or a part of central air-conditioning systems. Central air-conditioning system should be installed at the time of construction, since they are difficult to retrofit or install in a building, which was not designed to receive it, due to the large ducts needed to carry the air to the specific areas. These ducts must be carefully maintained to prevent growth of pathogenic bacteria in them. Another system of air-conditioning gaining popularity in residential areas and smaller commercial buildings is the split air-conditioning where the fan coils are connected to remoter condenser unit using piping instead of ducts.

**Demand controlled ventilation** : This is another technique of ventilation, which reduces the energy consumption in a building, while maintaining adequate air quality. Here, instead of a fixed air replacement rate, carbon-dioxide sensors dispersed inside the building areas are used to control the ventilation rate dynamically, based on emissions of actual building occupants.

**HVAC** : HVAC stands for 'Heating, Ventilation and Air-Conditioning'. This system is important in those places where humidity and temperature must be closely regulated while maintaining healthy and safe conditions inside buildings. These three terms are used in combination to ensure thermal comfort, accessible indoor quality and reasonable installation, operation and maintenance costs. HVAC systems determine the room air distribution i.e. how air is delivered to and removed from room spaces.

**Ventilation requirements in different areas** : Ventilation is used to remove unpleasant smells and excessive moisture, introduce outside air and to keep interior of a building air circulating to prevent stagnation of the interior air. Ventilation requirements vary from urban areas to rural areas and also post disaster situations. In urban areas the requirements differ between bungalows, high-rise buildings, slums and shanty settlements. The factors which determine the difference in ventilation are :

- Type of buildings, bungalows, high rise buildings, temporary shelters, tents, camps, hutments
- Size of the buildings and the floor areas.
- Type of roof inside the buildings such as cement-concrete, thatch, mud, tins or indigenous material, presence of false ceilings etc.
- Locally prevalent wind directions
- Number of persons occupying the room
- Proximity to commercial or industrial areas
- Sanitation of the surrounding area
- Nature of work being carried out inside the buildings
- Geographical locations such as closeness to sea, large water bodies, hilly areas

In urban areas, due to rise in ambient temperatures in the day and obstruction to wind movement due to building constructions, the residents use mechanical cooling devices and air-conditioning systems. Similarly in commercial and industrial establishments a combination of natural and mechanical ventilations is being used. Energy efficient systems are utilised in large buildings and storage areas. Urban slums are overcrowded and do not have free air circulation in most places. The houses are constructed close by each other and numerous small scale industries develop within these settlements. Most of the slum dwellings have erratic power supply in the developing countries and hence the dwellers largely rely on natural ventilation or the use of fans, circulators or air-coolers.

In rural areas the houses are mostly single storied and well spread out and thus air circulation around houses is not obstructed. Overcrowding does not usually exist and there is natural ventilation in plenty and hence the dwellers rarely use fans or air-coolers. Natural ventilation is however not able to prevent the odours arising out of animals residing nearby houses and improper disposal of garbage and solid wastes.

In post-disaster situations, the displaced persons need to be accommodated in shelters and camps constructed or occupied temporarily. These places are usually overcrowded and require proper sleeping arrangements and disposal of wastes of the dwellers. The odours and insanitation generated due to this



situation is compounded by the devastation caused by the calamity in the surroundings. There is usually a breakdown of power supply in the early days following the disaster. In such temporary shelters, arrangements should be made to ensure plenty of natural ventilation from the doors and windows and augmented by mechanical fans and coolers. However care must be taken to ensure that the air infiltration does not create a draught, especially in coastal areas and hills during cold or rainy weather conditions.

## Summary

**Housing** is described as houses and flats considered collectively. For the purpose of public health aspects, housing would also include adjacent walks, paths, streets, open space, shops, utilities, health centres, schools and administrative services. The effect of housing conditions on the health of human beings varies with the type of community and the prevalent socio-political conditions in the country. It has been shown that the people who live in bad housing and poor environmental conditions in any area experience higher mortality rates and are generally less healthy than those who live in districts where housing is good. People living in houses with poor water supply and inadequate means of excreta disposal and fly control report higher incidence of diarrhoeal diseases. Poor domestic surroundings could result in breeding of disease vectors.

Rural housing has few characteristics like Inadequate drainage of standing water around dwellings, littering with artificial containers and water stagnation in fields, Improper solid waste disposal and the cohabitation of cattle and pet animals creating ideal grounds for transmission of communicable diseases among the rural inhabitants. The settlements, which house people undergoing a social and economic change, often from a rural to urban way of life, to integrate with the urban society, are termed as transitional housings. The transitional house dwellers are affected by rapid urbanisation in the towns and cities and their houses are converted into substandard dwelling units. These shanty towns need to be either replaced with good housing, which provide complete services or the current dwellers could be provided with alternate land areas at low costs to construct their own homes. This could generate a sense of integration among the dwellers with the urban areas and decrease the public health impact of their temporary settlements. During natural and civil disasters, governments and international agencies need to provide comprehensive services to cover the provision of shelter, sanitation, food, epidemiological surveillance and medical care for displaced populations.

Housing standards vary from country to country and are not confined to merely calculating the per capita space and floor space. Socio-economic characteristics such as family income, family size, composition, living standards and cultural factors are also taken into consideration in determining housing standards. The Environmental Hygiene Committee has established minimum standards required to be maintained by building regulations in India.

The data from NFHS 3 shows that only about 26% of rural India lives in pucca houses, with only 28% having access to piped drinking water and 26% have access to toilet facilities.

While housing is a state subject but the Union Govt formulates policy for housing especially pertaining to weaker sections, and the schemes are implemented at the state level. States have established statutory housing boards for promoting various housing schemes. The National Housing Policy is enunciated in the national five year plans and the eighth and subsequent plans consist of creating an enabling environment for housing activity by eliminating various constraints and providing special assistance to the disadvantaged groups including the rural and the urban poor, the scheduled castes and tribes, physically handicapped, widows and single women.

**Ventilation** does not merely mean flow of air in a room or replacement of vitiated air inside the room by fresh air being blown from the windows, doors or ventilators. It also implies control of the quality of air flowing inside the room by modifying the temperature, humidity and purity to provide an environment, which is thermally controlled and comfortable, giving a sense of well-being and reducing the risk of transmission of airborne diseases. Ventilation standards have largely been fixed on the area and amount of ventilation air required to achieve a sense of freshness in a room and remove body odours. The optimum floor space requirements per person vary from 50 to 100 feet and cubic space of 1000 to 1200 cu feet per person per hour. The recommended number of air changes in living room should be 2 to 3 in an hour, while in work rooms and assemblies the air changes could be 4 to 6 per hour. HVAC (Heating, ventilation and air-conditioning) is important in those places where humidity and temperature must be closely regulated while maintaining healthy and safe conditions inside buildings.

## Study Exercises

**Long Question :** Enumerate the effects of improper Housing conditions on Health. Discuss the standards laid down for Housing.

**Short Notes :** (1) Criteria for Healthful Housing (2) Public Health aspects of Rural Housing (3) Steps to be taken by Public Health authorities to provide Housing for displaced during disasters (4) Overcrowding (5) Transitional housing (6) Housing policy in India (7) Ventilation standards (8) HVAC

### MCQs

1. As per the Housing standards recommended by The Environmental Hygiene Committee, Subsoil water should be below (in feet) (a) 2 (b) 5 (c) 10 (d) 20
2. As per the Housing standards recommended by The Environmental Hygiene Committee, height of the roof should not be less than (in feet) (a) 2 (b) 5 (c) 10 (d) 20
3. The minimum Floor area in a house required for one person should be (a) 100 sq. ft (b) 200 (c) 250 (d) 50
4. The minimum Cubic space in a house required for one person should be (in Cu ft) (a) 100 (b) 200 (c) 250 (d) 500
5. In a House, window area should be \_\_\_\_\_ of floor area (a)  $1/5^{\text{th}}$  (b)  $2/5^{\text{th}}$  (c)  $1/3^{\text{rd}}$  (d)  $1/2$
6. The recommended number of air changes in living room should be \_\_\_\_\_ (per Hour) (a) 1-2 (b) 2-3 (c) 3-4 (d) 4-5

**Answers :** (1) c; (2) c; (3) a; (4) d; (5) a; (6) b.

## Air Pollution

Clean air is considered to be a basic requirement of human health and well-being. However, air pollution continues to pose a significant threat to health worldwide. According to a WHO assessment of the burden of disease due to air pollution, more than 2 million premature deaths each year can be attributed to the effects of urban outdoor air pollution and indoor air pollution (caused by the burning of solid fuels). More than half of this disease burden is borne by the populations of developing countries. Source of major air pollutants and their effects on man are as mentioned in the Table - 1 and 2.

## Indicators of air pollution

The WHO Air quality guidelines are designed to offer global guidance on reducing the health impacts of air pollution. They recommend measurement of selected air pollutants, viz., particulate matter (PM), ozone (O<sub>3</sub>), nitrogen dioxide (NO<sub>2</sub>) and sulfur dioxide (SO<sub>2</sub>), applicable across all WHO regions. In addition, "smoke (soiling) index" and "coefficient of haze" are also commonly used indicators. In India, the Central Pollution Control Board through its National Air Quality Monitoring Programme monitors air quality in all major cities.

**Particulate Matter** : PM affects more people than any other pollutant. It consists of a complex mixture of solid and liquid particles of organic and inorganic substances suspended in the air. The particles are identified according to their aerodynamic diameter, as either PM<sub>10</sub> (particles with an aerodynamic diameter smaller than 10 µm) or PM<sub>2.5</sub> (aerodynamic diameter smaller than 2.5 µm). The latter are more dangerous since, when inhaled, they may reach the peripheral regions of the bronchioles, and interfere with gas exchange inside the lungs.

**Table - 1 : Major Air Pollutants and their Health Hazards**

Pollutant	Source	Pathological effects on man
Sulphur dioxide	Colourless gas produced by coal and oil combustion and certain industrial sources	Respiratory irritant, aggravates asthma and other lung and heart diseases, reduces lung function.
Nitrogen oxides	Brownish orange gas produced by motor vehicles and combustion at major industrial sources	Inhibits cilia action so that soot and dust penetrate far into the lungs.
Hydrogen sulphide	Refineries, chemical industries and bituminous fuels	Causes nausea, irritates eyes and throat.
Carbon monoxide	Burning of coal, gasoline, motor exhausts	Reduces oxygen carrying capacity of blood.
Hydrogen cyanide	Blast furnace, fumigation, chemical manufacturing, metal plating, etc.	Interferes with nerve cells, produces dry throat, indistinct vision, headache, etc.
Ammonia	Explosives, dye making, fertilizer plants and lacquers	Inflames upper respiratory passages.
Phosgene or carbonyl chloride	Chemical and dye making	Induces coughing, irritation and fatal pulmonary edema.
Aldehydes	Thermal decomposition of oils, fats, or glycerols	Irritate nasal and respiratory tracts
Arsines	Processes involving metal or acids containing arsenic soldering	Damage red cells in blood, kidneys and cause jaundice
Suspended particles (ash, soot, smoke, etc.)	Solid or liquid particles produced by combustion and other processes at major industrial sources (e.g. steel mills, power plants, chemical plants, incinerators and almost every manufacturing process)	Respiratory irritants aggravate asthma and other lung and heart diseases (especially in combination with sulphur dioxide); many are known as carcinogens. Toxic gases and heavy metals absorb onto these particulates and are commonly carried deep into the lungs. Cause emphysema, eye irritation and possibly cancer
Lead	Very small particles emitted from motor vehicles and smelters	Toxic to nervous and blood-forming systems, in high concentrations can cause brain organ damage.
Ozone	A colourless gas formed from reactions between motor vehicle emissions and sunlight. It is the major component of smog	Respiratory irritant, aggravates asthma and other lung and heart diseases, impairs lung functions. Ozone is toxic to plants and corrodes materials.

**Table - 2 : Major natural and man-made pollutant sources.**

Contaminant	Man-made sources	Natural sources
SO <sub>2</sub>	Fossil fuel combustion	Volcanoes, reactions of biological emissions
H <sub>2</sub> S and organic sulphides, CO	Chemical processes, sewage Auto exhaust, general combustion	Volcanoes, biological processes in soil and water, forest fires, photochemical reactions
NO, NO <sub>2</sub>	Combustion	Biological processing in soil, lightning
NH <sub>3</sub>	Waste treatment, combustion	Biological processes in soil
N <sub>2</sub> O	Small amounts from combustion	Biological processes in soil
CH <sub>4</sub>	Combustion, natural gas	Biological process in soil and water.
Isoprene and terpenes	None	Biological plant Emission
Total non CH <sub>3</sub> hydrocarbons	Combustion	Biological process in soil and vegetation
CO <sub>2</sub>	Combustion	Biological processes
CH <sub>3</sub> Cl	Combustion	Oceanic biological processes
HCl, Cl <sub>2</sub>	Combustion, Cl manufacturing	Atmospheric reactions of NaCl volcanoes

The guideline values (upper acceptable limits) are:

- PM<sub>2.5</sub> 10 µg/m<sup>3</sup> annual mean; 25 µg/m<sup>3</sup> 24-hour mean
- PM<sub>10</sub> 20 µg/m<sup>3</sup> annual mean; 50 µg/m<sup>3</sup> 24-hour mean

The major components of PM are sulfate, nitrates, ammonia, sodium chloride, carbon, mineral dust and water. Particles may be classified as primary or secondary, depending on how they are formed. *Primary particles* are emitted into the atmosphere through man-made (anthropogenic) and natural processes including combustion of fuels in vehicle engines or in households; industrial activities; erosion of road surfaces by road traffic and abrasion of brakes and tyres; and work in caves and mines. *Secondary particles* are also emitted largely from anthropogenic sources, but they are formed in the air, usually by chemical reactions between gaseous pollutants. Particles produced by outdoor sources (industry and traffic) penetrate easily into indoor spaces and add to the burden of PM emitted indoors.

Chronic exposure to particles contributes to the risk of developing cardiovascular and respiratory diseases, as well as of lung cancer. In developing countries, exposure to pollutants from indoor combustion of solid fuels on open fires or traditional stoves increases the risk of acute lower respiratory infections and associated mortality among young children; indoor air pollution from solid fuel use is also a major risk factor for chronic obstructive pulmonary disease and lung cancer among adults.

**Ozone (O<sub>3</sub>)** : Ozone at ground level - not to be confused with the ozone layer in the upper atmosphere - is one of the major constituents of photochemical smog. It is formed by the reaction with sunlight (photochemical reaction) of pollutants such as nitrogen oxides (NO<sub>x</sub>) from vehicle and industry emissions and volatile organic compounds (VOCs) emitted by vehicles, solvents and industry. The highest levels of ozone pollution occur during periods of sunny weather. Excessive ozone in the air can have a marked effect on human health. It can cause breathing problems, trigger asthma, reduce lung function and cause lung diseases. Guidelines values for upper limits are: 100 µg/m<sup>3</sup> (8-hour mean)

**Nitrogen dioxide (NO<sub>2</sub>)** : As an air pollutant, NO<sub>2</sub> has several correlated activities: -

- At short-term concentrations exceeding 200 µg/m<sup>3</sup>, it is a toxic gas which causes significant inflammation of the airways.
- NO<sub>2</sub> is the main source of nitrate aerosols, which form an important fraction of PM<sub>2.5</sub> and, in the presence of ultraviolet light, of ozone.

The major sources of anthropogenic emissions of NO<sub>2</sub> are combustion processes (heating, power generation, and engines in vehicles and ships). Epidemiological studies have shown that symptoms of bronchitis in asthmatic children increase in association with long-term exposure to NO<sub>2</sub>. Reduced lung function growth is also linked to NO<sub>2</sub>. The upper limits of guideline values are: 40 µg/m<sup>3</sup> (annual mean) and 200 µg/m<sup>3</sup> (1-hour mean).

**Sulfur dioxide (SO<sub>2</sub>)** : SO<sub>2</sub> is a colourless gas with a sharp odour. It is produced from the burning of fossil fuels (coal and oil) and the smelting of mineral ores that contain sulfur. The main anthropogenic source of SO<sub>2</sub> is the burning of sulfur-containing fossil fuels for domestic heating, power generation and motor vehicles. The use of tall chimneys at power stations has caused widespread dispersion of SO<sub>2</sub> affecting populations located far away from the sources. In many developing countries, the usage of coal high in sulfur is increasing. SO<sub>2</sub> can affect the respiratory system and the functions of the lungs, and causes irritation of the eyes. Inflammation of the respiratory tract causes coughing, mucus secretion, aggravation of asthma and chronic bronchitis and makes people more prone to infections of the respiratory tract. Hospital admissions for cardiac disease and mortality increase on days with higher SO<sub>2</sub> levels. When SO<sub>2</sub> combines with water, it forms sulfuric acid; this is the main component of acid rain which is a cause of deforestation. The upper limit of acceptable values are 20 µg/m<sup>3</sup> (24-hour mean) and 500 µg/m<sup>3</sup> (10-minute mean).

#### Prevention

Public health recognizes air pollution as an important determinant of health, especially in developing countries. There

is significant inequality in the exposure to air pollution and related health risk; air pollution combines with other aspects of the social and physical environment to create a disproportional disease burden in less affluent parts of society. Exposure to air pollutants is largely beyond the control of individuals and requires action by public authorities at the national, regional and even international levels. The health sector can play a central role in leading a multisectoral approach to prevention of exposure to air pollution with support of other relevant sectors (transport, housing, energy production and industry). The major modes of prevention are:

**(a) Containment** : This prevents pollutants from entering the atmosphere. This can be carried out by engineering methods like enclosure, ventilation or air scrubbing & arresting of pollutants. The following dust control devices are generally used in industry :

**(i) Dust collection systems** : These are designed to handle heavy dust loads; a dust collector consists of a blower, dust filter, a filter-cleaning system, and a dust receptacle or dust removal system, such as Cyclones, Electrostatic precipitators, and, Baghouses.

**(ii) Scrubber systems** : These are a diverse group of air pollution control devices that can be used to remove particulates and/or gases from industrial exhaust streams, such as Baffle spray scrubber, Cyclonic spray scrubber, Ejector venturi scrubber, Mechanically aided scrubber, Spray tower, and, Wet scrubber.

**(b) Replacement or modernisation of equipment/process:** This can result in decrease in pollution. e.g. Use of unleaded petrol.

**(c) Zoning** : During the planning process itself polluting industries are kept away from habitable locations.

**(d) Regulatory Measures** : The Air (Prevention and Control of Pollution) Act, 1981.

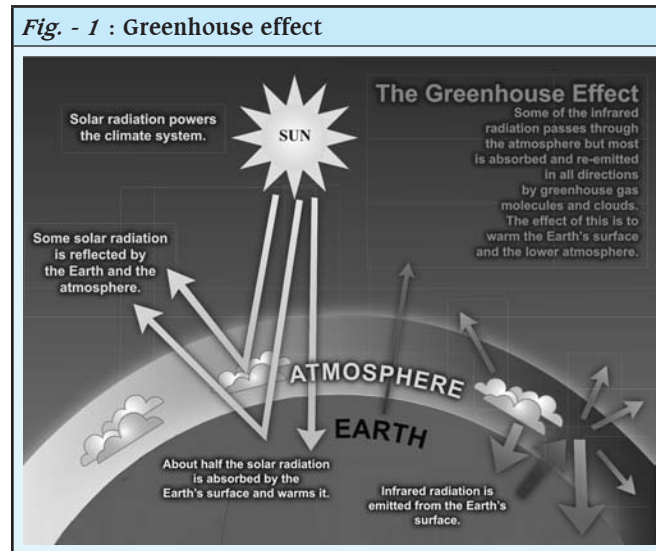
The objective of the Air (Prevention and Control of Pollution) Act, 1981 is to provide for the prevention, control and abatement of air pollution in India by the establishment of pollution control Boards at the Centre as well as State levels, and by conferring and assigning such Boards, powers and functions, with a view to implementing air pollution control measures. Details are discussed in the chapter on health legislations.

### Greenhouse Gases and Society

Greenhouse gases naturally blanket the Earth and keep it about 33°C warmer than it would be without these gases in the atmosphere. This is called the Greenhouse Effect. Over the past century, the Earth has increased in temperature by about 0.5°C and many scientists believe this is because of an increase in concentration of the main greenhouse gases: carbon dioxide (76%), methane (13%), nitrous oxide (6%), and fluorocarbons (5%). People are now calling this climate change over the past century the beginning of Global Warming. Fears are that if people keep producing such gases at increasing rates, the results will be negative in nature, such as more severe floods and droughts, increasing prevalence of insects, sea levels rising, and Earth's precipitation may be redistributed. These changes to the environment will most likely cause negative effects on society, such as lower health and decreasing economic

development. However, some scientists argue that the global warming we are experiencing now is a natural phenomenon, and is part of Earth's natural cycle. Presently, nobody can prove if either theory is correct, but one thing is certain; the world has been emitting greenhouse gases at extremely high rates and has shown only small signs of reducing emissions until the last few years. After the 1997 Kyoto Protocol, the world has finally taken the first step in reducing emissions.

The “*greenhouse effect*” is the heating of the Earth due to the presence of greenhouse gases. It is named this way because of a similar effect produced by the glass panes of a greenhouse. Shorter-wavelength solar radiation from the sun passes through Earth's atmosphere, and then is absorbed by the surface of the Earth, causing it to warm. Part of the absorbed energy is then re-radiated back to the atmosphere as long-wave infrared radiation. Little of this long-wave radiation escapes back into space; the radiation cannot pass through the greenhouse gases in the atmosphere. The greenhouse gases selectively transmit the infrared waves, trapping some and allowing some to pass through into space. The greenhouse gases absorb these waves and re-emits the waves downward, causing the lower atmosphere to warm. The diagram below explains the process of global warming and how greenhouse gases create the “greenhouse effect” (Fig. - 1).



### Greenhouse Gases

**Carbon-dioxide** : It is a colorless, odorless non-flammable gas and is the most prominent Greenhouse gas in Earth's atmosphere. It is recycled through the atmosphere by the process photosynthesis, which makes human life possible. Carbon-dioxide is emitted into the air as humans exhale, burn fossil fuels for energy, and deforest the planet. Every year humans add over 30 billion tons of carbon dioxide in the atmosphere by these processes. We use “fossil fuels” as coal, oil and natural gas to generate electricity, heat our homes, power our factories and run our cars. These fossil fuels contain carbon, and when they are burned, they combine with oxygen, forming carbon dioxide. Deforestation is another main producer of carbon dioxide. The causes of deforestation are logging for lumber,



pulpwood, and fuel wood. Also contributing to deforestation is clearing new land for farming and pastures used for animals such as cows. Forests and wooded areas are natural carbon sinks. This means that as trees absorb carbon dioxide, and release oxygen, carbon is being put into trees. This process occurs naturally by photosynthesis, which occurs less and less as we cut and burn down trees. As the abundance of trees declines, less carbon dioxide can be recycled. As we burn them down, carbon is released into the air and the carbon bonds with oxygen to form carbon dioxide, adding to the greenhouse effect.

**Methane :** Methane is a colorless, odorless, flammable gas. It is formed when plants decay and where there is very little air. It is often called swamp gas because it is abundant around water and swamps. Bacteria that breakdown organic matter in wetlands and bacteria that are found in cows, sheep, goats, buffalo, termites, and camels produce methane naturally. Since 1750, methane has doubled, and could double again by 2050. Each year we add 350-500 million tons of methane to the air by raising livestock, coal mining, drilling for oil and natural gas, rice cultivation, and garbage sitting in landfills. It stays in the atmosphere for only 10 years, but traps 20 times more heat than carbon dioxide.

**Nitrous Oxide:** Nitrous oxide is another colorless greenhouse gas; however, it has a sweet odour. It is primarily used as an anesthetic because it deadens pain and for this characteristic is called laughing gas. This gas is released naturally from oceans and by bacteria in soils. Nitrous oxide gas risen by more than 15% since 1750. Each year we add 7-13 million tons into the atmosphere by using nitrogen based fertilizers, disposing of human and animal waste in sewage treatment plants, automobile exhaust, and other sources not yet identified. It is important to reduce emissions because the nitrous oxide we release today will still be trapped in the atmosphere 100 years from now. Nitrogen based fertilizer use has doubled in the past 15 years. These fertilizers provide nutrients for crops; however, when they breakdown in the soil, nitrous oxide is released into the atmosphere. In automobiles, nitrous oxide is released at a much lower rate than carbon dioxide, because there is more carbon in gasoline than nitrogen.

**Fluorocarbons:** Fluorocarbons are a general term for any group of synthetic organic compounds that contain fluorine and carbon. Many of these compounds, such as chlorofluorocarbons (CFCs), can be easily converted from gas to liquid or liquid to gas. Because of these properties, CFCs can be used in aerosol cans, refrigerators, and air conditioners. Studies showed that when CFCs are emitted into the atmosphere, they break down molecules in the Earth's ozone layer. Since then, the use of CFCs has significantly decreased and they are banned from production in the United States. The substitutes for CFCs are hydrofluorocarbons (HFCs). HFCs do not harm or breakdown the ozone molecule, but they do trap heat in the atmosphere, making it a greenhouse gas, aiding in global warming. HFC's are used in air conditioners and refrigerators. The way to reduce emissions of this gas is to be sure that in both devices the coolant is recycled and all leaks are properly fixed

There are many environmental problems coming from the

increase concentration of greenhouse gases in Earth's atmosphere. Several signs indicate that we've begun changing Earth's climate: increased water vapor in the atmosphere, glaciers and polar ice caps appear to be melting, floods and droughts are becoming more severe, and sea levels have risen, on average, between 4 and 10 inches since 1990. We are already beginning to see this (global warming) taking place - a lot more flooding, a lot more droughts. By 2100, we might get a 2 foot sea level rise, but the catch is levels might continue to rise 2 or 3 feet per century, for 1000 years. These rises in sea level can increase the salinity of freshwater throughout the world, and cause coastal lands to be washed under the ocean. Warmer water and increased humidity may encourage tropical cyclones, and changing wave patterns could produce more tidal waves and strong beach erosion on the coasts.

Increasing amounts of greenhouse gases in the atmosphere and global warming could also lead to more health concerns. A statement released from the Intergovernmental Panel on Climate Change (IPCC) said, "Climate change is likely to have wide-ranging and mostly adverse impacts on human health, with significant loss of life." As temperatures increase towards the poles, similar to farmland, insects and other pests migrate towards Earth's poles. This could lead to 50 to 80 million additional cases of Malaria annually, a 10-15% increase. Climate change is already a factor in terms of the distributions of malaria, dengue fever, and cholera.

The most obvious health effect is directly from the heat itself. With an increase in heat waves, there will be more people who will suffer from heatstroke, heart attacks and other ailments aggravated by the heat. Hot conditions could also cause smoke particles and noxious gases to linger in the air and accelerate chemical reactions that generate other pollutants. This leads to an increase in risk of respiratory diseases like bronchitis and asthma.

**Energy and Greenhouse gases :** The present ways of producing Energy i.e. fossil fuels, chiefly coal, oil and natural gas, now supply most of the world's energy. Only a small amount comes from renewable sources, which do not release gases that trap heat in the atmosphere. If we could get more of our energy from renewable sources, we could reduce the amount of fossil fuels we burn. By the year 2050, renewable sources could provide forty percent of the energy needed in the world. Use of renewable energy can help both to slow global warming and to reduce air pollution. Hydro power, currently supplying only six percent of the world's energy, is a renewable energy source. Energy is produced by hydraulic turbines that rotate with the force of rushing water (higher to lower elevation). It is one of the most clean and cheapest ways of producing energy, but it can also change the flow of rivers and increase sediment which kills fish. It is a large investment for developing countries. Denmark is currently the world leader in wind power.

These fossil fuels, coal, oil, and natural gas also emit greenhouse gases when burned. Coal emits high amounts of greenhouse gases, and the world may be supplied with enough of it to last over 100 years. Oil emits high amounts of greenhouse gases and also other types of air pollution harmful to the environment. The world's oil supply is also estimated to

last over 100 years. Natural Gas is the lowest of all fossil fuels in greenhouse gas emissions; supplies are projected to last over 100 years.

**Kyoto Protocol** : The Kyoto Protocol is an international agreement linked to the United Nations Framework Convention on Climate Change. The major feature of the Kyoto Protocol is that it sets binding targets for 37 industrialized countries and the European community for reducing greenhouse gas (GHG) emissions. These amount to an average of five per cent against 1990 levels over the five-year period 2008-2012. The major distinction between the Protocol and the Convention is that while the Convention encouraged industrialised countries to stabilize GHG emissions, the Protocol commits them to do so.

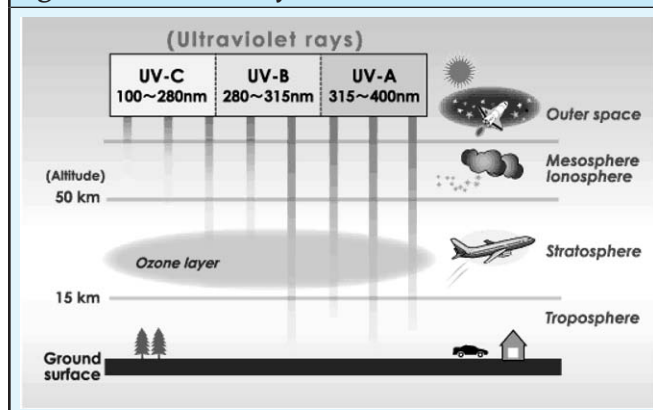
Recognizing that developed countries are principally responsible for the current high levels of GHG emissions in the atmosphere as a result of more than 150 years of industrial activity, the Protocol places a heavier burden on developed nations under the principle of “common but differentiated responsibilities.” The Kyoto Protocol was adopted in Kyoto, Japan, on 11 December 1997 and entered into force on 16 February 2005. 182 Parties of the Convention have ratified its Protocol to date. The detailed rules for the implementation of the Protocol were adopted at COP 7 in *Marrakesh* in 2001, and are called the “*Marrakesh Accords*.” Under the Treaty, countries must meet their targets primarily through national measures. However, the Kyoto Protocol offers them an additional means of meeting their targets by way of three market-based mechanisms.

Parties with commitments under the Kyoto Protocol have accepted targets for limiting or reducing emissions. These targets are expressed as levels of allowed emissions, or “*assigned amounts*”, over the 2008-2012 commitment period. Since carbon dioxide is the principal greenhouse gas, people speak simply of trading in carbon. Carbon is now tracked and traded like any other commodity. This is known as the “*carbon market*”.

The Kyoto Protocol is generally seen as an important first step towards a truly global emission reduction regime that will stabilize GHG emissions, and provides the essential architecture for any future international agreement on climate change. By the end of the first commitment period of the Kyoto Protocol in 2012, a new international framework needs to have been negotiated and ratified that can deliver the stringent emission reductions the Intergovernmental Panel on Climate Change (IPCC) has clearly indicated are needed.

**Ozone Hole** : For nearly a billion years, ozone molecules in the atmosphere have protected life on Earth from the effects of ultraviolet rays. The ozone layer resides in the stratosphere and surrounds the entire Earth. UV-B radiation (280- to 315-nanometer (nm) wavelength) from the Sun is partially absorbed in this layer. As a result, the amount of UV-B reaching Earth's surface is greatly reduced. UV-A (315- to 400-nm wavelength) and other solar radiation are not strongly absorbed by the ozone layer. Human exposure to UV-B increases the risk of skin cancer, cataracts, and a suppressed immune system. UV-B exposure can also damage terrestrial plant life, single cell organisms, and aquatic ecosystems.

**Fig. - 2 : Ultraviolet Rays**



In the past 60 years or so human activity has contributed to the deterioration of the ozone layer. Only 10 or less of every million molecules of air are ozone. The majority of these ozone molecules reside in a layer between 10 and 40 kilometers (6 and 25 miles) above the Earth's surface in the stratosphere. Each spring in the stratosphere over Antarctica (Spring in the southern hemisphere is from September through November); atmospheric ozone is rapidly destroyed by chemical processes. As winter arrives, a vortex of winds develops around the pole and isolates the polar stratosphere. When temperatures drop below -78°C (-109°F), thin clouds form of ice, nitric acid, and sulphuric acid mixtures. Chemical reactions on the surfaces of ice crystals in the clouds release active forms of CFCs. Ozone depletion begins, and the ozone “hole” appears. In spring, temperatures begin to rise, the ice evaporates, and the ozone layer starts to recover. The ozone “hole” is really a reduction in concentrations of ozone high above the earth in the stratosphere. The ozone hole has steadily grown in size (up to 27 million sq. km.) and length of existence (from August through early December) over the past two decades. After a series of rigorous meetings and negotiations, the Montreal Protocol on Substances that Deplete the Ozone Layer was finally agreed upon on 16 September 1987 at the Headquarters of the International Civil Aviation Organization in Montreal.

The *Montreal Protocol* stipulates that the production and consumption of compounds that deplete ozone in the stratosphere such as chlorofluorocarbons (CFCs), halons, carbon tetrachloride, and methyl chloroform are to be phased out. Scientific theory and evidence suggest that, once emitted to the atmosphere, these compounds could significantly deplete the stratospheric ozone layer that shields the planet from damaging UV-B radiation. Man-made chlorines, primarily chlorofluorocarbons (CFCs), contribute to the thinning of the ozone layer and allow larger quantities of harmful ultraviolet rays to reach the earth. The Govt of India has come up *Ozone Depleting Substances (Regulation) Rules 2000* under the Environmental Protection Act 1986 so as to control the production, emission and consumption of Ozone depleting substances.

**The Bhopal Disaster** : The Bhopal Gas Tragedy is a catastrophe that has no parallel in industrial history. In the early morning of December 3, 1984 a Union Carbide pesticide producing plant

leaked a highly toxic cloud of methyl isocyanine onto the densely populated region of Bhopal, central India. The cause was the contamination of Methyl Isocyanine (MIC) storage tank No. 610 with water carrying catalytic material. Of the 800,000 people living in Bhopal at the time, 2,000 died immediately, 300,000 were diseased and as many as 8,000 have died since. The leak was caused by a series of mechanical and human errors. A series of studies made five years later showed that many of the survivors were still suffering from one or several of the following ailments: partial or complete blindness, gastrointestinal disorders, impaired immune systems, post traumatic stress disorders, and menstrual problems in women. A rise in spontaneous abortions, stillbirths, and offspring's with genetic defects was also noted. Although Union Carbide denied liability, in 1989 the Indian Supreme court agreed to a settlement payment of \$470 million by Union Carbide to the survivors of the disaster.

## Noise Pollution

The word noise is derived from the Latin term *nausea*. It has been defined as unwanted sound. Noise can be described as sound without agreeable musical quality or as an unwanted or undesired sound. Thus noise can be taken as a group of loud, non harmonious sounds or vibrations that are unpleasant and irritating to ear. Sound, which pleases the listeners, is music and that which causes pain and annoyance is noise. Section 2 (a) of the Air (Prevention and Control of Pollution) Act, 1981 includes noise in the definition of 'air pollutant'. Section 2(a) air pollution means any solid, liquid or gaseous substance including noise present in the atmosphere in such concentration as may be injurious to human beings or other living creatures or plants or property or environment.

**Measurement** : Loudness/intensity depends on amplitude of noise which is measured in decibels. The zero on a decibel scale is at the threshold of hearing, the lowest sound pressure that can be heard. 20 db is whisper, 40 db the noise in a quiet office. 60 db is normal conversation, 80 db is the level at which sound becomes physically painful. The human ear responds to perceived intensity of sound which is expressed in dB (A). Frequency is measured in Hertz which represents one wave per second. The normal human ear can bear frequencies from 20-20,000 Hz.

**Sources of Noise Pollution** : Noise pollution like other pollutants is also a by- product of industrialization, urbanizations and modern civilization. Broadly speaking, the noise pollution has two sources, i.e. industrial and non- industrial. The industrial source includes the noise from various industries and big machines working at a very high speed and high noise intensity. Non- industrial source of noise includes the noise created by transport/vehicular traffic and the neighborhood noise generated by various noise pollution can also be divided in the categories, namely, natural and manmade. Most leading noise sources will fall into the following categories: roads traffic, aircraft, railroads, construction, industry, noise in buildings (as furniture and plumbing), and consumer products (as household commodities as mixies, vacuum cleaners, etc.) and "recreational" (as loud music, discos, religious and social assemblages, etc.).

**Harmful Effects** : Noise exposure can cause two kinds of health effects on humans. These effects are non-auditory effects and auditory effects.

**Non-auditory effects** : These include stress, related physiological and behavioural effects, and safety concerns. It decreases the efficiency of a man Noise causes lack of concentration in people. Thus they have to give more time for completing a job. Noise Pollution has been considered to be a cause of elevated blood pressure, sleep disturbance, and decreased school performance. Noise exposure has also been known to induce tinnitus, hypertension, vasoconstriction and other cardiovascular impacts. Beyond these effects, elevated noise levels can create stress, increase workplace accident rates, and stimulate aggression and other anti-social behaviors.

### Auditory Effects

(a) **Acoustic trauma** : Sudden hearing damage caused by short burst of extremely loud noise such as a gun shot or blasts.

(b) **Tinnitus** : Ringing or buzzing in the ear.

(c) **Temporary hearing loss** : Also known as temporary threshold shift (TTS) which occurs immediately after exposure to a high level of noise. There is gradual recovery when the affected person spends time in a quiet place. Complete recovery may take several hours.

(d) **Permanent hearing loss** : Permanent hearing loss, also known as permanent threshold shift (PTS), progresses constantly as noise exposure continues month after month and year after year. The hearing impairment is noticeable only when it is substantial enough to interfere with routine activities. At this stage, a permanent and irreversible hearing damage has occurred. Noise-induced hearing damage cannot be cured by medical treatment and worsens as noise exposure continues. When noise exposure stops, the person does not regain the lost hearing sensitivity. As the employee ages, hearing may worsen as age-related hearing loss or presbycusis adds to the existing noise-induced hearing loss.

Noise-induced hearing loss is a cumulative process, both level of noise and exposure time over a worker's work history are important factors. At a given level, low-frequency noise (below 100 Hz) is less damaging compared to noise in the mid-frequencies (1000 - 3000 Hz). Noise-induced hearing loss occurs randomly in exposed persons. Some individuals are more susceptible to noise-induced hearing loss than others. In the initial stages, noise-induced hearing loss is most pronounced at 4000 Hz but it spreads over other frequencies as noise level and/or exposure time increases.

Noise affects the cochlea in the inner ear. That is why noise-induced hearing loss is sensory-neural type of hearing loss. Certain medications and diseases may also cause damage to the inner ear resulting in hearing loss as well. Generally, it is not possible to distinguish sensory-neural hearing loss caused by exposure to noise from sensory-neural hearing loss due to other causes. Medical judgment, in such cases, is based on the noise exposure history. Workers in noisy environments who are also exposed to vibration (e.g. from a jack hammer) may experience greater hearing loss than those exposed to the same level of noise but not to vibration. Noise-exposed workers who are also exposed to ototoxic chemicals (e.g. toluene, carbon



disulfide) may suffer from more hearing impairment than those who have the same amount of noise exposure without any exposure to ototoxic chemicals.

Hearing loss is measured as threshold shift in dB units using an audiometer. The 0 dB threshold shift reading of the audiometer represents the average hearing threshold level of an average young adult with disease-free ears. The PTS (permanent threshold shift), as measured by audiometry, is dB level of sounds of different frequencies that are just barely audible to that individual.

**Effect on animals** : Noise can have a detrimental effect on animals by causing stress, increasing risk of mortality by changing the delicate balance in predator/prey detection and avoidance, and by interfering with their use of sounds in communication especially in relation to reproduction and in navigation.

### Noise mitigation

This is a set of strategies to reduce noise pollution. The main areas of noise mitigation or abatement are transportation noise control, architectural design, and occupational noise control. Roadway noise and aircraft noise are the most pervasive sources of environmental noise worldwide, and remarkably little change has been effected in source control in these areas since the start of the problem, a possible exception being the development of the hybrid vehicle.

**(a) Buildings** : Multiple techniques have been developed to address interior sound levels, many of which are encouraged by local building codes; in the best case of project designs, planners are encouraged to work with design engineers to examine tradeoffs of roadway design and architectural design. These techniques include design of exterior walls, internal walls and floor/ceiling assemblies; moreover, there are a host of specialized means for dampening reverberation from special purpose rooms such as auditoriums, concert halls, dining areas and meeting rooms. Many of these techniques rely upon materials science applications of constructing sound baffles or using sound absorbing liners for interior spaces.

**(b) Roadway noise** : The most fertile area for roadway noise mitigation is in urban planning decisions, roadway design, noise barrier design, speed control, surface pavement selection and truck restrictions. Speed control is effective since the lowest sound emissions arise from vehicles moving smoothly at 30 to 60 km per hour. Noise barriers can be applicable for existing or planned surface transportation projects. They are probably the single most effective weapon in retrofitting an existing roadway, and commonly can reduce adjacent land use sound levels by ten decibels

**(c) Aircrafts** : The most promising forms of aircraft noise abatement is through land planning, flight operations restrictions and residential soundproofing. Flight restrictions can take the form of preferred runway use; departure flight path and slope; and time of day restrictions

**(d) Industries** : Industrial noise control is really a subset of interior architectural control of noise, with emphasis upon specific methods of sound isolation from industrial machinery and for protection of workers at their task stations. In the case of industrial equipment, the most common techniques for

noise protection of workers consist of shock mounting source equipment, creation of acrylic glass or other solid barriers, and provision of ear protection equipment. In certain cases the machinery itself can be re-designed to operate in a manner less prone to produce grating, grinding, frictional or other motions that induce sound emissions.

**(e) Legal Control** : Under Cr PC Section 133 the magisterial court have been empowered to issue order to remove or abate nuisance caused by noise pollution. Noise pollution can be penalized under I.P.C. Public Nuisance 268-295 relating to public health, safety, decency, morals. Action can also be taken under the Law of Torts as Noise pollution is considered a civil wrong. The Factories Act does not contain any specific provision for noise control. However, under the Third Schedule Sections 89 and 90 of the Act, noise induced hearing loss, is mentioned as notifiable disease. Similarly, under the Modal Rules, limits for noise exposure for work zone area have been prescribed. In Motor vehicle Act rules regarding use horns and any modification in engine are made.

### Noise Pollution Control Rule 2000 under Environment Protection Act 1996

Under this Act State governments shall take measures for abatement of noise including noise emanating from vehicular movement and ensure that the existing noise levels do not exceed the standards specified. An area not less than 100 m around hospitals, education institutions and courts may be declared as 'silence area' for the purpose of these rules. A loud speaker or a public address system shall not be used except after obtaining written permission from the authority and the same shall not be used at night, between 10 pm to 6 am.

### Personal Protection

Ear plugs and ear muffs are important appliances, particularly used in the industries, which can effectively reduce the level of noise by 15 to 30 decibels and their use must be encouraged wherever possible.

### Soil Pollution

Soil pollution comprises the pollution of soils with materials, mostly chemicals that are out of place or are present at concentrations higher than normal which may have adverse effects on humans or other organisms. It is difficult to define soil pollution exactly because different opinions exist on how to characterize a pollutant; while some consider the use of pesticides acceptable if their effect does not exceed the intended result, others do not consider any use of pesticides or even chemical fertilizers acceptable. However, soil pollution is also caused by means other than the direct addition of xenobiotic (man-made) chemicals such as agricultural runoff waters, industrial waste materials, acidic precipitates and radioactive fallout. Consequently, the atmosphere, bodies of water, and many soil environments have become polluted by a large variety of toxic compounds. Many of these compounds at high concentrations or following prolonged exposure have the potential to produce adverse effects in humans and other organisms: These include the danger of acute toxicity, mutagenesis (genetic changes), carcinogenesis, and teratogenesis (birth defects) for humans and other organisms.



Some of these man-made toxic compounds are also resistant to physical, chemical, or biological degradation and thus represent an environmental burden of considerable magnitude.

**Industrial Wastes** : Industries are known to dispose of their pollution in pits, ponds of lagoons with little or no prior treatment. Leaking underground storage tanks compound the pollution of the soil. The most prominent chemical groups of organic contaminants are fuel hydrocarbons, polynuclear aromatic hydrocarbons (PAHs), polychlorinated biphenyls (PCBs), chlorinated aromatic compounds, detergents and pesticides. Inorganic species include nitrates, phosphates and heavy metals such as cadmium, chromium and lead; inorganic acids; and radionuclides (radioactive substances). Among the sources of these contaminants are agricultural runoffs, acidic precipitates, and industrial waste materials.

**Agricultural Wastes** : Fertilizers, pesticides and other chemical like soil conditioners and fumigants used in agriculture may remain for long in the soil. Some of these may enter the food chain and cause health problems in the population. On the other hand, Cattle and poultry produce and wastes are biodegradable. However when these are not properly disposed it may cause a nuisance of smell and sight and facilitate breeding of flies.

**Urban Community Wastes** : Refuse and other solids wastes when not disposed of properly can result in pollution of the soil. Even practices like sanitary landfill if not carried out in a systemized manner may result in contamination of the soil. Defecation in the open in farms etc. result in contamination of the soil with various biological contaminants harbored by the host.

**Radiological Wastes** : Occur from atmospheric fallout of a nuclear explosion, which may travel distances due to air currents. Disposal of radioactive wastes if not carried out as per laid out norms is another source of pollution.

#### Control measures

**(a) Natural** : Nature has an effective mode of controlling pollution. Most bacteria and viruses do not survive on the surface of the soil after exposure to sunlight. Rainwater also carries contaminants away from the source. Biological products which are below the upper surface of the soil are catabolised by the "Nitrogen Cycle".

**(b) Bioremediation** : In-situ biodegradation involves the enhancement of naturally occurring microorganisms by artificially stimulating their numbers and activity. The microorganisms then assist in degrading the soil contaminants. A number of environmental, chemical and management factors affect the biodegradation of soil pollutants, including moisture content, pH, temperature, the microbial community that is present, and the availability of nutrients. These physical parameters can be influenced, thereby promoting the microorganisms' ability to degrade chemical contaminants. Of all the decontamination methods bioremediation appears to be the least damaging and most environmentally acceptable technique.

**(c) Soil Washing** : For the removal and recovery of heavy metals various soil washing techniques have been developed including physical methods, such as attrition scrubbing and wet-screening, and chemical methods consisting of treatments

with organic and inorganic acids, bases, salts and chelating agents. The problem with these methods, however, is again that they generate secondary waste products that may require additional hazardous waste treatments.

**(d) Engineering measures** : Proper disposal of community wastes through composting, disposable in pits, sanitary landfills goes a long way in prevention of soil pollution. Industrial wastes should be properly treated prior to disposal. Non biodegradable products should be recycled or properly disposed. Farm wastes can be properly utilized by composting or used in biogas plants. The most common decontamination method for polluted soils is to remove the soil and deposit it in landfills or to incinerate it. These methods, however, often exchange one problem for another: land-filling merely confines the polluted soil while doing little to decontaminate it, and incineration removes toxic organic chemicals from the soil, but subsequently releases them into the air, in the process causing air pollution. Health education goes a long way in change of attitude of a community on oxygen defecation of disposal of agriculture wastes.

#### Radioactive Pollution

Radioactive contamination is the uncontrolled distribution of radioactive material in a given environment. Radioactive contamination is typically the result of a spill or accident during the production or use of radionuclides (radioisotopes), an unstable nucleus which has excessive energy. Contamination may occur from radioactive gases, liquids or particles. For example, if a radionuclide used in nuclear medicine is accidentally spilled, the material could be spread by people as they walk around. Radioactive contamination may also be an inevitable result of certain processes, such as the release of radioactive xenon in nuclear fuel reprocessing. Nuclear fallout is the distribution of radioactive contamination by a nuclear explosion.

**Ionising radiation** : These are radioactive rays capable of penetrating tissues. These can be of two types;

- (a) Electromagnetic - X-rays and gamma rays
  - (b) Corpuscular radiations - Alpha, beta particles & protons
- Alpha particles are ten times more harmful than X-rays but have little penetrating force. Gamma rays & X-rays are deep penetrating in nature.

**Non ionizing radiations** : These are of higher wavelengths & cannot penetrate. The spectrum ranges from Ultraviolet radiation, visible light, infrared radiation, microwave & radio frequency.

Activity of radioactive material is measured in Becquerel which is 1 disintegration per second. This was earlier measured as Curies. Potency of radiation is measured with -

**(a) Exposure** : Number of ions exposed in a ml of air is called Roentgen. Current exposure SI unit is Coulomb/kg.

**(b) Absorption** : Amount of radioactive energy absorbed by a gram of tissue/material is called Rad. The SI unit currently used is Gray (1Gy = 100 rads).

**(c) Dose equivalent** : The degree of potential danger to health is measured in Rem which is a product of Rad and a modifying factor. The newer unit is the Sievert (1 Sievert=100 Rems).

## Hazards

In practice there is no such thing as zero radioactivity. Not only is the entire world constantly bombarded by cosmic rays, but every living creature on earth contains significant quantities of carbon -14 and most (including humans) contains significant quantities of potassium-40. These tiny levels of radiation are not any more harmful than sunlight, but just as excessive quantities of sunlight can be dangerous, so too can excessive levels of radiation.

**Low level contamination** : The hazards to people and the environment from radioactive contamination depend on the nature of the radioactive contaminant, the level of contamination, and the extent of the spread of contamination. Low levels of radioactive contamination pose little risk, but can still be detected by radiation instrumentation. In the case of low-level contamination by isotopes with a short half-life, the best course of action may be to simply allow the material to naturally decay. Longer-lived isotopes should be cleaned up and properly disposed of, because even a very low level of radiation can be life-threatening, on long exposure. Therefore, whenever there's any radiation in an area, many people take extreme caution when approaching such areas.

**High level contamination** : High levels of contamination may pose major risks to people and the environment. People can be exposed to potentially lethal radiation levels, both externally and internally, from the spread of contamination following an accident (or a deliberate initiation) involving large quantities of radioactive material. The biological effects of external exposure to radioactive contamination are generally the same as those from an external radiation source not involving radioactive materials, such as x-ray machines, and are dependent on the absorbed dose.

**Biological effects** : The biological effects of internally deposited radionuclides depend greatly on the activity and the bio-distribution and removal rates of the radionuclide, which in turn depends on its chemical form. The biological effects may also depend on the chemical toxicity of the deposited material, independent of its radioactivity. Some radionuclides may be generally distributed throughout the body and rapidly removed, as is the case with titrated water. Some radionuclides may target specific organs and have much lower removal rates. For instance, the thyroid gland takes up a large percentage of any iodine that enters the body. If large quantities of radioactive iodine are inhaled or ingested, the thyroid may be impaired or destroyed, while other tissues are affected to a lesser extent. Radioactive iodine is a common fission product; it was a major component of the radiation released from the Chernobyl disaster, leading to many cases of pediatric thyroid cancer and hypothyroidism. On the other hand, radioactive iodine is used in the diagnosis and treatment of many diseases of the thyroid precisely because of the thyroid's selective uptake of iodine.

In general, the adverse effects on the human body may be acute or chronic (long term). Acute effects include acute radiation sickness. Chronic effects may manifest either as somatic effects or chromosomal effects which result in genetic abnormalities. The most important somatic effect is on haemopoietic system (leukaemias), cancers, particularly thyroid, and foetal

developmental abnormalities if mother is exposed during ante-natal period.

**Means of contamination** : Radioactive contamination can enter the body through ingestion, inhalation, absorption, or injection. For this reason, it is important to use personal protective equipment when working with radioactive materials. Radioactive contamination may also be ingested as the result of eating contaminated plants and animals or drinking contaminated water or milk from exposed animals. Following a major contamination incident, all potential pathways of internal exposure should be considered.

**Effective protection** : Effective protection can be given to workers in hazardous industries by provision of lead shields & lead rubber aprons. Exposed workers should wear TLD badge or dosimeters which show accumulated exposure to radiation. Periodic medical exam should also be carried out to monitor health of workers. Exposure to investigative radiology should be kept to the minimum, especially during pregnancy.

**The Chernobyl disaster** was a nuclear reactor accident in the Chernobyl Nuclear Power Plant in the Soviet Union on 26 April 1986. It was the worst nuclear power plant accident in history and the only instance so far of level 7 on the International Nuclear Event Scale, resulting in a severe release of radioactivity into the environment following a massive power excursion which destroyed the reactor. Two people died in the initial steam explosion, but most deaths from the accident were attributed to fallout. The plume drifted over extensive parts of the western Soviet Union, Eastern Europe, Western Europe, Northern Europe, and eastern North America. Large areas in Ukraine, Belarus, and Russia were badly contaminated, resulting in the evacuation and resettlement of over 336,000 people. According to official post-Soviet data, about 60% of the radioactive fallout landed in Belarus. The 2005 report prepared by the Chernobyl Forum, led by the International Atomic Energy Agency (IAEA) and World Health Organization (WHO), attributed 56 direct deaths (47 accident workers, and nine children with thyroid cancer), and estimated that there may be 4,000 extra cancer cases among the approximately 6,00,000 most highly exposed and 5,000 among the 6 million living nearby. Although the Chernobyl Exclusion Zone and certain limited areas will remain off limits, the majority of affected areas are now considered safe for settlement and economic activity.

**Radioactive wastes** are waste types containing radioactive chemical elements that do not have a practical purpose. They are sometimes the products of nuclear processes, such as nuclear fission. However, industries not directly connected to the nuclear industry can produce large quantities of radioactive waste. It has been estimated, for instance, that the past 20 years the oil-producing endeavors of the United States have accumulated eight million tons of radioactive wastes. The majority of radioactive waste is "low-level waste", meaning it contains low levels of radioactivity per mass or volume. This type of waste often consists of used protective clothing, which is only slightly contaminated but still dangerous in case of radioactive contamination of a human body through ingestion, inhalation, absorption, or injection. The United States currently has at least 108 sites it currently designates as areas that are

contaminated and unusable, sometimes many thousands of acres.

The issue of disposal methods for nuclear waste was one of the most pressing current problems the international nuclear industry faced when trying to establish a long term energy production plan.

Nuclear waste requires sophisticated treatment and management in order to successfully isolate it from interacting with the biosphere. This usually necessitates treatment, followed by a long-term management strategy involving storage, disposal or transformation of the waste into a non-toxic form.

Long-term storage of radioactive waste requires the stabilization of the waste into a form which will not react, nor degrade, for extended periods of time. One way to do this is through vitrification. It is also common for medium active wastes in the nuclear industry to be treated with ion exchange or other means to concentrate the radioactivity into a small volume. The much less radioactive bulk (after treatment) is often then discharged. For instance, it is possible to use a ferric hydroxide floc to remove radioactive metals from aqueous mixtures. After the radioisotopes are absorbed onto the ferric hydroxide, the resulting sludge can be placed in a metal drum before being mixed with cement to form a solid waste form.

High-level radioactive waste is stored temporarily in spent fuel pools and in dry cask storage facilities. This allows the shorter-lived isotopes to decay before further handling.

The process of selecting appropriate deep final repositories for high level waste and spent fuel is now under way in several countries with the first expected to be commissioned some time after 2010.

Storing high level nuclear waste above ground for a century or so is considered appropriate by many scientists. This allows for the material to be more easily observed and any problems detected and managed, while the decay over this time period significantly reduces the level of radioactivity and the associated harmful effects to the container material. Sea-based options for disposal of radioactive waste include burial beneath a stable abyssal plain, burial in a subduction zone that would slowly carry the waste downward into the Earth's mantle, and burial beneath a remote natural or human-made island. Another option is to find applications of the isotopes in nuclear waste so as to re-use them. Already, caesium-137, strontium-90 and a few other isotopes are extracted for certain industrial applications such as food irradiation and radioisotope thermoelectric generators. While re-use does not eliminate the need to manage radioisotopes, it may reduce the quantity of waste produced.

## Summary

**Air Pollution :** According to a WHO assessment of the burden of disease due to air pollution, more than 2 million premature deaths each year can be attributed to the effects of urban outdoor air pollution and indoor air pollution. Important pollutants are Sulphur dioxide, Nitrogen oxides, Hydrogen sulphide, Carbon monoxide, Hydrogen cyanide, Ammonia, Lead, Ozone etc and their main sources are mainly industries, motor vehicles, coal and oil combustion, Explosives, dye making, fertilizer plants

etc. The pathological effects on man are aggravation of asthma and other lung and heart diseases, reduction of oxygen carrying capacity of blood, damage kidneys, cause jaundice and also toxic to nervous system.

The WHO Air quality guidelines are designed to offer global guidance on reducing the health impacts of air pollution. They recommend measurement of selected air pollutants, viz. Particulate Matter (PM), Ozone (O<sub>3</sub>), Nitrogen dioxide (NO<sub>2</sub>) and Sulfur dioxide (SO<sub>2</sub>) applicable across all WHO regions. In addition, "smoke (soiling) index" and "coefficient of haze" are also commonly used indicators. In India the Central Pollution Control Board through its National Air Quality Monitoring Programme monitors air quality in all major cities.

Exposure to air pollutants is largely beyond the control of individuals and requires action by public authorities at the national, regional and even international levels. Intersectoral coordination is required with the health sector playing a central role. The major modes of prevention are Containment, dust control devices like Data collection systems, scrubber systems, replacement or modernisation of equipment/process and Zoning. The objective of The Air (Prevention and Control of Pollution) Act, 1981 is to provide for the prevention, control and abatement of air pollution in India by the establishment of pollution control Boards at the Centre as well as State levels, and by conferring and assigning such Boards, powers and functions, with a view to implementing air pollution control measures.

Over the past century, the Earth has increased in temperature by about 0.5°C and many scientists believe this is because of an increase in concentration of the main greenhouse gases: carbon dioxide (76%), methane (13%), nitrous oxide (6%), and fluorocarbons (5%). This climate change might be the beginning of Global Warming. The "greenhouse effect" is the heating of the Earth due to the presence of greenhouse gases. The Kyoto Protocol, an international agreement linked to the United Nations Framework Convention on Climate Change sets binding targets for 37 industrialized countries and the European community for reducing Greenhouse Gas (GHG) emissions. In the past 60 years or so human activity has contributed to the deterioration of the ozone layer. When temperatures drop below -78°C (-109°F), thin clouds form of ice, nitric acid, and sulphuric acid mixtures and Chemical reactions on the surfaces of ice crystals in the clouds release active forms of CFCs. Ozone depletion begins, and the ozone "hole" appears. The Montreal Protocol stipulates that the production and consumption of compounds that deplete ozone in the stratosphere such as Chlorofluorocarbons (CFCs), halons, carbon tetrachloride and methyl chloroform are to be phased out. The Govt. of India has come up with Ozone Depleting Substances (Regulation) Rules 2000 under the Environmental Protection Act 1986 so as to control the production, emission and consumption of Ozone depleting substances. In the early morning of December 3, 1984 a Union Carbide pesticide producing plant leaked a highly toxic cloud of methyl isocyanate onto the densely populated region of Bhopal, leading to Bhopal Tragedy with 2,000 immediate deaths, 8000 subsequent deaths and 300,000 diseased.

**Noise Pollution :** Noise can be described as sound without agreeable musical quality or as an unwanted or undesired



sound. Section 2 (a) of the Air (Prevention and Control of Pollution) Act, 1981 defines air pollution as any solid, liquid or gaseous substance including noise present in the atmosphere in such concentration as may be injurious to human beings or other living creatures or plants or property or environment. 60 db is normal conversation and 80 db is the level at which sound becomes physically painful. The normal human ear can bear frequencies from 20-20,000 Hz.

Broadly, the noise pollution has two sources, i.e. industrial and non- industrial. The industrial source includes the noise from various industries and Non- industrial source of noise includes the noise created by transport/vehicular traffic and the neighborhood noise. Noise exposure can cause non-auditory effects and auditory effects. Non-auditory effects include stress, related physiological and behavioural effects, and safety concerns. It decreases the efficiency of a man. Noise causes lack of concentration in people, elevates blood pressure, sleep disturbance, and decreased school performance. Noise exposure has also been known to induce tinnitus, hypertension, vasoconstriction and other cardiovascular impacts. Beyond these effects, elevated noise levels can create stress, increase workplace accident rates, and stimulate aggression and other anti-social behaviors. Auditory effects include: Acoustic trauma, Tinnitus, Temporary hearing loss, Permanent hearing loss.

Noise mitigation is a set of strategies to reduce noise pollution, which include transportation noise control; architectural design of Buildings, roads, aircrafts and industries; and occupational noise control. Noise pollution can be penalized under I.P.C. Public Nuisance 268-295 relating to public health, safety, decency, morals. Under Noise Pollution Control Rule 2000 under Environment Protection Act 1996 State governments shall take measures for abatement of noise including noise emanating from vehicular movement and ensure that the existing noise levels do not exceed the standards specified. Personal Protection by using Ear plugs and ear muffs is also important.

**Soil Pollution :** Soil pollution comprises the pollution of soils with materials, mostly chemicals that are out of place or are present at concentrations higher than normal which may have adverse effects on humans or other organisms. It is caused by agricultural runoff waters, industrial waste materials, acidic precipitates, and radioactive fallout. It leads to acute toxicity, mutagenesis (genetic changes), carcinogenesis and teratogenesis (birth defects) for humans and other organisms. Control measures include Bioremediation, Soil Washing, Engineering measures like Proper disposal of community wastes, Industrial and Agricultural wastes through composting, disposable in pits, sanitary landfills etc.

**Radioactive Pollution :** Radioactive contamination is the uncontrolled distribution of radioactive material in a given environment. Radioactive contamination is typically the result of a spill or accident during the production or use of radionuclides (radioisotopes). The adverse effects on the human body may be acute or chronic (long term). Acute effects include acute radiation sickness. Chronic effects may manifest either as somatic effects or chromosomal effects which result in genetic abnormalities. The most important somatic effect is on haemopoietic system (leukaemias), cancers particularly thyroid and foetal developmental abnormalities if mother is exposed during ante-natal period. Effective protection - Effective protection can be given to workers in hazardous industries by provision of lead shields & lead rubber aprons, TLD badge or dosimeters, Periodic medical exams. The Chernobyl disaster was a major nuclear reactor accident in the Chernobyl Nuclear Power Plant in the Soviet Union on 26 April 1986. Nuclear waste requires sophisticated treatment and management in order to successfully isolate it from interacting with the biosphere. This usually necessitates treatment, followed by a long-term management strategy involving storage, disposal or transformation of the waste into a non-toxic form.

## Study Exercises

**Long Questions :** (1) Enumerate the Sources and Health Hazards of Air Pollution. Describe the measures for its prevention and control (2) Enumerate the Sources and Health Hazards of Noise Pollution. Describe the measures for its prevention and control

**Short Notes :** (1) Chernobyl disaster (2) Bhopal gas tragedy (3) Radioactive pollution (4) Soil pollution (5) Air pollution Indices (6) Global warming (7) Ozone Hole (8) Auditory effects of Noise pollution

### MCQs

1. The main greenhouse gas which is largely contributing to Global warming is (a) Carbon dioxide (b) Methane (c) Nitrous oxide (d) Fluorocarbons
2. Kyoto Protocol is an international agreement which deals with (a) Radioactive pollution (b) Soil pollution (c) Emission of green house gases (d) Noise pollution
3. Bhopal Tragedy of 1984 was due to a toxic chemical called (a) Methyl cyanide (b) Methyl isocyanate (c) Methyl isochloride (d) none of the above
4. Soiling index is an index to measure (a) Radioactive pollution (b) Soil pollution (c) Air pollution (d) water pollution
5. The Chernobyl disaster was a major nuclear reactor accident in the Chernobyl Nuclear Power Plant in the Soviet Union occurred in the year (a) 1982 (b) 1986 (c) 1989 (d) 1990

**Answers :** (1) a; (2) c; (3) b; (4) c; (5) b.



# 6

## Nutrition in Public Health



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Rajul K Gupta

The term 'Nutrition' is derived from a Latin word *nutritic*, meaning nourishment (1). Nutrition can be considered to be the foundation of good health and freedom from disease. '*Nutrition science*' has been comprehensively defined by Robinson as '*The science of foods, nutrients and other substances therein; their action, interaction and balance in relationship to health and disease; the processes by which the organism ingests, digests, absorbs, transports and utilizes nutrients and disposes off their end products...*' (2). Simply put the word nutrition is used to refer to the processes of the intake, digestion and assimilation of nutrients and the application of this knowledge to maintain health and combat disease. See Box - 1.

**Box - 1 : Significance of nutrition**

Adequate nutrition is required for growth, development and maintenance of normal functions

Under nutrition contributes to 60% deaths amongst under five children (WHO, 2002)

More than 85% children in India suffer from malnutrition (44% Mild malnutrition, 38% moderate malnutrition and 4.6% severe malnutrition) (Gomez classification, NNMB 2007)

About 55% men and 75% non pregnant non lactating women are anaemic

Epidemiological data shows strong association between under nutrition and morbidity / mortality

Chronic degenerative disorders such as coronary artery disease, hypertension, type 2 diabetes, certain cancers, etc are related to diet and nutritional status

Obesity is associated with higher risk of developing cancer breast, colon, endometrium, gallbladder, esophagus, pancreas, etc.

Consumption of foods rich in dietary fibre and antioxidants is associated with reduced risk of certain cancers

Under nutrition during foetal and early childhood is known to be associated with chronic degenerative disorders in later life

Good nutrition is a fundamental requirement for positive health, functional efficiency and productivity. Nutritional status is internationally recognized as an indicator of national development. Nutrition is both an input into and an output of, the developmental process (3).

Nutrition is an extremely dynamic subject that changes every day. Continuous research and a constant study into nutrition therefore remains a subject of contemporary interest.

**History**

It is believed that *Hippocrates*, the Father of Medicine, paid strict attention to the diet of his patients as a feature of his

therapeutic regimens. For instance, his dietetic prescriptions reveal a close relationship of effects of individual foods on both sick and the well. Pulses, he said, should be eaten with cereals. The obese should be advised to labour much, drink little.... Remedial foods have been suggested for fever, 'hot intestines', dysentery, melancholic disorders etc. (4, 5). Ancient Indian texts give adequate indication of the importance that diet and nutrition were accorded during ancient times (Box - 2).

**Box - 2 : Aahara, Vichara, Yoga and Ayurveda : The Ancient Indian wisdom**

Aahara or the dietary philosophy has been central to the concept of ancient Indian system of medicine, Ayurveda. Prudent food with a strict dietary discipline was the hallmark of ancient Indian lifestyle and one of the secrets of a long and healthy life which the Indians enjoyed in the Vedic times. As per the principles of Ayurveda, the diet is supposed to change with the time of the day and seasons. 'Hot' and 'cold' temperaments of the food are supposed to be balanced with the weather, seasons and climate. These dictums were ingrained in the lifestyle along with good and noble thoughts (vichara) and the discipline of life (Yoga) for a long lasting good health and the ultimate union with the supreme power. Can we learn something from this traditional Indian wisdom!

The phrase '*science of nutrition*' was first used probably by Count Rumond in an essay on feeding poor people in 1795 (6). During the same period Lavoisier who was working on combustion and respiratory metabolism, is said to have established nutrition as a science (7). In 1753 James Lind published the first edition of A Treatise on the Scurvy which elaborated how 110 men were disabled by scurvy and were miraculously cured by an Indian remedy (the infusion of the needles of an evergreen tree). Lind was also the first one to study experimentally the value of different substances in the treatment of scurvy, and proved that dietary lemons and oranges cured scurvy (5).

In 1839, a Dutch physician Gerrit Mulder claimed that complex nitrogen compounds like egg albumin, serum albumin, fibrin and wheat gluten all contained a common radical, 'protein' (8). Marasmus was described in the year 1877 by Jules Poirot from France under the term "athrepsie".

The science of nutrition bloomed during the 20<sup>th</sup> century. Vitamins and amino acids were discovered, human nutritional requirements were established and the relationship between diet, nutrition and the human body in health and disease were recognized. These scientific advances evolved through several phases. Lafayette B. Mender (USA) identified the nutritive value of proteins during 1909-1928. In due course, various experiments and observations by different workers pointed towards some unknown food factors that were vital for the very sustenance of life. JBA Dumas (1871) was the earliest man of science to question the adequacy of diet composed only of proteins, carbohydrates, fats and salts. He had published his observations on the health of infants of Paris made during the siege by the Germans. Pekelharing demonstrated in 1905 the existence of unidentified nutrients in milk and why they were absolutely essential for survival of mice in minute quantities.

In 1912 Casimir Funk (Poland) propounded the theory that beriberi, scurvy, pellagra and possibly rickets were caused by deficiency of “special substances which are of the nature of organic bases” and coined the term ‘vitamine’. Thus the new concept of dietary deficiency diseases was born. In 1926 Goldberger and Lillie described malnutrition in rats also featuring growth arrest, ‘ophthalmia’, hair loss on ears, neck, chest and forearms etc. Fur became matted and fell exposing denuded pale pink skin. Oral and lingual ulcers and fissuring were also noticed. Diarrhoea was also seen in some rats. The condition was diagnosed as rat pellagra. Lean meat and yeast cured it. The curative agent was designated by Goldberger and Lillie as pellagra-preventive (P-P) factor. However, later it was found that this condition (in rats) was not analogous to human pellagra, but was caused due to the deficiency of riboflavin.

The dangerous disease Pellagra was earlier described in Northern Spain in 1735 by Casal. However, scientific world had to wait till Goldberger undertook a study in 1915. He studied the diets of patients and medical staff in State Asylums in South Carolina, Georgia and Mississippi. This study proved that the disease was caused by a deficiency rather than a poison or infection. The search for the pellagra preventing factor travelled through high proteins, yeast and liver and ended with the isolation of nicotinic acid from rice polishings by Funk in 1912. Many other workers also isolated this chemical from other food stuffs (5).

Verner McCollum (USA) discovered a fat soluble soluble factor that was essential for growth (Vitamin A) in 1916 (6). Chick, Windaus and Hess worked on Vitamin D, Evans and Bishop on Vitamin E, King and Gyorgy on Vitamin C, Dam on Vitamin K, Mitchell, Snell and Williams on folic acid and Hodjkin on Vitamin B.

McCance, Mac Kay, Widdowson, McLaren and Woodruff did pioneering work on iron deficiency. Ciceley Williams (England) described Kwashiorkor in 1933. Kerpel Fronuis, Gomez and Cravioto also worked on protein calorie deficiency.

Great debate started in the sixties and seventies on the causation and relationship between marasmus and kwashiorkor where eminent nutritional scientists, Waterlow, Gopalan, Scrimshaw, McLaren and others participated. Various studies on protein and energy requirements, the role of infection, metabolic and endocrine changes, and adaptation were carried out. Derrick Jelliffe, a pioneer in nutrition introduced the term ‘protein-calorie’ malnutrition, which was later modified to protein energy malnutrition and adopted by the FAO/WHO committee in 1971 to describe both kwashiorkor and marasmus.

### Into the 21st century : The era of interdisciplinary coordination

Agriculture cannot be kept away from nutrition. Great advances in agriculture were achieved with the green revolution in India. The introduction of genetically engineered food during the last decades of the twentieth century was followed by an ongoing international scientific debate. Parallel advances were achieved in animal nutrition and veterinary medicine, which increased animal food production. The relationship between mad cow disease and animal food as well as its relationship to Cruetzfeld Jacob disease in the humans is stimulating further

research on animal nutrition, communicable disease and food safety. The bird flu endemic has once again opened the Pandora’s Box : ‘*Are the non-vegetarian foods safe enough?*’ (9). Fierce research is on, to answer these questions through the integrated effort of multidisciplinary forces... medicine, virology, veterinary medicine, nutrition, food technology, public health, epidemiology, genetics, biotechnology, mathematical modelling, information technology.... These and many other advances in nutritional sciences represent the ceaseless effort, genuine initiative and devotion of many pioneer scientists all over the world through out the ages.

### Food and Nutrients : Major Categories of Foods and Nutrients

**Food** : Food is a substance eaten or drunk to maintain life and growth. The foods are generally classified into cereals (wheat, rice, maize etc.), legumes (pulses and peas), nuts and oilseeds, vegetables, fruits, milk and milk products and flesh foods (fish, meat and chicken and egg). Diet, on the other hand is what a person habitually eats and drinks.

**Nutrients** : The nutrients are chemical substances that are present in the food we eat. The important nutrients are proteins, fats, carbohydrates, vitamins and minerals. Foods contain various nutrients in different proportions. Depending on the relative concentration of various nutrients foods can be classified into protein, carbohydrate or fat rich foods.

**Why do we eat food? - Functions of food** : We eat to satisfy hunger (satiety) and to get energy for our day to day functioning. Food serves many functions in the body :

**a) Food builds body tissues** : The structural materials of food, proteins, minerals, vitamins and water are needed for growth and development. The food is also needed for the maintenance of the cells and tissues.

**b) Food regulates body processes** : Many a body processes are regulated by the ‘fuel’ supplied through food e.g. temperature control of the body (calories), control of osmotic pressure (proteins and electrolytes), maintenance of hydrogen ion concentration (pH through electrolytes), solvent power of fluids (proteins and water), nerve conduction (minerals), muscle elasticity (minerals), innumerable metabolic processes (vitamins and minerals).

**c) Food supplies energy** : The macronutrients (carbohydrates, proteins and fats) supply energy. These provide constant source of fuel to the body. It is measured in terms of a kilo calorie.

**d) Food gives us enjoyment** : We want to enjoy food and entertain our guests with tasty food.

These requirements may be met by various combinations of the three major food constituents : carbohydrates, proteins & fats, taken in different proportions. Although the actual distribution of each one of these nutrients in our daily diet is vital for good health, one hardly considers their proportion, as long as he enjoys the food. It must be appreciated that our lifestyle governs all facets of our life including our eating habits.

The community faces major nutritional problems from the consumption of inadequate or imbalanced diet. This is true for both healthy and sick. Economic prosperity and affluence, at least in a section of the society, are now threatening the



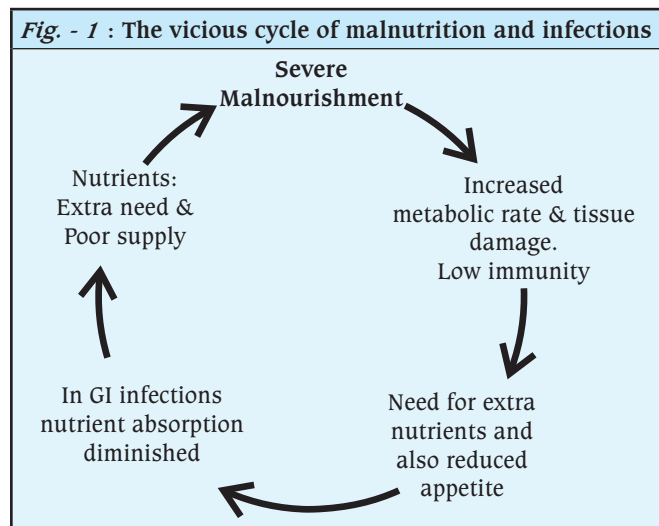
community through over nutrition and its related hazards.

### From Under-Nutrition to Over-Nutrition

Within the past few decades, there has been a significant reduction in cases of nutritional deficiencies. Classical nutritional deficiency syndromes of florid pellagra, beriberi, scurvy or kwashiorkor have almost disappeared. We do not come across the famines any more. This improved scenario is a result of multiple inputs namely, smaller families, better food security, economic development, improved health systems, conquest of infections, better health awareness and accountable governance. It is seen that malnutrition among preschoolers has reduced appreciably and nutritional status of adults too has improved significantly. There is not only a major reduction in malnutrition, but over the past decade or so we have stepped into the realm of over nutrition. The number of overweight and obese is steadily and alarmingly rising in India. This is owing to the rapid lifestyle changes that have swept India. Mechanization, motorization, static entertainment (television and computers), sedentary life, low physical activity and the fast food culture has taken its toll. The situation is so alarming that there is a recommendation to redrawn BMI standards with a more stringent 'pen', in a hope to stall the rapid progression of lifestyle diseases - diabetes, hypertension and the coronary artery disease.

### The Interplay between Malnutrition and Infection

There has been a close association between malnutrition and infections (Fig. - 1). It is a vicious cycle that is difficult to break in the setting of poverty, ignorance and lack of health services.



Let's take fever as an example. The raised temperature escalates the metabolic rate and thus increases the nutritional demand; it also increases the tissue breakdown further putting an extra nutritional load on the system. In almost all infections the appetite goes down and the absorption and assimilation is also hampered. The requirement of nutrients is increased and to make matters worse, the supply is diminished and the absorption is reduced. The body can cope up with this situation for few days but subsequently acute severe malnutrition develops. Repeated

attacks of acute respiratory or acute diarrhoeal infections are notorious to lead to a malnourished state. Measles is another dangerous condition that has a lasting negative effect on the system through compromised immunity, micronutrient deficiency and severe malnutrition.

Malnutrition in childhood diminishes the proper development of the immune response mechanism. The cellular immune responses are markedly impaired leading to a higher mortality from the seemingly common infections.

### Variability in Nutritional Requirements

Even though there is a concept of *standard requirements and intakes*, it must not be forgotten that each person has unique nutritional requirements. This is because each one of us has a unique genetic make up and body biochemistry. A nutrient intake sufficient for one person may be inadequate for other. There are many references in literature where it is quoted that where 2 mg Vitamin B<sub>6</sub> is normally adequate for most but there are individuals with inherited defects in B<sub>6</sub> metabolism and need 30 to 100 times that amount. Similarly the absorption and daily requirements of Calcium varies 3 to 5 folds in various normal individuals. The same can be said for Vitamin D and Iron where metabolic differences in handling these nutrients alter their requirement.

Besides these genetic differences, many other factors can also alter daily requirements, including age, environment and life style choices. Factors as diverse as pregnancy, lactation, sports training, smoking and pollutants can cause nutritional needs to vary. Some of these factors are summarized in the Box - 3.

Box - 3 : Factors altering the daily requirement of nutrients	
Biochemical individuality	Genetic differences
Gender	Pregnancy
Lactation	Growth
Infections	Other diseases
Surgery	Drug-Nutrient interaction
Smoking	Alcohol
Caffeine	Environmental pollutants
Activity	Exercise level
Diet factors e.g. intake of : Carbohydrates; Fat; Fibre; Proteins	

### Dietary Standards : Concept of Recommended Dietary Allowance (RDA)

It is extremely important to plan the rations and food supplies for various groups, may it be the general community or a specialized group like the armed forces, a school or a prison.

For such a planning we must have a set of standard allowances that are universally acceptable and followed. The first such example (for cereals) can be traced back to ancient Rome (see Box - 4). The concept of various macro-nutrients first evolved in the nineteenth century. At that time the dietary requirements were stated in terms of nutrients rather than foods. In the early twentieth century vitamins came on the landscape and their requirements were also worked out and stated (10).

**Box - 4 : The Roman Pound of Wheat**

The concept of recommended allowance for the day probably came from the Romans. The Romans gave their legionaries a ration of one 'librum' of wheat per day and that was supposed to meet their caloric requirement for the day. The 'librum' became the British Pound (abbreviated to and still used as 'lb'). One pound of cereal is now known to be good enough to provide energy needed for an adult man for resting metabolism.

**Recommended Dietary Allowances or Intakes (RDA or RDI)**

The RDA of a nutrient is the amount (of that nutrient) sufficient for the maintenance of health in nearly all people (11). In other words these are the estimates of nutrient intakes which individuals in a population group need to consume to ensure that the physiological needs of all subjects in that population are met. It is an estimate that corresponds to mean intake of the given nutrient + 2 Standard Deviation (that is about 25% of the mean has been added). It covers the requirement of 97.5% of the population. This is the safe level of intake and the chances of this level being inadequate is not more than 2.5%. This 'safe level' approach is however not used for defining the energy requirement, as any excess of energy intake is as undesirable as its inadequate intake. Hence for defining the RDA of energy only the average requirement is considered. The recommended dietary allowances for Indians are summarized in Table - 1 in 'Chapter on Nutritional Tables'.

**Can the RDA be Applied to Individuals?**

It must be appreciated that the RDA is the mean requirement figure for a nutrient (except energy), to which an allowance corresponding to 2 SD has been added. There are several individuals in a population whose requirement is actually well below or above the RDA. If all the students in a class of 100 were to eat food exactly as per their RDA about half would lose and the other half would gain weight, to the extent of being seriously undernourished or obese after a year! It is because the RDA for energy is a catering average; individuals however consume as per their appetite, which follows their energy expenditure. The RDA can therefore, not be used as standard to determine whether or not a given individual's requirement of a nutrient has been met. It is therefore important to keep the principles of probability in mind and be cautious, when applying RDA at an individual level (10).

RDAs provide a standard against which the nutrients in the food eaten by a section of the community /country can be assessed. It is thus possible to find out a group with a low intake of a particular nutrient. Further nutritional investigations are then mounted to go into the details and suitable measures can be recommended. As discussed earlier, RDAs should not be used to assess the diet of an individual patient as they are designed to be on the higher side than the average individual requirement. Whenever diets are required to be planned for a group like the armed forces, a school, hostel etc., the diet should meet the RDA. Similarly, RDAs are the starting point for the food and economic planning for the agricultural, economic and food sectors. The national level food balance sheets are prepared

keeping the RDAs in mind.

**Reference Man and Woman**

The final goal of all nutritional policies and recommendations at a national level is to provide adequate nutrition to its population in order to attain their full genetic potential of growth and development. It is important that the ideal/desirable weights and heights are considered to recommend nutrient intakes. For this purpose the ICMR expert committee recommended reference weights for adult men and women to be 60 Kg and 50 Kg respectively.

**Reference Indian Adult Man** : Reference Indian adult man is between 20-39 years of age and weighs 60 Kg. He is free from disease and physically fit for work. On each working day he is employed for 8 hours in occupation that usually involves moderate activity. While not at work he spends 8 hours in bed, 4-6 hours sitting and moving about and 2 hours in walking and in active recreation or household duties.

**Reference Indian Adult Woman** : Reference Indian adult woman is between 20-39 years of age and healthy; she weighs 50 Kg. She may be engaged in general household work, in light industry or in any other moderately active work for 8 hours. While not at work she spends 8 hours in bed, 4-6 hours sitting and moving about in light activity and 2 hours in walking or active household chores.

**Energy requirements for sedentary, moderate and hard work (12)** : Energy requirements of an individual vary over a wide range depending upon the sex, age, body size, BMR and degree of physical activity. As it has been discussed earlier, energy requirements are given in terms of a Reference man/woman. Energy requirements for other individuals with different weights and age have to be calculated.

The classification of physical activity as sedentary, moderate and heavy is essentially based on the occupational activity. Some more examples are given in the Box - 5. The energy requirements for these three categories are summarized in Table 1.

**Box - 5 : Some examples : Sedentary, moderate and hard workers**

**Sedentary worker** : Teacher, tailor, barber, priest, executive, peon, retired personnel, shoe maker, housewife, maid, nurse, doctor, clerk, shopkeeper, manager, goldsmith etc.

**Moderate worker** : Potter, basket maker, carpenter, mason, electrician, fitter, turner, driver, welder, fisherman, coolie, site supervisor, post man etc.

**Heavy worker** : Stone cutter, blacksmith, mine worker, wood cutter, farm labourer, army soldier etc.

**Table - 1 : Energy Requirements of Reference Indian Man and Woman**

Sex	Body weight (Kg)	Activity levels		
		<i>Sedentary</i>	<i>Moderate</i>	<i>Heavy</i>
Male	60	2425	2875	3800
Female	50	1875	2225	2925

## Prevention of Nutritional Disease and Upkeep of Nutrition in the Community - Role of Individuals, Family, Communities and Governments

It can be well appreciated that it is not merely the 'nutritional' factors that are responsible for nutritional disease. These conditions are truly multi-factorial in origin and progression. The scarcity of food, its nutritional value, distribution, balance in diet, cultural, local and religious factors and beliefs, other social factors like ignorance, poverty, taboos, fads, peer pressure, education, hygiene and sanitation practices, infections, availability of health services, level of immunization services, political will, corporate interests, national commitment, international influences like trade laws and treaties, export-import dynamics and compulsions, inter country relations, the state of global warming - each one of these have a bearing on the nutritional status of a society. When the etiology is so diverse, the prevention too has to be so much broad based and multifaceted. The issue can be tackled at the levels of the individual, family, community and governments.

**Individual level** : Health begins with the individual. The individual has to take care of himself. Selecting the correct kind of food is vital, based on his age, physiological state, taste and tradition. Besides good diet, physical activity, adequate sleep, mental peace and appropriate meditative or religious activities go a long way in keeping an individual healthy. Knowing the nearest health centre, services available there and warning signs of common illnesses is also important.

**Family level** : Most of the foods are 'handed over' to us through traditions, and it is not easy to break out of those. Within that framework, it might be decided by the head of the family as to what food stuff is to be brought, cooked or eaten. The family needs to be aware and educated on the issues of nutrition to select the correct foods in different situations of infancy, childhood, pregnancy or lactation. This can happen only when they have risen above the myths, taboos, fads and misconceptions encompassing foods. Misleading advertisements must be put in the right perspective. Children must be explained the hazards of junk food and food additives. Traditional values with respect to food must be highlighted. The family foods used during pregnancy, lactation and weaning must be acknowledged. Locally available foods that are easily available, cheap, fresh and suitable to a particular season are ideal and must be consumed in preference to 'imported' foods. A small kitchen garden will go a long way not only in appreciating good and wholesome food but also in fulfilling the nutritional needs of the family in the most inexpensive and enjoyable manner. The most crucial nutritional decisions are taken at the family level, so the family must be empowered through correct knowledge.

**Community level** : There might be a number of bottlenecks that exist at a local level which prevent the national programmes reach the grassroot. It is up to the community to meet this challenge of making these programmes actually beneficial to the people. For example the *Gram Sabha*, the local ICDS unit (*Anganwadi*) etc. must be aware of their rights and duties, and whom to approach in case of neglect. The community must be organized and 'live' up to these needs, otherwise they will have to be satisfied with whatever is 'served' to them!

**Government level** : The responsibility of maintaining the health of individuals lies with the state. The government endeavors to provide all the health services possible. Various nutritional programmes are being implemented as direct intervention to improve the nutritional status of the community. Noteworthy of these are the ICDS Programme, Balwadi nutrition programme and the Special Nutrition programme under the Ministry of Social welfare. Ministry of Health and Family Welfare runs the Nutritional anaemia prophylaxis programme, Iodine deficiency disorders control programme and the Vitamin A prophylaxis programme. The Mid Day Meal programme (for primary children) is being run by the Ministry of Education.

Besides these various indirect measures are being taken by the government for rural development, increasing agricultural production, population stabilization and improving the public distribution system. Research in the field of nutrition is being carried out at premier institutions like the National Institute of Nutrition at Hyderabad that has contributed to offering solutions to nutritional problems.

## Summary

The science of foods and nutrients and their action, interaction and balance in relationship to health and disease; the processes by which the organism ingests, digests, absorbs, transports and utilizes nutrients and disposes off their end products is termed as nutrition. Good nutrition is a fundamental requirement for positive health, functional efficiency and productivity. There has been a close association between malnutrition and infections. It is a vicious cycle that perpetuates in the setting of poverty, ignorance and lack of health services.

The variation in the daily requirements of nutrients depends on the genetic differences, age, environment and life style choices. Factors as diverse as pregnancy, lactation, sports training, smoking and pollutants can also cause nutritional needs to vary. However a set of universally acceptable standard nutrient allowances have been devised that are useful to plan the rations and food supplies for diverse groups. The RDA of a nutrient is the amount (of that nutrient) sufficient for the maintenance of health in nearly all people. The RDA is based on the concept of Reference Indian man and woman.

## Study Exercises

**Long Question** : Discuss the role of individual, family, community and government in the prevention of nutrition related diseases.

**Short Notes** : (1) Indian reference man (2) Nutritional requirement of sedentary man (3) Malnutrition-infection cycle

### MCQs

1. Who coined the term 'vitamin' : (a) McCollum (b) Funk (c) Hopkins (d) James Lind
2. A teacher will be classified as a (a) Sedentary worker (b) Moderate worker (c) Heavy worker (d) Average worker
3. A 'safety margin' of + 2 SD is not incorporated for the RDA of (a) Energy (b) Fats (c) Water soluble vitamins (d) Fat soluble vitamins
4. Which of the following diseases is most notorious to prove fatal in combination with malnutrition : (a) Tetanus (b) Anaemia (c) Measles (d) Diarrhoea



5. Choosing what type of food to eat in a household is the function of the (a) Family (b) Government (c) Community (d) Any of the above

**Answers :** (1) b ; (2) a ; (3) a ; (4) c ; (5) a.

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## The Proximate Principles and Energy

*Rajul K Gupta*

The human body requires various nutrients for survival, maintenance of health and to prevent disease. Proteins, fats, carbohydrates, vitamins, minerals and antioxidants are the most important of these. Proteins, fats and carbohydrates are the ones which form the backbone of the nutrients in terms of quantity and these are termed as the proximate principles of food. In order to appreciate the influence of food on health and the factors which affect food requirements, it is necessary to know the chemical composition of food and its metabolism in man. The most primary function of food is to be broken down in the body to generate energy, which is vital for the very survival of the body.

Energy for basal functions, work metabolism and heat for maintenance of body temperature is produced by the oxidation of carbohydrates, fats and proteins. The intake of food is normally balanced by hunger which thus, indirectly balances energy expenditure. Hunger may, however, not indicate this in various pathological states, notably in certain forms of malnutrition. Moreover, hunger can be modified not only by enough intake of food but also by doing less muscular work. Absence of hunger is not, therefore, necessarily an index of an adequate food intake. Before going into the biochemical and physiological qualities of food let us dwell on the basics of energy.

### Energy

Energy is required for maintaining the body temperature and vital activity of organs, for mechanical work and for growth. Even when an individual is at complete rest and no physical work is being carried out, energy is required for the activity

of internal organs and to maintain the body temperature. This energy is required for maintaining the basal or resting metabolism. Age, sex, height, weight and state of nutrition of the individual are some of the factors that influence it. The Basal Metabolic Rate (BMR) is determined experimentally when the subject is lying down at complete physical and mental rest, wearing light clothing in a thermo-neutral environment and in the post absorptive state (at least 12 hours after the last meal). The BMR is related more closely to lean body mass (fat free body) rather than to the surface area. The reported value of BMR for Indians is 1 Kcal / Kg/ hr.

### Units of Energy

Calorie is the basic unit of energy. Kilo calorie is defined as the heat required to raise the temperature of 1 Kg of water by 1°C from 14.5°C to 15.5°C. The Joule (J) is the SI unit of energy. It is defined as the energy expended when a mass of one kilogram is moved one meter by a force of one Newton (N). Since Joule is too small a unit to describe the energy value of diet, kilo Joule (KJ) and mega Joule (MJ) are of more practical use. One KJ is equal to 1000 J and one MJ is equal to 1000 KJ. However, the old unit of energy, namely, kilocalorie (Kcal) has been in use in nutrition for a long time and is still being used (1, 2). For conversion, 1 Kcal = 4.184 KJ and 1 KJ = 0.239 Kcal. Energy contents of common food items are shown in Table -1 & 2 :

### Proteins

Proteins are large molecules made up of nitrogen containing amino acids that are united together by peptide linkages. In adults approximately 16% of body weight is attributable to proteins. Next to water, protein is the major component of body tissues. Proteins are indispensable constituents of living protoplasm as they participate in all vital processes. Proteins are macromolecules consisting of amino acid chains. The human body has a limited capacity of converting one amino acid into another (1, 4). A total of 22 amino acids are now known to be physiologically important for the human body. Under proper conditions, the body is capable of synthesizing some of



**Table 1 : Major contributors of energy to our diet - (Some raw foods and their energy content per 100g) (1)**

Food stuff	Energy (Kcal)	Food stuff	Energy (Kcal)
<b>Cereals &amp; Millets</b>		<b>Non vegetarian foods</b>	
Wheat flour	341	Egg (hen)	173
Rice polished	345	Fish (Hilsa)	273
Bajra	361	Chicken	109
Maize dry	342	Mutton (lean)	118
Ragi	328	Pork (muscle)	114
<b>Pulses &amp; Legumes</b>		<b>Milk &amp; milk products</b>	
Bengal gram	360	Milk, cow	67
Soya bean	432	Milk, buffalo	117
Rajmah	346	Milk, human	65
Redgram (Arhar)	335	Butter	729
Greengram (Moong)	334	Ghee	900
Lentil (Masoor)	343	Cheese	348
Pea dry	315	Curd	60
<b>Fruits &amp; Vegetables</b>		<b>Nuts</b>	
Banana	116	Groundnut	567
Apple	59	Cashew nut	596
Grapes, pale green	71	Coconut, fresh	444
Custard apple	104	<b>Miscellaneous</b>	
Jack fruit	88	Jaggery	383
Raisins	308	Sugar	398
Potato	97	Veg oils	900

**Table 2 : Energy content of selected Indian food items (per serving) (3)**

Food item	Kcal	Food item	Kcal
Samosa (1 no.)	256	Dalia (1 plate)	80
Masala dosa (1 no.)	360	Khichri (1 plate)	160
Kachori (2 nos.)	500	Biscuits (4 nos.)	150
Omlette (1 egg)	236	Poha (1 plate)	120
Puri (4 nos. x 25 g each)	320	Bread (2 slices)	125
Chapati with ghee (4 nos.)	360	Chapati (2 nos. x 35 g each)	160
Cake (1 small piece)	250	Kheer (1 katori)	120
Butter chicken (1 katori)	400	Cornflakes (1 bowl)	190
Chicken biryani (200 g)	400	Veg salad	50
Malai paneer (1 katori)	270	Butter milk (1 glass)	90
Paratha (2 nos. x 50 g each)	360	Jam (1 table spoon)	40
Ice cream (100 ml)	250	Dhokla (2 pcs)	100
Pastry (1 no.)	290	Green leafy veg (1 katori)	130
Milk cake (1 piece)	300	Idli (2 nos. x 55 g each)	155
Butter (2 table spoon)	180	Dosa (2 nos. x 45 g each)	250
Fried Cashew (50 g)	375	Tinned cheese (2 tbsp)	105

these amino acids, provided the supply of nitrogen is adequate. These amino acids are known as nonessential amino acids. Others cannot be synthesized by the body and must therefore be supplied in diet. These are the eight essential amino acids viz. leucine, isoleucine, lysine, valine, methionine, threonine, tryptophan and phenylalanine. To these may be added histidine which appears to be essential for the growth of infants (5, 6).

**Sources of proteins** : There are two main dietary sources of proteins :

- (a) **Animal Sources** : These include eggs, milk, meat and fish
- (b) **Vegetable Sources** : Pulses, nuts, cereals, beans and

oilseed cakes

The major sources of proteins are depicted in Table - 3.

**Role in health and disease** : The important functions of proteins are summarized in the Box- 1.

### Quality of Proteins

The nutritive value of a protein depends upon its amino acid composition. A biologically complete protein is one which contains all the essential amino acids in adequate amounts to meet human requirements. Proteins from foodstuffs of animal origin, such as milk, meat and eggs are biologically superior to proteins of vegetable origin as animal proteins have all the

### Box - 1: Functions of Proteins

- (a) Proteins are important for body building, growth, repair and maintenance of body tissues
- (b) Proteins are required for the synthesis of plasma proteins, haemoglobin, enzymes and hormones
- (c) Proteins like collagen, actin and myosin form the structural tissues - skin and muscles
- (d) Proteins act as transport carriers for many molecules like iron, haemoglobin, lipids etc.
- (e) Antibodies are also proteins. Proteins are involved in the acute phase of inflammation as well
- (f) Albumin, a protein, acts as a buffer in the maintenance of blood pH (7)

**Table 3 : Major sources including their protein content (g per 100g)**

Food Item (Source)	Protein content (g)	Food Item (Source)	Protein content (g)
Eggs	13.3	Milk (Cow)	3.2
Meat (goat, lean)	21.4	Fish ( <i>Hilsa</i> )	21.8
Pulses (red gram)	22.3	Soya bean	43.2
Groundnuts	25.3	Wheat flour	12.1
Rice (raw, milled)	6.8	French Beans	1.7

essential amino acids present in them. Most of the vegetable proteins lack one or more amino acid and are thus classified as biologically incomplete proteins.

The essential amino acid that is in shortest supply in a given food item is known as the *limiting amino acid*, for example the limiting amino acid in wheat is lysine and in pulses it is methionine. The quality of vegetable proteins in a vegetarian diet can be improved by providing a suitable combination of vegetable proteins. A relative lack of a particular amino acid in one protein can be compensated by simultaneous consumption of another protein, which contains that limiting amino acid. This is known as *supplementary action*. Thus a diet combining wheat products such as bread (*chapati*) with pulses (*dal*) will compensate for these deficiencies (of lysine and methionine) and provide all the essential amino acids. Other similar examples from Indian diet are *Idli-Sambhar*, *Wada-Pav*, *Rice-Dal*, *Khichri* etc.

Quantitatively the quality of a protein is worked out in terms of biological value, digestibility co-efficient, net protein utilization and protein efficiency ratio. The working formulae for each of these parameters are shown in the Box- 2. The net protein utilization (NPU) is the most commonly used parameter. A protein with an NPU of more than 65 is considered as of optimum quality. Egg protein is considered to have an NPU of 100 and is considered as ideal or reference protein against which other proteins are compared with.

**Box- 2 : Quality of Proteins**

The quality of a protein depends upon its amino acid composition. A protein containing all amino acids is considered as 'ideal'. Egg protein is taken as the reference protein.	
Biological value (BV) =	$\frac{\text{Nitrogen retained} \times 100}{\text{Nitrogen absorbed}}$
Digestibility co-efficient =	$\frac{\text{Nitrogen absorbed} \times 100}{\text{Nitrogen intake}}$
Net Protein Utilization (NPU) =	$\frac{\text{Retained Nitrogen} \times 100}{\text{Intake of Nitrogen}}$
Protein Efficiency Ratio (PER) =	$\frac{\text{Weight gain in g}}{\text{Protein intake in g}}$

#### Recommended Dietary Allowance (RDA) for Proteins :

The requirement of proteins is generally accepted to be 1g/ Kg/day for adults. So the recommended dietary allowance for a reference adult male works out to 60g/day and for a reference adult female it is 50g/day. An additional allowance of 15g/day is recommended for pregnancy. During lactation an extra allowance of 25g in the first 6 months and 18g in the subsequent 6 months is recommended. Children have a higher protein requirement as elaborated in Table - 4 (1). A detailed account of the requirements of proteins for pregnant and lactating women, infants and children is discussed in the chapter on "*Physiological requirements of nutrients*". An attempt is also made to elaborate as to how this requirement could be met in the typical Indian conditions. Some tips on improving the consumption of proteins is given in the Box- 3.

*Deficiency* can occur when the diet does not provide enough protein in relation to the requirement which may be high as in the case of young growing children. Secondly, if energy intake is insufficient proteins will be diverted to produce energy and thus causing a deficiency of proteins. Childhood infections (esp. measles) also play an important role in triggering and sustaining a long term protein deficiency. Protein Energy Malnutrition (PEM) is a major cause of concern for children in our country. PEM is discussed in greater details in Chapter on 'Nutritional Deficiency Diseases'.

**Table - 4 : Recommended Dietary Allowance (RDA) for Proteins**

Group	Activity	Body weight	Requirement g/day
Man	Sedentary work		
	Moderate work	60	60
	Heavy work		
Woman	Sedentary work		
	Moderate work	50	50
	Heavy work		
	Pregnant woman	50	+ 15
	Lactation		
	0-6 months	50	+25
	6-12 months		+ 18
Infants	0-6 months	5.4	2.05/ Kg
	6-12 months	8.6	1.65/ Kg
Children	1-3 years	12.2	22
	4-6 years	19.0	30
	7-9 years	26.9	41
Boys	10-12 years	35.4	54
Girls	10-12 years	31.5	57
Boys	13-15 years	47.8	70
Girls	13-15 years	46.7	65
Boys	16-18 years	57.1	78
Girls	16-18 years	49.9	63

<b>Box - 3 : Recommendations on Diet for Proteins</b>
Eat nutritionally balanced diet to get adequate protein
Meat and fish are good sources
Vegetarians must eat proper combination of plant proteins from both cereal and pulses groups
Include Soyabean in your diet
Two to three servings of protein-rich food must be ensured every day
One serving may be equivalent to : - One to two cups of cooked meat, poultry, fish - Half cup of cooked dry beans/ lentils/ legumes - One egg - Handful of fried/roasted- salted groundnuts - Handful of roasted Bengal grams

<b>Table-5 : Major sources including their fat content (g/100g)</b>	
<b>Food Item (source)</b>	<b>Fat content (g/100g)</b>
Eggs (hen)	13.3
Milk, cow	4.1
Meat (Goat lean)	3.6
Fish (Hilsa)	19.4
Ghee	100
Butter	81.0
Groundnut	40.1
Mustard seeds	39.7
Coconut, fresh	41.6
Sunflower seeds	52.1

## Fats

Fats are organic compounds, which are insoluble in polar solvents (water) but soluble in organic solvents such as ether, chloroform and benzene. These are actual or potential esters of fatty acids. Fats are only distinguished from oils by their different melting points; fats are solid and oils liquid at room temperature. 'Fats' and 'oils' are the ones which the housewife buys and 'lipid' (Greek, *lipos* meaning fat) is the term used by biochemists. However, the general term fat is commonly used to refer to the whole group and is used interchangeably with lipids.

**Sources of fats** : Dietary fats are derived from two main sources:

**(a) Animal Sources** : They are milk and milk products (ghee, butter), lard, egg and fish oils. Animal fats in general are poor sources of essential fatty acids with the exception of certain marine fish oils such as cod liver oil and sardine oil, but they are good sources of retinol and cholecalciferol.

**(b) Vegetable Sources** : They include various edible oils such as groundnut, gingely, mustard, cottonseed, safflower, rapeseed, palm and coconut oil. Vegetable oils with the exception of coconut oil are all rich sources of essential fatty acids, but they lack retinol and cholecalciferol except red palm oil which is rich in carotenoids. Major sources including their fat content are given in Table - 5.

**Visible and invisible fats** : The visible fats are generally derived from animal fats e.g. butter or ghee or from plant (vegetable) oils like groundnut, mustard, coconut, sunflower or safflower seeds. Hydrogenated oils and margarine would also be classified as visible oils. The visible fat is added to food for cooking, flavouring or shortening. These are the major sources of fats in our diet. Chemically they are triglycerides of fatty acids and could be saturated or unsaturated. It is now believed that the bare minimal requirement of visible fats to meet the essential fatty acid requirements is 15 to 25 g per day. The upper limit is fixed at 30% of the total energy intake or less

than 80 g / day.

Some amount of fat is present in all food stuffs. From the nutritional standpoint, important of them are cereals, pulses, oilseeds, nuts, milk, eggs and meat. Contrary to general awareness, this invisible fat contributes substantially to the total fat consumption and essential fatty acid intake of our diet. Cereals and pulses which are otherwise perceived to be poor in fats contribute significantly towards fat intake of a Indian diet. This is because most Indians depend on the 'staple' of cereals, consumed in a large quantity. The invisible fats may account for 20 to 50% of all fats consumed, depending on the type of diet. It should however contribute to not less than 6% of total energy or about 15g of invisible fats per day.

## Types of Fatty Acids

Fatty acids are composed of a straight hydrocarbon chain with one methyl group ( $-\text{CH}_3$ ) and terminating with a carboxylic acid group ( $-\text{COOH}$ ). Hydrogen atoms are attached to the carbon chain; the number of hydrogen atoms determines the degree of saturation (with hydrogen atoms) of the fatty acid. A fatty acid with hydrogen atoms on every arm is said to be 'saturated'. Unsaturated fatty acids contain double carbon bonds where there is no hydrogen. If there is only one double bond, the fatty acid is termed as monounsaturated and when more than one double bond is present, the fatty acid will be polyunsaturated.

**Saturated Fatty Acids (SFA)** : *Saturate* (Latin, *to fill*, in this case with hydrogen). Saturated Fatty acids have a relatively high melting point and tend to be solid at room temperature. These are obtained from animal storage fats and their products e.g. meat fat, lard, milk, butter, cheese and cream. Fats from plant origin tend to be unsaturated with the exception of coconut oil and palm oil. A high intake of SFA is associated with an increase in LDL and total cholesterol and thus increases the risk of atherogenesis and cardiovascular disease. Some examples of SFAs are Myristic acid, Palmitic acid and Stearic acid.

**Monounsaturated Fatty Acids (MUFA)** : MUFA contain only one double bond and are usually liquid (oil) at room temperature. Olive oil and rapeseed oil are good dietary sources

of MUFA. MUFA are also present in meat fat and lard. Dietary MUFA does not raise plasma cholesterol. They lower LDL cholesterol without affecting the HDL. Oleic acid is an example of MUFA.

**Polyunsaturated Fatty Acids (PUFA)** : PUFA contain two or more double bonds and they too are liquid at room temperature. They are easily oxidized in food and in the body. PUFA have a vital role in immune response, blood clotting and inflammation. PUFA are divided into omega-3 ( $\omega 3$ ) or omega 6 ( $\omega 6$ ) groups of PUFA. Omega-3 ( $\omega$ ) polyunsaturated fatty acids PUFA are found in fish and fish oils. The health benefits of these include reducing the cardiovascular risk factors (see Box - 4). Research also indicates their beneficial role in cognitive function of brain. Some common omega-3 fatty acids are  $\alpha$ -linolenic acid (linseed, soyabean, rapeseed, leafy vegetables), eicosapentaenoic acid (marine algae, fish oils) and docosahexenoic acid (fish oils).

**Box-4 : Omega-3 ( $\omega 3$ ) Fatty Acids in Prevention and Therapy**

**Coronary artery Disease (CAD)** : Omega-3 ( $\omega 3$ ) Fatty Acids reduce the tendency of platelet aggregation, blot clot formation and thus atherosclerosis. Chances of cardiac arrhythmias also go down, thus benefiting in CAD.

**Hypertension** : They lower the high blood pressure in hypertensives.

**Hyperlipidaemia** : They lower the high blood lipids (triglycerides and total cholesterol), while increasing HDL-c.

**Bronchial asthma** :  $\omega 3$  Fatty Acids reduce inflammation, frequency and severity of asthma.

**Diabetes** : They lower the high blood triglycerides blood pressure and reduce leakage of proteins from small vessels, thus improving the overall metabolism and the diabetic state.

**Autoimmune disorders** : Omega 3-Fatty Acids are known to reduce pain, inflammation and joint stiffness in rheumatoid arthritis. Other autoimmune disorders also improve with their supplementation.

**Miscellaneous** : They are found to be useful in conditions like migraine, inflammatory skin disorders and osteoarthritis.

**Trans Fatty Acids (t-FA)**

Trans fatty acids rarely occur in nature. These are produced during the partial hydrogenation of PUFA. In Indian homes this process takes place commonly when oil is heated over and over again as it happens during the process of frying *puri*, *pakori* or *samosa*, esp. when the same oil is boiled repeatedly. Trans fatty acids have been associated with adverse effects on lipoprotein status by elevating LDL and depressing HDL.

**Essential Fatty Acids (EFA)**

If fats are entirely excluded from the diet, retarded growth, dermatitis, kidney lesions and an early death might result. Studies have shown that feeding of certain unsaturated fatty acids e.g. linoleic and linolenic acid is effective in curing the condition. It is therefore evident that certain unsaturated fatty acids cannot be synthesized in the body and must be acquired from diet. These are essential fatty acids. EFA are commonly found in plant and fish oils (8). The EFA requirement is 3-6% of the total energy intake depending on the age and physiological status of the individual. Fatty acid content of different fats is given in Table - 6.

**Why fats in diet?** : If the contemporary literature is to be believed, one tends to agree that fats are well known for their role in causation of many chronic diseases rather than any worthwhile virtue! Then why should fat be consumed at all and how much? The main functions of fat are elaborated in the Box - 5.

Unlike proteins where the precise intake, assimilation, excretion and thus requirement can be worked out, the quantity of fats that should be included in a well balanced diet is a matter of conjecture. The following aspects however are important in considering the recommendation for fat intake :

- The quantity of fat intake should be good enough so that requirement of essential fatty acids (which are a component of fats) is met.
- Absorption of fat soluble vitamins should not be compromised.
- Fat intake should be sufficient enough to make diet palatable.
- Some stores must be maintained in the body to tide over a lean period.
- It should not be so much in quantity that it causes undesirable effects on health.

**Cholesterol**

Cholesterol is always talked as if it is the hazardous abnormal fat. It is considered by many as a type of a saturated fat. In fact it is only a fat related compound. Chemically it falls under the group of sterols. It is named after the body material where it was first identified, the gallstones (Greek, *chole*, bile; *steros*, solid)

**Synthesis** : It is synthesized only in the animal body. All plant products are free of cholesterol. The human body synthesizes indigenous cholesterol primarily in liver (but also in adrenal cortex, skin, intestines, testis and ovaries), for sustaining life. It is a normal constituent of bile and a principal part of the gall stones

**Sources** : The important dietary sources are egg yolk, meat (liver and kidney). There are no plant sources of cholesterol

**RDA** : Since it is synthesized indigenously in the body, there is no dietary requirement of cholesterol. However, the upper limit of cholesterol consumption has been put at 300mg per day

**Functions** : It is vital as a precursor to various steroid hormones e.g. sex hormones and adrenal corticoid hormones.

**Hazards** : In dysfunctional lipid metabolism, it is considered the major factor for atherosclerosis. Epidemiological studies have linked high cholesterol intake to the increased risk of coronary heart disease



**Table - 6 : Approximate fatty acid composition of common fats and oils (g/100g) (8)**

Oil/Fat	Saturated	MUFA	Linoleic acid	$\alpha$ -linolenic acid	Predominant FA
Coconut	90	7	2	<0.5	SFA
Palm kernel	82	15	2	<0.5	SFA
Ghee	65	32	2	< 1.0	SFA
Vanaspati	24	19	3	<0.5	SFA (t-FA)
Red palm oil	50	40	9	<0.5	SFA + MUFA
Palm oil	45	44	10	<0.5	SFA + MUFA
Olive	13	76	10	<0.5	MUFA
Groundnut	24	50	25	<0.5	MUFA
Rape/Mustard	8	70	12	10	MUFA
Sesame	15	42	42	1.0	MUFA + PUFA
Rice bran	22	41	35	1.5	MUFA + PUFA
Cotton seed	22	25	52	1.0	PUFA
Corn	12	32	55	1.0	PUFA
Sunflower	13	27	60	<0.5	PUFA
Safflower	13	17	70	<0.5	PUFA
Soyabean	15	27	53	5.0	PUFA

**Table - 7 : RDA of Fats for Indians**

Group	Particulars	Body wt (Kg)	RDA Fat (g/d)
Man	Sedentary work	60	20
	Moderate work		
	Heavy work		
Woman	Sedentary work	50	20
	Moderate work		
	Heavy work		
	Pregnant woman	50	30
	Lactation		
	0-6 months	50	45
	6-12 months		
Infants	0-6 months	5.4	
	6-12 months	8.6	
Children	1-3 years	12.2	25
	4-6 years	19.0	
	7-9 years	26.9	
Boys	10-12 years	35.4	22
Girls	10-12 years	31.5	
Boys	13-15 years	47.8	22
Girls	13-15 years	46.7	
Boys	16-18 years	57.1	22
Girls	16-18 years	49.9	

Based on these aspects, the ICMR has recommended levels of fat intake for Indians (RDA) that are summarised in Table - 7.

**Recommended Dietary Allowance :** The RDA for adults is 20g of visible fat per day. For pregnant and lactating women it is 30 and 45 g respectively. The RDAs for various groups are given in Table - 7 (1). Fat content of diet should not exceed 20 to 30% of the total calories consumed. The dietary cholesterol should be limited to 300 mg/day.

**Hazards of Excess Fat in Diet :** Excess fat is dangerous on two accounts. First, in case it is consumed in a higher quantity and secondly if the wrong quality of fat is consumed.

**Quantity of Fat :** With an improving economy and a richer lifestyle we tend to consume a higher calories especially from the fat source. Higher calories lead to obesity and many other lifestyle diseases. A high level of fat in diet is notorious in the causation of atherosclerosis and so is a major risk factor for Cardiovascular Diseases (CVD) including coronary artery disease and strokes. Any amount that contributes to more than 30% of total calorie intake is considered as high. Low physical activity and sedentary lifestyle further augment the risk.

**Quality of Fat :** High levels of saturated fatty acids are more dangerous. A proportionately higher content of polyunsaturated

#### Box - 5 : Functions of Fats

They are concentrated sources of energy providing about 37.7 KJ/g or 9 Kcal /g.

Fats serve as vehicle for fat soluble vitamins (A,D, E and K).

Fats are structural components of cell and cell membrane.

They are the sources of essential fatty acids. Linoleic acid and arachidonic acid are precursors of prostaglandins which are required for a wide variety of metabolic functions.

Apart from their nutritional significance, fats improve the palatability of diet, delay gastric emptying & raise the caloric density.

Some fats can be converted to biologically active compounds such as steroid hormones, interleukins, thromboxanes and prostaglandins and bile acids (from cholesterol).

fatty acids is found to be protective for CVD. Unfavourable levels of certain lipoproteins have adverse effects on health. High levels of LDL are associated with higher atherosclerotic risk so LDL is colloquially known as '*bad cholesterol*'. A high level of HDL has favourable effect on the cardiovascular system and is termed as '*good cholesterol*'.

Tips on fat intake	
Food preparation	Use minimal oil for preparation
	Rotate the types of oil used
	Use only lean cuts of meat
Meat	Prefer fish to poultry
	Prefer poultry to mutton/beef/pork
	Limit added oils in meat preparations
Eggs	Avoid more than one egg a day
	Avoid adding oil to egg preparations
	Use egg whites freely
Milk	Prefer low fat milk

## Carbohydrates

Carbohydrates are the basic source of fuel to run life on earth. It is these carbohydrates into which the energy from sun is converted through the process of photosynthesis by plants. In fact this is the energy that is used by all living organisms. Thus carbohydrates can be considered as the very 'basis' of life. Chemically carbohydrates are polyhydroxy aldehydes or ketones, or substances that produce such compounds when hydrolyzed. They contain carbon, oxygen and hydrogen in proportion approximating that of a 'hydrate of carbon' ( $\text{CH}_2\text{O}$ ), hence the term carbohydrate.

**Classification** : From the nutritional or functional point of view, carbohydrates can be divided into two categories.

**(a) Available carbohydrates** : These are the carbohydrates which can be digested in the upper gastrointestinal tract, absorbed and utilized. These are further sub-classified as polysaccharides, disaccharides, monosaccharides.

(i) *Polysaccharides* such as starch, dextrin and glycogen

(ii) *Disaccharides* such as lactose, sucrose and maltose

(iii) *Monosaccharides* such as glucose, fructose and galactose.

**(b) Dietary Fibre** : The second category comprises of unavailable carbohydrates or dietary fibre, which are difficult to digest. These are cellulose, hemicellulose, gums, pectins etc. A detailed account of these is given later in this chapter.

**Sources of Carbohydrates** : The major source of dietary carbohydrates in an Indian set up is starch from cereal grains, millets, legumes, roots and tubers (Table - 8).

With increasing prosperity as in industrial societies, sugar has replaced complex carbohydrates as the main source. The presence of monosaccharides (free glucose or fructose) is limited to fruits and vegetables, otherwise they are not abundant in natural foods. Fructose is found in honey, fruits and vegetables. Sucrose and Lactose are the commonest disaccharides. Sucrose is extracted from sugar cane. Table sugar is 99% sucrose. Sucrose gets hydrolysed into glucose and

**Table - 8 : Major sources of carbohydrates (per 100 g) (1)**

Food stuff	Carbo- hydrates (g)	Food stuff	Carbo- hydrates (g)
<i>Cereals &amp; Millets</i>		<i>Pulses &amp; Legumes</i>	
Wheat flour	69.4	Bengal gram	60.9
Rice polished	78.2	Soya bean	20.9
Bajra	67.5	Rajmah	60.6
Maize dry	66.2	Redgram (Arhar)	57.6
Ragi	72.0	Pea dry	56.5
<i>Fruits &amp; Vegetables</i>		<i>Miscellaneous</i>	
Banana	27.2	Milk, cow	4.4
Apple	13.4	Groundnut	26.1
Mango	16.9	Cashew nut	22.3
Raisins	74.6	Coconut, fresh	13
Tapioca	38.1	Jaggery	95
Sweet potato	28.2	Sugar	99.4
Potato	22.6	Honey	79.5

fructose. Lactose is found in milk. It is hydrolysed to glucose and galactose. Maltose is present in malted wheat and barley. Other sources are nuts and seeds.

**Functions of Carbohydrates** : Carbohydrates are the most significant and cheapest source of energy in the diet. One gram of carbohydrates provides 4 Kcal energy. Carbohydrates provide 60 to 85% of energy in our Indian diet. Various kinds of sugars (glucose, fructose, sucrose etc.), most literally, impart the sweet taste to life! Carbohydrates play an important role wherein glycogen resources in the muscles and liver are in a state of dynamic exchange with the energy balance (of intake and expenditure) through the liver. A constant supply of carbohydrates has a protein sparing action and proteins are not required to be broken down for energy. Similarly fats are also spared to be used up if enough carbohydrate supply is maintained. The brain exclusively uses glucose and is dependent on its constant supply for its functioning.

Fibre, which is a type of carbohydrate, has the important function of increasing faecal bulk, stimulating peristalsis and blocking cholesterol synthesis in the liver.

**Requirement of Carbohydrates** : In a prudent diet carbohydrates should contribute to 60 to 70% of total energy (1). This translates to about 360 to 400g carbohydrates for a 2400 Kcal diet. Details about role and requirements of dietary fibre are discussed in forthcoming paragraphs.

**Problems Due to Deficiency and Excess** : Whenever there is a deficiency of carbohydrates in diet not compensated by other nutrients, a situation of energy deficiency sets in. This is typically seen in infants and children wherein protein calorie malnutrition is not uncommon. A similar situation of energy deficiency may result in food deprived people in cases of starvation as encountered in famines and droughts. Anorexia nervosa is a condition with a major psychological component,

wherein the patient doesn't eat food and ends up being cachexic. A very low carbohydrate diet results in utilization of other macronutrients (lipids and proteins) for energy and result in production of ketone bodies (ketosis). Eventually bone mineral loss, hypercholesterolaemia and increased risk of urolithiasis may result.

Consumption of an excess of carbohydrates seems to be a bigger problem in the present day scenario of progressive economies. If the intake is large enough to provide excessive calories such an individual ends up being obese and might fall prey to a host of lifestyle diseases (discussed in another chapter). It is interesting to note that excess of even few calories per day (100-200 Kcal) over a couple of months accumulates enough calories to cause obesity.

### Dietary Fibre

Denis Burkitt (a surgeon) and Hugh Trowell (a physician), served for 30 years, after the World War II, in Makerere University, Kampala, Uganda, before returning to Britain. They were struck by the great difference in the pattern and nature of disease affecting the affluent West as opposed to more primitive communities. They concluded that the large amount of dietary fibre was not only responsible for the faecal bulk but was also directly or indirectly related to the difference in the pattern of disease. A 'fibre hypothesis' was thus formulated which suggested that unrefined complex carbohydrates protected against the 'western ailments': colonic cancer, diverticular disease, appendicitis, constipation, hemorrhoids, hiatus hernia, varicose veins, diabetes, heart disease, gall stones, obesity etc.

Dietary fibres are the remnants of the plant cell resistant to hydrolysis by alimentary enzymes and do not provide significant nourishment. They remain in the ileum but are partially hydrolyzed by the colonic bacteria. The term 'dietary fibre' is a broad term which includes Non Starch Polysaccharide (NSP) and related material such as resistant starch, resistant oligosaccharides, lignin and complex assemblies of plant tissue where polysaccharides occur in close association with other molecules (9).

**Classification** : Fibres can be *Carbohydrate fibres* and *non-carbohydrate fibres*. The carbohydrate fibres include Non Starch Polysaccharides (NSP) which are normally present in cell wall, cement, plant gums, mucilages and algal polysaccharides; and the Resistant Oligosaccharides (ROS) which are found in leguminous seeds e.g. Rajma, soy beans and gram (10). The *Non Carbohydrate fibres* include Lignin which is a large compound forming the woody part of some plants. It strengthens the plant cell walls.

Fibre can also be classified according to solubility in water, as soluble or insoluble. Insoluble fibre consists mainly of cellulose, hemicellulose and lignin. Since they remain undigested in the gut they form bulk and help in movement of the food and peristalsis. Thus they help in elimination of waste products as well. After absorption of water the fibre swells up and facilitates the gut movement further.

On the other hand the natural gel forming fibres like pectins, gums and mucilages are soluble.

**Sources and Losses** : Cereals, fruits and vegetables are the chief sources of fibres. The important sources of soluble and insoluble fibre are summarised in Table - 9.

Table - 9 : Major food sources of fibre	
Insoluble fibres	
<b>Vegetables</b> : Peas, beans, amaranth leaves	
<b>Cereals</b> : Rye, bran flakes, brown rice, Corn, whole wheat	
<b>Whole meal cereals</b> : <i>Dalia</i> , whole meal flour, <i>Ragi</i> porridge	
<b>Breads</b> : Granary bread, brown bread	
<b>Legumes</b> : Bengal gram (whole), Lentils pulses and <i>dals</i>	
<b>Sprouts</b> : Sprouted grains, legumes	
<b>Fruits</b> : Fruits with edible seeds	
Soluble fibre	
<b>Citrus fruits</b> : Orange, lime	
<b>Berries</b> : Straw berry, rasp berry	
<b>Other Fruits</b> : Pomegranate, Figs, grapes, guava, Sapota, Custard apple	

**Functions** : Dietary fibre stimulates chewing, improves flow of gastric juice and provides a sense of satiety. Insoluble fibre binds to water in the colon and swells. Hence, it forms substrate for colonic bacterial fermentation. This stimulates peristalsis which increases transit time in the colon thereby reducing the risk of constipation and possibly that of colon cancer. Some fibres like lignin helps in prevention of absorption of bile acids by binding to them. On the other hand soluble fibres prevent the micelle formation by binding with bile acids and other lipids (11).

**Recommended Dietary Allowance** : The diet should contain 35-40 grams of dietary fibre per day (15g per 100Kcal) (1). Fibre content of selected food stuffs are given in Table - 10.

Table - 10 : Dietary fibre content of common foods (g/100g)			
Foodstuff	Fibre content (g per 100g)	Foodstuff	Fibre content (g per 100g)
Cereals & Legumes		Fruits	
Rice, raw, milled	0.2	Guava	5.2
Wheat flour, whole	1.9	Mango, papaya	0.7
Bengal gram, whole	3.9	Pomegranate	5.1
Red gram ( <i>Dal arhar</i> )	1.5	Peach, pears, apple	1.0-1.2
Peas dry, <i>Rajmah</i>	4.5	Figs, Sapota	2.2-2.6
Green vegetables		Nuts	
Cabbage, cauliflower, Fenugreek ( <i>maithi</i> )	1.0 -1.2	Areca nut	11.2
Amaranth	1 to 6.1	Coconut fresh	3.6
Spinach, radish leaves	0.6	Groundnut	3.1

**Dietary Fibre in Health and Disease** : Fibre helps in achieving prevention of cardiovascular disease through various mechanisms

- Soluble fibre binds with bile acids and alters the quantity of cholesterol or fatty acids absorbed.
- The re-absorption of bile acids is slowed by soluble fibre to increase cholesterol losses in faeces.
- Intestinal bacteria reduce soluble fibre to short chain fatty acids which block cholesterol synthesis in the liver.

Fibres also help in the maintenance of weight and prevention of obesity. Soluble fibre blunts the response of blood glucose through prevention of direct glucose absorption in the gut. This helps in the control of hyperglycaemia. Soluble and viscous fibres (pectin and gums) have the greatest hypoglycemic effect (12).

Fibre is also considered to be an important contributory factor to the prevention of colonic cancer (13).

In addition, fibre increases faecal bulk and relieves constipation. This reduces the incidence of colonic cancers, diverticulitis and appendicitis. The alteration in cholesterol production and further metabolism reduces the formation of gallstones as most of them are of cholesterol origin.

## Study Exercises

**Short Notes** : (1) Dietary fibre in prevention of lifestyle diseases (2) Hazards of excess fats in diet (3) Invisible fats (4) Dietary importance of egg (5) Supplementary action of proteins

### MCQs

- Which is true for cholesterol (a) It is a type of saturated fatty acid (b) It is present in egg yolk, ghee and coconut oil (c) The dietary requirement of cholesterol is zero (d) Everyone with high cholesterol gets IHD
- Which of the following is not a source of dietary fibres (a) Vegetable fibres (b) Muscle fibres (c) Bran (d) Fruits

- The limiting amino acid in wheat is \_\_\_\_ and in pulses it is \_\_\_\_ (a) Lysine, methionine (b) Methionine, lysine (c) Cysteine, lysine (d) Lysine, cysteine
- Which lipoprotein is termed as 'good' cholesterol : (a) LDL (b) HDL (c) VLDL (d) Chylomicrons
- Which of these will provide energy the quickest : (a) Milk (b) Chapati (c) Butter chicken (d) Fruit juice

**Answers** : (1) b; (2) b; (3) a; (4) b; (5) d.

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*"Milk and leaves occupy a unique position, as they correct the defects of cereals, tuber, roots and meats. Thus...they be distinguished by the term 'Protective foods'."*

~ EV McCollum (1)

By and large vitamins were discovered during the search for cures of classic deficiency diseases. In 1753 when James Lind, a British naval surgeon, observed that fresh lemons, limes and oranges, prevented/cured scurvy, the British sailors always carried lemons with them on long voyages and were nicknamed

as 'limeys'.

Many subsequent observations and experiments in 1896 by C Eijkman on rice polishings and beriberi, Frederick Hopkins of Cambridge University on milk in 1906, Verner McCollum (USA) on the fat soluble factor (Vitamin A) in 1916 just to name a few, established them to be vital for life that paved the way for the vitamins to be named so (from the words *vital amine*) by Casimer Funk, a Polish scientist in 1912.

**Definition** : Vitamins are organic compounds required in very small but definite quantities for normal growth and maintenance of a healthy life. They are not synthesised in the body and have to be supplied in the diet. They do not furnish energy and play no part in the constitution of the structure of tissues, but are essential for the transformation of energy



and regulation of tissue metabolism. They are necessary for the efficient functioning of the organism as a whole, each in a specific manner. Deficiency of vitamins causes profound changes in structural and functional wellbeing, the picture of each deficiency being specific.

**Dietary sources :** Vitamins are widely distributed in diet. Fresh milk, meat, eggs, fresh vegetables and fruits are rich sources. Cereals (esp. whole unrefined cereals) which form the bulk of our diet are also important sources. Storage, processing and cooking of food may cause considerable vitamin loss, so that the maintenance of an adequate intake is more difficult when fresh food is scarce. The pharmaceutical use of vitamins should be restricted to rectify or supplement the envisaged or existing deficiency in the diet or to meet the increased physiological demands (e.g. in pregnancy). No physiological benefit, however, can be expected from a large dose of vitamins under normal circumstances.

**Classes of vitamins :** Vitamins have long been classified into two groups; water soluble and fat soluble. The water soluble group comprises of vitamins B and C; the fat soluble vitamins are A, D, E and K. This division is still useful, since it helps to understand the distribution of vitamins in foods and their absorption and metabolism in the body.

**Storage and excretion :** There is an important distinction in the handling of the two classes of vitamins by the body. An excess intake of water soluble vitamins is excreted in the urine. Thus, there is virtually no danger in giving an excess of these vitamins. On the other hand, the fat soluble vitamins cannot be excreted in this way. Any excess of these vitamins, beyond the immediate requirement is stored in the liver. The storage capacity of the human liver is large and it normally holds a reserve of vitamins sufficient for many months; this is a useful provision for times when the dietary supply may temporarily be cut off. However the amount that can be stored is not unlimited (2).

**Functions :** As mentioned earlier they do not furnish energy and play no part in the constitution of the structure of tissues directly, but are essential for control of cell metabolism, transformation of energy, and prevention of specific nutritional deficiencies.

Many vitamins are now known to have antioxidant properties. This has rejuvenated the interest of scientist in exploring further the hidden potential of these vitamins in maintaining health and also curing disease. The scope of vitamins has now widened from their earlier role of curing specific deficiencies to preventing cancers and even aging! A summary of the traditional functions of major vitamins are given in tables at the end of this chapter.

## Water Soluble Vitamins

### Thiamine (Vitamin B<sub>1</sub>)

Thiamine hydrochloride is a crystalline substance which is readily soluble in water. It is rapidly destroyed by heat in neutral or alkaline solutions. In acid solutions however, it is resistant to heat up to 120°C. It is mainly excreted in urine. Thiamine is present in the body mostly as thiamine pyrophosphate (TPP) but about 10 percent as thiamine triphosphate. TPP is the

active form of thiamine in the body.

**Sources :** The important stores are seeds of plants. The germ of cereals, nuts, pea, beans and other pulses and in addition yeast is a rich source. In cereal grains, thiamine is found in highest concentration in the germ or embryo, less in bran and least in endosperm. All green vegetables, roots, fruits, nuts, flesh foods and dairy produce contain significant amounts of the vitamin. Pork has a higher content of thiamine than beef or mutton. Highly processed foodstuffs like white bread, polished rice and refined sugar are deficient in thiamine (See Table-1).

**Table 1: Thiamine content of selected food items (per 100g) (4)**

Food stuff	Thiamine (mg)	Food stuff	Thiamine (mg)
<i>Cereals</i>		<i>Vegetables</i>	
Wheat flour	0.49	Beans	0.10
Rice polished	0.06	Spinach	0.03
<i>Bajra</i>	0.33	Carrot	0.04
Maize dry/ <i>Ragi</i>	0.42	Capsicum	0.55
<i>Pulses &amp; Legumes</i>		<i>Fruits</i>	
Bengal gram	0.30	Pineapple	0.2
Soya bean	0.73	Guava	0.03
Green gram	0.47	<i>Amla</i>	0.03
Red Gram	0.45	Tomato	0.12
Peas dry	0.47	Mango	0.08
<i>Non vegetarian foods</i>		<i>Nuts</i>	
Egg	0.10	Groundnut	0.90
Liver sheep	0.36	Cashew nuts	0.63
Milk cow	0.05	Almond	0.24
Fish, <i>Rohu</i>	0.05	Coconut, fresh	0.05
Mutton	0.18	Coconut, dry	0.08

**Losses :** Milling of cereals below an extraction rate of 75 percent reduces the content of thiamine to a great extent. As thiamine is readily soluble in water, considerable amounts may be lost when foodstuffs are cooked in an excess of water which is afterwards discarded. It is relatively stable to heat up to boiling point, provided that medium is slightly acidic, as in baking with yeast. But if baking powder is used, or if soda is added in the cooking of foodstuffs, almost all the vitamin may be destroyed.

**Functions :** Thiamine is one of the most important water soluble vitamins and acts as a coenzyme in many metabolic reactions. The important ones being the oxidative decarboxylation of pyruvic acid and transketolase reaction in HMP shunt. The vitamin is essential for the health of the nerve tissue and for normal cardiac and gastro-intestinal functions (5,6).

**Requirements :** Since thiamine plays an important role in carbohydrate metabolism, its dietary allowance is related to energy intake. It is 0.5mg per 1000 Kcal (4).

**Deficiency** : Thiamine deficiency causes beriberi and Wernicke-Korsakoff psychosis. Three forms of Beriberi are known: Wet Beriberi (cardiac), Dry Beriberi (neurological) and Infantile Beriberi. The early symptoms and signs are common in both dry and wet Beriberi. The onset is usually insidious, though sometimes precipitated by unwanted exertion or a minor febrile illness (5).

#### Beriberi

(*Singhalese*, meaning “*I can’t, I can’t*”). The disease caused by the deficiency of thiamine, characterized by oedema resulting from cardiac failure (Wet beriberi) or peripheral neuritis, pain in limbs and paralysis (Dry beriberi).

(a) *Wet beriberi* is the acute form. It is characterized by high output cardiac failure, bounding pulse, warm extremities, peripheral oedema and cardiac dilatation.

(b) *Dry beriberi* is the chronic form of disease and is characterized by progressive peripheral neuropathy. The tendon jerks are sluggish and anaesthesia of the skin (especially over tibia) is common. The muscles become progressively wasted and weak and walking becomes increasingly difficult. The thin, even emaciated individual needs at first one stick, then two and may finally become bedridden.

(c) *Infantile beriberi* occurs in the first few months of life (of an infant), if the diet of mother is deficient in thiamine. The infant remains constipated and appears plump due to water retention. The heart is enlarged and the heart sounds are muffled. The infant may die of a heart failure if untreated (7)

(d) *Wernicke-Korsakoff psychosis* is seen in chronic alcoholics with poor diet. It is characterised by confusion, low levels of consciousness and poor coordination (encephalopathy). Memory loss often follows the encephalopathy.

#### Riboflavin

Riboflavin, the word comes from a Latin word *flavous*, yellow, containing a sugar named ribose). As is clear from the name it is a yellow green fluorescent compound, soluble in water but not in fats. Though stable in acid solution, in alkaline solution it is readily destroyed by heat. It is also destroyed by short visible and ultraviolet rays.

**Sources & Losses** : The best sources of riboflavin are liver, milk, eggs and green vegetables (See Table-2). Cereals and yeast extracts also contain the vitamin. Cooking does not destroy the vitamin apart from losses that occur when the water in which green vegetables have been boiled is discarded. If food, especially milk, is left exposed to sunshine, large losses may occur.

**Functions** : Riboflavin is involved in oxidation-reduction reactions within the cells in many metabolic pathways. The important functions of riboflavin include:

- Promotion of normal growth
- Assisting synthesis of steroids, RBC and glycogen
- Maintenance of mucous membranes, eyes and the nervous system
- Aiding iron absorption (5)

**Table 2 : Riboflavin content of selected food items (per 100g) (4)**

Food stuff	Riboflavin (mg)	Food stuff	Riboflavin (mg)
<b>Cereals</b>		<b>Vegetables</b>	
Wheat flour	0.17	Beans	0.06
Rice polished	0.06	Spinach	0.26
Bajra	0.25	Carrot	0.02
Maize dry	0.1	Amaranth	0.30
<b>Pulses &amp; Legumes</b>		<b>Fruits</b>	
Bengal gram	0.15	Pineapple	0.12
Soya bean	0.39	Guava	0.03
Green gram	0.47	Raisins	0.19
Red Gram	0.45	Tomato	0.06
Peas dry	0.47	Mango	0.09
<b>Non vegetarian foods</b>		<b>Nuts</b>	
Egg	0.40	Groundnut	0.13
Liver sheep	1.7	Cashew nuts	0.19
Milk cow	0.19	Almond	0.57
Fish, Rohu	0.07	Coconut, fresh	0.10
Mutton	0.14	Coconut, dry	0.01

**Requirements** : The requirement of this vitamin is also related to energy intake. It is about 0.6 mg per 1000 Kcal. The daily safe requirement ranges from 0.7 to 2.2 mg/day (4).

#### Deficiency

Certain conditions are known to be at high risk of Riboflavin deficiency (Box - 1).

#### Box - 1 : Increased Risk of Riboflavin Deficiency

**Growth** : childhood, adolescents

**Pregnancy, lactation**

**Malabsorption** : Tropical sprue; Celiac disease; Chronic diarrhoea; Irritable bowel syndrome

**Drugs impairing absorption** : Thyroid hormones; Oral contraceptives; Phenothiazines; Barbiturates

**Alcoholism**

(1) The clinical signs suggestive of riboflavin deficiency are cheilosis, angular stomatitis, glossitis, magenta tongue, nasolabial seborrhoea and genital (scrotal or vulval) dermatosis. Corneal vascularisation is also seen but is not a specific sign of riboflavin deficiency.

(2) Severe deficiency is rarely seen, however the elderly, people suffering from anorexia nervosa and chronic dieters are at a higher risk.

(3) Secondary nutrient deficiencies may be seen in riboflavin deficient people like: Hypochromic anaemia, Vitamin B<sub>6</sub> deficiency and Pellagra (6).

### Niacin (Nicotinic Acid & Nicotinamide)

Niacin is the generic term for a group of compounds that prevent pellagra. It is a white crystalline substance readily soluble in water and is resistant to heat, in solution or in a dry state. Although related chemically to nicotine it possesses very different physiological properties. It occurs naturally in the body in the form of an amide - nicotinamide.

**Sources :** Nicotinic acid is widely distributed in plant and animal foods. Meat (especially the organs), fish, chicken, eggs, milk, whole meal cereals, groundnuts and pulses are good sources (See Table-3). In some cereals, especially maize, the greater part of the vitamin may be in a bound unabsorbable form. The human body is not entirely dependent on dietary sources of nicotinic acid as it may also be synthesized from tryptophan. On an average about 60 mg of tryptophan is needed to form 1mg niacin (4).

**Table - 3 : Niacin content of selected food items (per 100g) (4)**

Food stuff	Niacin (mg)	Food stuff	Niacin (mg)
<b>Cereals</b>		<b>Vegetables</b>	
Wheat flour	4.3	Cauliflower	1.0
Rice polished	1.9	Spinach	0.5
Bajra	2.3	Carrot	0.6
Maize dry	1.8	Amaranth	1.2
Jowar	3.1	Potato	1.2
Barley	5.4	Radish	1.4
<b>Pulses &amp; Legumes</b>		<b>Fruits</b>	
Bengal gram	2.9	Raspberry	0.8
Soya bean	3.2	Guava	0.4
Green gram	2.4	Raisins	0.7
Red Gram	2.9	Tomato	0.4
Peas dry	3.4	Mango	0.9
Lentil	2.6	Custard apple	1.3
<b>Non vegetarian foods</b>		<b>Nuts</b>	
Egg	0.1	Groundnut	19.9
Liver sheep	17.6	Cashew nuts	1.2
Milk cow	0.1	Almond	4.4
Fish, Rohu	2.8	Coconut, fresh	0.8
Mutton		Coconut, dry	3.0

**Functions :** Nicotinamide is incorporated into the pyridine nucleotide coenzyme, and various other coenzymes, which are involved in numerous oxidoreductase reactions including glycolysis, fatty acid metabolism, tissue respiration and detoxification.

**Requirement and Intake :** Since this vitamin takes part in many reactions of energy metabolism, its requirement is also related to energy requirement. Its safe level is estimated to be 6.6mg niacin equivalents per 1000 Kcal. The daily requirement varies from 8 to 26 mg (4).

**Deficiency :** Pellagra (Latin *pelle*, skin; Greek *agra*, seizure) results from the deficiency of niacin. This is characterized by the three 'D's (5).

(a) **Dermatitis:** (Pellagrous dermatosis) Skin exposed to sunlight gets inflamed, that progresses to pigmentation, cracking and peeling. The neck is frequently involved and the distinctive distribution of skin lesions is known as Casal's Collar.

(b) **Diarrhoea:** This is often accompanied by inflamed scarlet tongue.

(c) **Dementia :** It may present as mild confusion and disorientation to mania and psychosis.

### Folic Acid (Folate or Pteroyl Glutamic Acid)

It is a yellow crystalline substance, sparingly soluble in water and a stable molecule. When heated in neutral or alkaline media it undergoes rapid destruction. Free folate is actively absorbed from the upper small intestine. It is stored mainly in the liver. Small amount is excreted in urine and faeces. Free folic acid is converted in the liver into tetrahydrofolic acid (folinic acid) which is the functionally active form in the body.

**Sources and Losses :** It occurs in green leaves, pulse, cereals, liver, kidney, mushroom and yeast. Canning, prolonged heating, reheating and discarding 'cooking' water causes serious losses of folic acid. Reducing agents in food tend to protect folic acid. Folic Acid content of selected food items is depicted in Table-4.

**Table - 4 : Folic Acid content of selected food items (per 100g) (4)**

Food stuff	Folic Acid ( $\mu$ g)	Food stuff	Folic Acid ( $\mu$ g)
<b>Cereals</b>		<b>Vegetables</b>	
Wheat flour	35.8	Cabbage	23
Rice raw, milled	8.0	Spinach	45.5
Bajra	45.5	Carrot	123
Maize dry	20.0	Amaranth	149
Jowar	20.0	Ladies finger	105
Ragi	18.3	Spinach	123
<b>Fruits &amp; Nuts</b>		<b>Pulses &amp; Legumes</b>	
Tomato	30	Bengal gram	186
Guava	20	Soya bean	100
Groundnut	20	Green gram	140
Coconut, fresh	12.5	Red Gram	103
Coconut, dry	16.5	Peas dry	7.5
Lentil	36		
<b>Non vegetarian foods</b>			
Egg	78.3	Milk cow	8.5
Liver sheep	188	Mutton	5.8

### Functions

(a) Folinic acid plays important role in the synthesis of purines, pyrimidines, glycine and methionine. It is essential for the synthesis of DNA.

(b) It is a potent anti anaemia factor in the treatment of megaloblastic anaemia of malnutrition, pregnancy and malabsorption. It is also effective in treatment of pernicious anaemia.

#### **Folic Acid and Plasma Homocysteine**

A high plasma homocysteine level is a risk factor for heart disease and stroke. A strong inverse correlation between folate intake and plasma homocysteine has been found. A significant dose response relationship has also been established. Folate supplementation is known to proportionately reduce the plasma homocysteine levels and thus the risk of heart disease.

**Requirement and Intake:** The requirement of folic acid ranges from 50 µg to 100 µg. In pregnancy it increases to 150-300 µg (4).

**Measurement:** Recent intake can be assessed by serum folate. Cellular status is assessed by red cell folate levels.

#### **Uses of Folates in Prevention and Therapy**

**Birth Defects:** Use of supplementary folates (400µg/day) during the early weeks of conception & pregnancy can reduce birth defects like neural tube defects, cleft lip and palate.

**Atherosclerosis:** Folates are known to reduce high homocysteine levels and thus help prevent atherosclerosis.

**Nervous Disorders:** Folate supplementation is beneficial in depression, irritability and impaired concentration. It is also useful as an adjunct therapy in MDP and senile dementia.

**Infections:** Folates augment the immune function of the body, thereby reducing infections.

**Cancers:** Folate also reduces the chances of cervical, colonic and lung dysplasia.

**Deficiency:** Dietary folate deficiency is not uncommon. Deficiency results in megaloblastic anaemia. Deficiency may be accompanied by depression, insomnia, forgetfulness, irritability and dementia. Low folate levels are also associated with neural tube defects. Lack of folic acid is known to cause accumulation of homocysteine (hyperhomocysteinaemia), which is a potential risk factor for coronary artery disease. High folate levels overcome the hyper-homocysteinaemia. Low folate levels can also cause an altered methylation of DNA, increasing the risk of cancer (5, 6).

#### **Vitamin B<sub>12</sub> (Cyanocobalamin)**

Cobalamin is a complex molecule containing 4-percent cobalt, besides phosphorous and nitrogen. Cyanocobalamin is the commercially available form. Vitamin B<sub>12</sub> is the 'extrinsic factor' originally postulated by Castle. It requires the 'intrinsic factor', secreted by the parietal cells of the stomach, to be absorbed. It is freely soluble in water and resistant to boiling in neutral solution though unstable in the presence of alkalis.

**Sources:** It is unique among vitamins in that it is not present in any vegetable foods. It is present in animal products - milk, milk products, meat and fish. It is also synthesized by the micro organisms in the gut and assimilated in the food chain.

#### **Functions**

- (a) It recycles the folate coenzyme.
- (b) Vitamin B<sub>12</sub> plays important role in the synthesis of DNA.
- (c) It helps in maintenance of myelin in the nervous system.
- (d) It has an important role in the treatment of pernicious anaemia.
- (e) It also helps in conversion of homocysteine to methionine.

**Measurement:** Serum B<sub>12</sub> is assessed by radioligand binding or microbiological assay. Absorption is assessed by Schilling test (5).

**Requirement and intake:** The daily losses of this vitamin range from 0.25 µg to nearly 1 µg. An intake of 2 µg per day has been recommended by FAO/WHO. The ICMR has, however, suggested a daily intake of 1 µg of the vitamin for Indian adults (4).

**Deficiency:** Since the vitamin doesn't occur in vegetable foods, vegans and strict vegetarians are at a high risk of its deficiency. Malabsorption, gastric atrophy, and reduced production of 'intrinsic factor' are some other causes of deficiency. Pernicious anaemia, which is a megaloblastic anaemia, results due to deficiency of this vitamin. Neurological symptoms characterized by loss of sensation and motor power in the lower limbs (due to degeneration of myelin) may also be seen. Since it is also synthesized in the gut, many cases of vitamin B<sub>12</sub> deficiency are not seen very frequently.

#### **Vitamin C (Ascorbic Acid)**

It is a water soluble, crystalline, white substance. Ascorbic acid is very sensitive to oxidation, which is accelerated by heat, alkaline solutions, light and traces of metals, especially copper. It is present in all body tissues but is found in a high concentration in the adrenal glands, pituitary gland, and intestinal wall.

**Sources and Losses:** Its rich sources are citrus fruits (oranges, lemons), guavas, papayas, pineapple, mangoes, gooseberry (amla), kiwi fruit and green leafy vegetables. Root vegetables also contain vitamin C, esp. sweet potato. It is also synthesized in germinating seeds, pulses and grains (See Table-5).

**Table - 5 : Vitamin C content of selected food items (per 100g) (4)**

Food stuff	Vitamin C (mg)	Food stuff	Vitamin C (mg)
<i>Fruits</i>		<i>Vegetables</i>	
Tomato	31	Cabbage	124
Guava	212	Spinach	28
Straw berry	52	Drum stick	120
<i>Amla</i>	600	Amaranth	179
Lime	63	Chillies, green	111
<i>Mousambi</i>	50	Potato	17
Orange	30	Bitter gourd	96
Papaya	57	Capsicum	137



The vitamin C content of fruits and vegetables is reduced by storage and damage to plant cells by rough handling, bruising or cutting, which results in release of enzyme ascorbic acid oxidase which oxidizes ascorbic acid. Also cooking of vegetables destroys vitamin C through the enzyme action and heat and by its extraction into cooking water. High pressure steaming as well as rapid frying of green vegetables destroys the oxidase enzyme thereby causing a greater retention of vitamin C than boiling.

**Functions** : Ascorbic acid is a powerful reducing agent (antioxidant) and is essential for many oxidation-reduction reactions.

- It is required for the formation of collagen and is therefore necessary for the formation and maintenance of the normal structure of the intercellular ground substance (connective tissue), bone, tendons, skin, teeth and capillaries.
- It is important for hydroxylation of dopamine to nor-adrenaline.
- It enhances the absorption of iron, through the conversion of ferric ( $\text{Fe}^{3+}$ ) to ferrous ions ( $\text{Fe}^{2+}$ ).
- It has anti-oxidant property like vitamins A and E, which has an important role in free radical scavenging, as an anti-aging and anti-cancer factor.
- It influences the maturation of the red blood cells, synthesis of bile and metabolism of drugs and carcinogens by the liver (5)

**Requirement** : The requirement of vitamin C is 40 mg/day for adults. For lactating women 80 mg/day is recommended (4)

**Deficiency** : Vitamin C deficiency is not common now. It causes defective formation of intercellular ground substance whose characteristic gross lesions occur in gums, bones and capillaries. Reparative process especially involving connective tissues, as in wound healing, are interfered in vitamin C deficiency due to the lack of the formation of collagen. Deficiency leads to a condition called as *scurvy*. The signs and symptoms include spongy and bleeding gums, perifollicular haemorrhages in the skin, sub periosteal haematomas and poor wound healing. Fatigue and muscle weakness is also reported.

## Fat Soluble Vitamins

### Vitamin A (Retinol)

Hopkins conducted an experiment in young rats (1906-1912). These were fed on casien, starch, sugar, lard and inorganic salts. These rats failed to grow and died. An addition of only 3 ml milk enabled them to thrive! An '*Accessory food factor*' was thus demonstrated. Mc Callum isolated it in 1913 and was named as Vitamin A. Wald was awarded Nobel Prize for description of '*dark vision*' and its association with Vitamin A (2,8)

Vitamin A is a term for the biologically active compound retinol and its provitamin (precursor) carotenoids. Retinol is a fat soluble pale yellow compound. It is stable to heat at ordinary cooking temperatures but liable to oxidation and destruction on rancidity of fat. However, carotenoids cannot wholly be converted into retinol in the body and man absorbs and utilizes these pigments less efficiently. 6 microgram of  $\beta$ -carotene has the biological activity of 1 microgram retinol (RE). Other Carotenoids have even lesser vitamin A activity (4)

**Sources and losses** : Retinol is found in foods of animal origin. The important sources of Retinol are meat, liver, kidney, milk, fish and eggs (See Table- 6). Retinol can also be formed in the intestinal mucosa from the pigments known as carotenoids which are widely distributed in plants. Carotenoids are found in coloured fruits and vegetables. The green outer leaves of vegetables (e.g. cabbage) are good sources of carotene. One of these,  $\beta$ -carotene is by far the most important source of retinol (provitamin A) and is found in abundance in yellow-orange vegetables and fruits (e.g. pumpkin, papaya, mango, apricots, yellow peaches and green leafy vegetables).  $\beta$ -Carotene, another carotenoid, is found in carrots, lutein in dark green leafy vegetables and  $\beta$ -Cryptoxanthin in citrus fruits. The pigments with *no* vitamin A activity include lycopene in tomatoes and zeaxanthin in sweet corn (4)

Vitamin E protects it from oxidation. It is destroyed by exposure to sunlight. Foods which are heated for long period of time lose an appreciable amount of vitamin A. Boiling, canning or freezing of foods does not cause loss but drying and dehydration causes considerable loss.

Table - 6 : $\beta$ -Carotene content of selected food items ( $\mu\text{g}$ ) per 100g (4)			
Food stuff	$\beta$ -Carotene ( $\mu\text{g}$ )	Food stuff	$\beta$ -Carotene ( $\mu\text{g}$ )
Cereals		Vegetables	
Wheat flour	25	Pumpkin	1160
Rice raw, hand pound	2	Fenugreek leaves	9100
Bajra	132	Carrot	6460
Maize dry	90	Amaranth	8340
		Spinach	9440
Pulses & Legumes		Fruits	
Bengal gram	189	Apricot	2160
Soya bean	426	Raspberry	1248
Green gram	94	Papaya	880
Red Gram	132	Tomato	590
Peas dry	39	Mango	1990
Non veg foods		Nuts	
Egg	420	Groundnut	37
Liver sheep	6690	Cashew nuts	60
Milk cow	53	Almond	0
Mutton	9	Coconut, fresh	0

**Retinol Equivalents** : Vitamin A activity of a diet is usually expressed in Retinol Equivalents. As mentioned, the term vitamin A is applied to both retinol (preformed vitamin A) and pro-vitamin A (beta-carotene). One microgram retinol is considered as 1 Retinol Equivalent (1RE). It is also known that the biological activity of 6  $\mu\text{g}$  beta carotene has an activity of 1  $\mu\text{g}$  retinol. International Unit or IU is an old unit and is sometimes used. 1 IU is equal to 0.3  $\mu\text{g}$  of Retinol (Box - 2).

**Box - 2 : Vitamin A Activity**

1 Retinol Equivalent (RE) equals

- 1 µg of retinol
- 1 µg retinol activity
- 6 µg β-carotene
- 3.33 IU (International Units)

OR

- 1 µg β-carotene = 0.167 µg retinol
- 1 IU Vitamin A = 0.3 µg of Retinol

**Functions**

- It is vital for the formation of retinal pigment rhodopsin in rods of the retina. Exposure to light results in a series of changes in its configuration, which leads to the adaptation of vision in dark. Retinol deficiency leads to impairment of dark adaptation or night blindness.
- Retinol is essential for integrity of cellular structure esp. epithelial tissue - respiratory, gastrointestinal, genitourinary and skin.
- It has a role in the immune defence mechanism of the body.
- Vitamin A has an antioxidant property of free radical scavenging (For details refer to chapter on antioxidants).

**Requirements & Recommended Dietary Allowance :** The recommended intake is 600 mg of retinol equivalent per day for adults (including children above 6 years and pregnant women). Lactating mothers require 950 mg. In converting the carotene figures to retinol, a conversion factor of 0.25 has been suggested by ICMR (6). For vitamin A the RDA is given in terms of retinol (vitamin A alcohol). If the diet contains vitamin A and carotene, its content can be expressed as retinol using the following formula:

$$\text{Retinol content} = \mu\text{g retinol} + \mu\text{g of } \beta\text{-carotene} \times 0.25$$

**Deficiency :** Deficiency of Vitamin A leads to ocular and extra ocular manifestations. The ocular manifestations are more common. The ocular manifestations resulting from vitamin A deficiency are termed as *Xerophthalmia*. Deficiency is often seen to be associated with weaning, protein energy malnutrition and a diet poor in vegetables, fruits, milk and butter. The deficiency signs / symptoms are given in the Box - 3.

**Box - 3 : Signs and symptoms of Vitamin A Deficiency**

Dryness, itching, redness of conjunctiva

Night blindness (inability to see in dim light)

Other signs of xerophthalmia : Bitot spots; Corneal xerosis; Keratomalacia

Dry, rough, itchy skin; rash

Dry, brittle hair and nails

Loss of acuity of senses: smell and taste

Loss of appetite

Anaemia, fatigue

Poor growth

Low immunity: Increased vulnerability to infections

Increased risk of certain cancers

**Toxicity - Hypervitaminosis A :** There are exotic stories of arctic explorers and fishermen who reported reddening and exfoliation of skin after feasting on polar bear liver or halibut liver. Hypervitaminosis A can be induced by a single dose of retinol greater than 200mg (200,000 RE). Chronic hypervitaminosis may result from chronic misuse of supplements which is, greater than 4000 RE (infants) to 7000 RE (adults) consumed daily. Persistent large doses of vitamin A (more than 100 times the required amount), overwhelm the liver storage capacity and produce intoxication and liver disease.

Hypervitaminosis A is characterized by skin/mucous membrane changes. Dry lips (cheilitis), dryness of nasal mucosa and eyes, erythema, scaling, peeling of skin, hair loss and nail fragility are other signs. Headache, nausea and vomiting follow. Bone abnormalities in the form of hip fractures are also reported. Retinoids can be toxic to the fetus, causing craniofacial, CNS, cardiovascular and thymic malformations. Pregnant women are therefore advised against exceeding daily intakes of 3000 RE of vitamin A.

**Vitamin D (Calciferols)**

The term Vitamin D refers to two molecules - ergocalciferol (Vitamin D<sub>2</sub>) and cholecalciferol (Vitamin D<sub>3</sub>). Cholecalciferol is the natural form of vitamin and is produced by the ultraviolet irradiation (through sunshine) of 7-dehydrocholesterol widely distributed in animal fats such as the oily secretions in mammalian skin. Dietary ergocalciferol and cholecalciferol are biologically inactive and are activated to 25-hydroxy-cholecalciferol in liver. Further conversion in the kidney results in the production of the more active form 1,25-dihydroxy cholecalciferol (Calcitrol) (8).

**How much sunshine is good enough?**

Even a brief and casual sunlight exposure of the exposed parts of body (face and arms) is good enough to provide about 5 µg equivalent of vitamin D. The ultraviolet penetration depends on melanin content of the skin and is higher in light skinned people. Window panes and use of sunglasses and sun screen creams block ultraviolet penetration, thus limiting the vitamin D intake. Dark clothing, face masks and *burqa* will also block UV rays and Vitamin D availability. Therefore a person getting even a casual exposure to sun gets enough Vitamin D through the skin conversion. Conversely, those permanently indoors (as in cold countries) or keeping themselves covered from head to toe (practice of compulsory *burqa* cover) are those who might be at a risk of vitamin D deficiency.

**Food sources :** Cod liver oil, other oily fish, milk, margarine, eggs, liver.

**Functions :** Vitamin D regulates the absorption and excretion of calcium from the small intestine and also plays an essential part in the mechanism for mineralizing bone. It is considered as a hormone rather than a vitamin.

**Measurement :** Vitamin D status can be assessed by the measurement of plasma 25-hydroxy-cholecalciferol. In severe deficiency plasma calcium and phosphate fall and alkaline phosphatase is elevated.

**Requirement and Intake** : The vitamin D requirement for a child is placed at 100 to 400 IU/day (2.5-10  $\mu\text{g}$ ). This requirement can be obtained from exposure of the body to sunlight. ICMR expert group therefore has not recommended any dietary intake. Whenever this requirement is not met, a therapeutic supplementation may be needed (4). The food and nutrition board, USA recommends a daily dietary intake of 5  $\mu\text{g}$  for adult males, females, pregnant and lactating women.

**Deficiency** : People who stay indoors and are fully covered (purdah system amongst women in some religious/ethnic groups) are at a higher risk of deficiency due to lack of exposure to UV radiation due to sunlight. Malabsorption also increases the risk of deficiency. Severe deficiency results in rickets in children, characterized by reduced calcification of bone epiphysis. It leads to skeletal deformities, bone pain and muscle weakness. In adults deficiency results in osteomalacia.

### Vitamin E (Tocopherol)

Eight naturally occurring forms of vitamin E are synthesized in plants; four tocopherols ( $\alpha, \beta, \gamma$  and  $\delta$  tocopherols) and four tocotrienols ( $\alpha, \beta, \gamma$  and  $\delta$  tocotrienols). Alpha tocopherol which is synthesized commercially has the highest biological activity, and is used as the standard against which activity of other forms is measured. Being fat soluble, vitamin E is found in all cell membranes (5).

**Sources** : Vitamin E is widely distributed in foods and the richest sources are vegetable oils like groundnut, sunflower, safflower, cotton seed, corn, wheat germ, rape seed, palm and other oils. Nuts (like almonds and peanuts) are also good sources. Eggs, butter, whole meal cereals are moderately good sources. Meat, fruits, vegetables contain small amounts. Foods rich in PUFA are also rich in Vitamin E.

#### Tocopherol

(Greek, *tokos*, childbirth; *pherin*, to carry)

This vitamin was so named in Greek, as the work of early investigators indicated a strong relationship to reproductive function in rats, which was not found to be true in humans.

#### Functions

- Like vitamin A and C, it has a strong antioxidant property and protects cell membranes and lipoproteins against damage from free radicals. It also prevents the non-enzymatic destruction of polyunsaturated fatty acids by molecular oxygen.
- It maintains the cell membrane integrity.
- It has a role in the DNA and prostaglandin synthesis.

**Requirement & Intake** : The human requirement of vitamin E is not known with certainty (4). The US authorities have recommended a daily intake of 12mg/day.

**Deficiency** : Deficiency of vitamin E in animals interferes with normal reproduction and causes a form of muscular dystrophy, but the effects if any, on human beings are being studied. However, a genetically inherited disease Familial Isolated Vitamin E (FIVE) deficiency is known. Patients develop reduced tendon reflexes by age 3-4, loss of touch and pain sensation, unsteady gait, loss of coordination and impaired eye movement in adolescence. Deficiencies have also been seen in people with

severe fat malabsorption (5).

### Vitamin K

It exists in nature in two forms. Vitamin  $K_1$  (phylloquinone), originally isolated from lucerne, is the only form that occurs in plants. It is a yellow oil, soluble in fat solvents, but only slightly soluble in water. Vitamin  $K_2$  (menaquinone) is produced by bacteria in the lumen of large intestine.

**Food sources** : Green leafy vegetables, vegetable oils esp. soya bean oil, eggs, meat and dairy products are good food sources of vitamin K.

#### Functions

- Vitamin K promotes the synthesis of  $\gamma$ -carboxy glutamic acid (Gla) in the liver which is essential for formation of prothrombin (or factor II) and also factors VII, IX and X. It is well known that these factors participate, in the coagulation of blood.
- Some other proteins also contain Gla and require vitamin K for their synthesis e.g. osteocalcin, a bone protein made by osteoblasts (5).

**Requirement & Intake** : No recommendations are given by the ICMR. The US authorities recommend an intake of 120 $\mu\text{g}$  for males and 90 $\mu\text{g}$  for females.

**Deficiency** : This is characterized by poor blood clotting and results in low prothrombin activity. Neonates are born with very low stores of vitamin K due to sterility of intestines (and absence of bacteria producing vitamin K). So neonates are given an injection of this vitamin at birth. Adults rarely manifest the deficiency, but can be seen in cases of obstructive jaundice as lack of bile leads to poor absorption of vitamin K. The anticoagulants Warfarin and Dicoumarol can cause a deficiency.

### Summary

Vitamins which were historically considered as the vital amines have not lost their vitality, and are as important today as they were at the time of their discovery. They help in many metabolic reactions and are essential for control of cell metabolism, transformation of energy, and prevention of specific nutritional deficiencies. Their role as antioxidant agents has enabled scientists to refocus their attention on vitamins. A summary of the most important vitamins is tabulated at the end of chapter.

### Study Exercises

**Long Questions** : (1) Enumerate the water soluble vitamins. What is the role of vitamin C in the human body? (2) Name the fat soluble vitamins. Discuss the dietary sources, functions and deficiency symptoms of Vitamin A.

**Short Notes** : (1) Hypervitaminosis A (2) Beriberi (3) Vitamins as antioxidants

#### MCQs

- Which of the following will help you increase the iron absorption from diet : (a) Nicotinic acid (b) Ascorbic acid (c) Pantothenic acid (d) Folic acid
- Which of the following is not a source of beta carotene (a) Green vegetable (b) Potatoe (c) Liver (d) Papaya
- Which of the following is not known to have an

- antioxidant effect (a) Vitamin A (b) L-Ascorbic acid (c) Alpha-Tocopherol (d) Phyloquinone
4. Which of the following does not fall under 'xerophthalmia' (a) Conjunctival xerosis (b) Corneal xerosis (c) Retinal xerosis (d) Lachrymal xerosis
5. Which of these is available only from animal sources (a) Vitamin B<sub>12</sub> (b) Vitamin B<sub>1</sub> (c) Vitamin B<sub>6</sub> (d) Vitamin B<sub>2</sub>

**Answers :** (1) b; (2) c; (3) d; (4) d; (5) a.

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<i>Fat Soluble Vitamins</i>				
Vitamin	Function	RDA	Deficiency	Sources
<b>Vitamin A</b> (Retinol, Retinal, Carotenes, Cryptoxanthines)	Vision, Integrity of epithelium, Gene regulation, Antioxidant	600 µg/ day	Xerophthalmia, Dry skin, impaired immunity, growth and reproduction	Retinol (animal foods): liver, egg, meat, milk Provitamin A (plant foods) yellow, green vegetables
<b>Vitamin D</b> (Cholecalciferol, D <sub>3</sub> ; Ergocalciferol, D <sub>2</sub> )	Calcium homeostasis, Bone metabolism	100 - 400 IU /day - (Child)	Rickets in children Osteomalacia in adults	Synthesised in skin with exposure to sunlight; Fish oils, milk
<b>Vitamin E</b> (Tocopherols)	Cellular membrane antioxidant	12mg / day	RBC breakdown, anaemia, nerve damage, retinopathy	Vegetable oils, green vegetables, cereal germ, nuts, seeds
<b>Vitamin K</b> (Phylloquinones, Menaquinones, Menadione)	Clotting of blood, Calcium metabolism	120 µg / day (Males) 90 µg / day (Females)	Bleeding tendencies	Synthesis by intestinal bacteria, green vegetables soya oil, liver, milk

<i>Water Soluble Vitamins</i>				
Vitamin	Function	RDA	Deficiency	Sources
<b>Vitamin C</b> (Ascorbic acid)	Reductant in hydroxylations in collagen and carnitine synthesis Metabolism of drugs	40mg /day	Scurvy: Spongy, bleeding gums, fatigue, haemarthrosis	Citrus fruits, guava, amla, green vegetables, tomatoes, strawberries
<b>Vitamin B<sub>1</sub></b> (Thiamine)	Normal growth Coenzyme for decarboxylation of 2-keto acids and transketolation reactions	0.5mg / 1000Kcal	Beriberi - Cardiac (wet), Neuritic (dry) and Infantile	Meat, liver, legumes, wheat germ
<b>Vitamin B<sub>2</sub></b> (Riboflavin)	Normal growth Coenzyme in redox reactions of fatty acids and TCA cycle	0.6mg / 1000Kcal	Ariboflavinosis: Magenta tongue, Cheilosis, angular stomatitis, corneal ulcer	Milk, meat, green vegetables
<b>Niacin</b> (Nicotinic acid, Nicotinamide)	Coenzyme for dehydrogenases	6.6mg / 1000Kcal	Pellagra, characterized by 3 Ds- dermatitis, diarrhea, dementia	Meat, groundnuts, legumes, grains
<b>Vitamin B<sub>6</sub></b> (Pyridoxamine)	Coenzymes in amino acid metabolism	2mg / day	Anaemia, neuritis, convulsions	Grains, seeds, poultry, meat
<b>Folic Acid</b>	Coenzymes in single carbon metabolism	100µg / day	Megaloblastic anaemia	Liver, green vegetables yeast, fruits
<b>Vitamin B<sub>12</sub></b> (Cobalamin)	Coenzymes in amino acid, propionate and single carbon fragment metabolism	1µg / day	Pernicious anaemia	Liver, lean meat fish, seafood, milk



Rajul K Gupta

Minerals are required in small quantities and constitute only a small portion of the body weight but enter into the metabolism to a much greater degree than their mere weight indicates. A large portion of the ash of the body is composed of calcium, magnesium, sodium, potassium, phosphorous, sulphur and chlorine. The main functions of the minerals include: providing rigidity and relative permanence to the bones and teeth; providing essential elements for the formation and activities of the muscular, glandular, neural, and epithelial tissues; forming components of enzyme systems; and providing dynamic characteristics to the intra and extra cellular fluids for regulation of pH, osmotic pressure and electro-neutrality and those of secretion and excretions (1).

Minerals like zinc, molybdenum, copper, manganese and magnesium are either structural parts or functionally activate many enzyme systems. Iodine is a part of hormone, thyroxine. Sodium and potassium are important in fluid dynamics and energy transfer. They along with chloride, carbonates and bicarbonates maintain the acid base balance. Some amount of minerals is excreted daily through urine, sweat, skin and intestinal exfoliations and thus has to be replaced. Growing infants, children, pregnant and lactating women require a higher quantity of some of these minerals to meet the physiological needs. Deficiency, leads to a deranged function of systems and various pathological states in extreme conditions.

### Classification

Minerals can be classified into macrominerals and microminerals (See Box- 1). Macrominerals also referred to as major minerals are distinguished from the microminerals by their occurrence in the body. Taking this as criterion, various definitions of macrominerals have evolved, such as "those which constitute at least 0.01% of body weight (5g in a 60 Kg man)" ; or a more quantifiable and unambiguous definition like "mineral whose requirement is more than 100mg per day". Calcium, phosphorous, magnesium, sodium, potassium, chloride and sulphur are the macrominerals (2).

#### Box - 1 : Classification of Minerals

The Macrominerals
Calcium, phosphorous, magnesium, sodium, potassium, chloride, sulphur
The Microminerals
Iron, zinc, iodine, Copper, manganese, molybdenum, selenium, chromium and fluorine, cobalt, nickel, tin, silicon, vanadium, arsenic, cadmium, boron, aluminium

As a corollary microminerals or trace elements can be defined as those comprising less than 0.01% of total body weight or more appropriately those which are needed in a concentration of less than 1ppm (3). These were initially known as trace because their concentration in tissues could not be easily

ascertained by early analytic methods (4). Classically, iron appears to be the mineral that divides the macrominerals from microminerals. Thus a trace element (or micromineral) can be defined as one that is required by the body in the concentration equal to or less than that of iron (5). Microminerals include iron, zinc, iodine, copper, manganese, molybdenum, selenium chromium and fluorine. Cobalt, nickel, tin, silicon, vanadium, arsenic and boron can be classified as ultra-trace elements (2). An element is termed 'essential' if a dietary deficiency of that element consistently results in a suboptimal biological function that is preventable or reversible by physiological amounts of the element (6).

### Calcium (Ca)

Calcium is essential for the building of bones and teeth. It is the most abundant mineral in the human body. Most is deposited as hydroxyapatite, in bones and teeth. Constant levels of calcium in the body/plasma is maintained under the influence of parathyroid hormone and calcitonin. Factors promoting absorption of calcium are vitamin D, proteins and lactose.

**Sources, Absorption and Losses :** Rich sources of calcium are milk and milk products, ragi, fish (if eaten whole), dried fruits such as raisins, apricots and dates, and betel leaves with lime, pulses and tofu (See Table- 1).

Table 1: Calcium content of common foods (mg/100g)

Foodstuff	Calcium (mg per 100g)	Foodstuff	Calcium (mg per 100g)
Cereals & Legumes		Fruits	
Rice, raw	10	Figs	187
Wheat flour, whole	48	Raisins	87
Ragi	344	Dates, dried	120
Red gram (Dal arhar)	73	Lemon	70
Bengal gram, whole	202	Apricots, dry	110
Vegetables		Miscellaneous	
Turnip greens	710	Fish, Rohu	650
Amaranth species	200-800	Coconut dry	400
Cauliflower greens	626	Gingelly seeds	1450
Onion	46.9	Almond	230
Spinach	73	Milk, cow	120
Cluster beans	130	Mutton	150

Calcium in food is not uniformly available to the body e.g. calcium in vegetables and fruits is poorly absorbed due to the presence of oxalic acid in these foods which forms insoluble calcium oxalate. Spinach is one of the foods which is very rich in oxalic acid. Phytic acid in the pericarp of cereal grains unites with calcium to form phytin, which is not absorbed. However, many cereals such as rye and wheat contain an enzyme

phytase, which splits phytic acid so that it can no longer bind with calcium and thus makes calcium available for absorption. Excess of fatty acids, particularly saturated fatty acids in the small intestine may form insoluble soaps with calcium and may carry significant amount of calcium into faeces. Calcium in milk and dairy foods is more readily absorbed (7, 8).

#### **Foods interfering with absorption of Calcium**

Protein intake >20% of calories

Phosphorus (milk, meat, colas)

Oxalates (Spinach, tomato)

Sodium (salt)

Tannins (black coffee, tea)

Alcohol

#### **Functions**

**Bone formation** : More than 99% of body calcium is found in the bones. Calcium is essential for providing the structural rigidity to bones and teeth.

**Nerve conduction**: Calcium is responsible for the maintenance of optimum excitability of the nervous and muscular tissues.

**Blood Coagulation**: Calcium has an important role in the coagulation of blood as factor IV.

**As a cofactor** : Calcium acts as a co-factor for a number of enzymes e.g. lipase (9).

**Requirement and Intake** : The suggested levels for calcium intake for adult men and growing children are 400 to 600mg/day. In case of pregnant and lactating women it is 1000mg/day (10).

**Deficiency** : Plasma calcium levels are tightly controlled and are not usually affected by dietary insufficiency in healthy adults. Reduction in the level of circulating ionised calcium produces a clinical condition known as tetany. This is characterized by twitching of muscles of face, hand and feet. Cardiac arrhythmias may also result. A long term calcium deficiency during the bone formative age can cause stunted skeletal growth and a low bone density. Vitamin D deficiency leads to rickets in children due to poor calcium absorption (9).

Osteoporosis is an abnormal thinning of bones. It is not due to a primary calcium deficiency but results from conditions leading to chronic calcium deficiency. These factors are inadequate calcium intake, poor absorption, abnormal hormone levels, upsetting the calcium homeostasis and subnormal physical activity. Osteoporotic bones are more likely to get fractured with trivial injuries (falls), as commonly seen in post-menopausal women and the elderly.

### **Phosphorus**

The role of phosphorus in bone formation is almost as important as calcium and so it is a macromineral of extreme value. It gets deposited in bones and teeth as calcium phosphate. An adult human body contains about 400-700 g of phosphorus as phosphate mostly in bones and teeth (10).

**Sources** : Phosphorus is widely distributed in food stuffs and therefore, its deficiency rarely occurs. Milk, milk products,

cereals, meat, fish, nuts, fruits and vegetables are good sources. A large part of phosphorus present in vegetable foods occurs in combination with phytin (fibre) and is available to the body only to the extent of 40-60 percent.

#### **Functions**

**Bone formation** : It is essential for the formation of bones and teeth along with calcium as hydroxyapatite.

**Energy metabolism**: It also plays an important role in all metabolism for derivation of energy from the phosphate bonds in adenosine triphosphate (ATP).

**Acid base balance**: Phosphorus acts as an important buffer that prevents changes in the pH of body fluids.

**Miscellaneous**: It is an important constituent of nucleic acids, phospholipids and membranes (11).

**Requirements** : It is suggested that phosphorus intake should be about 1 g per day that is about twice as large as that of calcium (10).

**Deficiency** : Phosphorus deficiency is unlikely to occur as it is widely available in foodstuff. However hypophosphataemia may occur in pathological conditions (sepsis, liver disease, alcoholism, diabetic ketoacidosis) patients on prolonged parenteral nutrition, hypophosphataemic rickets and excessive use of aluminium-containing antacids (9).

### **Sodium**

Sodium is one of the most abundant minerals present in the human body. An adult male has total body sodium of about 92-110 g, almost equally divided into the Extracellular Fluid (ECF) and bone. In the blood and interstitial fluid it is found to be largely combined with chloride and bicarbonate. Intracellular fluid contains about a third of the sodium content of the extracellular fluid (9).

**Sources** : Common salt (sodium chloride) is the cheapest, best and most widely available source of sodium; 3 g salt is roughly equivalent to 1.2 g of sodium. Indian diet is particularly rich in sodium (pickles, chutneys, etc.). It is also present in food additives like monosodium glutamate, mainly used in Chinese cuisine. Natural foods like meat, milk, eggs, vegetables and fruits all contain sodium. Salt is added to almost all processed foods, thereby increasing their sodium content.

**Functions** : Sodium is the main cation in the ECF of human body. It takes an important part in osmotic processes. It is important in the blood pressure regulation along with potassium. Acid-base regulation is a function of sodium. It also maintains the osmotic pressure. Sodium is also a vital component of the electrophysiological control of muscles and nerves.

**Requirement** : The daily intake varies from 2 to 20 gm/day. The recommended daily intake of sodium chloride is about 5 g (10).

**Deficiency** : Excessive sweating as in hot and humid climates and extreme exertion, diarrhoea and dehydration can lead to sodium deficiency. This may be manifested as muscle cramps and severe dehydration and hypovolemia.

### **Potassium**

The adult human body contains about 250 g of potassium

which is twice the amount of sodium. Potassium occurs widely in foodstuffs, so there is little likelihood of its deficiency. It is the principal intracellular cation.

**Sources** : Most foods contain useful amounts of potassium, particularly those of vegetable origin. Fruits like melons, apricots, fruit juices, vegetables including potatoes, pulses, meat and whole grain cereals are good sources (See Table- 2).

Table - 2: Potassium content of common foods (mg/100g)			
Foodstuff	Potassium (mg per 100g)	Foodstuff	Potassium (mg per 100g)
Cereals & Legumes		Fruits	
Rice, flakes	154	Apricots	430
Wheat flour, whole	315	Peaches	453
Ragi	408	Musk melon	341
Red gram (Dal arhar)	1104	Mosambi	490
Bengal gram, whole	808	Cherries	320
Vegetables		Miscellaneous	
Spinach	206	Rohu	288
Amaranth	341	Coconut meal, deoiled	2003
Brussels sprouts	477	Mutton	270
Sweet potato	393	Milk cow	140
Brinjal	200	Drumstick	259

**Functions** : Potassium is the principal ion in the intracellular compartment, thus plays an important role in the water balance of the body with sodium being in the extracellular compartment. Along with sodium, potassium too is involved in acid-base regulation. Potassium along with sodium is essential for the cellular uptake of molecules through the sodium-potassium pump. Potassium is necessary for the release of insulin from the pancreatic cells in response to high blood glucose. There is an important role of the sodium to potassium ratio in the regulation of blood pressure, rather than sodium alone. This ratio should ideally be 1:1 to have a healthy blood pressure.

**Requirements** : The daily requirement of potassium has not been determined accurately (10). The acceptable intake appears to be about 4.7 g per day, almost the same as of sodium.

**Deficiency** : Dietary deficiency is not common. However deficiency could be caused by diarrhoea, vomiting, dehydration, purgatives, chronic acidosis or alkalosis, diuretics, etc. Potassium deficiency affects the electrophysiology of cell. It may cause cardiac arrhythmias and muscle weakness (9).

## Magnesium

Magnesium has wide ranging body functions. All human tissues contain small amounts of magnesium. The adult

body contains about 25 g of the metal and greater part of this amount is present in bones in combination with phosphate and bicarbonate. About one fifth of the total magnesium in the body is present in the soft tissues, where it is mainly bound to protein. Inside the cells, the metal is concentrated within the mitochondria.

**Sources** : Most foods contain useful amounts of magnesium, particularly those of vegetable origin. Green vegetables, pulses, meat, nuts and whole grain cereals are good sources. Hard drinking water may make a significant contribution to magnesium intake.

**Functions** : Magnesium is an integral part of bones and teeth. Within the mitochondria it is a co-factor for co-carboxylase and co-enzyme A and is concerned with intracellular energy metabolism. It is important in the replication of DNA, synthesis of proteins and RNA. It is essential for muscle and nerve cell function.

**Requirements** : Estimated to be about 350 mg/day for adults (10).

**Deficiency** : It is unlikely that magnesium deficiency would arise in man from simple lack of food. Vitamin D appears to increase magnesium absorption from the intestine. Excessive losses of magnesium in the faeces or urine occur in many diseases e.g. renal or adrenal disease, malabsorption, use of some drugs (e.g. diuretics) and in re-feeding syndrome. Magnesium deficiency leads to apathy and muscular weakness and sometimes to tetany, convulsions, cardiac arrhythmias and cardiac arrest (9).

## Iron

Iron is probably one of the most studied minerals in context of human health. It is one of the most important micronutrients and is of fundamental importance to life. The body of an adult human contains iron equal in weight to a large 'nail' (about 4 g), of which more than two thirds (about 2.4g) is present in haemoglobin. The rest of the iron in the body is present as a reserve store in liver and to a lesser extent in other organs.

**Sources** : The sources of iron can be divided into two main groups:

**(a) Haem Iron Sources**: These are essentially the non-vegetarian sources of iron e.g. meat, fish and eggs. Milk is considered a poor source of iron but breast milk is an efficient source for the infant.

**(b) Non-haem Iron Sources** : These are the vegetarian sources, namely cereals, dark green leafy vegetables, pulses, nuts and dry fruits. Absorption of iron from these foods is only 1 to 20 percent (See Table- 3).

Non-haem iron is poorly absorbed (1-20%) and is influenced by dietary constituents. Certain compounds like Phytic acid (in cereals, fibre), polyphenols (in plants), tannins (in tea), phosphates (in milk and eggs) present in foods of vegetable origin inhibit the absorption of iron. There are also factors in the diet that increase non-haem iron absorption, such as red meat, fish, chicken and liver. Ascorbic acid and low pH also enhance the absorption of non-haem iron. Haem-iron is absorbed directly into the mucosal cells where iron is released by haem oxidase and then bound to transferrin.

Table - 3: Iron content of common foods (mg/100g)			
Foodstuff	Iron (mg per 100g)	Foodstuff	Iron (mg per 100g)
Cereals & Legumes		Fruits	
Rice, raw milled	0.7	Apricots	2.2
Wheat flour, whole	4.9	Pineapple	2.42
Jowar	4.1	Water melon	7.9
Lentil	7.6	Custard apple	4.31
Bengal gram, whole	5.3	Mango	1.3
Soyabean	10.4	Pomegranate	1.79
Vegetables		Miscellaneous	
Spinach	1.14	Fish, <i>Hilsa</i>	2.1
Amaranth	1.8-38.5	Milk cow	0.2
Cauliflower greens	40	Mutton, muscle	2.5
Radish leaves	18.0	Jaggery	2.64

Maximum absorption of iron takes place in duodenum and upper part of small intestine. The amount of iron absorbed from a given meal depends to a large extent on the iron status of the individual. Iron absorption increases during growth and pregnancy.

When the body needs iron it passes directly through the mucosal cells and is transported by transferrin to the bone marrow. If iron is not required it is stored in the mucosal cells as transferrin. It will be lost in faeces when the mucosal cells are exfoliated. Excess iron is stored as ferritin or haemosiderin in the liver, spleen, or bone marrow. It can be mobilized from these stores when demand is increased.

It is lost mainly during menstruation and from the gastrointestinal tract. Physiological losses from all other routes (exfoliation from alimentary, urinary and respiratory tract and by dermal and hair losses and losses in the sweat) also occur. Excretion of iron is very low (about 1mg/day in men).

**Functions** : Iron is a component of haemoglobin and myoglobin. Iron is an essential component of heme. It is also a constituent of important enzymes like cytochromes, catalase, peroxidase, etc. As a part of these haemocomplexes and metallo-enzymes, it serves important functions in oxygen transport and cellular respiration. It is also involved in cellular immune response for appropriate functioning of phagocytic cells (9, 11).

**Requirements** : The requirement of iron is quite small, in the vicinity of 1 to 3 mg/day. It changes constantly depending on the age, sex and the physiological status of the individual like pregnancy, lactation and growth. But since the absorption of iron is rather poor, the dietary intake of iron should be 10 to 25 times the requirement. Hence the RDA of iron is about 28 mg for males and 30 mg for females (38mg for pregnant females) (10).

Group	Requirement	RDA
Male	0.9 mg	28 mg
Female	2.8 mg	30 mg
Pregnancy	3.5 mg	38 mg
Lactation	2.4 mg	30 mg

**Deficiency** : Iron deficiency anaemia is the most common nutritional deficiency in the world. It is estimated that up to half of all women and two-thirds of all pregnant women have anaemia esp. in developing countries (9). Contrary to common belief, the prevalence of anaemia in males is also of a very high magnitude of about 40%.

Increased risk of Iron Deficiency
Women
Growing children and adolescents
Pregnancy
Heavy menstruation
Chronic bleeds <ul style="list-style-type: none"> <li>● Haemorrhoids</li> <li>● Peptic ulcers</li> <li>● Irritation from drugs/alcohol</li> <li>● Acute gastritis</li> </ul>
Iron poor diets
Strict vegetarians
Heavy tea/coffee drinkers
Reduced gastric acid secretion
Atrophic gastritis
Stomach surgery
Chronic antacid use
Reduced transport due to deficiency of <ul style="list-style-type: none"> <li>● Vitamin A</li> <li>● Vitamin B<sub>6</sub></li> <li>● Copper</li> </ul>

The details of the condition are extensively elaborated in a separate chapter on nutritional deficiencies.

**Toxicity** : The major cause of iron overload is hereditary haemochromatosis, another cause could be transfusion overload. The latter may be seen in cases receiving frequent transfusions as in Sickle cell anaemia and Thalassemia. Haemosiderosis is a condition seen in individuals consuming an abnormally large amount of iron.

Recent studies suggest that iron plays an active role as a pro-oxidant (opposite to the 'favourable' antioxidant activity of certain vitamins and minerals) (See Box- 2).

## Iodine

Iodine has also been studied for a very long time. As early as 2800 BC Shan Nuang in China suggested sea weeds as a remedy for goiter. It was discovered as an element in 1811 by Courtois (France). It is an essential trace element because it is



#### Box - 2 : Pro-oxidant activity of Iron

There is no doubt in the fact that iron is an important mineral involved in various vital metabolic functions. But lately, a pro-oxidant role of iron is being studied. Excess iron promotes lipid peroxidation and tissue damage *in vitro*. There is a possibility that, via these pro-oxidant effects, disturbances in iron metabolism play a pathogenic role in many diseases. Therefore iron may be potentially harmful in some situations, esp. during preexisting inflammation and disease (12). For more details section on 'Antioxidants' can be referred to.

an integral component of the thyroid hormones: thyroxine and triiodothyroxine, both of which have important metabolic roles. Iodine deficiency is endemic in the mountainous areas with poor soil content such as the sub-Himalayan regions. This is due to iodine being washed from the soil. Its deficiency causes the widely prevalent preventable iodine deficiency disorders that affect all ages: abortions, still births, cretinism, mental retardation, deaf-mutism, dwarfism and goiter.

**Sources and losses** : The presence of iodine in the food is a function of the iodine content of local soil. Wherever the soil contains adequate amount of iodine, all crops growing there are rich in iodine. Among the natural foods the best sources of iodine are seafoods and vegetables grown on iodine-rich soils. Dairy products, eggs, cereal grains, legumes and green leaves (spinach) are also reasonable sources of iodine. Water contains traces of iodine which contributes to as much as 10% of our total iodine intake.

**Goitrogens** : Certain vegetables of Brassica group such as cabbage, cauliflower and radish contain goitrogens such as thiocyanates and cynoglycosides. Consumption of large quantities of these foods may lead to the development of goiter by making the iodine present in food unavailable to the body. Goitrogens are inactivated by heating.

**Absorption** : Dietary iodine absorbed from the small intestine follows two main pathways within the body. Approximately 30 percent is used up by the thyroid gland for the synthesis of thyroxine hormone; the remainder is excreted in the urine (9).

**Functions** : Iodine is an integral component of the thyroid hormones thyroxine ( $T_4$ ) and tri-iodothyronine ( $T_3$ ). In addition, the fetus and neonate normal protein metabolism in the brain and CNS requires iodine.

**Requirement** : The daily requirement of iodine is  $150\mu\text{g}$  for an adult (10). However the requirements differ with age and physiological states. See box-3.

#### Box - 3 : RDA of Iodine

Infants	$50\mu\text{g}$
Children	$100\mu\text{g}$
Adults	$150\mu\text{g}$
Pregnancy	$200\mu\text{g}$

**Deficiency** : Endemic goiter of varying degrees is found in a large proportion of the population in India, where the soil and thus food materials are deficient in iodine. This is particularly true for the sub-Himalayan regions of India. By virtue of the slopes, iodine from the top soil constantly gets washed off by rains. Other regions located close to the hills e.g. Western and Eastern Ghats, Jharkhand, Chhatisgarh etc also face this problem. Hence, iodine deficiency of varying degree is

encountered in many districts in India. The deficiency of iodine leads to various deficiency disorders, commonly termed as *Iodine Deficiency Disorders (IDD)* that shows a wide spectrum of picture ranging from still births to goiters in adults (See Box - 4). Fortification of salt with iodine is carried out to reduce IDD. The PFA act has specified an iodine concentration of 30 and 15 ppm in salt at source and consumer ends respectively thereby providing 150 mg of iodine in 10 gm of salt.

#### Box - 4 : Iodine Deficiency Disorders

**Adults** : Iodine deficiency disorder (IDD) in adults results in hypothyroidism and raised levels of TSH, which cause hyperplasia of thyroid tissues resulting in goitre. Hypothyroidism is characterized by lethargy, poor cold tolerance, bradycardia, and myxoedema. Infertility is known to occur in IDD.

**Fetus & infants**: In the fetus, IDD results in cretinism. The same is manifested as mental retardation, hearing, speech defects, squint, disorders of gait, and growth retardation in infant life.

**At birth** : IDD is also linked to an increase in the rates of still birth, miscarriage. Neonatal hypothyroidism is a sensitive indicator of the incidence of IDD in a community.

#### Recent Advances : Detection of iodine in salt

It must be appreciated that mere iodination of salt does not ensure availability of iodine to the consumer. Iodine has a property to 'sublimate' and is thus constantly lost from its 'iodized vehicle (salt)' on keeping. It is therefore recommended to consume the iodized salt within a period of 6 months of iodization. There is a simple inexpensive rapid test (UNICEF) available to detect the level of iodine in salt. Test kits can be obtained by directing requests to MBI, 85 GN Chetty Road, III Floor, T Nagar, Madras 600 017 (13)

## Fluorine

It is normally present in the bones and teeth and is essential for the normal mineralisation of bones and formation of dental enamel.

**Sources** : Fluorine is widely but unevenly distributed in nature. It is found in many foods, but seafoods, cheese and tea are rich sources. However, the main source of fluorine to man is drinking water. The fluoride content of drinking water in India is about 0.5 mg/l but in fluorosis endemic areas, the natural waters have been found to contain as much as 3 to 12 mg of fluoride/l. A concentration of 0.5 to 0.8 mg/l in water is considered a safe limit in India. In temperate climate where the intake of water, is low, the optimum level of fluorine in drinking water is accepted as 1 mg/l (14).

**Deficiency** : Deficiency of fluoride in water below 0.5 mg/1 is usually associated with dental caries.

**Excess** : Ingestion of large amounts of fluorine (>2-3ppm in water) is associated with dental and skeletal fluorosis. Skeletal fluorosis has been reported to be health problem in rural districts of Andhra Pradesh, Haryana, Karnataka, Kerala, Punjab, Rajasthan and Tamil Nadu. Scientists working at the National Institute of Nutrition Hyderabad found new form of fluorosis characterized by genu valgum and osteoporosis of the lower limbs in some districts of Andhra Pradesh and Tamilnadu.

## Zinc

Zinc is present in small amounts in all tissues of the body. Total content of the body is over 2.0 g.

**Sources** : Zinc is widely distributed in food stuffs of both animal and vegetable origin. Good sources of zinc are meat, whole grains and legumes. Its bioavailability in vegetable foods is poor due to presence of phytates which impair its absorption.

**Requirement** : The daily requirement of zinc is about 15 mg in men and 12 mg in women (15).

**Functions** : Zinc is part of over 100 enzymes and is thus of importance in protein and carbohydrate metabolism, bone metabolism, and oxygen transport. Zinc is also important in the immune response and gene expression. It is an important structural constituent of leucocytes and has a vital role to play in the synthesis of nucleic acids (9). Lymphoid tissue too contains substantial amounts of zinc. Zinc interacts with insulin in the pancreas and serves in the efficient storage of the hormone. Zinc is a also powerful antioxidant.

**Deficiency** : A clinical syndrome characterized by small stature, hypogonadism, mild anaemia and low plasma zinc occurs in older children and adolescents in poor peasant communities in Iran and elsewhere in Middle East, where the staple diet is unleavened bread. The zinc intake is low and its absorption is impaired by phytate in the unleavened bread. However, the common deficiency symptoms are:

- Severe deficiency results in growth retardation, failure to thrive, delayed sexual maturation esp. in children.
- Deficiency of zinc impairs cellular immune mechanism while excess of it may depress neutrophils.
- Zinc deficiency may present as a tetrad of symptoms comprising of neuro-psychiatric changes, dermal lesions, diarrhoea and alopecia (Acro-dermatitis Enteropathica). Zinc supplementation has been found useful in these conditions (9,15).

## Copper

It is an essential trace element as it is a component of many metallo-enzyme systems and iron metabolism is closely dependent on it. The amount of copper in the adult body is estimated to be 80 -100mg. Copper is widely distributed in nature and therefore primary copper deficiency in adults has never been reported in adult man. Even poor diets provide enough copper for human needs.

**Sources** : Meat, nuts, cereals and fruits are good sources.

**Functions** : Many metalloenzymes contain Copper. These enzymes have various functions which are summarized in the Box- 5 (9).

Box - 5 : Functions of some copper containing metalloenzymes	
Enzyme	Function
Caeruloplasmin (Ferrioxidase 1)	- Iron oxidation and transport
Superoxide dismutase	- Antioxidant
Cytochrome-c oxidase	- Electron transport
Dopamine hydroxylase	- Hydroxylation of Dopa in brain
Tyrosinase	- Formation of melanin
Clotting factors V and VIII	- Thrombogenesis

**Requirement** : Suggested daily intake is 1-2 mg (10).

**Deficiency** : Copper deficiency is rare. Hypocupraemia occurs in patients with nephrosis, Wilson's disease and sometimes in protein energy malnutrition. Neutropaenia is the commonest documented abnormality of copper deficiency. Infants, especially those who are premature, may develop copper deficiency which usually presents as chronic diarrhoea. Neutropaenia and later anaemia develop and they do not respond to iron. Menke's disease, a rare hereditary defect of copper absorption is invariably fatal. Copper deficiency may be a risk factor for coronary heart disease as it has been associated with raised plasma cholesterol levels and heart-related abnormalities.(9)

## Selenium

There is a resurgence of interest in the mineral selenium due to its antioxidant properties. It is an essential component of glutathione peroxidase, an important enzyme. It is present in all body tissues except fat.

**Sources** : Meat, fish, nuts and eggs are good sources. Lacto-ova vegetarians and vegans may be at risk of deficiency.

**Functions** : Selenium is an integral part of over 30 selenoproteins; the most important of which are glutathione peroxidases and iodothyronine deiodinases. Glutathione peroxidase has an important role in the detoxification of peroxides and free radicals. Its antioxidant action might be protective against certain cancers especially prostate, lung, colon and non-melanoma skin cancers. It may also be helpful in delaying the aging process. It is also involved in the production of tri-iodothyronine from thyroxine. It also contributes to antibody responses, the production of eicosanoids as well as cytotoxicity of natural killer cells (9).

**Requirements** : Recommended daily intake is 70 µg (11).

**Deficiency** : Its deficiency has a wide range of symptoms, not all attributable to glutathione peroxidase. Its deficiency is associated with increased coronary artery disease. Keshan disease (endemic cardiomyopathy) in China and Kashin Beck syndrome, an osteo-arthritis in children of 05-13 years age is seen in selenium deficient areas (9,10).

### Who is likely to get Selenium Deficiency?

**Poor Soil Content** : Poor soil content of Selenium compromises its dietary availability through poor contents of crops and animals. It is seen in large parts of Scandinavia, China, Central Europe, Africa and New Zealand.

**Increased Oxidative Stress** : Strenuous exercise, physical activity, smoking, exposure to environmental chemicals, radiation and chronic illness increase oxidative stress. This escalates the turnover of glutathione peroxidase which in turn increases the requirement of Selenium and likelihood of its deficiency.

**Malabsorption** : As caused in pancreatic disorders, cystic fibrosis, inflammatory bowel disease also put one to the risk of Selenium deficiency.

## Summary

Minerals are single inorganic elements, used by the body to activate, regulate and control metabolic activities, in structural building of cell/tissue and in neural transmission and muscle

contraction. They could be macrominerals or microminerals depending on their requirements (more than 100 mg and less than 100 mg/day respectively). Salient features are tabulated in Summary Box 1 and 2.

### Summary Box - 1 : The Macrominerals

Mineral	Function	RDA	Deficiency	Sources
Calcium	Bone & teeth formation, Blood clotting, Muscle contraction, Nerve transmission	Adults: 400 mg Pregnancy & Lactation 1 g	Tetany, Rickets, Osteoporosis	Dairy products, Meat products, Leafy vegetables
Phosphorus	Bone & teeth formation, Energy metabolism, Nucleic acid synthesis, Acid base balance	1 g	Not seen often Can cause bone loss, anorexia	Dairy products, Meat products, Leafy vegetables
Sodium	Extracellular fluid component, Water balance Acid base balance Nerve transmission, Muscle action	5 g	Cramps, Acid-base imbalance, Water imbalance	Table salt
Potassium	Major Intracellular fluid component, Acid-base balance; Nerve transmission, Muscle action	5 g	Muscle weakness, Arrhythmias	Fresh fruits, meats, whole grains, vegetables
Magnesium	Coenzyme in metabolic reactions, Nerve conduction	350 mg	Tremors, spasm	Meat, cheese, eggs, nuts, legumes

### Summary Box - 2 : The Microminerals

Mineral	Function	RDA	Deficiency	Sources
Iron	Haemoglobin & Myoglobin formation, Cellular oxidation reactions, Antibody formation	Male:28mg Female:30mg Pregnancy:38mg Lactation:30mg	Anaemia, fatiguability. Impaired immune function	Meat products, Liver, Green leafy vegetables
Iodine	Thyroxine synthesis	Adults 150µg Pregnancy 200µg	Goitre, cretinism, hypothyroidism, Infertility, still births	Iodized salt, Plant products grown in iodine rich soil
Zinc	Essential enzyme constituent, Protein metabolism, Immune function, Insulin storage, Sexual maturation	15mg	Retarded sexual and physical activity; Impaired wound healing	Dairy products, Meat products, Eggs, whole grains
Selenium	Antioxidant function Forms glutathione peroxidase, spares Vitamin E	70 µg	Impaired immune function, Keshan disease	Liver, meats, whole grains, sea food
Fluoride	Bone and teeth constituent	< 1mg	Dental caries	Flouridated water, toothpaste

## Study Exercises

**Long Question :** Which are the minerals of importance to public health in India? Discuss the sources, requirement and functions of Iodine.

**Short Notes :** (1) Importance of selenium as an antioxidant (2) Osteoporosis (3) Trace elements.

### MCQs

1. Which of the following iron sources falls under the category of non heme iron (a) Jaggery (b) Meat (c) Eggs (d) Milk
2. Calcium homeostasis is maintained by (a)  $T_3$  and  $T_4$  (b) Vitamin D and parathyroid hormone (c) Phosphorus and magnesium (d) Calcitonin and bone matrix
3. Ideal sodium potassium ratio should be (a) Not specified (b) 1:1 (c) 1:2 (d) 2:1
4. Which of the following does not fall under 'IDD' : (a) Cretinism (b) Mongolism (c) Deaf-mutism (d) Infertility
5. Which of these is not a constituent of metallo-enzymes (a) Copper (b) Zinc (c) Iron (d) Nickel

**Answers :** (1) a; (2) b; (3) b; (4) b; (5) d.

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## Major Foods and their Nutritive Value

Rajul K Gupta

### The Major Food Groups

There are innumerable food items that constitute human diet. The major foodstuffs can be broadly classified into ten major groups. These are shown in the Box-1.

Foods have different nutritional profiles. Moreover, availability of foods varies at different places and in different seasons. People from diverse cultures, religions and states tend to consume different types of food stuff. But one thing that is common for the good health of all humans is the absolute necessity of a well balanced diet. To formulate a well balanced diet for optimum health, it is extremely important to appreciate the details of these food items and their nutritive value. Therefore these facts are required to be learnt before we could proceed further in unveiling the complex relationship of food,

health, disease and its prevention. This chapter endeavors to elaborate in brief the commonly used food items.

#### Box - 1 : Ten major food groups

Cereals and millets
Pulses and legumes
Vegetables, roots and tubers
Fruits and nuts
Animal foods <ul style="list-style-type: none"><li>• Meat/Poultry</li><li>• Milk and milk products</li><li>• Eggs</li></ul>
Oilseeds
Sugar, jaggery, salt
Non - Alcoholic beverages
Alcoholic beverages
Spices and condiments



## Cereals and Millets

Cereals and millets form the staple food for human diet as they are cheap and have a high energy value, approximately 350 Kcal/100g. In an agricultural country like ours, rice, maize, wheat and millets (*jowar*, *bajra* and *ragi*) form the bulk of the diet which makes up for as much as three fourth of the total energy requirement of a rural Indian. Thus knowing about the nutritive quality of these staple cereals is of great importance. Cereals and millets provide almost all major nutrients, as elaborated below.

**Carbohydrates** : Cereals are most important sources of carbohydrates and energy in our diet. They provide 60 to 75 % of the total energy in our diet.

**Proteins** : Cereals are moderate sources of proteins (about 6 to 12g/100g). Cereal protein is of poor quality as it is deficient in essential amino acids. Wheat proteins are deficient in Lysine and maize in Tryptophan. Pulse proteins on the other hand, are rich in these deficient amino acids (lysine and tryptophan). A predominantly cereal diet should therefore invariably be supplemented with other sources of proteins like the pulses, especially for the vegetarians. This helps to improve the quality of protein in our diet. This is called as the supplementary action of proteins.

Cereal proteins are quantitatively an ample amount of protein in an otherwise protein deficient Indian diet. As much as 50% of the total proteins in Indian diet is contributed to by cereal proteins. Hence cereals constitute a vital source of proteins in our diet.

**Micronutrients** : Cereals contain minerals like iron and calcium, little carotene but no vitamin C. *Ragi* is particularly rich in calcium. The millets are also rich in phytates and tannins which interfere with the absorption of minerals. Whole (unrefined) cereals are relatively good sources of the B complex vitamins. Most of the vitamins lie in the outer layers so milling and polishing removes these vitamins to a great extent.

**Fibre** : The outer layers of cereals and millets contain the all important fibre in plenty (1-8g/100g). The fibre is lost depending on the level and extent of milling.

**Milling** : Now a days machine milling of cereals has become an integral part of the processing of grains. Milling not only does the basic processing but also makes the grain more shiny, whiter and sparkling ('refined white flour and polished white rice'). This appeals to the sense of sight and thus improves the palatability. But we have to pay the cost for it in terms of losing its nutritive value. Milling separates germ and outer layers (pericarp and testa) that are discarded as bran. Such highly milled wheat and rice is thus devoid of fibre. Since the vitamins are also concentrated in the outer layer of the whole grains, which are removed by machine milling, these refined cereals lose not only much of their fibre but also the vitamin, mineral and protein content during processing (1).

Machine milling and refining cause considerable deterioration of nutritive value of cereals that eventually affects public health. For example, beriberi is endemic in countries where polished rice is habitually eaten. Even though whole meal flour has marginally lower energy value than white flour, the protein

content of whole meal flour is relatively higher (3). Milling is undoubtedly a necessary evil. Cereals should not be 'hard' milled. Highly milled cereals should be avoided. It is advisable to consume whole wheat atta of 85 percent extraction. Not more than 5 percent bran should be permitted to be removed during milling. Parboiling of rice is also an effective solution. Parboiled rice is the only cereal which does not suffer appreciably when machine milled.

*Effects of Refining on Nutrient Content of Wheat Flour (per 100 g) (2).*

Nutrient	Content before refining (per 100 g)	Content after refining (per 100 g)
Thiamin	580 µg	140 µg
Vitamin B <sub>6</sub>	750 µg	130 µg
Niacin	2520 µg	340 µg
Folate	57 µg	6 µg
Vitamin E	1.4 mg	0.3 mg
Calcium	44 mg	23 mg
Zinc	29 ppm	8 ppm
Copper	4 ppm	1.3 ppm
Iron	35 ppm	10 ppm

## Rice

Rice is staple to more than half of the world population.

**Nutritive value** : Rice is high in energy (about 350 Kcal/100g). The protein content is moderate, 6-9 g%. It is richer in lysine than other cereals. Rice is also fairly rich in thiamine, riboflavin and niacin. It is a poor source of vitamins A, C and D. It is poor in calcium and iron as well.

**Nutritive losses** : Milling and polishing cause the greatest nutritional loss. Polishing is a process where milled rice is passed through rubber rollers to make it smooth, shiny and whiter. During processing the B -complex vitamins, fibre and proteins are lost to a great extent, depending on the level of milling and polishing. Rice also loses substantial amount of water soluble vitamins and minerals during washing it in plenty of water and discarding it. Similarly draining the water in which the rice was cooked also causes loss of water soluble nutrients.

**Preventing nutritive losses** : The nutritive losses because of milling, polishing, other processing and cooking practices can be prevented by taking suitable and timely measures. One such widely used method is parboiling.

**Parboiling** : It is an old technique practiced in India for a long time at the household level. This involves steaming the rice that renders it partially cooked. The technique is now being used at a commercial level as well. The 'Hot Soaking Process' of parboiling has been recommended by the Central Food Technological Research Institute, Mysore.

**The process** : The paddy is soaked in hot water at 70°C for 3 to 4 hours. With this soaking the outer husk splits and becomes easier to remove. The excess water is drained. This paddy is then steamed for about 10 minutes. The paddy is dried. At a

domestic level it is home pounded and commercially, it is milled for final use. Advantages of parboiling are given in Box - 2.

<b>Box - 2 : Advantages of parboiling</b>
Parboiling causes the B group vitamins in the outer layers (aleurone) to diffuse in to the interior of the grain (endosperm) thus saving them from being lost during milling.
Drying the rice causes the germ to attach firmly to grain, so that the germ is not lost during milling and polishing.
The heat hardens the grain as the starch gets gelatinized. This increases the keeping quality and storage capacity of rice.
The parboiled grain also becomes more resistant to insects.

**Disadvantage of parboiling** : There are no disadvantages of the parboiled rice except for the fact that it imparts an off flavour to rice. The rice also attains a pale hue. The off flavour is not liked by people who are used to eating the non-parboiled rice.

### Wheat

Wheat is the most widely consumed cereal in North India. It is used to make flour (atta for chapattis and puri), maida for bread, dalia and also suji, to make various savouries.

**Nutritive value** : The calorie content of wheat is almost the same as that of rice i.e. about 350 Kcal/100g. The protein content is higher than that of rice i.e. 9 to 16g %. The quality of protein is however poor as it is deficient in the essential amino acids lysine and threonine.

**Nutritive losses and their prevention** : Hard milling, extraction and discarding the bran causes loss of fibre, vitamins and proteins. As discussed earlier it is advisable to consume whole wheat atta and dalia. Products made up of refined flour like white bread, biscuits, cakes, noodles and burgers should be discouraged.

### Maize

Maize is the staple diet in many parts of Africa and Central Asia. However, in most parts of India and many other parts of the world it is commonly eaten only as corn. It is also used to make cornflakes. Cornflour is used in confectionery and to

make custards.

**Nutritive value** : The calorie content of maize is about 342 Kcal/100g. The protein content is higher than that of rice i.e. 9 to 16g %. The quality of protein is poorer as it is deficient in lysine and tryptophan. It also contains excess leucine which interferes with conversion of tryptophan to niacin (60mg of tryptophan is required to produce 1mg niacin). Thus maize eaters may face the deficiency of niacin and a higher risk of pellagra. Maize is also rich in carotenoids. Nutritive values of common Cereals and Millets are given in Table - 1.

### Millets

Millets are consumed without milling. The commonly used millets are *jowar* (sorghum), *bajra* (pearl millet) and *ragi*. These are traditional foods in many parts of India. *Jowar* and *Bajra* are widely used in Maharashtra and Rajasthan respectively.

**Nutritive value** : The calorie content of millets is about 350 Kcal/100g. The protein content is about 8 to 14g %. They are also rich in minerals. *Ragi* contains a high amount of calcium - 344 mg / 100 g.

*Jowar* is important millet in the western and central India (esp. Maharashtra, MP and Andhra Pradesh) and is the staple for many Indians. It is nutritious millet with a high iron content of 4.1 mg/100g. The protein content is in the range of 9 to 14%. Like other millets the protein is limited in the amino acids lysine and threonine. In some species the leucine content might be higher that interferes with the conversion of tryptophan to niacin thus sole consumption of *Jowar* could be pellagrogenic.

*Bajra* (Pearl millet) is grown in the arid regions of our country. It is relished in Rajasthan, Gujarat and some parts of Maharashtra as porridge. It is also used to make flour for preparing chapatis. The protein content is in the range of 10 to 14%. The iron content of *Bajra* is the highest among all cereals and millets at 8mg/100g. It is also relatively rich in calcium, carotene, riboflavin, niacin and folic acid.

### Pulses and Legumes

Pulses and legumes comprise of dried peas, beans, dals and grams and are an integral part of the Indian diet. Commonly used dals are red gram (*arhar*), green gram (*moong*), lentil (*masoor*), bengal gram (*channa*) etc. They are, therefore a

**Table - 1 : Nutritive value of common cereals and millets (per 100g) (1)**

Food stuff	Proteins (g)	Fat(g)	Fibre (g)	Carbohydrates (g)	Energy (Kcal)	Iron (mg)	Carotene (µg)	Thiamine (mg)	Riboflavin (mg)	Niacin (mg)	Folic acid (µg)	Vitamin C (mg)
Rice parboiled	6.4	0.4	0.2	79	346	1	9	0.21	0.05	3.8	8.9	0
Rice polished	6.8	0.5	0.2	78.2	345	0.7	0	0.06	0.06	1.9	8	0
Wheat	11.8	1.5	1.2	71.2	346	5.3	64	0.45	0.17	5.5	142	0
Wheat flour	12.1	1.7	1.9	69.4	341	4.9	25	0.49	0.17	4.3	35.8	0
Maize dry	11.1	3.6	2.7	66.2	342	2.3	90	0.42	0.1	1.8	20.0	0
<i>Bajra</i>	11.6	5	1.2	67.5	361	8	132	0.33	0.25	2.3	45.5	0

### *Soya bean - The 'Queen' of pulses and legumes*

Soya bean is a pulse which has very high protein (43.2g/100g) and fat content (19.5g/100g). It possesses high contents of iron as well. It is also rich in carotene, niacin and folic acid. The nutritive value of soya bean proteins is equivalent to milk proteins even though the protein quality is inferior. The rather bland taste of unprocessed soya bean can be made up by suitably cooking or processing it. It can be simply cooked as dal or can be prepared with other legumes as mixed dal. Soya bean can be processed into many foods which are enjoyed by the community. It is commonly eaten as nuggets (baris). Its flour can be mixed in wheat flour to make it more nutritious. Soya milk and curd is also popular. It can be processed to fried nuggets (kurkure), which are relished by the children. In the South East Asian countries its preparations like tofu, miso and soya sauce are relished. By virtue of its high fat contents its oil is extracted and used as cooking oil. This oil is one of the very few oils rich in alpha-linolenic acid (>5%) besides its high contents of linoleic acid (53%). Soya bean is truly the 'Queen' of pulses and legumes.

### *Nutritional profile of Soya bean (per 100g)*

Nutrient	Contents	Nutrient	Contents
Protein	43.2 g	Thiamin	0.73 mg
Fat	19.5 g	Riboflavin	0.39 mg
Iron	10.4 mg	Niacin	3.2 mg
Carotene	426 µg	Folate (total)	100µg

valuable constituent of the vegetarian diet. Pulses are cheap and easily available.

**Nutritive Value :** Pulses and legumes are colloquially referred to as the poor man's meat as they have high protein content of about 20-25g%. Although they are poor in methionine and cysteine and the biological values of their protein is inferior to foods of animal origin (meat, fish eggs and milk), they are a substantial source of proteins for those not consuming meat. Pulse protein is rich in lysine which compensates for the low lysine content of cereal proteins. They are an important source of vitamins and minerals like calcium, iron and vitamin B. Bengal gram (*channa dal*) and to a lesser extent green gram (*moong*) contain a small amount of ascorbic acid in the dry state. The energy content is approximately the same as that of cereals i.e. about 350 Kcal/100g (1).

**Germination of Pulses :** The ascorbic acid content of all unsplit pulses can be increased by germinating or sprouting. Whole unsplit dal or gram is first soaked in water for 12 to 24 hours and then spread on a damp blanket in a thin layer to allow access of air and covered with another blanket kept damp by sprinkling water. In few hours small sprouts appear; when

these are 10 to 20 mm long the process is complete. The vitamin C content is maximal after about 30 hours of germination. Germination causes an increase in vitamin B also (4).

**Fermentation** too improves the nutritional value of pulses. The vitamin content of B group of vitamins esp. thiamin, riboflavin and niacin goes up. The digestibility of pulses also improves with germination. The nutritive value of common pulses and legumes is summarized in Table - 2.

## **Animal Foods**

### **Meat and fish**

**Meat** is a word commonly used for the flesh of cattle (beef), goat and sheep (mutton), pig (pork) or chicken. It is a good source of high quality protein (15 to 20g per 100g). Moreover this protein is qualitatively as good as that of fish, egg, milk, cheese and other dairy produce, since it contains all essential amino acids. It is also a good source of most B vitamins like nicotinic acid. Meat is rich in phosphorous but poor in calcium. Liver, a component of meat, too has not only high quality proteins but also vitamin A and vitamin B complex. Meat is also rich in minerals especially iron and zinc. The iron content

**Table - 2 : Nutritive value of common pulses and legumes (per 100g)**

Pulses and legumes	Proteins(g)	Fat (g)	Fibre (g)	Carbohydrates (g)	Energy (Kcal)	Iron(mg)	Carotene (µg)	Thiamine (mg)	Riboflavin (mg)	Niacin (mg)	Folic acid (µg)	Vitamin C (mg)
Peas dry	19.7	1.1	4.5	56.5	315	7.05	39	0.47	0.47	3.4	7.5	0
Green gram	24.5	1.2	0.8	59.9	348	3.9	94	0.47	0.47	2.4	140	0
Bengal gram	17.1	3	3.9	60.9	360	4.6	189	0.30	0.15	2.9	186	3
Soya bean	43.2	19.5	3.7	20.9	432	10.4	426	0.73	0.39	3.2	100	-
Rajmah	22.9	1.3	4.8	60.6	346	5.1	-	-	-	-	-	0
Redgram	22.3	1.7	1.5	57.6	335	2.7	132	0.45	0.45	2.9	103	0

of meat is of the heme variety which has high bioavailability. Meat has a high content of fat including the saturated fatty acids, which may be a risk for good health.

*Fish* is generally considered good for health as it is rich in unsaturated fatty acids including the omega 3 fatty acids and vitamins A and D. Fish has high quantity of proteins (15 - 25g/100g), which are of high biological value and are easily digestible. Sea fish is also rich in minerals like Iodine. With the current emphasis on higher intake of polyunsaturated fatty acids, including the omega-3 fatty acids fish is of immense value in diet.

### Milk and Milk Products

Milk is the complete food on which the young one may subsist for up to six months. It is the sole food for all growing young mammals. The human milk might be poorer than cow's or buffalo's milk, but is adequate for the infant. Milk is used to prepare curd, yogurt, butter, ghee and buttermilk. These are used extensively for the preparation of many traditional Indian sweets.

**Nutritive Value of Milk :** All the important nutrients are well represented in milk except for iron and nicotinic acid. Newly drawn milk contains 2 mg of vitamin C per 100 ml but this readily disappears on storage, heating or processing in any other way. On the average, one liter of cow's and buffalo's milk contains 32 and 43 g of protein respectively. Human milk contains about 1.1g % proteins. Milk proteins are caseinogen (85%), lactalbumin (12%) and lactoglobulin (3%). These proteins are of high biological value and are rich in tryptophan and cysteine. Calcium caseinogenate is a complex formed with calcium in milk.

The fat content in milk varies from 3.4 (human) to 6.5 % (buffalo), depending on the source. Milk fat is an emulsion of extremely fine particles of the glycerides of butyric, palmitic and oleic acid rendering it easily digestible and this is especially so in cow's milk. Milk is also rich in linoleic acid and oleic acid. Milk is a good source of vitamin A and D as well. Milk contains more than 30 types of sugars, Lactose being the most predominant of them. A litre of milk contains as much as 50 g of lactose. Milk is also very rich in calcium (1200 mg per litre

of cow's milk) and phosphorus. One litre of cow's milk provides about 670 Kcal (2.8 MJ) of energy (1).

**Curd :** Curd is traditionally relished in the Indian diet. It is produced by the action of lactobacilli on lactose (in milk), which is broken down to lactic acid. The proteins are coagulated by the acid and curd is formed. Curd and whole butter milk are easily digestible. They have the same nutritive value as that of the original milk from which they were prepared, being very good sources of protein, calcium, vitamin A and riboflavin.

**Cream, Butter and Ghee :** Cream, butter and ghee are the various types of fats extracted from milk. Cream can be extracted by centrifugation of unboiled milk. Butter is the fat extracted from buttermilk. Ghee is the clear fat extracted after boiling butter. Cream has nutritive value in between whole milk and butter. Good butter should not contain more than 16 percent of water and not less than 80 percent of fat. 100gm butter yields about 729 Kcal (3.05 MJ). On the other hand, ghee is almost 100% fat, 100 g of ghee yielding 900 Kcal (3.76 MJ). Nutritive value of milk and milk products is summarized in Table - 3.

**Skimmed and Toned Milk :** The milk available in market may be pure milk from cow or buffalo. Sometimes a mixture of buffalo's and cow's milk might also be available. Some people prefer low fat or fat free milk. This is the skimmed milk from which fat has been removed. This is useful for those who have been recommended low fat in diet, due to a medical condition. Toned milk can be manufactured by adding 1 part water and 1/8 part skimmed milk to 1 part milk. This blend is then stirred, pasteurized and bottled. It becomes quite similar to cow's milk.

**Tinned Milk :** Powdered or tinned milk could be an alternative to whole milk when fresh milk cannot be made available. Condensed, evaporated or homogenized milk can be tinned. It could be sweetened or unsweetened. Condensed milk contains 50 percent cane sugar, which is a good preservative. Dried or powered milk is reconstituted by adding 7 volumes of boiled water just before consumption. Tinned milk should be reconstituted as per instructions.

### Eggs

Eggs contain all the nutrients required for the embryo. They

**Table - 3 : Nutritive value of milk and milk products (per 100ml) (1)**

Food stuff	Proteins (g)	Fat (g)	Energy (Kcal)	Iron (mg)	Carotene (μg)	Thiamine (mg)	Riboflavin (mg)	Niacin (mg)	Folic acid (μg)	Vitamin C (mg)
Milk, buffalo	4.3	6.5	117	0.2	48	0.04	0.10	0.1	3.3	1
Milk, cow	3.2	4.1	67	0.2	53	0.05	0.19	0.1	5.6	2
Milk, human	1.1	3.4	65	-	41	0.02	0.02	-	1.3	3
Ghee	-	100	900	-	600	-	-	-	-	-
Butter	-	81	729	-	960	-	-	-	-	-
Cheese	24.1	25.1	348	2.1	82	-	-	-	-	-
Curd	3.1	4	60	0.2	31	0.05	0.16	0.1	3.3	1



have a high nutritive value. An egg provides about 70 Kcal. An egg contains about 6 g protein. The proteins are of a high biological value. The NPU of egg protein is 100 and is taken as the standard protein, to compare other proteins with. An egg contains about 6 g of fat. It also has a high cholesterol content of 250mg. The fat is present in the yolk. It is finely emulsified and hence easily assimilated. The minerals and vitamins exist in the yolk, which is also a valuable source of calcium, phosphorus, iron and vitamins A and D. The white of the egg is one of the best sources of riboflavin. It is however deficient in Vitamin C. Nutritive value of egg is given in Table - 4.

### Vegetables

Vegetables and fruits add colour and variety to our food. It is the vegetables and fruits that impart a seasonal touch to the diet, as they change with the seasons. We have green leafy vegetables, coloured vegetables, roots and tubers.

**Nutritive Value** : Vegetables esp. green leafy and coloured vegetables are a store-house of vitamins, minerals, various phytochemicals and antioxidants, hence they along with fruits are termed as the *protective foods*.

**a) Vitamins and Antioxidants** : They contain ample amounts of carotene, ascorbic acid, folic acid, calcium, iron and riboflavin. The carotenoids, vitamin C and numerous other phytochemicals possess antioxidant properties (See Box - 1). A yellow vegetable like pumpkin is rich in carotene. However, the carotene of green vegetables like drumstick, cabbage, amaranth and methi is better utilized than of yellow vegetables. Gourds are generally of poor nutritive value; but the bitter gourd is relatively rich in ascorbic acid. The tomato has good ascorbic acid, riboflavin and antioxidant lycopene contents. Onion may not have outstanding nutritive properties, but is virtually irreplaceable because of its value as a flavouring agent and appetizer.

**b) Minerals** : Vegetables are good source of minerals like calcium, phosphorus, iron, zinc and many trace elements. The absorption and bioavailability of some of the minerals may not be very good due to various reasons. Iron from green leafy vegetables is not very well absorbed as it is present in the ferric state which is not conducive for absorption. In addition calcium, oxalates, phosphates and phytates present alongside (in the vegetables) inhibit the absorption of minerals further.

**c) Fibre** : Vegetables are rich in fibre, especially the soluble fibre. Fibre is considered extremely important for normal bowel motility, getting rid of toxins from the intestine and guarding it against the rapid absorption of glucose and lipids, thus

preventing hyperglycemia and hyperlipidaemia.

<i>The Rainbow of Phytochemicals</i>		
Colour	Fruit or vegetable	Phytochemicals
Red	Tomato	Lycopene
Yellow-green	Pumpkin, papaya	Zeaxanthin
Red-purple	Beet root,	Anthocyanins
Orange	Pumpkin, papaya, mango	Beta carotene
Orange-yellow	Apricots, apple, cherry, tomato, orange	Flavonoids
Green	Leafy vegetables, cabbage	Glucosinolates
White-green	Garlic, onion	Allyl sulphides

**d) Calories** : There are not many foods in our diet that could be claimed to be low in calorie and yet nutritious! Vegetables have this unique distinction. By virtue of their high moisture and fibre content the calorie content of most of the green vegetables is in the range of 20 to 60 Kcal/100g. This is a boon for those who have been advised to restrict calories.

Root and tuber vegetables are of variable nutritive value. The carrot is outstandingly rich in carotene. Most roots and tubers contain starch and moderate amounts of ascorbic acid. Potatoes and sweet potatoes having high carbohydrate content have a good energy value and contain moderate quantities of ascorbic acid. Nutritive values of common vegetables are given in Table - 5.

### Fruits

Fruits hold a special place in the nutrition of man. They can be eaten any time and as much. Everyone loves them. Different fruits are available in different seasons. They are extremely nutritious. Being eaten raw and fresh, the minerals, vitamins and phytochemicals present in them, do not have to suffer the humiliation of 'mutilation' through heat and fire. Fruits can be classified into citrus, non-citrus and dry fruits.

### Nutritive Value

**a) Vitamins and Antioxidants** : It is known since James Lind that citrus fruits like oranges, lime, lemon, mosambi, malta, etc are rich sources of vitamin C. Guava and amla too are very rich sources of vitamin C. Papaya and mango are rich in carotene and moderately rich in vitamin C. Pineapples, strawberries

**Table - 4 : Nutritive value of egg (per 100g\*) (1)**

Food stuff	Proteins (g)	Fat (g)	Energy (Kcal)	Iron (mg)	Carotene (μg)	Thiamine (mg)	Riboflavin (mg)	Niacin (mg)	Phosphorus (mg)	Calcium (mg)
Egg, hen	13.3	13.3	173	2.1	420	0.1	0.4	0.1	220	60
Egg, duck	13.5	13.7	181	2.5	405	0.12	0.26	0.2	260	70

\* One egg weighs about 60 to 70 g

**Table - 5 : Nutritive value of common vegetables (per 100g) (1)**

Vegetable	Fibre (g)	Carbohydrates (g)	Energy (Kcal)	Iron (mg)	Carotene (μg)	Thiamine (mg)	Riboflavin (mg)	Niacin (mg)	Folic acid (μg)	Vitamin C (mg)
Beans	1.8	4.5	26	0.61	187	0.10	0.06	0.7	45.5	24
Spinach	0.6	2.9	26	1.14	5580	0.03	0.26	0.5	123	28
Tomato	0.8	3.6	20	0.64	351	0.12	0.06	0.4	30	27
Carrot	1.2	10.6	48	1.03	1890	0.04	0.02	0.6	15	3
Onion	0.6	11.1	50	0.6	15	0.08	0.02	0.5	-	2
Potato	0.4	22.6	97	0.48	24	0.1	0.01	1.2	7	17
Cauliflower	1.2	4	30	1.23	30	0.04	0.1	1	-	56
Cabbage	1	4.6	27	0.8	120	0.06	0.09	0.4	23	124
Pumpkin	0.7	5.8	39	-	50	0.06	0.04	0.5	13	2

and papaya are moderately rich sources of vitamin C. Yellow peaches are a good source of carotene. Banana, orange and strawberries are moderate sources of folates. Dried fruits like dry figs provide thiamin, niacin and riboflavin. Dried apricots and prunes are rich in vitamin A (See Table- 6).

**b) Minerals :** Watermelon is rich in iron. Custard apple is rich in phosphorus and iron. Apricots, lime, guava and figs are rich in calcium. Apricots are rich in zinc too. Banana and apples are moderately rich in potassium. Dried fruits : Raisins, figs, dates and dry apricots are rich in iron. Dried figs are also rich in phosphorus, calcium, potassium and zinc (1).

**c) Energy :** Banana and plantain have high energy value.

**d) Fibre :** Fruits are rich in fibres. Their soluble fibre is particularly useful in inhibiting the rapid absorption of glucose and lipids from the intestine. This is helpful in prevention of hyperglycemia and hyperlipidaemias

A daily recommendation of about 400g of fruits and vegetables has been made by the American Dietetic Association. It is wise to consume fresh, seasonal and locally available fruits that are less costly and more affordable than the imported fruits. Nutritive values of common fruits are given in Table - 6.

#### Nuts

The common nuts in use are almond, cashew nut, groundnut, coconut, pistachio, walnut, etc. Nuts are relished by the young and all primarily for their taste. Nuts have a very high nutritive value (See Table - 7).

Nuts have a high fat and protein content and hence a high energy value. They are a good source of fats, vitamins and proteins as well. They contain minerals too in good quantities. Groundnuts are a good source of proteins, fats & vitamin B complex esp. niacin. Even though the proteins are of low biological value, it is a cheap and ample source of proteins (See Box - 3). Pistachio

**Table - 6 : Nutritive value of common fruits (per 100g) (1)**

Fruit	Fibre (g)	Carbohydrates (g)	Energy (Kcal)	Iron (mg)	Carotene (μg)	Thiamine (mg)	Riboflavin (mg)	Niacin (mg)	Vitamin C (mg)
Guava	5.2	11.2	51	0.27	0	0.03	0.03	0.4	212
Amla	3.4	13.7	58	1.2	09	0.03	0.01	0.2	600
Mango	0.7	16.9	74	1.3	2743	0.08	0.09	0.9	16
Orange	0.3	10.9	48	0.32	1104	-	-	-	30
Banana	0.4	27.2	116	0.36	78	0.05	0.08	0.5	7
Lime	1.3	10.9	59	0.3	15	0.02	0.03	0.1	63
Grape blue	2.8	13.1	58	0.5	3	0.04	0.03	0.2	1
Papaya	0.8	7.2	32	0.5	666	0.04	0.25	0.2	57

**Table - 7 : Nutritive value of common nuts (per 100g) (1)**

Nuts	Proteins (g)	Fat (g)	Carbohydrates (g)	Energy (Kcal)	Iron (mg)	Carotene (μg)	Thiamine (mg)	Riboflavin (mg)	Niacin (mg)	Vitamin C (mg)
Almond	20.8	58.9	10.5	655	5.09	0	0.24	0.57	4.4	0
Cashew nut	21.2	46.9	22.3	596	5.81	60	0.63	0.19	1.2	0
Coconut dry	6.8	62.3	18.4	662	7.8	0	0.08	0.01	3	7
Groundnut	25.3	40.1	26.1	567	2.5	37	0.90	0.13	19.9	0
Pistachio	19.8	53.5	16.2	626	7.7	144	0.67	0.28	2.3	-
Walnut	15.6	64.5	11	687	2.64	6	0.45	0.40	1	0

**Box - 3 : Groundnuts - The King of Nuts**

Groundnuts are the cheapest and arguably the most nutritious of all nuts. It contains almost as much oils and fats as an oilseed does (40%). Its MUFA content is one of the highest amongst all Indian oilseeds, at 50% (exceeded only by mustard and rape seed). Its protein content is very high (25.3%). Its niacin content is unmatched (about 20mg/100g), that is 5 to 20 times higher than other nuts. It is a household item in many Indian states like Maharashtra, Gujarat and Andhra Pradesh. It is relished boiled, roasted, fried or simply salted. It can be made into powder or flour. Groundnut chikki (with jaggery) is not only favourite with children, but is extremely nutritious even for the pregnant and lactating. Powdered or ground groundnuts are also used in vegetable preparations and curries. Owing to its low cost and high nutrition value, it finds favour in various national nutritional programme menus like in 'multipurpose food and balahar' as well.

Multipurpose food used in national nutritional programme is made using a mixture of 75 percent groundnut flour (from which fats have been extracted) and 25 percent roasted red gram. It is further fortified with vitamins and minerals. It is a rich source of proteins.

Its low cost, high nutritive value, immense variety of preparations and delicious taste crowns the groundnuts as the 'King of nuts'.

is rich in iron, containing 7.7 mg/100g. Almond and cashew nuts are also moderate sources of iron and proteins.

### Fats and Oils

Fats and oils hold a vital place in our daily diet. They are an integral part of cooking as they not only impart good taste, but also contribute to the texture, crispness and energy to our food. They also serve as a medium for cooking as their boiling point is very high.

Fats that are liquid at room temperature are termed as oils. Fats and oils could be of either plant or animal origin. Vegetable oils such as mustard, ground nut, gingelly, coconut and safflower oils are widely used for cooking purposes. Vegetable oils (except red palm oil) are free of any vitamin A activity and contain predominantly unsaturated fatty acids. However, coconut and palm oils are the only commonly used plant oils that are rich in saturated fatty acids.

Butter and ghee are fats of animal origin. These are also used as a cooking medium. They are rich in vitamin A and D. All fats and oils provide 9 Kcal per gram. Excess consumption of these is in disrepute as they are considered to be atherogenic. Excess consumption also contributes to dyslipidaemia, a risk factor for cardiovascular diseases.

### Sugar and Jaggery

It is pure sucrose & is used for its sweetening effect & energy value. Excessive consumption of such refined sugar that

provides only 'blank calories' at the expense of complex carbohydrates lowers the relative vitamin, mineral and protein intake. Jaggery is a sweet food popular in rural India. Besides being tasty, it contains an appreciable amount of carotene & iron.

### Salt

Salt contains the essential mineral sodium. Even though the daily sodium requirement is very low, the average daily diet contains salt much in excess. The recommended daily salt intake is 5 g. Excess of salt and a skewed sodium potassium ratio (>1) is known to be a causative factor of hypertension. It is the added salt that is harmful to the body rather than the moderate amounts put in food preparations.

Where does 'High' Salt Come From ?		
High salt	Very High Salt	Excessively High Salt
Bread	Cheese	Pickles
Potato chips	Processed meat	Chutneys
Cornflakes	Soups	Salted Nuts
Canned vegetables	Ketchups	Salted fish
Canned fruits	Processed butter	Chaat

### Sugar substitutes

There are occasions when sugar substitutes have to be used instead of sugar. They are preferred for their very high sweetening power and negligible calorific value. These are commonly used for preparing ice creams, candies, toffees, jellies, sweets, etc. They are also used as sweetening agents in cold drinks, flavoured milk and even in tooth pastes. They are also popular amongst diabetics and people desirous of losing weight. Sugar substitutes can be classified into two groups :

(a) *Nutritive sweeteners* : Sugar alcohols (sorbitol, mannitol, xylitol) used as sugar substitutes in candies, chewing gum and beverages. These provide 4 Kcal/gm of energy.

Advantages :

- These are not absorbed as rapidly as sucrose, so can be used in those who cannot tolerate a high blood sugar level.
- The risk of dental caries is lower, as these alcohols can not be used by oral bacteria.

(b) *Non-nutritive sweeteners* : These do not supply any calories. Common examples are aspartame, sucralose, alitame and saccharin. They are several hundred times sweeter than sugar, so a small quantity is sufficient to sweeten the food.

### Spices and Condiments

Spices are used to flavour food and improve its palatability. They stimulate the appetite and thus improve health. They are essential to the Indian culinary art. They are used in very small quantities as flavouring agents and for their carminative properties. Green or dry chillies have a high carotene and vitamin C content. As per the new research turmeric (*haldi*) has very high antioxidant content and has medicinal value. Tamarind (*imli*) is widely used for its preservative effect and high vitamin C content. Cloves, Black pepper, ginger, garlic and red chillies have been shown to have antioxidant properties. Spices and condiments are used to prepare pickles and chutney which are used as appetizers.

### Non Alcoholic Beverages

Earlier it was thought that by themselves tea, coffee, cocoa or other non-alcoholic beverages do not provide energy or vitamins except that from the sugar and milk added to them. Tea contains alkaloids like caffeine, theophylline and theobromine which are cortical stimulants and help relieve fatigue. If used in excess they may cause insomnia, tachycardia and gastritis in some individuals. Recent studies show that they contain substantial amounts of antioxidants which have distinct health benefits. Alcoholic beverages have been discussed in another chapter.

### Summary

The ten major food groups are cereals/millets, pulses/legumes, vegetables (including roots and tubers), fruits/nuts, animal foods (meat/poultry, milk and milk products, eggs), oilseeds, sugar, jaggery, salt, beverages and lastly spices/condiments. Each of these has their own vital value in our diet and for good health.

Cereals and millets contribute to up to 75% of total energy intake. They also contain substantial amount of proteins and invisible fats which contribute handsomely to an Indian diet that is otherwise considered to be poor in these nutrients. Excessive milling denudes cereals of their outer cover and with that the major portion of vitamins, minerals and proteins are lost. Coarse ground flour (atta) and parboiled rice help in reducing the nutritive losses due to milling.

Pulses are the major contributors of proteins esp. in a vegetarian diet. Cereal proteins are poor in lysine which are compensated by the pulse proteins that are rich in these amino acids but poor

in methionine. Groundnuts and soya beans are of exceptionally high nutritive quality with high content of proteins, fat and vitamins. Fats are the storehouse of energy, present in animal oils (ghee/butter) or in vegetable oils (mustard, groundnut, etc).

Fruits and vegetables are rich sources of vitamins, minerals and antioxidants. Roots and tubers also contain starch that is high in calories. Milk which is a complete food is essential for infants and children. Egg protein is one of the best quality proteins available to us and its use must be encouraged. Meat contains high quality iron and proteins. But owing to its high saturated fat content, excessive consumption of meat should be guarded against. Spices and condiments not only provide flavour to the diet but also contribute to the antioxidant content of food.

### Study Exercises

**Long Question** : Enumerate major food groups. Describe the importance of legumes in diet.

**Short Notes** : (1) Importance of fruits in diet (2) Parboiling of rice (3) Nutritional importance of eggs.

### MCQs

1. The highest content of niacin is present in : (a) Jaggery (b) Groundnuts (c) Pistachio (d) Milk
2. Yellow-orange fruits and vegetables are rich in (a) Carotenes (b) Vitamin D (c) B Complex vitamins (d) Zinc
3. Food item with highest protein content is (a) Groundnuts (b) Meat (c) Soyabean (d) Fish
4. Egg is a poor source of vitamin (a) A (b) B (c) C (d) D
5. Jaggery is a rich source of (a) Carotene and thiamine (b) Zinc and iron (c) Iron and carotene (d) Sugar and proteins

**Answers** : (1) b; (2) a; (3) a; (4) c; (5) c.

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*Rajul K Gupta*

It is amazing as to how the same human body changes and behaves differently in different 'periods' of its lifecycle. At different stages of the organism with reference to changing age and continuously changing physiological status, the requirement of nutrients is based on activity, BMR, growth rate, etc. These factors change constantly as the organism grows over a lifetime. With these variations change the nutritional requirements. This chapter discusses the nutritional requirements over a lifecycle and how to meet that changed requirement through a typical Indian diet.

### Pregnancy & Lactation

#### Physiological Changes During Pregnancy and Lactation

Immense physiological changes take place in the human body during pregnancy. The uterus undergoes hypertrophy and hyperplasia, there is an increased vascularity within the uterus (and placenta). The heart rate, stroke volume and cardiac output increase so do the tidal volume and oxygen consumption. The renal plasma flow and GFR also increase. Appetite changes; cravings and aversions set in for certain foods. This is augmented by certain endocrine changes. Changed peristalsis state leads to constipation. Besides these the requirement for energy and various other nutrients go up steeply to cater for the developing fetus (1). The physiological changes continue during lactation. There are hormonal changes followed by physiological changes in the mammary system, involution of uterus continues. Psychological and emotional changes too play a part. The process of lactation requires energy. The additional

energy required is based on the volume of milk secreted, its energy content and the efficiency of conversion of food energy into milk energy. Women secrete up to 850 ml milk per day at 80% efficiency of conversion of food energy into milk energy.

All these changes demand a change in the woman's lifestyle including her dietary habits, to cope up with the increased requirement of nutrients. The nutrient requirements during pregnancy and lactation are discussed here. A Table summarizing the same is also appended (Table - 1).

#### Nutrient Requirements During Pregnancy and Lactation

**Energy requirements** : The energy equivalent of the raised resting oxygen consumption is of the order of about 27,000 Kcal, over the entire duration of pregnancy. The diet also has to provide energy for the fat and proteins laid out in the foetus and maternal tissues. The maternal fat deposited is about 4 kg. The total energy cost of pregnancy could be put at about 73,000 Kcal. Most of this extra energy is needed in the latter two trimesters. An additional requirement of 300Kcal per day is to be met, throughout the pregnancy. The additional energy requirement during lactation has been worked out to 550 Kcal in the first 6 months and 400 Kcal thereafter.

**Protein requirements** : The rapid growth of foetus, development of placenta and other maternal tissues, the expanding fluids (blood volume, amniotic fluid) and other storage reserves demand extra proteins. It has been recommended that an additional 15 g of proteins per day must be catered for during pregnancy. During lactation, extra protein demand is incurred for the production of milk. Therefore an additional intake of 25 g proteins/day in the first six months and 18 g in the next 6 months (6 - 12 months) is recommended.

**Fats & Essential Fatty Acids (EFA)** : The linoleic acid requirement during pregnancy is put at 4.5% of total energy. This can be met by the normal intake of invisible fats along with an intake of 12.5% of total energy equivalent of visible fats. The EFA requirement goes up further during lactation

**Table - 1: Nutrient requirements for a sedentary woman during Pregnancy and Lactation (2,4)**

Nutrient	RDA (Sedentary woman)	Pregnancy		Lactation (1st 6 months)		Lactation (6-12 months)	
		Add	Total	Add	Total	Add	Total
Energy (Kcal)	1875	300	2175	550	2425	400	2275
Proteins (g)	50	15	65	25	75	18	68
Fat (g)	20	10	30	25	45	25	45
Iron (mg)	30	8	38	0	30	0	30
Vitamin A (RE)	600	0	600	350	950	350	950
Thiamin (mg)	0.9	0.2	1.1	0.3	1.2	0.2	1.1
Riboflavin (mg)	1.1	0.2	1.3	0.3	1.4	0.2	1.3
Niacin (mg)	12	2	14	4	16	3	15
Pyridoxine (mg)	2	0.5	2.5	0.5	2.5	0.5	2.5
Folic Acid ( $\mu$ g)	100	300	400	50	150	50	150
Vitamin B <sub>12</sub> ( $\mu$ g)	1	0	1	0.5	1.5	0.5	1.5
Vitamin C (mg)	40	0	40	40	80	40	80

to 6% of total energy. This can be met by the normal intake of invisible fats along with an intake of 17.5% of total energy equivalent of visible fats. This would correspond to a total of about 45g of visible fats.

**Iron** : Additional iron is required to meet the augmented demand for foetal growth, expansion of maternal tissue including RBC mass, iron content in placenta and blood loss during parturition. These additional requirements should be added to the basal ones. Owing to these additional needs the iron requirements go up in the second and third trimester to 3.3 mg and 5 mg respectively (taken as RDA of 38mg during pregnancy). However due to amenorrhoea during pregnancy, the menstrual loss of iron is prevented saving some iron loss. Breast milk contains iron, so this iron need is to be catered for during lactation. But since there is lactational amenorrhea, there is no menstrual loss and the total daily iron requirement remains the same as that of a normal woman i.e. 1mg/day (or the RDA of 30mg).

Taking the poor absorption of iron (only 3 - 5%) from habitual Indian diets into consideration, the RDA of iron for pregnant women has been slated at 37.5mg, rounded off to 38mg per day and for lactating women at 30mg per day.

#### Vitamins

**Vitamin A** : The vitamin A requirements during pregnancy were calculated on the basis of vitamin A content of livers of the newborn. The additional intake required for this purpose is about 25 µg/day throughout pregnancy. Since this constitutes a very small fraction of the RDA no additional dietary allowance was recommended for pregnancy. On the other hand, a substantial amount of vitamin A is secreted in human milk, hence an additional intake of 350 µg/day is recommended for the lactational period.

**Thiamine** : The intake of thiamine is based on the energy intake and is normally recommended at 0.5 mg/1000Kcal. The calorie intake does go up during pregnancy and markedly so during lactation so would the thiamine intake. Hence when computed on the basis of energy allowance, it works out to an additional 0.2 mg for pregnancy and 0.3 mg and 0.2 mg for the first six months and latter six months of lactation respectively.

**Riboflavin** : The RDA of riboflavin is based on the total calorie requirement and is taken as 0.6 mg/1000 Kcal. The higher energy intake during pregnancy and lactation calls for this additional demand which corresponds to an additional 0.2 mg for pregnancy and 0.3 mg and 0.2 mg in the first six months and latter six months of lactation respectively. This increment is the same as that for thiamine.

**Niacin** : The niacin RDA is fixed at 6.6 mg per 1000 Kcal as is done for adult subjects. This corresponds to an additional 2 mg for pregnancy and 4 mg and 3 mg in the first six months and latter six months of lactation respectively.

**Pyridoxine** : The Pyridoxine requirement also goes up during pregnancy and lactation. It is recommended that an additional 0.5 mg/day of pyridoxine be catered for pregnancy as well as lactation.

**Folic Acid** : The additional requirement of folic acid during pregnancy is known to increase by 200 to 400 µg/day. The additional RDA is put at 300 µg/day for the duration of pregnancy. It is however difficult to provide this amount through diet alone, so supplementation through medicinal folates have to be made. An amount of about 25 µg/day is lost through lactation. An additional amount of 50 µg/day is therefore recommended during lactation.

**Vitamin B<sub>12</sub>** : About 0.25 to 0.30 µg of this vitamin is lost per day during lactation. An additional intake of 0.5 µg per day is recommended.

**Vitamin C** : There is no data to indicate that vitamin C requirement is increased during pregnancy. The foetal requirement is too small to justify any additional requirement. Therefore no additional allowances are considered necessary. The additional requirement during lactation is about 20 mg per day. Taking into consideration the cooking losses of 50%, an additional allowance of 40 mg per day is recommended.

#### Effect of Micronutrient Deficiency During Pregnancy

The micronutrient demands of the rapidly growing fetus are mandatory and inevitable. It is extremely sensitive to the deficiency of micronutrients during the organogenesis and growth. Whenever there is micronutrient deficiency in the mother's diet, the high demand of the foetus is initially met by the maternal resources. But when these resources are exhausted, the maternal reserves are tapped and besides foetus, the mother's health is also compromised. The likely adverse effects of micronutrient deficiency on foetus and mother are shown in Box - 1.

#### Diet During Pregnancy

Various studies indicate that diet of pregnant ladies in India are generally deficient, esp. so in the rural areas and in the urban lower class (5). These two groups form a major proportion of our society. The diet is mainly a cereal based diet supplemented with little pulses and vegetables. Many a times only a chilly - salt mixture or onion is eaten with rice or chapati, with no pulses, vegetables, fat or fruits. Milk is used only to prepare tea. Usually only two main meals are taken. The nutrient value of such a diet is grossly limited even for a non pregnant woman.

This inadequate diet is not only limited in calories, but is poor in proteins, fats and micronutrients as well. The pregnant woman becomes malnourished. She is more prone to post-partum haemorrhage and death. This anaemic and malnourished woman delivers a physically and/or mentally retarded neonate. There may be bone deformities, mental deficiencies and due to low immunity and nutritional reserves such a child would be more prone to infections and malnutrition. In case it was a girl child, she grows into a nutritionally deficient teenaged girl and mother. The cycle continues and so perpetuates the malnutrition cycle. It is therefore important to offer and consume a balanced diet. The diet should be so modified that more of the protective foods (vitamins and minerals) and body building foods (proteins) are included rather than only excess of energy. A typical balanced diet (raw) is given in Table - 2. The general advise to be given is laid out in Box - 2.

**Box - 1 : Adverse effects of micronutrient deficiency on foetus and mother**

Nutrient	Adverse effect on mother	Adverse effect on foetus/infant
Thiamin	-	Infantile Beriberi
Folic Acid	Anaemia	Iugr, Neural Tube Defects, Low Birth Weight, Abortion
Vitamin A	Anaemia	Low Birth Weight, Premature Birth
Vitamin D	Increased risk of osteomalacia	Impaired Bone Development, Hypocalcemia, Rickets
Vitamin E	-	Birth Defect, Spontaneous Abortion
Calcium	Higher risk of hypertension, eclampsia, osteoporosis	Impaired Bone Development, Hypocalcemia, Rickets
Magnesium	Higher risk of hypertension, eclampsia	Premature Birth
Iron	Anaemia	Low Birth Weight, Premature Birth, Higher Infant Mortality
Iodine	Hypothyroidism	Still Birth, Cretinism, Neonatal Hypothyroidism, Deaf Mutism
Zinc	-	Birth Defect, Premature Birth, Low Birth Weight, Hypogonadism

**Table - 2 : Balanced diet for a pregnant woman\* (3)**

Food Group	Food stuff	Amount per day
Cereals	Rice, wheat, millets	300 g
Fats	Oil, <i>ghee</i> , butter	30 g
Sugars	Sugar, <i>Jaggery</i>	20 g
Milk	Milk, curds, etc	500 ml
Pulses & Nuts	Pulses, legumes, dry beans, nuts	60 g
Fruits & vegetables	Fruits	200 g
	Vegetable	350 g
	Green Leafy Vegetables	150 g
	Other vegetables	120 g
	Roots and tubers	100 g

\*The diet shown in the table is a vegetarian diet for a pregnant sedentary woman, for non vegetarians additional 30 g of flesh foods (meat, fish, chicken) or one egg is suggested in lieu of 30 g pulses..

**Box - 2 : Public Health Manager's Advise to Pregnant ladies**

- Eat one extra meal a day, to ensure adequacy of all nutrients
- Try and eat with the whole family and not alone
- Prefer high fibre cereals and legumes - include sprouts
- Include ample amounts of vegetables and fruits
- Take meat, milk and eggs regularly
- If vegetarian, insist on at least ½ lit of milk, and extra pulses
- Prefer nutritious foods like groundnuts and soya beans
- No fad diets
- Take iron and folate supplements regularly
- No un-prescribed medicines, alcohol and tobacco
- Attend ANC clinic regularly and follow your doctor's advise

**The Meals :** In the first trimester the woman suffers from gastritis and morning sickness. In the third trimester the abdomen feels too full and she may not be able to eat much food. Therefore it is advisable to eat small quantities of food more frequently, rather than large quantities in, say only two meals. This means that long inter - meal spans must be interrupted with snacks like the mid - morning snacks after breakfast and the evening snacks with tea.

### Diet During Lactation

Just like the diet of a pregnant woman the diet consumed by a lactating woman is also poor in quality and quantity, particularly in the poor rural and urban slum areas, if particular attention is not paid to it. First, the woman might have been undernourished during pregnancy and such a person, when starts breastfeeding her child puts herself to great nutritional strain. Secondly her own demand of nutrients is very high as she has to breastfeed the child. Thirdly, women esp. in the rural, hilly and tribal areas breastfeed the child for a prolonged period. Lactational amenorrhoea serves as a contraceptive incentive for them, and the breast feeding continues till they become pregnant again. This cycle of pregnancy, lactation and repeated pregnancies continue, rendering the mother malnourished. The principles of diet during lactation are basically the same as during pregnancy (please refer

to the earlier paragraphs for nutritional requirements during lactation). A lactating mother must increase her diet by about 10% than what she was eating during pregnancy. A typical diet is outlined in Table - 3.

Table - 3 : Balanced diet for a lactating woman* (3)		
Food Group	Food stuff	Amount per day
Cereals	Rice, wheat, millets	330 g
Fats	Oil, <i>ghee</i> , butter	30 g
Sugars	Sugar, <i>jaggery</i>	20 g
Milk	Milk, curds, etc	500 ml
Pulses & Nuts	Pulses, legumes, dry beans, nuts	90 g
Fruits and vegetables	Fruits	200 g
	Vegetable	350 g
	Green Leafy Vegetables	150 g
	Other vegetables	130 g
	Roots and tubers	120 g
*The diet shown in the table is a vegetarian diet for a lactating sedentary woman, for non vegetarians additional 30 g of flesh foods (meat, fish, chicken) or one egg is suggested in lieu of 30 g pulses.		

### Nutrient Requirements for Infants and Children

Weight for weight, the infants and children require more food as compared to adults. This is because the children not only need food for maintaining the BMR, thermogenesis, repairing wear and tear, but also for the important function of continuous growth. Child therefore needs all kinds of extra nutrients, namely, proteins, fats carbohydrates, minerals and vitamins.

#### Energy Requirements of Infants and Children

**Infants :** The energy requirement for Indian infants are adapted from the FAO/WHO expert group and the same is summarized in the Table - 4.

Table - 4 : Daily Energy Requirements of Infants		
Age	Kcal/kg	Average during 1st year
0 - 3 months	116	103 Kcal/kg
3 - 6 months	99	
6 - 9 months	95	
9 - 12 months	101	

**Children :** Based on the FAO/WHO recommendations the energy requirements are worked out for Indian children. These are given in Table - 5.

#### Protein Requirements

**Infants :** The protein requirements for infants are derived from the breast milk intake of normally growing infants (FAO/WHO expert consultation group, 1985) and the same is summarized in the Table - 6.

**Children :** The RDAs are given in Table - 7.

Table - 5 : Daily Energy Requirements for Children		
Age (years)	Boys (Kcal/kg)	Girls (Kcal/kg)
1-3	1287	1193
4-6	1752	1630
7-9	2075	1833
10-12	2194	1965
13 - 15	2447	2056
16 - 18	2642	2064

Table - 6 : Daily Protein* Requirement for Infants	
Age (months)	Proteins (g/kg body weight)
0 - 3	2.3
3-6	1.85
6-9	1.65
9-12	1.5
*In terms of milk proteins	

Table - 7 : Daily Protein* Requirements of Children		
Age (years)	Boys (g/kg body weight)	Girls (g/kg body weight)
1 - 2	1.81	1.81
2 - 3	1.67	1.67
3 - 4	1.61	1.61
4 - 6	1.52	1.52
7 - 9	1.48	1.48
10-12	1.46	1.45
13 - 15	1.4	1.33
16 - 18	1.31	1.21
*In terms of proteins present in routine Indian diets (cereals and pulses)		

#### Fat Requirements

**Children and Adolescents :** The minimum visible fat intake would also be 5% of total energy. For their energy intake of 2400 Kcal, minimum visible fat intake works out to 12 g/day, but the desirable intake levels should be 20 g/day, which helps to reduce the bulk of diet.

**Young Children ( 1 to 5 years) :** For young children the linoleic acid requirement of 3% of the total energy can be satisfied by the minimum visible fat intake of 10 g/day (which would also be 5% of total energy intake). Hence visible fat intake of up to 25 g/day is desirable.

**Infants :** Breast milk meets the EFA needs of infants which is about 6% of total energy intake. It provides about 30g fat per day, of which about 10% is linoleic acid and 1% linolenic acid. Infants who are not taking breast milk for some reason should be given enough vegetable oils with high linoleic acid content (e.g. safflower, sunflower, corn, soyabean, cottonseed oils) to provide 6% energy equivalent.



## Minerals Requirements

**Calcium, Phosphorus and Magnesium** : These minerals are extremely important for the infants and growing children. They help in bone formation, teeth development, neuro - muscular activities, impulse conduction and structural and metabolic integrity of cells. Suggested intakes of calcium and phosphorus are summarized in Table - 8.

## Iron Requirements

**Infancy and childhood** : The demand of iron is not great during infancy as the infant is born with storage iron and a high haemoglobin count, which disintegrates to provide iron. Therefore as little as 0.3 mg iron per day is sufficient to meet his excretory losses. The demand of iron picks up in the second year of life when 0.4 mg iron is required every day. From second to the twelfth year in males and 10th in females, the mean increase in body weight is 2.5 - 2.7 kg/year, which corresponds to an iron demand of 0.3 mg/day. The daily requirement is further increased by a rise in the haemoglobin concentration by about 1 g/100ml during this period. The amount of iron required to replace the losses, also increases from 0.2 mg /day in infancy to 0.5 mg/day in the 12th year (a total requirement of 0.5 mg and 0.8 mg respectively).

**Adolescence** : During adolescence, there is an increase in iron demand owing to increase in body mass, growth, further increase in haemoglobin. The obligatory losses also increase with age. In young girls from 13 years onwards, the menstrual losses also become significant (about 0.45 mg daily).

Considering all these issues the iron requirement for Indians have been worked out which are summarized in Table - 9.

## Vitamin Requirements

**Vitamin A** : The RDA of vitamin A for infants are recommended on the basis of its intake through breast milk and extrapolated for children. A summary of the recommendations is given in Table - 10.

**Water Soluble Vitamins** : The RDA of various B complex vitamins for infants & children are summarized in Table - 11.

**Table - 8 : Suggested intakes of Calcium and Phosphorus (mg/day)**

Group (years)	Calcium (mg)	Phosphorus (mg)
Infants	500	750
Children 1 - 9 yrs	400	400
Children 10 - 15yrs	600	600
Children 16 - 18yrs	500	500

**Table - 10 : Recommended Daily Intake of Vitamin A for infants and Children**

Group	Age	Retinol (µg)
Infants	0 - 6 months	350
Infants	6 - 12 months	350
Preschool children	1 - 5 years	400
School children	7 - 12 years	600
Adolescents	13 - 18 years	600

**Diet for the infants up to 6 months of age** : The documented virtue of breast milk goes back to 2000 years to the *Charak Samhita*. There is no variation in the opinion of the scientists that breast milk is the best for the baby. It contains all the nutrients required by the baby in the correct proportion for at least the first 4 - 6 months. It is well balanced nutritionally and immunologically and is easily digestible.

**Composition of Breast Milk** : Breast milk is an astonishing emulsion that contains more than 200 known substances, including more than 30 types of sugars, 10 types of fats and many proteins and minerals. Its primary constituents are :

**Nutrients** : Milk contains almost all known nutrients : fats, proteins, sugars, minerals, vitamins, etc.

**Enzymes** : These are present to digest and absorb the nutrients.

**Immune factors** : Many antibodies, lysozymes, etc are present to protect the baby from infections.

**Growth factors and hormones** : These are present for adequate growth of child.

**Breast feeding** : The mother must begin breast feeding at the earliest. The milk that is secreted by the woman in the first week after birth is a thick yellowish mixture, called as colostrum. It is highly recommended that the colostrum must be fed to the child as it is not only rich in fats, proteins, minerals and vitamins but also has anti - infective properties (antibodies, immunoglobulins, etc). The carotene content of colostrum is 10 times higher than milk. Vitamin A and E along with other antioxidants play an important role in the growth and immunological defence of the neonate. The practice of pre - lacteal feeding with honey, glucose water or formula feeds must be discouraged. It is advisable to exclusively breast feed the child till about 4 to 6 months. Following this some liquid feeds/supplements may be started (e.g. orange / tomato juice).

**Non availability of breast milk** : Use of milk other than mother's must be avoided as far as possible. In case breast milk

**Table - 9 : Daily Iron Requirements**

Group	Age	Daily requirement (mg)	RDA (mg)
<i>Infants</i>	0 - 6 months	0.32	-
<i>Children</i>	1 - 3 yrs	0.35	11.5
	4 - 6 yrs	0.55	18.4
	7 - 9 yrs	0.78	26
<i>Adolescents</i>			
Boys	10 - 12 yrs	1.03	34.2
Girls	10 - 12 yrs	0.95	18.9
Boys	13 - 15 yrs	1.24	41.4
Girls	13 - 15 yrs	1.4	28
Boys	16 - 18 yrs	1.49	49.5
Girls	16 - 18 yrs	1.5	29.9

Table - 11: Recommended Daily Intake of B Complex Vitamins for Infants and Children					
Group	Age	Pyridoxine (mg)	Folate (µg)	Vitamin B <sub>12</sub> (µg)	Vitamin C (mg)
Infants	0-6months	0.3	25	0.2	25
	6-12 months	0.4	25	0.2	
Preschool children	1-3 years	0.9	40	0.2 to 1.0	40
	4-6 years	0.9	50		
School children	7-9 years	1.6	60		
	10-12 years	1.6	70		
Adolescents	13-15years	2	100		
	16-18 years	2	100		

is not available the best alternative is cow's or buffalo's milk. Whenever this milk is to be given in the first month one part of boiled clean water must be added to 2 parts of milk. With passing time the proportion of water must be reduced to 1 part water and 3 parts milk. By 8 weeks of age the infant gets whole milk without any dilution. Since this milk is poor in iron, iron supplementation is recommended from 2 to at least 8 months.

**Diet for the infants from 6 months to 1 year** : Breast milk is good enough to meet the nutritional requirements of infant till about 4 to 6 months of age, thereafter the requirements of the infant goes up and the milk yield also starts declining. As a result it is advisable to supplement feeding at six months of age to maintain good growth rate. Introduction of a dilute and nutritionally inadequate cereal gruel as a supplement to breast feeding is unpardonable. This is the time when the mother might become pregnant again and breast feeding is ceased abruptly. A child in such a situation is quite likely to end up as a malnourished child. The weaning has to be understood and practiced scientifically, if good growth of the child is to be maintained.

**Weaning** is the introduction of supplementary foods to augment the energy and nutrient intake of the infant. During this phase breast feeding is continued and maintained till about 1 year of age. Supplementary foods are gradually introduced and increased in quantity whilst breast feeding is slowly withdrawn. The process starts with omitting one breast feed and supplementing it with a chosen food in suitable quantity. Gradually the baby is given higher quantities of top - feeds and more frequently. This allows the mother to withdraw and eventually cease breast feeding smoothly. It is ideal to wean the child completely by 18 months of age. Some basic guidelines to weaning an infant through 4 to 12 months are given in

Table - 12.

**Supplementary Feeding for infants aged 6 months to 1 year** : Depending on the age of the baby the supplements could be :

**a) Liquid supplements** : Breast milk must be continued in this period of the 1st year of life. However supplementation and substitution with certain liquids is recommended. Foods that can be used could be fruit juices like orange, *mousambi* and grapes. These would cater for mineral and vitamin requirement of the growing infant. Green leafy vegetable soups can be used as alternatives. Cow/buffalo milk is also introduced in a graded manner as described in an earlier paragraph.

**b) Mashed solid supplements** :

(i) *Mashed solids* like boiled and mashed potatoes with salt and *ghee*, cereal gruels like sweet *dalia*, porridge, etc. must be introduced in the 7th month. These foods contribute to the energy required for the rapidly growing baby. Well boiled and if required mashed *dals* can also be added. These will add to the variety and protein content of diet.

(ii) *Vegetables* : Green leafy vegetables can be used as semisolid soups suitably garnished with salt and *ghee*.

(iii) Other vegetables can also be used. The skin and seeds of these boiled vegetables can be removed and only the pulp used for the baby. The mother should start feeding with small quantity and increase gradually.

(iv) *Boiled egg* : It is a very useful, nutritious and easy to cook foodstuff. One may start with egg yolk. Egg white can be introduced later. Initially a partially boiled egg can be given later on a boiled or poached egg is fed.

(v) *Meat* : Well cooked, finely minced or ground meat or mashed fish can also be introduced at this time.

Table - 12: Guidelines to weaning		
Age	Supplementary foods	Frequency
4-6 months	Mashed banana, Wheat flour, porridge, Ground rice and/or <i>ragi</i> mixed with oil or <i>ghee</i>	Start with 1 feed/day. Gradually increase to 3 feeds/day by 6 months of age
6-9 months	Banana, mango, <i>chickoo</i> , Boiled egg yolk, <i>Khichri</i> , Mashed vegetables, <i>Chapati</i> softened in milk, Green leafy vegetables. Add little <i>ghee</i> /oil to all	4-5 times a day
9-12 months	Fruits, <i>Khichri</i> , <i>Upma</i> , <i>Idli</i> , <i>Chapati</i> , Curd-rice, Vegetables, Egg (boiled/scrambled), Minced meat/fish	4-5 times a day

(vi) **Fruits** : Mashed ripe banana, mango, *chickoo*, apple, etc can be given depending on the availability and taste.

c) **Unmashed solid supplements** : When the baby starts cutting his teeth it is time to introduce chopped and solid foods. Chopped vegetables and minced meat of a coarser consistency can be used. Bit of potato, well cooked rice or *dalia* can also be given. A piece of toast, biscuits, banana, carrots can also be given for healthy teeth and gums. Fruit slices should be preferred to fruit juices now.

#### Supplementary Feeds for children aged 1 to 2 years

**Cereals** : Cereals (wheat or rice) based preparations which the child could easily masticate and digest must be encouraged. Potato, sweet potato, tapioca and other starchy vegetables must be continued. These can be given at least three times a day.

**Pulses** : A pulse or legume preparation must be given at least once a day, to cater for the protein requirement.

**Milk** : While the breast milk quantity is being tapered off, the dairy milk must be supplemented, starting from about 200ml to 500 ml a day.

**Vegetables and Fruits** : Well cooked green leafy vegetables and other vegetables must be given twice a day to the child. Fruits must also be given at least once a day.

**Eggs** : One egg a day, prepared in any form is advisable to be given. As discussed earlier, it could be half boiled, boiled, poached or in any other acceptable form.

**Meat** : Meat, fish, chicken and their products can also be given as per dietary practices. Easily digestible forms are preferable. Minced meat, *keema*, mashed, shredded or meat soups can be used.

**Diet for children aged 3 to 5 years** : A three year old child might not be eating much more than a two year one, as the rate of growth in this period (2 - 4 years) is not as fast. So the mother need not be unnecessarily alarmed as long as it is following the height weight norms (Table - 13). The principles of diet are the same as those for a 1 to 2 year child. The only difference might be that a 3 to 5 years child is able to eat a variety of foods as he is capable of chewing and he likes to experiment with new foods. Hence the mother may try and feed him everything that is cooked for the family. Thus the child adapts to the adult diet. The frequency of feeding the child is however more as compared to adults. Children routinely need mid - meal snacks, couple of glasses of milk, variety of 'well presented' foods and an early dinner.

**Table - 13 : Expected Height and weight for age (NCHS Standards)**

Age (yrs)	Boys		Girls	
	Height (cm)	Weight (kg)	Height (cm)	Weight (kg)
2	85.6	12.3	84.5	11.8
3	99.1	15.7	93.9	14.1
4	102.9	16.7	101.6	16
5	109.9	18.7	108.4	17.7

## The Nutritional Requirements for the Elderly

Provision of good nutrition for the elderly is not as easy as it appears. Many physiological, social, economic, medical and psychological alterations take place in the old age, which directly or indirectly affect the food intake, digestion and nutritional status. The BMR goes down with age and so does the physical activity. These factors dictate the reduction of diet. Just like every other system the efficiency of gastrointestinal system goes down, resulting in a lower appetite. The elderly may be lonely and socially aloof, so the zest to cook and enjoy food is lost, thereby compromising with availability of good food intake. The old man may be affected by many chronic illnesses that restrict his food intake, for example salt has to be restricted in hypertension, sugar in diabetes, fat in CVD and proteins in renal disease. The 'taste' of food is thus lost and so is the interest. Certain psycho - social factors like loneliness, lack of family support, feeling of worthlessness, stresses of daily living and possible economic constraints further limit the intake (6).

### Nutritional Requirements

**Energy** : There has not been any conclusive word regarding energy requirement and recommendation for the elderly. Results of various studies have at best been highly variable. Therefore the expert groups have not come out with any special requirements for the elderly. But since it is known that BMR and physical activity go down in the elderly the energy requirement might have to be curtailed. Some authorities recommended energy requirement to be reduced by 11% in elderly men and 10% in women, as compared to young adults (7).

**Proteins** : Lean body mass protein, turnover and protein synthesis fall with age. WHO/FAO/UNU expert group has recommended a safe protein intake of 1 to 1.25g/kg per day.

**Fats and Oils** : Fats and oils are recommended at the same level as for the young. In case the person suffers from any chronic lifestyle disease e.g. CVD, hypertension, stroke, etc he might be advised to restrict fat.

**Vitamins** : It is felt that the vitamin requirement goes up in old age. However no special requirement has been slated for them.

**Calcium** : Calcium along with vitamin D is required for the integrity of bones. A deficiency of calcium may lead to osteoporosis in the elderly. Sufficient amount of calcium must therefore be taken every day. A slightly higher amount of calcium is recommended, about 0.8 - 1g per day.

**Iron** : The elderly may have lower iron requirements than the young. At the same time there might be a higher prevalence of disorders that might interfere either with iron absorption (atrophic gastritis etc.) or cause blood loss (hiatus hernia, peptic ulcer, haemorrhoids and cancer). Hence their iron requirement cannot be scaled down and it should be the same as for the young.

**Diet for the Elderly** : Except for a marginal reduction in energy requirement, the need for other nutrients almost remains the same. Besides the diet being nutritionally adequate the food preparations for the elderly should be tasty, soft and easily palatable. These basic principles are summarized in Box - 3

and some common preparations to be preferred are listed in Box - 4.

<b>Box - 3 : Principles of Diet for the Elderly</b>	<b>Box - 4 : Foods to be preferred</b>
Simple but nutritious food	<i>Dalia</i>
Include green leafy vegetables	<i>Khichdi</i>
Eat plenty of fruits	<i>Upma</i>
Include whole cereals	<i>Kheer</i>
Insist on frequent, small meals	<i>Pohe</i>
Drink plenty of fluids	Canned foods
Avoid fasting	Fruit juices
Avoid fried foods	Vegetable soups
Consume low salt and sugar	Meat stew
Food should be easy to cook	

With this background of nutritional requirements in mind, a typical balanced diet, along with the nutrients supplied with it is given in Table - 14.

<b>Table - 14 : Balanced Diet for the Elderly</b>		
<b>Foodstuff</b>	<b>Quantity (raw in gm)</b>	
	<b>Males</b>	<b>Females</b>
Cereals	350	225
Pulses	50	40
Vegetables	200	150
Green leafy vegetables	50	50
Roots and tubers	100	100
Fruits	200	200
Milk and milk products	300	300
Sugar	20	20
Fats and oil	25	20
<b>Approximate nutrient contents of above food items</b>		
Calories	2200	1700
Protein	65 g	50 g
Fat	50 g	40 g
Calcium	1 g	0.9 g
Iron	38 mg	30 mg
Vitamin A (Retinol)	1030 µg	930 µg
Thiamin	1.96 mg	1.45 mg
Riboflavin	1.78 mg	1.51mg

## Summary

**Pregnancy and lactation :** Many physiological changes take place during pregnancy and lactation. The nutritional requirement increases substantially during this time. The daily energy requirement increases by 300 Kcal, protein and fat requirement by 15 g and 10 g respectively. The iron requirement

also goes by about 8 mg. The demand during lactation is still higher. The energy requirement goes up by 550 Kcal and protein and fat requirement by 25 g each. Suitable modification in diet should be made through addition of another meal, mid meal snacks and nutrient dense foods. Protein, iron and vitamin rich foods should be included in diet. It is wise to include fruits, vegetables, whole grains, milk products, meat, egg, legumes, nuts, etc. Also include vitamin C rich foods to improve iron absorption. Minimise coffee/tea during mealtime. It is advisable to take iron - folate supplement. Don't take any medicines without prescription and abstain from smoking and alcohol.

**Infants and children :** Weight for weight the infant and children require more food than adults. It is advisable to exclusively breast feed infants till about 6 months. Thereafter they should be gradually weaned through introduction of fruit juice, cow's milk, semisolid foods, boiled vegetables, potatoes, eggs and fat. As the children grow, so do their nutrient requirements. It is wise to keep an eye on the age - weight chart while the child is growing up.

**Elderly :** It is a challenge to meet the nutritional requirements of the elderly people for more than one reason. There is not enough research to base our recommendations for various nutrient requirements. Unlike adults where only the physical requirements govern the nutritional demand, in elderly the social, psychological, economic, emotional and physical needs are all important when it comes to eating food. Moreover the biological process of ageing differs in each individual. The challenges increase with increasing longevity. Illness, psychological voids, bereavements all pose varied impact. It is understood that the nutritional requirements for elderly are almost the same as that for adults. The food must be simple, easy to cook and more palatable.

## Study Questions

**Long Question :** What are the nutritional requirements elderly age? Elaborate a plan to meet these requirements.

**Short Notes :** (1) Weaning (2) Meeting Iron demand of a pregnant woman (3) Diet during lactation

### MCQs

- Which of the following is not true regarding diet for the elderly : (a) Their poor dentition restricts their food intake (b) The zeal to cook and eat goes down (c) Their food requirement is about half that of a robust young adult (d) There is not enough research to accurately predict RDA for elderly.
- Which of the following is not true regarding diet during lactation : (a) Energy requirement during lactation is higher than during pregnancy (b) Iron requirement during lactation is higher than during pregnancy (c) Vitamin C requirement during lactation is higher than during pregnancy (d) Vitamin A requirement during lactation is higher than during pregnancy
- Higher need of vitamin A during pregnancy can be met by all except : (a) Carrots (b) Cod liver oil capsules (c) Extra egg whites (d) Extra milk



4. Which of the following is true about diet during pregnancy: (a) Salt intake must be minimized to prevent edema (b) Diet before pregnancy has no bearing on health of neonate (c) Strict weight control helps minimize childbirth complications (d) One extra meal per day is recommended during pregnancy
5. Which of these is not true for weaning : (a) Weaning means gradually replacing breast milk with other foods (b) It should be started at 1 year of age (c) One must start weaning with fruit juices and cow's milk (d) Infant is more vulnerable to infections during this period

**Answers :** (1) c; (2) b; (3) c; (4) d; (5) b.

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## Nutritional Deficiency Diseases of Public Health Importance

*Rajul K Gupta*

A large part of our population particularly the poor suffer from serious deficiencies in their diet. This might be an actual deficiency or one due to lack of knowledge about food and nutrients. As a consequence of this, several nutritional deficiencies with clinical manifestations and disabilities are encountered in our country. Most important of them are Protein Energy Malnutrition (PEM), Anaemia, Vitamin A Deficiency and Iodine Deficiency Disorders (IDD) and have been the concern of health authorities in our country for a very long time. Anaemia is the most prevalent affecting all ages. In India an astounding three fourths of all females and more than half of all males suffer from anaemia. PEM and vitamin A deficiency occur mostly among preschool children. More than 85% of Indian children suffer from some degree of undernutrition (mild, moderate or severe), making it a national priority. Vitamin A deficiency is of grave concern as it causes blindness that is easily preventable. Thyroid insufficiency due to iodine deficiency, which affects all age groups results in many a serious condition including goitre, impaired metabolism, cretinism, mental retardation and deaths (still births).

### Protein Energy Malnutrition (PEM)

*Malnutrition* is a range of conditions occurring when intake of one or more nutrients doesn't meet the requirements. Protein Energy Malnutrition (PEM) is a malnutrition resulting from the deficiency of protein and/or energy in diet. PEM is an important nutritional problem among preschool age children. This leads to various degrees of growth retardation. When growth retardation is severe, functional deficiencies, like resistance to infection and poor intellectual development may result. The main cause of PEM is food inadequacy i.e. the deficiency of

energy or proteins or both. In these cases deficiency in other nutrients like vitamin A, iron, calcium and riboflavin is also seen. It is also known that infections like measles and diarrhoea aggravate PEM. In 1959, Jelliffe introduced the term 'Protein Calorie Malnutrition' (PCM) as there was close association between the two poles of the syndrome namely, Kwashiorkor and Marasmus. The term PCM, was later rephrased as Protein Energy Malnutrition (PEM).

Undernutrition includes underweight (being underweight for one's age), stunted (being too short for one's age), wasted (being dangerously thin), and micronutrient malnutrition (being deficient in vitamins and minerals).

### Magnitude of the Problem

**World :** The magnitude of the problem at a global level can be reckoned from the fact that malnutrition contributes to 60% of the total 10 million deaths of children under five years of age. Its contribution to child deaths is highest during first six months of life (1).

**India :** As per NFHS-2 (1998-99), 47% of children under three years are *underweight*, 45.5% *stunted* and 15.5% *wasted*. India fares poorly even among the South East Asian countries, occupying the third place from the bottom with only Nepal and Bangladesh faring worse than India. The prevalence of low birth weight continues to be about 30% for last three decades. *Low birth weight* babies are more likely to die because of neonatal infections and undernutrition (1). *Chronic Energy Deficiency* in adults is 39% in females and 37% in males (NNMB 2002) (2).

As per the NFHS report of the National Health Profile, 2007, considering various parameters, as many as one fourth to half of all Indian children are undernourished in various age groups (3). Even during the first six months of life, when most babies are breastfed, 20-30 percent of children are undernourished according to each of the three criteria, namely stunting (or too short a height for age), wasting (or too thin for height) and underweight. However, malnutrition peaks during the first two years of life. From 11.9% prevalence among 0-6 month old

infants, it reaches to 58.5% in one to two year old children. This steep rise in malnutrition during the first two years is mainly due to poor infant feeding practices (1). Among the children *under 3 years of age*, 38.4% are stunted, 19.1 are wasted and as many as 45.9% are underweight. The highest number of underweight children (under 3 years) is reported from Madhya Pradesh 60.3%. Other states reporting high percentage of underweight children are Jharkhand (59.2%), Bihar (58.4%) and Chattisgarh (52.1%). Mizoram reports the lowest number of underweight children at 21.6%. Other states reporting low percentage of underweight children are Sikkim (22.6%), Manipur (23.8%), Punjab (27%), Kerala (28.8%) and Goa (29.3%) (3). In the under-fives year age group, almost half of all children are stunted, which indicates that they have been undernourished for some time. Twenty percent are wasted, which may result from inadequate recent food intake or a recent illness. Forty-three percent are underweight, which takes into account both chronic and acute undernutrition.

Adults in India suffer from a dual burden of malnutrition; more than one-third of adults are too thin, and more than 10 percent are overweight or obese. Only 57 percent of men and 52 percent of women are at a healthy weight for their height.

Undernutrition is particularly serious in rural areas. The condition is worst in the lower wealth quintiles, among scheduled tribes and scheduled castes, and among those with no education. More than two out of five women are too thin in Bihar, Chhattisgarh, Jharkhand, Madhya Pradesh, and Orissa; similar proportions of men are too thin in Tripura, Madhya Pradesh, and Rajasthan.

Overweight or obesity is most common among adults in Punjab, Kerala, and Delhi. These conditions are most common in older adults, those in urban areas, the well-educated, and those in the highest wealth quintile (3).

**Etiology and Epidemiology** : PEM characteristically occurs in children less than 5 years of age, whenever the diet is poor in energy and proteins. PEM was earlier attributed to the concept of 'protein gap' (deficiency of proteins in diet), which has now given way to the new etiological theory of 'Food gap', wherein it is not only the deficiency of proteins but inappropriate food (low in energy density, protein and micronutrients - Vitamin A, Iron, Zinc) which is poor both quantitatively and qualitatively, is the chief cause of PEM (5).

Under-nutrition in fetal life, esp. last trimester, lactation failure, low energy dense weaning foods, incorrectly constituted formula, contaminated water and infections (diarrhoea, measles, acute respiratory infections, intestinal worms etc.) also play important role in the causation of PEM. The other associated *social factors* are poverty, poor environmental conditions, large families, poor MCH services and poor cooking practices. Ignorance and the inability to provide adequate food also seem to be important contributory factors.

**Classification of PEM** : Even though Marasmus and Kwashiorkor are the two main and polar forms of PEM, clinically it can be broadly classified into five forms (Table-1). These varied syndromes result from the types, severity and duration of dietary deficiency.

**Table - 1 : Classification of PEM (FAO/WHO) (6)**

Type	Percent of standard body weight	Oedema	Deficit in weight for height
Kwashiorkor	80-60	+	+
Marasmic-kwashiorkor	<60	+	++
Marasmus	<60	0	++
Dwarfing	<60	0	Minimal
Underweight	80-60	0	+

**Marasmus** : Conditions conducive to the evolution of marasmus typically exist in the lower socio-economic classes of the urban community. A low birth weight neonate born to an economically and nutritionally deprived working woman in a setting of ignorance and poverty is most vulnerable to marasmus. The weaning is often early and abrupt. The mother stops breast feeding for various reasons. Most often she has to return to work early. She might be suffering from infections like mastitis, etc. which don't allow breastfeeding to continue. The infant might be having an illness (gastrointestinal or respiratory infections), during which it is not wise to feed the child, in the mother's opinion. Social influences in the form of peer pressure, advertisements of alternative feeds could also be major reasons for discontinuing breast feeding. Another quick pregnancy could change the priority and infant is neglected. Taboos restricting the use of colostrums and breast milk also limit its full utilization. The sheer inconvenience or non availability of a private place to breast feed the child at the work place could dissuade the mother.

*A typical epidemiological case is illustrated as follows* : Let us take a pregnant construction labourer in an urban setting as an example. Being economically deprived she is in a poor nutritional state. More often than not, she has rapid succession of pregnancies. She delivers low birth weight babies. She breastfeeds the infant for a short duration since she has to return to work at the earliest. The infant is handed over to the elder sibling. This is invariably followed by dirty and dilute formula for feeding. The infant is inadequately fed because of ignorance and to limit expenditure. The diet is low in both proteins and energy. Moreover poor housing/sanitation, lack of fuel, water and utensils makes it impossible to prepare a clean and healthy weaning food. Repeated infections develop (particularly gastroenteritis), which are treated by starvation for long periods. The child is fed with water, weak tea and rice water. This forced early, abrupt and faulty weaning takes its toll on the nutritional state of the infant. The infant ends up being Marasmic.

**Clinical features of Marasmus** : Marasmus is most commonly seen in children aged less than 5 years (most cases are less than 1 year of age in the urban areas). There is failure to thrive, irritability or apathy. Many infants are hungry and some anorexic. Diarrhoea and dehydration are frequent. The weight is grossly below standards and the child is 'skin and bones' owing to loss of subcutaneous tissue. The common clinical

features of marasmus are enumerated in Box - 1. A standard text on paediatrics could be consulted for more details on the clinical aspects.

<b>Box - 1 : Clinical features of Marasmus</b>	
Constant features	<ul style="list-style-type: none"> <li>• Growth retardation</li> <li>• Wasting of muscles and subcutaneous fat</li> <li>• 'Wisened old man's look'</li> </ul>
Other features	<ul style="list-style-type: none"> <li>• Hair changes like easily pluckable hair</li> <li>• Infection</li> <li>• Vitamin deficiency</li> <li>• No psychomotor changes</li> </ul>

**Kwashiorkor** : The term Kwashiorkor was introduced by Cicely Williams into modern medicine. It comes from language of 'Ga' tribe of Ghana, meaning "*Sickness the older child gets when the next baby is born*".

If the epidemiological events for the causation of PEM had to be greatly simplified, while marasmus is seen in an early and abruptly weaned baby in an urban setting, the other 'pole' of PEM, Kwashiorkor is typical in an older child who is breast fed for a rather prolonged period and weaned late in a rural setting. Poverty, insufficient food and land, poor agricultural practices, religious issues and taboos compromise the nutrient intake. Protein sources like milk, eggs and meat are costly so their supply tends to be inadequate. In some areas Kwashiorkor runs an endemic course, when food supply becomes scarce every year before the harvest season.

In such children the protein and energy supplies are almost always at brink. Frank Kwashiorkor may be precipitated by acute febrile infections like ARI, measles, whooping cough or diarrhoea as the nutritional demand shoots up.

**Clinical features of Kwashiorkor** : Kwashiorkor is most commonly seen in children aged 2 to 5 years of age. Many children of a given locality sharing the same socio-economic milieu may suffer from Kwashiorkor. The child may be brought to the doctor for an underlying infection. Failure of growth may be an early sign. There may be weight loss, anorexia or diarrhoea. Oedema is present, which is more marked on the lower limbs. Quite often it is grossly present all over the body including face. The common clinical features of Kwashiorkor are enumerated in Box - 2.

**Prevention of PEM** : "Prevention of PEM is the fight against poverty and ignorance" (7). As was discussed earlier it must be appreciated that there is no single shot solution to the treatment or prevention of PEM. It is a complex problem involving each of the social, economic, educational, political, administrative, medical and health dimensions. An integrated effort involving all these and also awareness and a positive attitude towards the condition might help to limit it. The most vital preventive measures that are executable through the classical health and medical infrastructure and classifiable under the traditional heads of the preventive strategy are enumerated here. Details on mitigation of poverty, improving the health infrastructure, provision of health care and hygiene-sanitation facilities, strengthening immunization facilities, making the PDS more efficient or provision of nutritional education though extremely important, are beyond the scope of this book. Hence these issues have not been elaborated.

#### Health promotion

- (a) Good ante-natal care
- (b) Education on food, hygiene and family planning
- (c) Education on the importance of colostrum, diet during lactation
- (d) Various measures under the ICDS initiative, like good nutrition, immunization, education, hygiene and sanitation etc.
- (e) Promotion of breast feeding
- (f) Good weaning practices, correct time of weaning, importance of low cost weaning foods
- (g) Prevention and control of infections during weaning
- (h) Improve family diet
- (j) Correct knowledge on balanced diet
- (k) Utilization of family planning practices
- (l) Hygiene & sanitation

#### Specific protection

**a) Diet** : Protein and energy rich food should be consumed by children. Special attention must be paid to diet during weaning. Adequate quantities of fruits and vegetables must be included in the diet.

**b) Immunization** : The child must be immunized as per the national schedule.

#### Early Diagnosis & Treatment

**a) Growth monitoring** : Vulnerable children must be identified. Children must be monitored through growth charts. Early diagnosis of growth failure must be done and treated as appropriate.

<b>Box - 2 : Clinical features of Kwashiorkor</b>	
Constant features	Other features
<ul style="list-style-type: none"> <li>• Oedema</li> <li>• Growth retardation</li> <li>• Muscular wasting</li> <li>• Retention of subcutaneous fat</li> <li>• Psychomotor changes</li> </ul>	<ul style="list-style-type: none"> <li>• Hair changes - Flag sign</li> <li>• Diffuse pigmentation of skin and dermatoses-- Flaky paint dermatosis</li> <li>• Moon face</li> <li>• Anaemia</li> <li>• Hepatomegaly</li> <li>• Associated vitamin deficiencies (retinol, tocopherols, folate, pyridoxin, Vitamin K)</li> <li>• Associated mineral deficiencies (iron, potassium, zinc, copper, selenium, magnesium)</li> <li>• Associated acute infections</li> </ul>



**b) Early diagnosis and treatment** : Early diagnosis and treatment of infections is also vital. To achieve this, health worker must be alert and mothers should be aware of the signs and symptoms of common infections. Preparation and use of ORS should be known to all mothers. The services available through the IMNCI initiative must be fully utilized.

**c) Medical advice** : In extreme and serious cases early medical advice and treatment facilities must be available. Hospitalization of the case remains the only choice in complicated cases.

**Rehabilitation** : Even if PEM patients are treated well in a hospital setting, many follow up studies have shown that they tend to die of the same disease and infections for which they were treated earlier. It is because the immediate disease in question was treated but the family and community milieu which was responsible for the problem remains largely unchanged. The poverty, hygiene, sanitation, dietary/ feeding knowledge and practices, taboos, predisposing factors for infection etc remain the same. While it may not be possible for the medical fraternity to improve the socio-economic condition of the family, but substantial changes can be brought to the knowledge, attitude and practice about the disease. After an intensive hospital resuscitation session, knowledge can be imparted to the mothers about the disease. Correct feeding practices and skills can be taught. Myths and taboos can be busted. These principles can be undertaken in three settings :

**(a) Residential Units** : Mothers are admitted with their sick children. The mother gets hands on experience in the practical learning of preparation and administration of a therapeutic diet for her child with an expert. This demonstration and involvement of the mother in her child's recovery goes a long way in understanding the problem and mitigating it.

**(b) Day Care Centre** : The mother attends the day care centre along with the child where cooking and feeding is taught to the mother. While the child attends every day, involvement of the mother is partial.

**(c) Domiciliary Rehabilitation** : The expert comes home and assesses the situation as a whole. The mother is then rendered suitable advice with regards not only to feeding but also about improving various domestic contributory factors to PEM.

## Anaemia

Anaemia is a global menace affecting both developing and developed countries with major consequences for human health as well as social and economic development. It occurs at all stages of the life cycle, but is more prevalent in women esp pregnant women and young children. In 2002, iron deficiency anaemia (IDA) was considered to be among the most important contributing factors to the global burden of disease (8). The numbers are staggering; as many as 2 billion people or over 30% of the world's population is anaemic. This is frequently exacerbated by infectious diseases like malaria, tuberculosis, HIV/AIDS, hookworm infestation and schistosomiasis in some areas. It is a major public health problem. More subtle in its manifestations than, protein-energy malnutrition, iron deficiency exacts its heaviest overall toll in terms of ill-health, premature death and lost earnings. Iron deficiency and anaemia reduce the work capacity of individuals and populations, bringing serious economic consequences and obstacles to

national development. Overall, it is the most vulnerable, (poorest and the least educated) who are disproportionately affected by iron deficiency, and it is they who stand to gain the most by its reduction. See Box - 3 and 4.

### Box - 3 : Facts about Anaemia (9)

In developing countries every second pregnant woman and about 70% of preschool children are estimated to be anaemic.

Anaemia is aggravated by infectious diseases like worm infestations, malaria, HIV and tuberculosis.

The major health consequences include poor pregnancy outcome, impaired physical and cognitive development, increased risk of morbidity in children and reduced work productivity.

Anaemia contributes to 20% of all maternal deaths

### Box - 4 : Consequences of Anaemia

**General** : Weakness, easy fatigability, lethargy, Inhibition of lymphocyte proliferation lowered cell mediated immunity, reduced neutrophil bactericidal activity, vulnerability to infections, diminished physical and earning capacity, reduced work capacity reduced endurance

**Pregnant and Lactating Women** : Weakness, diminished physical and mental capacity, increased morbidity from infectious diseases, Increased risk of low birth baby, abortion, premature delivery, intra-uterine growth retardation, Congenital fetal malformations, PPH, maternal mortality

**Children** : Low birth weight, Perinatal mortality, impaired cognitive performance, motor development and scholastic achievement, Psychological and behavioural effects like inattention, fatigue and insecurity

**Defining Anaemia** : Anaemia is traditionally defined as the reduced oxygen carrying capacity of the blood due to a reduction in its haemoglobin content. The WHO defines anaemia as "a condition in which the haemoglobin content is lower than normal as a result of deficiency of essential nutrients, regardless of the cause of such deficiency". The WHO has further defined as to when should the haemoglobin content be considered as low. The level of 'low' haemoglobin levels vary with sex, age and physiological status. These are summarised in Table - 2 .

**Table - 2 : Haemoglobin thresholds used to define Anaemia (10)**

Age or gender group	Haemoglobin threshold (g/dl)
Children (0.50-4.99 yrs)	11.0
Children (5.00-11.99 yrs)	11.5
Children (12.00-14.99 yrs)	12.0
Non-pregnant women ( $\geq 15.00$ yrs)	12.0
Pregnant women	11.0
Men (15 yrs and more)	13.0



**Anaemia as a public health problem** : Globally, anaemia is considered to be a problem of public health significance when the prevalence exceeds certain levels, as elaborated in Table-3.

**World** : Anaemia is a huge public health problem globally. As per the WHO (2008) estimates about half (48.8%) of the entire world population suffers from anaemia. More than 3/4th of all preschool children, 1/3rd of all school aged children, 69% of all pregnant women and 73% of the non pregnant women have anaemia. More than 40% men suffer from anaemia (8).

**India** : Anaemia is a major health problem in India, especially among women and children (See Table- 4). Specific groups are elaborated here. The WHO classifies India to be having a 'severe' level of public health problem in the form of anaemia (>40% prevalence in all groups - preschool children, pregnant women, non pregnant women) (8). Among the age group of 6 and 59 months, the great majority i.e. 70 percent of children are anaemic. This includes 26 percent who are mildly anaemic, 40 percent who are moderately anaemic and 3 percent who suffer from severe anaemia. Boys and girls are equally likely to have anaemia. Children of mothers who have anaemia are much more likely to be anaemic. Although anaemia levels do vary, by and large anaemia among children is widespread in every group and every state in India. Even when the mothers were Class XII educated and/or economically well off, the prevalence of anaemia amongst their children too was 50% (3).

More than half of women in India (55%) have anaemia. About 39 % have mild anaemia, 15 % moderate anaemia and 2 percent severe anaemia. Anaemia is particularly high amongst women with no education, women from scheduled tribes, and women in the lowest wealth quintiles. Pregnant and lactating women too have high prevalence of anaemia (3).

*Among men*, while globally the prevalence of anaemia is about 40%, only one-fourth of the Indian men are anaemic. Men under 20 and over 40 years of age are more likely to suffer from

anaemia. Men at higher risk of anaemia are the widowed men, scheduled-tribe men, and men belonging to the lowest wealth quintile. In these vulnerable groups the prevalence of anaemia goes up to 40% (3).

**Etiology** : Causation of anaemia is a maze of a multitude of social, cultural, religious, dietary and environmental factors. Poor economic condition, religious practices disallowing certain nutritious foods, dietary practices like vegetarianism limiting food choices, faulty cooking practices discarding nutrients from food, faulty child rearing practices (premature weaning) enabling predisposition of PEM and anaemia, large families limiting food intake and poor environmental sanitation and non availability of sanitary latrines and drinking water, all predispose to anaemia either directly or indirectly.

Anaemia is the result of a wide variety of causes that can be identified, but more often they coexist. Globally, the most significant contributor to the onset of nutritional anaemia is iron deficiency so the terms iron deficiency anaemia and anaemia are often used synonymously, and the prevalence of anaemia has often been used as a proxy for iron deficiency anaemia. It is generally assumed that most of the cases of anaemia are due to iron deficiency. Therefore the causes of iron deficiency are discussed in detail here. These can be enumerated in a simply manner as shown in the Box - 5.

**a) Inadequate intake of iron** : The sources of iron have been discussed in greater details in the chapter on minerals. Poor diet is an important cause of inadequate intake of iron. While economic constraints make one's diet poor, it is also the ignorance about the dietary sources of iron which also makes even a well to do man's diet poor in iron. For example it is generally believed that spinach is a 'very good' source of iron. But the fact is that it is a poor source as it contains only 1.1mg iron per 100g. On the other hand almost all other green leafy vegetables like radish leaves (18 mg), rape leaves (12.5mg),

**Table - 3 : Classification of anaemia as public health problem (3,8)**

Prevalence of anaemia	Health significance	Examples (Countries)	Examples (Indian states)
<4.9%	No public health problem	Chile (Non pregnant women), USA (Preschool children)	-
5.0-19.9%	Mild public health problem	Australia, Israel, UK, USA and most Western European countries	-
20.0-39.9%	Moderate public health problem	Japan, Malaysia, China, Pakistan and most of the middle east countries	Goa, Kerala (pregnant and non pregnant women), Mizoram, Manipur (Non pregnant women), Delhi (pregnant women)
> 40.0%	Severe public health problem	India, most of the SE Asian and African countries	All Indian states, except the categories mentioned in the row above

**Table - 4 : India - WHO estimates of anaemia prevalence amongst preschool children and women (8)**

Age	Cut off haemoglobin	Prevalence %	Estimated Number	Level of public health problem
Preschool children (6m-3yrs)	<11g/dl	74.3%	8,90,90000	Severe
Pregnant women (15-49 yrs)	<11g/dl	49.7%	1,27,99000	Severe
Non-pregnant women (15-49yrs)	<12 g/dl	52.0%	13,44,95000	Severe

turnip greens (28.4mg), amaranth species (1.8 -38.5mg), methi leaves (1.9 mg) and lettuce (2.4) mg all contain high iron.

<b>Box - 5 : Causes of Anaemia</b>
<b>Inadequate intake of iron</b> <ul style="list-style-type: none"> <li>• Poor diet</li> <li>• Poverty</li> <li>• Ignorance</li> <li>• Inadequate folate/vitamin C intake</li> </ul>
<b>Poor absorption and bioavailability of iron</b> <ul style="list-style-type: none"> <li>• Absorption -Only 5%</li> <li>• Poor absorption-Non haeme iron (Ferric iron)</li> <li>• Inhibitors: Phosphates, phytates, oxalates, fibre</li> <li>• Tea (tannin), Eggs (Phosphate), Milk (Calcium)</li> </ul>
<b>Excessive loss of iron</b> <ul style="list-style-type: none"> <li>• Normal man (1mg/day)</li> <li>• Menstruation (2mg/day)</li> <li>• IUDs</li> <li>• Intestinal worms</li> <li>• Malaria</li> <li>• Repeated / frequent pregnancies</li> </ul>
<b>Increased demand of iron</b> <ul style="list-style-type: none"> <li>• Pregnancy</li> <li>• Growth</li> </ul>

**b) Poor absorption and bioavailability of iron :** It must also be appreciated that the non heme iron (as present in green leafy vegetables) is absorbed poorly. Moreover a poor intake of vitamin C also limits the absorption of non heme iron, as ascorbic acid acts as a dietary reducing agent converting the non absorbable Ferric (Fe<sup>3+</sup>) ions into Ferrous (Fe<sup>2+</sup>) ions. Similarly concomitant intake of folate also helps in haemopoiesis and thus preventing anaemia. There are certain inhibitors of iron absorption which are inherently present in our diet. For example phytates are present in fibres and cereals, phosphates in milk and eggs, oxalates in vegetables, tannins in tea, calcium in milk, etc. All these normal constituents of diet tend to retard the absorption of iron, contributing to anaemia.

**c) Excessive loss of iron :** The normal physiological loss of iron per day is about 1mg for men and 2mg for women. But there are certain conditions in which this loss becomes excessive and abnormal. Heavy blood loss may be a result of abnormal menstruation (menorrhagia, metrorrhagia), parasite infections such as hookworms, ascaris, and schistosomiasis. Acute and chronic infections, including malaria, tuberculosis, and HIV can also lower blood haemoglobin concentration. Other conditions like haemorrhoids, peptic ulcers and cancer may also result in blood loss causing anaemia. In our context IUD insertions and repeated pregnancies/deliveries are also frequent causes of anaemia.

**d) Increased demand of iron and other micronutrients :** There are certain periods in the life cycle when iron requirements are especially high. Commonly this happens during growth and pregnancy. This has already been deliberated in the previous chapter.

A neonate is born with sufficient iron resources, therefore the chances that it should get anaemia in the early infancy (6

months) are remote. Moreover breastfed infants are in a happy iron state as iron from breast milk is very well absorbed. It is the preterm and low birth weight babies that have poor iron stores. The requirement of folates is also high for the preterm babies. Preterm babies are thus more likely to develop anaemia at 2-3 months. Babies that are not allowed colostrum intake and are not breastfed are also likely to develop anaemia as iron from artificial feeds or animal milk is not well absorbed. A condition "Goat Milk Anaemia" is known in babies that are fed goat milk as it is deficient in folate.

**Prevention and Control of Anaemia :** Given the multifactorial nature of this disease, correcting anaemia often requires an integrated approach. The benefits of preventing and controlling anaemia are substantial. Timely intervention can restore personal health and raise national productivity levels by as much as 20%. In order to effectively combat it the contributing factors must be identified and addressed. Additional iron intake is usually provided through iron supplements to vulnerable groups, in particular pregnant women and young children. Food based approaches to increase iron intake through food fortification and dietary diversification are important sustainable strategies for preventing IDA in the general population.

Strategies should also include addressing other causes of anaemia and should be built into the primary health care system and existing programmes. These strategies should be tailored to local conditions, taking into account the specific etiology and prevalence of anaemia in a given setting and population group. The main strategies for prevention and control of anaemia are as follows :

**1. Breastfeeding and appropriate weaning :** While it is true that milk is not a very rich source of iron, but the bioavailability of iron from breast milk is exceptionally good. Breast milk thus is a source that in itself is adequate to suffice the iron requirement of the young infant, till about 6 months of age. Breast feeding is therefore the first step to the prevention of anaemia. The iron requirement of a growing infant increases by 1 year. It is important to wean the child with iron rich foods. Food stuffs like meat/chicken soups, vegetable soups, jaggery, etc must be included. Iron supplementation must be considered if necessary. Prevention and control of infections and deworming must also be carried out.

**2. Dietary modification :** The diet must be assessed and suitable dietary modification must be undertaken with a view to increase iron intake. Nutritious diet which includes rich sources of iron must be consumed. Use of green leafy vegetables, pulses, non vegetarian foods, *ragi*, jaggery and fruits like custard apple must be promoted. Foods with high contents of vitamin C (lime, lemons, guava, *amla*, orange, green vegetables, etc.) must be encouraged as vitamin C promotes iron absorption through reduction. Food stuffs that inhibit iron absorption like tea, tamarind and high fibre should be spaced out away from the main (iron containing) meal.

**3. Deworming :** Deworming as required, must be undertaken for all, esp. infants and children.

**4. Control of infection :** Prevention and control of infections through good health care, immunization, early diagnosis and treatment, hygiene and sanitation practices and potable

water provision facilities is an important indirect step towards anaemia control.

**5. Supplementation** : Iron supplementation is routinely recommended for the pregnant women and children, under the national programme. Details are available on the chapter on National Nutritional Programmes. Therapeutic iron supplementation may also be required in moderate to severe cases of anaemia.

**6. Iron Fortification** : Trials are already completed at the National Institute of Nutrition for fortification of certain food items with iron. Common salt can be fortified with Ferric-orthophosphate or Ferrous sulphate and Sodium bisulphate. Double fortification of salt with iron along with Iodine is also feasible. However these fortified foods are still awaiting induction at a public level.

**7. Nutrition education** : It can be well appreciated that anaemia is not caused solely due to poverty and lack of resources. Ignorance on various facets of dietary intake, hygiene, sanitation, immunization, dietary interactions is also important and must be dispelled. This could be achieved through health education. The health education can be carried out at all levels including children at schools, for housewives, men and pregnant women. Using the locally available foods that are fresh, nutritious and cheap is also an important part of the nutritional education.

**8. Home gardening** : Promoting and utilizing a kitchen garden and poultry can go a long way in having good nutrition and preventing anaemia.

**9. Care of pregnant and lactating women** : Adequate care of the pregnant and lactating women can go a long way in preventing anaemia in them as well as the infant.

## Iodine Deficiency Disorders (IDD)

Iodine deficiency is a major public health problem throughout the world, particularly for pregnant women and young children. They are a threat to the social and economic development of community. IDD is the cause of cretinism and a substantially increased perinatal mortality. A large proportion of mental retardation in infants and young children is attributable to IDD. In fact, iodine deficiency is the greatest cause of preventable brain damage in childhood. Hence no effort must be spared to implement measures to eliminate it.

**Etiology** : The content of iodine in water, crops or food materials is a function of the soil content of iodine. Therefore populations living in areas where the soil has low iodine content suffer from iodine deficiency. Heavy rainfall, past glaciation and snow drain of iodine from the top soil layer. Crops grown in this iodine depleted soil are devoid of iodine leading to a low dietary supply of iodine (11). Although goitre is primarily due to iodine deficiency in some areas, certain chemicals, collectively known as goitrogens that are present in some of the habitual foods, may contribute to the precipitation of iodine deficiency when iodine intake is marginal. These are present in vegetables of Brassica family, e.g. mustard, cabbage, etc.

### Magnitude of the problem

**World** : It is estimated by the WHO that Iodine nutrition is optimal in 43 countries (including India). Nevertheless, in 54

countries, located in all regions of the world, iodine intake of the population is insufficient and it is a public health problem (11). More than 7% of world population suffers from iodine deficiency. In the developing countries alone, 800 million people are at risk and 200 million suffer from Goitre. As many as 3 million cretins are born. In our neighbourhood other South East Asian countries like Bangladesh, Bhutan, Indonesia, Myanmar, Nepal, Sri Lanka and Thailand are also prone to iodine deficiency.

**India** : Even though WHO classifies India as a country with 'optimal iodine nutrition', about 1/3rd (31.3%) of Indian school age children have a urinary iodine excretion of less than 100µg/l. This indicates 'insufficient iodine intake' and 'mild iodine deficiency'. This might be true for the country as a whole, but the fact remains that the 'sub-Himalayan goitre belt' is the world's most intense Goitre endemic region affecting nearly 120 million people. More than 55 million people suffer from the condition in this region. The total Goitre prevalence amongst school age children in India is 17.9% (11). The prevalence of goitre in an iodine replete population should be 5% or less.

Lately it has been appreciated that it is not only the sub Himalayan regions that are endemic for IDD but some extra Himalayan foci close to low lying hills like Chota Nagpur region of Bihar, hilly regions of Madhya Pradesh and Chattisgarh, Aravali ranges of Rajasthan, Narmada valley in Gujarat, parts of Western Ghats (Maharashtra, Kerala and Karnataka), Eastern Ghats (Andhra Pradesh and Tamilnadu) and Nilgiris are also endemic for IDD.

It is estimated that the total population at risk in India is about 200 million and 70 million are estimated to suffer from IDD.

**Clinical Features** : IDD may present as a spectrum of disorders and illnesses throughout the life cycle (See Box-6) (12). Though goitre is the most visible manifestation of IDD, the spectrum ranges from abortions, stillbirths and congenital anomalies to frank cretinism and mental/physical underdevelopment. If iodine deficiency occurs during the most critical period of brain development (from the fetal stage up to the third month after birth), the resulting thyroid failure will lead to irreversible alterations in brain function. Iodine deficiency might be responsible for a mean IQ loss of up to 13.5 points in the population (13). Cretinism is the most extreme and well known manifestation of IDD. Numerically however, subtle degrees of mental impairment (leading to poor school performance), reduced intellectual ability and impaired work capacity are of considerably greater significance, in a large number of children (12).

**Indicators for Assessment and Monitoring** : Urinary Iodine Excretion (UI), Total Goitre Prevalence (TGP), radiology, ultrasonography, TSH, T3 and T4 level estimation are useful to *assess* and *monitor* the cases.

Urinary iodine (UI) excretion is a marker of recent dietary intake of iodine (over the past 48 hrs.) & therefore, is the index of choice for evaluating the degree of iodine deficiency & its correction. Iodine concentration in casual urine specimen provides an adequate assessment of the population iodine nutrition. Median urinary iodine is used to classify countries into different grades of public health significance. Median UI of



**Box - 6 : Clinical Features of IDD through the Life Cycle**

*Foetus and neonate* : Abortions, stillbirths, congenital anomalies, high unexplained perinatal and infant mortality, low birth weight, neonatal goitre, lethargy, poor feeding, prolonged physiological jaundice. Congenital anomalies like umbilical hernia and large anterior fontanella.

*Infancy & early childhood* : Signs of cretinism that include mental deficiency, squint, short stature, hoarseness of voice, deaf-mutism and motor spasticity characterized by proximal rigidity of both lower and upper extremities and trunk.

*Child & adolescent* : Poor scholastic performance, retarded mental and physical development. Goitre and/or signs of juvenile hypothyroidism (growth retardation, mental retardation, hoarse voice). In addition there may be features of puffiness, thickened and dry skin, dry and rare hair/eyelashes/eyebrows and much delayed sexual maturation.

*Adult* : Mental and physical underdevelopment. Patients appear to be slow and rather 'sleepy'. Impaired mental function and impaired decision making. On examination, an enlarged thyroid may be palpable in normal position of neck (goitre), equal to the size of terminal phalanx of patient's thumb or visible in addition to being palpable. There may be symptoms of hypothyroidism - intolerance to cold, weight gain, somnolence, hoarseness of voice, menorrhagia and non-pitting oedema.

<100 µg/l indicates insufficient iodine intake and hence mild to severe iodine deficiency. A very commonly used epidemiological parameter is TGP (Box-7).

**Box - 7 : Total Goitre Prevalence (TGP) (12)**

The size of thyroid gland changes inversely in response to alterations in iodine intake, with a lag interval that varies from a few months to several years. The prevalence of goitre is an index of the degree of longstanding iodine deficiency and therefore, is less sensitive than urinary iodine in the evaluation of a recent change in the status of iodine nutrition. Thyroid size is traditionally determined by inspection and palpation. However, the evaluation of the prevalence of goitre based on palpation has been questioned because the reproducibility of assessment by palpation is low, especially with the size estimation of smaller glands, particularly in children. But it is still employed as a useful field tool for assessing goitre prevalence. The prevalence of goitre in an iodine replete population is below 5%.

Table - 5 shows the revised and simplified classification of goitre.

**Table - 5 : Classification of goitre (14)**

Classification	Description
Grade 0	Not palpable or visible goitre
Grade 1	A goitre that is palpable but not visible when the neck is in the normal position (i.e. the thyroid is not visibly enlarged). Thyroid nodules in a thyroid which is otherwise not enlarged fall in this category
Grade 2	A swelling in the neck that is visible when the neck is in a normal position and is consistent with an enlarged thyroid when the neck is palpated

**Determining presence of iodine in salt** : Presence of iodine in salt can be qualitatively determined using rapid test kits (containing starch-based indicator e.g. MBI Kit by UNICEF). One drop of this solution placed on salt containing iodine (potassium iodate) produces a blue/purple color. Coverage of adequately iodised salt is an important indicator used for assessment of iodine status in a population besides urinary iodine excretion

and total goitre prevalence. To meet the WHO criteria for monitoring progress towards sustainable IDD elimination, salt iodization coverage or proportion of households consuming adequately iodized salt should be more than 90% (See Box-8).

**Box - 8 : Present Status of Salt Iodization**

Unfortunately the legal policy on mandatory iodization of salt has not been consistent. As a result only about half of all households in India (49% as per NFHS-2 report year 2000 and 51% as per NFHS-3 report) are using sufficiently iodized salt. Use of iodized salt varies greatly by region; it is highest in the northeast region and in some states in the north. However, now a nationwide ban on non-iodized salt is taking effect and the current figures could well be more encouraging.

**Prevention and Control** : The recommended strategy for IDD control is based on correcting the iodine deficiency by increasing iodine intake through supplementation or food fortification. Under the *National IDD Control Programme* four main components of the IDD control strategy are :

1. Use of Iodized salt or oil
2. Iodine monitoring
3. Manpower training
4. Mass communication

**Using iodized Salt / Oil** : This prevents iodine deficiency. Control and prevention of goitre has been principally based on providing extra iodine to the population through iodised salt distribution or iodised oil injection (in hyper-endemic areas). Commonest prophylactic public health measure against endemic goitre is iodization of salt. Various agents can be used. Potassium iodate is most commonly used. Sodium & Potassium iodide can also be used. Iodization of salt is undertaken in a dose of 30 ppm at source so as to render at least 15 ppm at the consumer end.

**Iodized Oil** : Injectable and oral iodized oil are available as oral drops (400 mg/ml) and intramuscular (IM) injections (480mg/ml). Single IM injection of iodized oil can protect a woman through pregnancy and one year post partum. Oral supplementation is to be repeated every 6 months to 1 year (See Table - 6). More details are available in standard recommendations (15).



**Table - 6 : Iodized Oil - Recommended Doses and Duration of Action (15)**

Age groups	Duration of effect of iodine			
	Oral iodine (mg)			Intramuscular (mg)
	3 months	6 months	12 months	> 1 year
Women of child bearing age	100-200	200-480	400-960	480
Pregnant women	50-100	100-300	300-480	480
0 - 1 year	20-40	50-100	100-300	240
1 - 5 years	40-100	100-300	300-480	480
6 - 15 years	100-200	200-480	400-960	480
Males 16 - 45 yrs	100-200	200-480	400-960	480

With the wide availability of iodized salt, iodized oil is now recommended only for populations living in severely endemic areas where a quick and definite outcome is required within a short period or where there is no access to iodized salt.

**Nutritional Education** : The importance of iodized salt in prevention of IDD has to be emphasized repeatedly to the community. It must be reiterated that only iodized salt must be consumed by all. It must be consumed within 6 months of iodization, as the concentration of iodine diminishes with time. The community must be made aware of the fact that selling of non-iodized salt may attract legal action. Suitable health education methods must be resorted to, for effective dissemination of this information e.g. through lectures, road shows, audiovisual aids, schools and women groups, etc. The experiences of IDD patients and their parents may help in making the community more aware of this malady.

The other strategies namely iodine monitoring, manpower training and mass communication are discussed in the chapter on national nutritional programmes.

### Vitamin A deficiency

Vitamin A Deficiency (VAD) is the leading cause of preventable blindness in children. It also increases the risk of disease and death from severe infections. In pregnant women VAD causes night blindness and may increase the risk of maternal mortality.

#### Magnitude of the Problem

**World** : Vitamin A deficiency is a public health problem in more than half of all countries, especially in Africa and South-East Asia. Young children and the pregnant women bear the major brunt of Vitamin A deficiency in poorer developing countries. Millions of children (esp preschool children) are at risk of xerophthalmia. About 36 countries in South East Asia, Western Pacific and Africa are severely affected. World - over 256 million people suffer from preclinical xerophthalmia and 2.7 million from xerophthalmia. As many as 7,00,000 patients develop corneal lesions and 3,50,000 become blind of xerophthalmia.

**India** : In India it is commonest amongst preschool children particularly in Andhra Pradesh, Tamilnadu, Karnataka, West Bengal and Bihar. The prevalence of Bitot Spots in the 1 to 5 years age group is about 1 to 5%. Very few studies report corneal lesions in India (0.05-0.1 per 100 preschool children in South India) (17)

**Etiological Factors** : Vitamin A deficiency is most common in the age group of 1 to 3 years, the preschool children. It results from a very complex web of causation involving ignorance, poverty, infections, lack of food, malnutrition, environmental and social factors. A compromised state of any one of these factors could tip the balance leading to vitamin A deficiency.

**Weaning and Infections** : It is often seen to be associated with weaning. The mothers may not be conversant with the correct weaning practices. During weaning the child is offered low vitamin A diet in the form of dilute milk, poor starchy food with hardly any fruits, vegetables butter or other animal products. It is primarily because of ignorance and economic reasons. The vitamin A content of this poor diet cannot keep pace with the high demand of the growing child. Repeated infections during this crucial period of weaning, teething and increased exposure to the outside world further puts pressure of extra vitamin A and other micronutrients on the system. Concomitant protein energy malnutrition makes the situation worse making the child immunologically even more vulnerable to infections. Consequently attacks of measles, acute respiratory infections and diarrhoea further compromise the child's vitamin A status. This prepares a favourable ground for xerophthalmia to flourish.

**Other Social Factors** : These also play an important role in the causation of xerophthalmia. Cultural beliefs on breast feeding and weaning practices are vital. Discarding colostrums, early or late weaning, restriction of certain food items, excessive dilution of milk, vegetarianism, unscientific management of infections, belief in quacks and unsound indigenous 'medicine', all play an important role in the causation of this problem. While poverty and inability to manage nutritious food could be a genuine reason, ignorance about the disease and faulty food practices is also rampant and is largely preventable through nutritional education.

**Poor Environment Sanitation Practices** : Non availability of sanitary latrines, open air defecation, poor hygienic practices and lack of potable water invite infection and disease, which have a definite role to play in causation of the condition.

**Clinical Features** : The clinical features of vitamin A deficiency can be divided into two broad groups, namely those concerning the eyes (xerophthalmia) and the extra-ocular features.

**Xerophthalmia** : Xerophthalmia is the ocular manifestation of vitamin A deficiency in various clinical forms. Xerophthalmia

assumes extreme importance because of its seriousness may lead to blindness and is preventable. Public health problem of xerophthalmia can be ascertained by prevalence of the levels of its various stages amongst preschool children in the community (Table - 7).

**Table - 7: Xerophthalmia as a public health problem (18)**

WHO Classification	Clinical condition of xerophthalmia	Prevalence among preschool children
XN	Night blindness	>1%
X1A	Conjunctival xerosis	-
X1B	Bitot's spots	>0.5%
X2	Corneal xerosis	-
X3A	Corneal ulceration/keratomalacia (involving <1/3 of cornea)	>0.01%
X3B	Corneal ulceration/keratomalacia (involving >1/3 of cornea)	>0.01%
XS	Corneal scar	>0.05%
XF	Xerophthalmic fundus	-
Bio-chemical	Plasma retinol <0.35 $\mu\text{mol/l}$	>5%

**Night Blindness** : Night blindness is classically associated with vitamin A deficiency. The age group most commonly affected is the pre-school children. Mother of the child typically complains that in the evening child strikes against a stone while playing and falls down frequently. He is unable to see the contents of his food plate and gropes for food. In a dimly lit classroom he can't see what's written on the black-board. Night blindness usually responds rapidly to vitamin A tablets/oil or injections.

**Conjunctival Xerosis** : Conjunctival xerosis is one of the earliest detectable signs of vitamin A deficiency. It manifests as thick, wrinkled (vertically folded) conjunctiva with a tendency to dryness. It is restricted to 'exposed' bulbar conjunctiva. The dryness looks like "Waxy Paint" as there is loss of transparency and no shine in the affected conjunctiva. It is un-wettable, classically referred to as a "Receding tide" of the tear drop. The un-wettability is because of the affected epithelium leading to reduced goblet cells/mucin secretion from the lachrymal glands. The 'break-up time of tears' is also reduced.

**Bitot's spots** : Bitot's spots are white triangular patches present on the conjunctiva. They resemble flakes of foam or plaster on the surface of the conjunctivae. They are formed due to Vitamin A deficiency leading to hyper-keratinizing metaplasia of the epithelium and accumulation of seborrhoeic excretions.

**Corneal xerosis** : If the preceding condition (conjunctival xerosis) is not treated early, corneal xerosis results. The cornea becomes pale, lustreless and loses its sheen. This may progress to a state of *corneal ulceration* and subsequently *keratomalacia* may ensue. There may be an eventual perforation through which the contents of the eye may extrude out and the patient loses his sight.

**Extra - ocular manifestations** : Some extra-ocular manifestations of vitamin A deficiency are also known. Follicular hyperkeratosis, growth retardation and anorexia are some of them. They respond to vitamin A supplementation.

**Treatment of Xerophthalmia (17)** : An established case of xerophthalmia responds well to treatment with vitamin A. The following regime can be followed :

- 2,00,000 IU (110mg) of Retinol palmitate (oil miscible vitamin A) is administered orally for 2 days. In cases of persistent vomiting/diarrhoea, water miscible vitamin A 1,00,000 IU is administered as IM Injection, followed by 2,00,000 IU, 1 to 4 weeks later.
- For infants less than 1 year old or less than 8 Kg weight, half the dose is used.

#### Prevention

**Dietary modifications** should be achieved through promotion of growth, production and consumption of vitamin A / beta-carotene rich foods. Rich sources of vitamin A like dark green leafy vegetables, deep yellow/ orange fruits, eggs, milk and meat must be included in diet.

**Nutrition education** : Educate the community on the importance of vitamin rich diet, its regular intake and the harmful effects of its deficiency. Importance of home gardening, consumption of fresh seasonal fruits and vegetables must be reiterated. Healthy food preservation techniques must also be emphasized. Public meetings, schools and mass media can be used to the fullest to disseminate these messages.

**Fortification** of ghee, hydrogenated vegetable oil and butter are being done as a government policy to augment the vitamin A status of the community. Technology for the fortification of sugar, mono sodium glutamate, bread and milk also exists.

**Periodic massive dosage (17)** : Vitamin A administration is now integrated with immunization program. The first dose of 100,000 IU is given at 9 months of age along with measles vaccines. Thereafter, the second and subsequent doses of 200,000 IU are given at 6 monthly intervals till 3 years of age. In all, a total dose of 9,00,000 IU is administered.

**Long term action** : Constant nutritional education emphasizing good diet (including fruits and vegetables), importance of immunization, environmental sanitation, breast feeding, early treatment of infections and good maternal and child health care would go a long way in the prevention of this condition.

#### Diseases Due to Excess and Deficiency of Fluorine

**Fluorine Excess (Fluorosis)** : Ingestion of large amounts of fluorine occurs when the drinking water contains fluorine in excess of 3-5 ppm. Such a situation leads to endemic fluorosis. It is associated with dental and skeletal fluorosis. Fluorosis has been reported to be a health problem in rural districts of Andhra Pradesh (esp. Nellore, Nalgonda and Prakasam districts), Haryana, Karnataka, Kerala, Punjab, Rajasthan and Tamil Nadu.

**Clinical Features** : Fluorosis presents as dental or skeletal fluorosis, depending on the water content of fluorine, duration and level of exposure.

**Dental fluorosis** : For a patient to suffer from dental fluorosis, the fluorine intake through water has to be moderately in

excess ( $> 1.5$  ppm). Moreover, if this exposure takes place during calcification of teeth (first 7 years of life), the teeth are more likely to get affected by fluorosis. The mottling of teeth is common. The enamel loses its lustre and the texture becomes rough. There could be brown bands alternating with white chalky patches. Mottling may progress to small pits. Upper incisors are affected the most, even though all the teeth are vulnerable. Dental fluorosis as such, is not usually associated with skeletal fluorosis or impairment of health.

**Skeletal Fluorosis and Fluoride Poisoning :** When the concentration of fluorine exceeds 10 ppm, a crippling skeletal fluorosis may ensue. This may occur as a result of high fluoride content of water (endemic) or as a result of an industrial poisoning. As a result there may be heavy deposition of fluorides in the bone (sclerosis). The condition may begin as anorexia. There may be sclerosis of spine, pelvis and limbs. The ligaments of spine may be calcified, producing a 'poker back'. The tendinous insertion of muscles may be ossified, producing the characteristic 'rose thorn' shadow in the X-Ray.

**Genu valgum :** Scientists working at the National Institute of Nutrition, Hyderabad found new form of fluorosis characterized by genu valgum and osteoporosis of the lower limbs in some districts of Andhra Pradesh and Tamilnadu. This was seen in people subsisting on sorghum (*Jowar*) as staple. It was concluded that *jowar* promoted a higher retention ingested fluoride in the body.

**Prevention :** In the endemic areas, fluoride is present in excess in water and if the community is dependent solely on that water, it is not easy to prevent the condition. It becomes even more difficult because there are no household methods to remove fluoride from water. However the following preventive measures are suggested :

**1. Changing water source :** Running surface water has lower fluoride content as compared to ground water. The community should shift from ground water (wells) to running water (rivers) if possible. Ideally the water should have a fluoride content of less than 0.5ppm.

**2. Defluoridation :** There is technology available that can be used to remove fluoride from water. An Indian technology called as the Nalgonda technique is an accepted defluoridation technique. It involves sequentially adding lime and alum to water. It is then followed up with flocculation, sedimentation and filtration of water.

**3. Avoiding additional fluoride :** Any additional fluoride intake must be avoided in endemic areas, as through fluoride tooth pastes for children up to 7 years of age.

#### Fluorine Deficiency - Dental Caries

**Epidemiology :** Communities subsisting almost exclusively on meat, like the Eskimos (raw walrus meat and fish), Masai tribes in Kenya (milk, raw blood and milk) have little caries. Caries occurs among people who adopted the British dietary habits throughout the world. Medieval records suggest that dental health was much better then. Altered dietary habits took a severe toll on dental hygiene in the past century or two. The dietary changes thought to be important are :

a) Decline in milk consumption.

b) General use of refined sugar that was earlier an aristocratic delicacy.

c) Introduction of roller milled fine flour.

Further lifestyle changes like introduction and wide use of sweetened soft drinks, refined wheat flour, excessive use of sugar, sweets and chocolates, sweetened milk and tea, made the teeth more vulnerable to caries.

**Host factors :** The buffering action of saliva and its ability to reduce acidity helps in preventing caries. Lysozymes present in saliva also help in caries prevention. Decreased saliva secretion due to less chewing, leads to caries.

**Agent factors :** *Streptococcus mutans* is notorious to cause caries. It flourishes in the mouth and teeth on sugars and refined carbohydrates.

**Time :** The frequency of consumption of refined carbohydrates and sugars and the duration for which they stay in the mouth is directly related to the chances of causation of caries.

**Substrate and diet :** The substrate for the bacteria is defined by the diet one eats. Refined carbohydrates and sugars are fermented by the bacteria and produce caries. Sucrose, fructose, glucose, xylitol and other sweeteners all cause caries. Strongly acidic drinks (sweetened, aerated drinks) consumed frequently can predispose to caries. A sharp increase in caries is seen in the developing countries with the increasing consumption of sugars. Firm fruits like apples have scouring action that reduces the chances of caries. Cheese increases pH and also saliva flow, inhibiting bacteria. Chewing betel increases saliva flow and lime content of pan also increases the pH thus preventing caries.

**Fluoride :** The water content of fluoride at a rate of 0.5 to 1 ppm prevents caries. In areas where fluoride content of water is low the prevalence of caries is high. Addition of fluoride to water can prevent caries in these situations.

#### Prevention

**Reduction of sugar intake :** Since sugar intake has a bearing on dental caries it is advisable to reduce sugar consumption. The following measures could be useful :

- Reduce sugar in diet. Avoid adding sugar to milk, tea and coffee. No added sugar to be made available. Reduce consumption of sweets, chocolates and cold drinks.
- No sugar should be added to infant/baby foods/pediatric medicine, fruit juices, vitamin preparations
- Sugar added to jams, jellies, cold drinks must be reduced to the minimum,
- Sugar free snacks and drinks must be made available

**Promotion of dental hygiene :** It is important to appreciate and promote dental hygiene. Regular brushing and dental checkups are important in prevention of dental caries.

**Fluoridation of water supplies :** In areas where fluoride levels are less than 0.7 ppm, it is advisable to add fluoride to raise its level optimally. This single measure is known to reduce the caries incidence by half.

**Professional dental care :** Besides regular dental examination, dentists help in prevention and deterioration of caries through filling cavities, cleaning, removing calculus, removing overcrowding of teeth through orthodontic treatment etc.



Application of topical fluoride solution and sealants is also effective. Good school dental hygiene services are also very useful.

## Summary

Four important nutritional deficiency disorders are Protein Energy Malnutrition (PEM), Anaemia, Vitamin A Deficiency and Iodine Deficiency Disorders (IDD). Anaemia affects three fourths of all females and more than half of all males. PEM and vitamin A deficiency occur mostly among preschool children. Vitamin A deficiency is an easily preventable cause of blindness. Thyroid insufficiency due to iodine deficiency, results in many a serious condition including goitre, impaired metabolism, cretinism, mental retardation and deaths (still births).

PEM contributes to 60% of the total 10 million deaths of children under five years of age. The cause is diet poor in energy and proteins latest concept being of 'Food gap', wherein it is not only the deficiency of proteins but inappropriate food (low in energy density, protein and micronutrients - Vitamin A, Iron, Zinc) which is poor both quantitatively and qualitatively. PEM is classified into Kwashiorkor, Marasmic- kwashiorkor, Marasmus, Dwarfing and Underweight. Marasmus is characterised by Growth retardation, wasting of muscles and subcutaneous fat. Clinical features of Kwashiorkor include oedema, growth retardation, muscular wasting, retention of subcutaneous fat and psychomotor changes. Prevention of PEM includes Health promotion (Good ante-natal care, education on food, hygiene and family planning, good weaning practices). Specific protection measures are adequate Diet and Immunization. Growth monitoring, early diagnosis and treatment of infections and Hospitalization of the case are measures of Early Diagnosis & Treatment. Rehabilitation of a PEM case requires substantial changes in the knowledge, attitude and practice about the disease.

Anaemia is a global public health menace affecting over 30% of world population. The health implications range from General symptoms like : weakness, easy fatigability, lethargy, reduced work capacity, reduced endurance to pregnant and lactating women suffering increased risk of low birth baby, abortion, premature delivery, intra-uterine growth retardation, and in children suffering from low birth weight, impaired cognitive performance, motor development and scholastic achievement, inattention, fatigue and insecurity. Anaemia threshold is 11.0 for young children and pregnant women, 12.0 in Non pregnant women and 13.0 in men over 15 yrs.

Anaemia can be due to inadequate intake of iron, poor absorption and bioavailability of iron, excessive loss of iron and increased demand of iron. Measures for prevention and control of anaemia are Breastfeeding and appropriate weaning, Dietary modification (Use of green leafy vegetables, pulses, non vegetarian foods, *ragi*, jaggery and fruits like custard apple to be promoted), deworming & control of infection, iron supplementation, iron fortification and nutrition education.

Iodine deficiency is a major public health problem throughout the world, particularly for pregnant women and young children causing avoidable pregnancy losses and mental retardation/ cretinism. Iodine deficiency in soil is main cause in addition to certain chemicals (goitrogens) that are present in some of

the habitual foods, like vegetables of Brassica family (mustard, cabbage etc.). The 'sub-Himalayan goitre belt' is the world's most intense goitre endemic region affecting nearly 120 million people. The total population at risk in India is about 200 million and 70 million are estimated to suffer from IDD. Clinical Features of IDD through the Life Cycle can be divided into Foetus and neonate (Abortions, stillbirths, congenital anomalies, high unexplained perinatal and infant mortality, low birth weight); Infancy & early childhood (mental deficiency, squint, short stature, hoarseness of voice, deaf-mutism and motor spasticity); Child & adolescent (Poor scholastic performance, retarded mental and physical development, Goitre) and in Adult (mental and physical underdevelopment, goitre, intolerance to cold, weight gain, menorrhagia). Urinary Iodine Excretion (UI), Total Goitre Prevalence (TGP), radiology, ultrasonography, TSH, T3 and T4 level estimation are useful to assess and monitor the cases. National IDD Control Programme has four main components : Use of Iodized salt or oil, Iodine monitoring, Manpower training and Mass communication.

Vitamin A deficiency (VAD) is the leading cause of preventable blindness in children. It also increases the risk of disease and death from severe infections. It is commonest amongst preschool children particularly in Andhra Pradesh, Tamilnadu, Karnataka, West Bengal and Bihar. The causes include weaning infections and poor environmental sanitation. The clinical features of vitamin A deficiency include those concerning the eyes (xerophthalmia, night blindness, conjunctival xerosis, Bitot's spots, corneal xerosis, corneal ulceration and keratomalacia) and the extra-ocular features. Prevention measures are dietary modifications (dark green leafy vegetables, deep yellow/ orange fruits, eggs, milk and meat), nutrition education of community, fortification (of ghee, hydrogenated vegetable oil and butter) and periodic massive dosage.

Fluorosis is a condition resulting due to Ingestion of large amounts of fluorine when the drinking water contains fluorine in excess of 3-5 ppm. Dental and skeletal fluorosis are two forms known. Preventive measures are changing water source, defluoridation and avoiding additional fluoride for at least next seven years.

Fluoride deficiency leads to dental caries. The water content of fluoride at a rate of 0.5 to 1 ppm prevents caries. Other measures are reduction of sugar intake (reduce sugar in diet, avoid adding sugar to milk, tea and coffee, reduce consumption of sweets, chocolates and cold drinks, no sugar should be added to infant/baby foods/pediatric medicine, lowering sugar added to jams, jellies, cold drinks to the minimum); Promotion of dental hygiene (regular brushing and dental checkups); Fluoridation of water supplies (where fluoride levels are less than 0.7 ppm) and professional dental care.

## Study Exercises

**Long Questions :** (1) Define PEM (Protein Energy Malnutrition). Explain in detail etiology, classification, management and prevention of PEM (2) Describe in detail epidemiology of Anaemia in India. Elaborate on community measures for prevention of Anaemia in Pregnant and lactating women (3) Explain the process of assessing level of Iodine in salt. Describe various control and prevention measures undertaken



by National Iodine deficiency Disorder Control Programme (4) What are various grades of Xerophthalmia used to assess Vitamin A deficiency? Explain the preventive measures against Vitamin A deficiency in Pre-school children (5) Describe in detail the Epidemiology of Fluorosis.

**Short Notes :** (1) PEM (2) Kwashiorkor (3) Marasmus (4) Food Gap (5) Prevention of PEM (6) Classification of anaemia as public health problem (7) Prevention & Control of anaemia (8) sub-Himalayan goitre belt (9) Goitrogens (10) Urinary Iodine Excretion (11) Treatment of Xerophthalmia (12) Dental Fluorosis (13) Prevention of Dental Caries

#### MCQs

- (1) Jelliffe gave the \_\_\_\_\_ term in year 1959 (a) PEM (b) PCM (c) Food Gap (d) Marasmus.
- (2) The highest number (60.3%) of underweight children (under 3 years) is reported from (a) Bihar (b) Madhya Pradesh (c) Uttar Pradesh (d) Jharkhand
- (3) In \_\_\_\_\_ child is 'skin and bones' owing to loss of subcutaneous tissue (a) Kwashiorkor (b) Stunting (c) Nephrotic Syndrome (d) Marasmus
- (4) Term 'Kwashiorkor' was introduced by \_\_\_\_\_ into modern medicine (a) Cicely Williams (b) Jelliffe (c) Ghai (d) Barbar Mc Clintok
- (5) Anaemia contributes to \_\_\_\_\_ % of all maternal deaths (a) 10% (b) 20 % (c) 5% (d) 30%
- (6) It is generally believed that spinach is a 'very good' source of iron. But the fact is that it is a poor source as it contains only \_\_\_\_\_ mg iron per 100g (a) 5.5 (b) 6.0 (c) 1.1 (d) 10.0
- (7) Apart from India, other South East Asian country/ies prone to iodine deficiency is/are \_\_\_\_\_ (a) Myanmar (b) Thailand (c) Sri Lanka (d) All of these.
- (8) It is estimated that the total population at risk in India is about \_\_\_\_\_ million and \_\_\_\_\_ million are estimated to suffer from IDD (a) 20 & 7 (b) 100 & 35 (c) 40 & 14 (d) 200 & 70.
- (9) For infants less than 1 year old or less than 8 Kg weight, the dose of Vit A used is \_\_\_\_\_ (a) 4,00,000 IU (110mg) of Retinol palmitate (oil miscible vitamin A) administered orally for 2 days (b) 2,00,000 IU (110mg) of Retinol palmitate (oil miscible vitamin A) administered orally for 2 days (c) 1,00,000 IU (110mg) of Retinol palmitate (oil miscible vitamin A) administered orally for 2 days (d) 2,00,000 IU (110mg) of Retinol palmitate (oil miscible vitamin A) administered orally for 1 day

(10) Hb Threshold (mg%) to label Anaemia in Non-pregnant women ( $\geq 15.00$  yrs) is \_\_\_\_\_ (a) 13.0 (b) 12.0 (c) 10.5 (d) 11.0

(11) For a patient to suffer from dental fluorosis, the fluorine intake through water has to be at least (a)  $> 1.5$  ppm (b) 1.0 ppm (c) 0.5 ppm (d) 5.0 ppm.

(12) Poker Back, Rose Thorn appearance on Chest X-Ray and Genu Valgum are features of \_\_\_\_\_. (a) Hypervitaminosis D (b) Hypervitaminosis A (c) Skeletal fluorosis (d) Congenital Hypercalcemia.

**Answers :** (1) b; (2) b; (3) d; (4) a; (5) b; (6) c; (7) d; (8) d; (9) c; (10) b; (11) a; (12) c.

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While food is the most important item to sustain life on this planet, next only to oxygen, it is a potent source of pathogens, toxins and disease. A food borne disease is one where the agent is toxic or infectious, and is transmitted to the body through food. Detailed discussions on the epidemiology and prevention/control of specific food and water borne diseases have been made in the section on communicable diseases of this book and readers are advised to refer to the same. In this chapter, we would discuss the details of prevention and control of food borne infections.

## General Principles

### Procurement and Storage

**Procurement :** Food should be procured from a reliable supplier. The hygiene standards maintained by the supplier should be noted, such as cold and chilled storage, separation of raw and cooked foods, handling of raw and cooked foods, cleanliness of premises and equipment. No more food should be purchased than the amount which can be stored in the available deep freeze cabinet or refrigerator (4°C).

**Non-vegetarian foods :** Raw and cooked meat and poultry, milk, cream, and fish should be bought in quantities sufficient for one day only. Meat and fish should not be refrigerated for more than three days.

**Dry and canned foods :** Dry foods and canned foods should be bought in reasonable quantities. Avoid overstocking; there is danger from vermin and deterioration where storage facilities are poor. These products should be stored in a dry, well ventilated storeroom.

**Refrigerate perishable foods :** Meat, poultry, dairy products, fish, and cooked rice must be refrigerated. Store raw and cooked meat and poultry separately to prevent cross-contamination. The temperature of the refrigerator should be 1-4°C.

**Storing non-perishable food :** Non-perishable food must be stored in a storeroom. It should be kept cool, well ventilated, and dry. Adequate precautions must be taken for rodents, flies and cockroaches. Surfaces of shelves, walls and floors should be easy to clean.

**Deep freeze unit :** For longer storage Deep freezer is used. A temperature of -18°C is desirable.

**Vegetables :** Vegetables should also be procured on a daily basis. They must be kept in a cool dry storage place away from direct sunlight. Most vegetables can be refrigerated.

**Food Handlers' Hygiene :** Cooks should be provided with special clothing consisting of 4 aprons, 4 caps (or pugreese), 4 shirts, 2 shorts, 2 trousers to wear while on duty. A clean set of jharons (mops) should be available to the cooks every morning. Facilities for scrubbing hands with brush and washing with soap and running water should always be available.

Immaculate personal hygiene of the cooks is of prime importance in the prevention of food borne infections. Infective organisms from all sources can be passed to food by hands. All cooks should take a thorough bath before starting daily work, keep their hair and nails clipped short and invariably scrub and wash their hands with brush, soap and water after every visit to the latrine or urinal and before handling food or raw rations. As far as possible, touching food with bare hands must be avoided. There should be access to toilets, hand washing facilities and wash rooms for the kitchen staff. The cooks must be subjected to regular medical examinations for communicable diseases that have a potential to be transmitted through food (e.g. wounds, boils, diarrhoea). Those found positive must be immediately excluded from kitchen duties and treated. Since it is not possible to detect carriers from a medical examination, it is worthwhile doing a stool examination as well. They should also be vaccinated against the enteric group of fevers.

**Kitchen hygiene and sanitation :** Besides personal hygiene, it is vital to have an immaculate kitchen hygiene as well. The storing, cooking and all working surfaces must be cleaned after each session of cooking. Utensils, equipment and mops, etc should also be in a good shape. More details are discussed in another section of this chapter.

**Cooking Practices :** The following healthy cooking practices must be adhered to :

1. Food must be 'fully' cooked and not merely cooked partially.
2. Food must be cooked rapidly and consumed quickly. Otherwise refrigerate at the earliest (store cooked food below 4°C).
3. Reheating of food must be avoided. If it is essential to reheat, the food must be heated to beyond 60°C for at least 5 minutes, ensuring that heat penetrates to the core of food. A mere warming of food is not good enough.
4. Insist on consuming fresh and hot food.
5. Use of pressure cookers, microwave, frying and grilling are safer cooking methods as compared to inadequate boiling, roasting or warming.

### Serving of food

1. Avoid prolonged exposure of susceptible foods to warm environment. This will encourage rapid bacterial growth and deterioration of food. Keep cold food cold, below 5°C.
2. Avoid warm storage of cooked food. Keep hot food hot, above 63°C or else below 4°C.
3. Do not reheat cold food to store in a warm holding apparatus (hot cupboard, hot case, casserole). Place only hot food in such equipment, that too for a short while before consumption.
4. Minimize handling of cooked foods with bare hands. Use suitable kitchen tools.
5. Use new clean paper/cloth for wrapping and covering food.
6. Keep animals and insects out of the kitchen.

### Sanitation of Some Specific Foods

Some foods require special attention. These are mainly the non vegetarian foods and fresh salads.

**Poultry :** Poultry may harbour food-poisoning organisms on the skin, offal and inside the carcass. Thus care should be taken where and how birds are dressed. Surfaces and utensils should be well cleaned after use, and hands should be washed well after handling the raw materials. Clothes should not be used to wipe carcasses either inside or outside, or to cover them. Frozen meat and poultry should be thawed properly before cooking

**Sausages :** Sausages, raw scraps, and minced meat may be contaminated with salmonellae. Great care should be taken when preparing sausages for cooking. If they are pricked the fork should be washed immediately with hot water. Sausages should be well cooked.

**Meat :** Dishes should be prepared fresh from raw meat. If there is likely to be any delay in using cooked meat, steaming under pressure is the best way to ensure the destruction heat-resistant organisms; it is a safe method of cooking. If left-overs are used after warming, they must be cooked thoroughly to boiling point to destroy contaminants and toxins which may have been formed. Spores on the outer surfaces of meat are more likely to survive if not well cooked. So it must be cooked thoroughly and eaten freshly cooked. It must not be allowed to cool slowly and stored at atmospheric temperature, as that promotes rapid multiplication of bacteria.

**Salads and fruits :** Salad vegetables including spinach, cabbage and lettuce could have been grown in sewage farming. Salads and cut fruits (which cannot be peeled), should be scrubbed and washed well, preferably with water containing hypochlorite.

**Cooked rice :** Cooked rice should not be stored without refrigeration.

**Milk/eggs :** Milk should be consumed after pasteurization or boiling. The most hygienic way to consume eggs is to boil them and eat.

**Health education :** There should be a continuous endeavor to educate the kitchen staff and public at large regarding food hygiene and its practice.

## Milk Hygiene

There is a potential of disease causation through milk when it is not handled hygienically and therefore it is important to care for milk hygiene. The milk hygiene begins at its source of production namely the dairy farm. Milk can become a good nidus for many organisms (2). Some common diseases conveyed through milk are summarized in Table - 1.

**Sanitation of Dairy Farms :** Dairy farms should ensure a pure, wholesome and protected milk supply. A dairy consists of the farm, the milk depot and the pasteurization and bottling/ packing plant, staff changing rooms, and a manure disposal yard. The dairy proper has milk receiving, pooling, cooling and blending room. A pasteurization plant should also be integrated. All these are housed in permanent, solid, fly and dust

proof structures.

To prevent outbreaks of milk borne diseases hygiene of cattle, personnel, equipment, process (of milching and pasteurization), as well as sanitary packing and delivery should be ensured. A periodical medical examination of personnel, inspection of premises and equipments, veterinary inspection of cattle, scrutiny of the process in the dairy, inspection of functional efficiency of the farm, depot and plant, and laboratory tests for purity and quality of pasteurization are required to be carried out. These measures should ensure the following :

**Care of Cattle :** The quality and the quantity of milk not only depends upon the particular breed but also on the care that is devoted to the cattle. The milk yield also depends on comfort, feeding, watering, and cleanliness; hence a clean, airy, cool and spacious cattle shed is of prime importance. Ample water supply for drinking, to wash the cattle sheds and bathe the cattle should be available. Fodder, cottonseed, oilcake, bran and meal consisting of a coarsely crushed mixture of grains must be given to each animal. Stores should be rat proof. Sick animals must be immediately isolated and contacts segregated. Cattle should be inspected by a veterinary surgeon at least once a month. Preventive inoculation against common diseases must be ensured.

**Cow Sheds :** The cow shed should be well drained and higher than the surrounding ground. The floor area per cattle head should be minimum 6 m<sup>2</sup>. The walls should be of reinforced concrete and whitewashed inside. Good cross ventilation is essential. The shed should be well lit. The whole flooring should be of impervious concrete. The sheds should be washed every day and cleaned twice a day. They should be sprayed with insecticide once a week.

**Disposal of Cattle Dung and Sullage :** All channels carrying sullage and liquid cattle dung should always be made of concrete. Semisolid cattle dung, a potent source of fly breeding, should be removed daily to a cow dung depot made of concrete and situated at least 200 m away from the cattle sheds. Anti-fly measures must be ensured.

**Health of Workers :** Medical inspection of the employees should be carried out very regularly and frequently, strict attention being paid to personal cleanliness. A regular immunization

**Table - 1 : Diseases conveyed through milk**

Disease	Organism	Reservoir/Source
Tuberculosis	<i>M tuberculosis</i> (bovine)	Cattle
Brucellosis	<i>B abortus</i> / <i>melitensis</i>	Cattle, Goat
Q Fever	<i>Coxiella burnetti</i>	Cattle
Septic Sore throat	<i>Streptococcus pyogenes</i>	Cattle, milk handlers
Food Poisoning	<i>Staphylococcus aureus</i>	Cattle, milk handlers
Diarrhoea and dysenteries	<i>Shigella</i> , <i>E histolytica</i>	Milk handlers
Cholera	<i>Vibrio cholerae</i>	Water, milk
Enteric fever	<i>Salmonella</i> species	Milk
Viral hepatitis, polio	Hepatitis A, Polio viruses	Milk
Diphtheria	<i>Corynebacterium diphtheriae</i>	Milk



against enteric group of fevers must be ensured. All cases of illnesses, especially diarrhoea, dysentery, enteric fever, infected fingers or boils, running nose or ears, sore throat, or cough must be attended to. Exclusion of carriers of communicable diseases should also be rigidly enforced.

All indoor workers should scrub their hands thoroughly with soap, hot water and a nail brush and change into their working clothes including cotton masks. All workers should have adequate sanitary and bathing facilities. They should wash their hands with soap and water before entering the processing premises or milking.

#### Pasteurization

Boiling kills the microorganisms but is likely to adversely affect the quality, taste and flavour of milk, as milk constituents are heat-labile. Pasteurization involves rapidly heating milk (to less than the boiling point), maintaining it uniformly over a definite period and rapidly cooling it. This destroys most of the pathogenic microorganisms, reduces the total quantity of all the microorganisms without affecting its inherent qualities (taste and flavour). It may not sterilize milk but makes it non-infective, retains its nutritive and aesthetic qualities and improves its keeping quality. The important pathogens that are destroyed by pasteurization of milk are *M tuberculosis*, *B abortus*, *Streptococci* and *Staphylococci* and the non-lactose fermenting pathogenic organisms of the *Salmonella-Shigella* group. The subsequent rapid cooling of the heated milk inhibits the multiplication of any viable residual microorganisms or of the ones subsequently gaining access to the liquid. The low temperature must be maintained till the milk is consumed.

The nutritive value of pasteurized milk remains reasonably satisfactory. Its fat, protein, calcium, phosphorus, and vitamins A and D contents are not affected. There is a 10% loss of vitamins B and 20% loss of vitamin C. Pasteurization improves the keeping quality of milk, reduces the number of bacteria, and destroys tuberculosis bacilli and other pathogenic organisms except spores and thermophilic bacteria. However, milk with a high bacterial count in a raw state will not pasteurize so efficiently as clean milk. Pasteurized milk can be preserved for 8 to 12 hours at 18°C.

**Methods of Pasteurization :** The methods of pasteurizing milk are as follows :

**(a) Holder (Vat) method :** This method consists of heating the milk to the temperatures between 63°C and 65.5°C and holding it in large tanks at that temperature for 30 min before cooling it rapidly to 5°C. Milk gets heated efficiently and pathogenic bacteria are killed with certainty. From these holding tanks the milk runs directly to the cooler and then to the packing / bottling machine through a closed system.

**(b) Continuous Flow Method :** This method is the modification of the Holder method. The milk is first heated to 63°C or more and then led through a series of heated metal coils so that the milk remains at that temperature in the apparatus for 30 minutes.

**(c) High Temperature Short Time (HTST) Method :** In this method milk is heated to 72°C for 15 seconds and then rapidly cooled to 4°C.

**(d) Ultra high temperature (UHT) Method :** Milk is rapidly heated usually in two stages, the second stage being under pressure, between 125° to 150° C for a few seconds only. It is then rapidly cooled and packed / bottled as quickly as possible.

**(e) Pasteurization in Bottles :** The filled bottles can also be pasteurized. They are well sealed and heated by a shower of hot water or steam. The simplest method is to place the milk bottles in water-bath brought to 63°C held there for 30 min and then chilled. The theoretical risk of contamination after pasteurization is entirely eliminated.

**Supervision of Pasteurization Process :** The pasteurization process needs constant supervision and the following are the most important factors to ensure efficient pasteurization :

- Raw milk must be clean and free from extraneous matter.
- A pasteurization chart should show the range of and the period for which the temperature, as specified for the method, was maintained.
- Milk must be protected from contamination during cooling and bottling / packing; unprotected open coolers are undesirable.
- Excessive foaming of milk must be avoided as the temperature of the foam is too low to kill pathogens and may even encourage the growth of thermophilic organisms.
- The apparatus must be efficiently cleaned and sterilized after each day's work.
- Besides ensuring efficient supervision, the process of pasteurization should be checked from time to time by the colorimetric phosphatase test as described earlier.
- If there is any doubt, about the effectiveness of pasteurization, the issue of such milk must be reconsidered. It is much safer for the consumer to assume that the milk he receives is untreated and is therefore boiled rather than to enjoy a false security.

**Inspection of Milk :** Inspection of milk involves physical and laboratory tests. Objectives of inspecting fresh milk are to detect visible dirt, deterioration, adulteration, nutritive quality, keeping quality, and to ascertain efficiency of pasteurization. The physical tests involve the inspection and taste of milk. The interpretation is given in Table - 2.

#### Laboratory Tests

**Specific Gravity :** The specific gravity of milk should be 1.029 to 1.033 but milk diluted with water can be readily restored to its normal specific gravity by adding sugar or cornflour.

**Chemical Tests :** A further chemical analysis is necessary to detect adulteration.

**(i) Gerber's Test :** Gerber's Test is carried out for estimation of fat.

**(ii) Total Solids :** These are estimated by the evaporation of whole milk in a water bath and then weighing the dried residue. Solids Not Fat (SNF) are estimated by deducting the fat value from the total solids.

**(iii) Methylene Blue Test :** It is carried out for testing the keeping quality and bacterial contamination in the milk. The basis of the test is that the dye is reduced and decolourised



Table - 2 : Interpreting Physical Tests of Milk Inspection		
Visual Inspection	Likely Cause	Interpretation
Ropy milk or slimy milk	Disease of the udder or contamination with <i>Lactis vascosus</i> .	Not acceptable
Blue milk	Infection of animal due to tuberculosis or <i>Ps cyanogena</i> .	Not acceptable
Red milk	Crushed udder	Not acceptable
Highly coloured	Presence of colostrum.	Acceptable
Dirty milk	Manurial dust from the flanks and tail of the cow, or dirt in the container	Not acceptable
Taste	Likely Cause	Interpretation
Altered taste	Feeding of the cow (e.g. with turnips).	Acceptable
Medicinal taste	Cow is being administered some drugs	Not acceptable
Souring of milk	Likely bacterial fermentation	Not harmful, but not acceptable either

by the bacterial enzymes. The rate of reduction is an index of the extent of bacterial contamination. One ml of methylene blue solution of 1 : 300,000 strength is added to 10 ml of milk sample in a test tube and then incubated at 37 °C in a water bath or incubator. The mixture should not decolourise within 5½ hours. If kept at room temperature above 37 °C it should not decolourise within 4½ hours.

(iv) **Phosphatase Test** : This test is meant for ascertaining the efficiency of pasteurization and depends on the fact that the enzyme phosphatase is destroyed by the pasteurization temperatures; but not completely destroyed at a lower temperature, or in a shorter period than that required for pasteurization. Milk containing as little as 0.25 percent of raw milk in the properly pasteurized milk still contains detectable quantities of enzyme. The test is performed by addition of disodium phenyl-phosphate to pasteurized milk. The enzyme phosphatase, if present, splits up the phenol by means of a phenol test reagent which gives different shades of blue colour depending upon the amount of phosphatase enzyme present. The colour is matched against the standard colours in a Lovibond colorimeter. Pasteurized milk must not contain more than 2.3 Lovibond units.

(v) **Bacteriological Tests** : These are rarely carried out as a routine but when indicated, are used for detection of *M tuberculosis*, *B abortus* or some other bacteria. Under such circumstances 100 ml of milk is centrifuged at 3000 rpm for half an hour. Deposits of centrifuged milk also can be cultured for other organisms in appropriate media such as the Wilson Blair medium for the enteric group of organisms and the tellurite medium for *C diphtheriae*.

**Inspection of Dairies and Milk Depots** : The dairy should be inspected in a definite sequence and with a view to scrutinize all details in the process of production of milk / milk products, their wholesomeness, quality and safety for consumers. All the concerns described above should be covered. Sampling of milk may be carried out periodically at the dairy farm, milk depot and also at various points on the consumer line. The tests for nutritional ingredients, adulteration, pasteurization, bacterial contamination and keeping may be specifically requested as indicated.

## Meat hygiene

Meat has got high nutritive value but it deteriorates fast. That is why it is notorious for severe bacterial infections and food poisonings. Meat hygiene is therefore extremely important at all levels of food processing.

### Inspection of Meat

**Fresh Meat** : The common signs of deterioration can be elicited by the following methods (3).

- (a) **Smell** : The outside of the carcass should be smelt. A foul smell is a reliable indication of decomposition.
- (b) **Appearance and Firmness** : Fresh meat is firm and elastic. Decomposed meat loses its firm elastic consistency and tends to become soft and slimy.
- (c) **Colour** : It should be uniform. On decomposition the fat becomes pale and the muscle appears dark brown to black. Discoloured patches may emerge with time.
- (d) **Skewer Thrust Test** : A skewer must be thrust into the substance of the meat and should be smelt. Meat with an unpleasant smell is unfit for consumption.

**Fresh Fish** : The common signs of deterioration are as follows:

- (a) **Smell** : It is probably the most important test of soundness. Fish with an unpleasant smell should be rejected, even if all other tests are in its favour.
- (b) **Appearance** : When freshly caught the gills are bright pink, but after death they rapidly become darker and in a matter of an hour or so assume a liver colour. The longer the fish is kept, the darker are the gills.
- (c) **Firmness** : The flesh should be firm to touch, not rapidly separated from the bones, and should not tear easily. If flesh pits readily under pressure, decomposition must be suspected.
- (d) **Colour** : It should be uniform. There should be no evidence of discoloured patches on the skin. These are usually seen first along the line of the backbone.
- (e) **Eyes** : These should be prominent and not sunken, collapsed or dull.

(f) **Floatation Test** : If not eviscerated, a sound dead fish sinks in water while a decomposed one floats, belly up.

#### Tinned Meat and Fish

During canning the interior of the tin and its contents are subjected to heat, though an absolute sterility is not achieved, but the growth of remaining live organisms and spores is so inhibited that hermetically sealed cans should normally remain sound for several years. Under tropical conditions, the rate of deterioration is somewhat accelerated and spoilage may result even in an intact tin. The date of packing and the recommended last date for usage, must therefore always be kept in mind. The acidity of preservative sauce may cause erosion of the tin and eventually results in pin point leaks. This may lead to bacterial infection.

#### *Tins / Cans to be Viewed with Suspicion*

- Damaged, dented or rusted tins
- Leaking tins
- Excessively convex tins
- 'Blown' tin (owing to the formation of gas from decomposition)
- A bulging tin under pressure ('Springer')
- Tainted, foul smelling or bad taste of contents
- If in doubt, subject to laboratory analysis

**Poultry** : Although it is the custom in temperate climates to allow poultry and game to hang for some days in order to improve flavour and tenderness, this is usually not practicable in India. Fresh poultry have bright prominent eyes, the feet are limp and pliable, the flesh moderately firm and the skin pale. Staleness is shown by stiff and dry feet, dull and collapsed eyes, soft and flabby flesh and probably a greenish discolouration around the crop.

#### Slaughter House Sanitation

Filthy slaughter houses are always a menace to the public health due to large collection of offal undergoing putrefaction and the continuous flow of blood, urine and faecal matter in the surrounding areas. A poorly managed slaughter house emanates rotten smell and it becomes a source of disease and nuisance to the public. Fly breeding and contamination of meat are the two major health hazards. Thus, for proper sanitary control, all slaughtering should be carried out in well maintained, licensed public slaughter houses (abattoirs) wherein hygiene rules must be followed strictly. A good slaughter house should conform to these basic standards (3) :

**Design** : The slaughter house should be well ventilated and totally fly proof. It should have sufficient running water supply. Adequate provision should be there to deal with blood, offal and waste animal products. It should be fitted with scaffolding having chrome plated hooks for dressing of animals.

**Building** : The slaughter house should be built with brick and concrete and well protected against rodents, cats and dogs. A concrete boundary wall is desirable. Adequate toilet/wash and hand-washing facilities (with soap and water) must be available.

**Floor and walls** : Special notice should be taken of the floor and general cleanliness of the place where the carcasses are dressed. Floor should be made of impervious concrete. The interior walls should also be of smooth concrete, which should be lime washed frequently.

**Drains** : Concrete channels should drain all liquid waste from the lairs and the slaughter room to a place of disposal outside, through covered drains. All the drains must be cleaned frequently. The manholes must also be frequently checked. Drains must be in a good state of repairs as damaged/broken drains are unhygienic.

**Waste disposal** : The liquid waste should be run into a water carriage sewer. All solid refuse should be burnt in the incinerator.

**Employees** : The employees must preferably be permanent. They must wear clean clothing and be free from communicable diseases. They must undergo initial and periodical examination. They must also take routine immunization.

**Inspection of Slaughter House** : A regular inspection of slaughterhouses is essential to ensure that it does not become a focus for the spread of infections. The abattoir must be inspected regularly and thoroughly. The most important points to note are :

- (a) The structural soundness of the building. The construction of the floor which should be made of cement concrete.
- (b) The fly proofing, rat proofing and dog proofing of the premises.
- (c) The method of disposal of offal, blood, animal excreta and discarded animal tissues.
- (d) The sanitation of the lair.
- (e) The spaciousness of the separate slaughtering, skinning and hanging rooms and their ventilation.
- (f) Availability of water for maintaining the sanitation.
- (g) The maintenance of equipment of slaughtering, skinning and handling and finally the personal hygiene of the workers.

#### Sanitary Inspections & Suggested Standards for Food Catering & Eating Establishments

A high standard of tidiness and cleanliness of all premises of the catering and eating establishments should be ensured. The following important aspects must be monitored :

**(a) Kitchen premises - General Principles** : The entire kitchen premises should be spacious, lighted, fly proof, rat proof, airy and spotlessly clean at all times. The kitchen complex should have a separate cooking room (actual kitchen), a storeroom for fresh provisions, a preparation room, a scullery and a room for the cooks' clothing. The design of a kitchen must be planned with the principles of hygiene in mind with regard to the sources of food-poisoning bacteria, importance of hot and cold storage and prevention of cross-contamination. So far as possible there should be separate work areas for raw and cooked food.

**Floors** : Floors must have non-slip surfaces, should be impervious to moisture and easy to clean. There should be a provision to raised or move the equipment to allow floor to be cleaned underneath.

**Walls** : Walls should also be impervious walls that reduces condensation and is easy to clean. The wall and floor junctions should be covered for easy cleaning, and equipment should be fixed away from the wall to allow for cleaning.

**Ceiling** : Ceiling should be smooth, should resist condensation, and easy to clean. Provision for exhaust/chimney-vents must be made.

**Lighting** : Lighting must be good, both natural and artificial, particularly over the work and preparation areas, sinks and cooking equipment. Shadows must be avoided.

**Ventilation** : Natural and mechanical ventilation is necessary to prevent a rise in temperature, smoke and humidity.

**Conveniences** : Toilets should not open directly into food-preparation rooms. Foot-operated flushes are desirable. Wash basins should be available in or adjacent to the toilet.

**(b) Kitchen proper** : The kitchen should be sufficiently large. A properly constructed cooking range is recommended. This will not only economize the consumption of fuel but also keep the kitchen clear of smoke. The kitchen should be fly proof and well ventilated. It should be meticulously clean and tidy. The floor should be well cemented and free from cracks and crevices. The cooking range should be flanked with platforms for cooks to sit and for prepared food to be kept, awaiting removal to a food serving hatch, racks or hot-plates. Chapati baskets must be lined with clean cloth which is washed daily. All food should be kept covered.

**Kitchen equipment** : Ease of cleaning is an important factor in selecting all surfaces, equipment, and utensils. The following facts must be kept in mind :

- (1) Keep surfaces, equipment and utensils clean and in good repair; they should not be old or worn.
- (2) Slicing machines, mincing machines, and can openers require frequent and thorough cleaning; they must be easy to dismantle and reassemble. In-plant cleaning may be necessary for fixed parts of equipment.
- (3) Use separate boards for raw meat, cooked meat, and vegetables.

Choose appropriate materials for ease of cleaning; for example, synthetic and/or natural rubber hardened with plastic fillers, high molecular weight, medium-density polyethylene, or phenolic fibre laminates. For cleaning, use hot water and a detergent combined with or followed by a disinfecting agent such as hypochlorite; avoiding cloths and using disposable paper instead.

**(c) Preparation Room** : Preparation room is meant for the preliminaries of cooking such as peeling, cutting and washing of food. Provision of fly proofing and good ventilation is necessary. The preparation of vegetables should always be done on a zinc-topped table or granite slabs fitted with a chopping board on it rather than on the floor. The peeling and refuse should be deposited directly in a covered refuse bin. A meat chopping block preferably of a special hardened plastic (high density polypropylene) must be provisioned that is thoroughly washed and cleaned after use. It must be disinfected with a suitable agent (e.g. hypochlorite) and covered with a layer of powdered salt and dried in the sun.

Preparation room should be supplied with hot and cold water for which foot operation is preferable. A soap dispenser, kept in a hygienic condition is also a must. A nail brush with plastic or nylon back and bristle should be available. Hand drying should be done using individual methods such as paper towels. Common towels may cause cross infection.

**(d) Store Room** : A separate fly proof and airy store-room for raw fresh food stuffs should be provided. Raw foodstuffs should be kept in baskets/ crates ensuring free circulation of air and stacked on shelves. A cool room or refrigerator must be available where fresh fruits, vegetables, milk and curd can be stored. Meat, fish and poultry should be kept refrigerated or frozen. Grains, pulses, flour and other dry stuff should be kept in racks, away from the walls, either in neatly tied bags or in boxes in a separate well ventilated store-room. Equipment and utensils should be stored separately. A room for the cooks clothing and other necessities should be provided separately.

**(e) Scullery** : The scullery should be dry, clean and tidy. Sinks should be adequate, and draining boards should be sufficient and clean. All utensils after use should be thoroughly cleaned, washed, dried and kept in clean places. Tables should be scrubbed with washing soda and water twice a day using a hard brush.

**(f) Dining Room** : The dining room should be clean, fly proof, well lit and ventilated. While serving food, it should not be exposed to flies or dust. It should be presented in a manner that will enhance the acceptability or appeal, and reduce wastage. An effort should be made to supply hot food. A hot plate should be incorporated in the serving hatch or platform.

**(g) Washing Arrangements** : Efficient washing-up arrangements are necessary to clean and remove bacteria from all dining room and kitchen equipment. The essential provisions are :

- (1) Good layout of washing-up area.
- (2) Correct temperature of wash and rinse water.
- (3) A good detergent suited to the type of water.
- (4) Orderly methods of work in rinsing, stacking, racking, and storage.

#### **Methods of Washing the Crockery, Cutlery and Utensils**

- **One Sink Method** : This is commonly used but is an inefficient method since crockery and cutlery may still be contaminated with bacteria.
- **Two Sink Method** : It is suitable for domestic as well as for large scale use. The dishes are rinsed, scraped, and wiped off, with paper. Food particles are removed. Utensils are then washed in hot water, (46-50°C) with measured detergent. They are rinsed in racks in hot water at 77-82°C. Both wash and rinse waters should be changed as soon as they become soiled or cold. They must be dried before storage.
- **Dish washing machine** could also be used.
- **Mops and cloths** : They harbour bacteria and can contaminate hands, equipment and cutlery. They require daily washing and disinfection preferably by heat. Paper should be used in place of dish cloths and towels.



#### (h) Waste disposal

**Within the kitchen :** Scraps of food attract bacterial growth and vermin. It is therefore important to dispose off the waste correctly. Waste must be collected in pedal-operated bins which can be emptied regularly and washed out or in paper or plastic bags on pedal-operated stands. Bags can be sealed and put into dustbins, incinerated, or collected by the local refuse collection service.

**Outside the kitchen :** Sufficient waste bins or paper or plastic sacks must be provided to prevent over spilling. Bins with well-fitting lids should be placed in the shade on a stand (10 to 12 inches) high above a concrete area with drainage which can be easily cleaned. Plastic bags with lids should be wall-mounted to give good ground clearance for hosing down. Bins should be kept as dry as possible.

**(j) Vermin and fly control :** Rats, mice, flies, cockroaches and ants are the most common pests. If premises does not provide food and shelter infestation can be prevented. For details on extermination the chapter on entomology may be referred to.

#### *Control of Flies*

- (1) Do not provide a breeding ground such as uncovered refuse bins. Bins should be kept as dry as possible.
- (2) Destroy flies by insecticidal spraying of the refuse area in summers to prevent breeding.
- (3) Prevent access to kitchen and food by fly-proof windows, doors and ventilators. Food must be kept covered.
- (4) Electrical fly killers will kill flies without the hazards associated with aerosol sprays.

#### *Cockroaches*

These are active at night. They get attracted to warm places, such as heating pipes. The hiding places (cracks and crevices) which provide shelter must be sealed off. Close-fitting lids prevent access to food. The area should be treated with suitable insecticide.

#### *Sprays and other insecticide formulations*

These must be used with great care in the kitchen premises. Pyrethrum spray is relatively safer to be used in this setting.

### Hazard Analysis and Critical Control Points (HACCP)

HACCP is an approach to food safety focusing on identifying and controlling critical points in the food production and distribution chain that may lead to food hazard. HACCP incorporates a set of food safety strategies specific to the tasks and settings of the food chain. These strategies apply to farmers working in the field to those responsible for food handling and production before it reaches the consumers table. Food handlers at all levels are trained to implement key strategies to eliminate or control food borne infection triggers at critical points in the 'operation'.

**Principles of HACCP :** The standard approach to HACCP has been specified by the Codex Alimentarius, 1997, and follows the following seven basic principles :

1. Analyze hazards : In a setting of food hygiene the hazard could be biological, (microbes); chemical (toxin); or physical

(ground glass or metal fragments). These potential hazards and measures to control them are identified.

2. Identify critical control points. These are points in a food's production from its raw state through processing and transport to consumption at which the potential hazard can be controlled or eliminated. Examples are cooking, cooling, packaging, and metal detection.
3. Establish preventive measures with critical limits for each control point. For a cooked food, for example, this might include setting the minimum cooking temperature and time required to ensure the elimination of a harmful microbes.
4. Establish procedures to monitor the critical control points. Such procedures might include determining how and by whom cooking time and temperature should be monitored.
5. Establish corrective actions to be taken when monitoring shows that a critical limit has not been met--for example, reprocessing or disposing of food if the minimum cooking temperature is not met.
6. Establish procedures to verify that the system is working properly for example, testing time-and-temperature recording devices to verify that a cooking unit is working properly.
7. Establish effective record keeping : This would include records of hazards and their control methods, the monitoring of safety requirements and action taken to correct potential problems.

### Summary

Prevention of food borne infections and food poisoning can be achieved through appropriate steps taken at the all levels of food processing i.e. production, supply, procurement, processing of raw food, transport, cooking, storage, distribution and finally serving and eating of food. Immaculate personal hygiene of cooks, design and hygiene of the kitchen premises, appropriate storage of food and healthy cooking practices are vital for prevention of food borne diseases.

Milk and meat are also potential sources of various food borne diseases. Adequate hygiene measures should be implemented through their entire course of procurement and processing. Sanitation of dairy and slaughter house is of paramount importance in achieving this aim. Pasteurization of milk is the process of rapidly heating, maintaining it uniformly over a definite period and rapidly cooling it thus destroying most of the pathogenic microorganisms. Various methods of pasteurizing milk are: Holder (Vat) method, Continuous Flow Method, High Temperature Short Time (HTST) Method, Ultra High Temperature (UHT) Method. Various methods and tests are used to monitor pasteurization.

### Study Questions

**Long Question :** Enumerate the hazards of an unsanitary kitchen. What measures would ensure adequate kitchen hygiene of a large eating establishment?

**Short Notes :** (1) Botulism (2) HACCP (3) Golden principles of food hygiene (4) Pasteurization (5) Hygiene inspection of meat



### MCQs

1. Which is true for mushrooms : (a) It is a nutritious food (b) Some mushrooms could cause food borne disease (c) Some mushrooms could cause food poisoning (d) All of the above
2. Which of the following is generally not a source of food borne diseases (a) Dust (b) Skin infection (c) Home preserved food (d) Fruits
3. Pasteurization destroys (a) All pathogenic organisms (b) Some pathogenic organism (c) Most pathogenic organisms (d) No pathogenic organisms
4. Which of these insecticides is relatively safe for kitchen use : (a) Abate (b) Sodium Hypochlorite (c) Baygon (d) Pyrethrum

5. Which of these is the ideal method of disposing off solid refuse from slaughter house : (a) Incineration (b) Land fill (c) Sell it off to a contractor and get some money (d) Chemical treatment

**Answers :** (1) d; (2) d; (3) c; (4) d; (5) a.

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In the less fortunate parts of the world, immense food related problems are a painful reality. Every day 800 million people in the developing world, ie 18% of the total world population, have to sleep hungry. In South East Asia, one out of four persons go hungry. In Sub Saharan Africa the condition is still worse; one third of the population does not get enough food. World over, 175 m children (under five years of age) are underweight. As many as two billion women and children are anaemic, 250 million children suffer from xerophthalmia, two billion people are at risk of Iodine deficiency...; the magnitude of the problems related to nutritional inadequacies is colossal.

### Interventions by India

Over the past five decades India has been able to achieve self sufficiency in food production, through various interventions. Green revolution brought about an exponential increase in agricultural production, laying the foundation of self sufficiency. The government of India launched and improved the Public Distribution System, thereby facilitating the easy accessibility of food grains to the common masses at an affordable price.

Research in the field of nutrition was strengthened with the augmentation of the ICMR governed National Institute of Nutrition (NIN) at Hyderabad and the CFTRI at Mysore. In this series of events, various direct interventions were introduced through National Nutritional Programmes in the late 1960s and early 1970s. In addition certain interventions were inherently built up within other (non nutritional) programmes to improve the nutritional status of community.

### Current Nutritional Deficiency Status

The nutritional state of the country still remains much below the desirable levels. Even though the agricultural production may be good, it does not automatically ensure enough nutrition of masses, owing to various reasons. These could be as diverse as poverty, lack of food security and ignorance.

The figures speak for themselves. More than one fourth (26.1%) population is below poverty line. As many as half (49%) of rural and more than one third (36%) of rural Indian children are underweight. A staggering 2.2 million are afflicted with cretinism and 6.6 million are mildly retarded. Nutritional blindness affects 7 million children in India, mainly because of vitamin A deficiency.

Many a challenges remain before us as far as nutritional adequacies are concerned. National programmes reflect the concern of the government of India towards the problem and is a way to bridge this inadequacy. Various nutritional programmes have been conceived over the past five decades with an aim of improving the nutritional state of our country. These have met with reasonable degree of success. A brief outline of some of the more important programmes is given here.

### Direct Interventions : The Nutritional Programmes

The various nutritional programmes are being run by different ministries. These programmes are listed below :

#### *Ministry of Social Welfare*

- ICDS programme
- Balwadi nutrition programme
- Special Nutrition programme

#### *Ministry of Health and Family Welfare*

- Prophylaxis against nutritional anaemia

- Vitamin A prophylaxis programme
- Iodine Deficiency Disorders Control programme

*Ministry of Education*

- Mid Day Meal programme

### **Balwadi Nutrition Programme**

The Balwadi Nutrition Programme was initiated in 1970 by the Ministry of Social Welfare. It was meant for the children from rural areas, in the 3 to 6 years age group. It was run through Balwadis. Meals were provided to the children with an aim of catering for 300 Kcal and 10 to 12 g protein per day for each child. The Balwadis had also endeavored to provide pre-primary education to the children.

### **Special Nutrition Programme**

Special Nutrition Programme was also started in 1970 by the Ministry of Social Welfare. This programme was operational in the urban slums and tribal areas in addition to the rural areas. It had a wider scope than the Balwadi Nutrition Programme as it not only benefited children from 1 to 6 years but also the pregnant women. It provided supplementary nutrition for 300 days in a year. Children obtained food, providing 300 Kcal and 10 to 12 g protein. Pregnant women were provided with food supplementing 500kcal and 25 g protein. This programme has slowly been merged with the ICDS in most of the states.

### **Applied Nutrition Programme**

The Applied Nutrition Programme was introduced as a pilot project in Orissa in 1963, which was extended later to other states. It had focused on production of more vegetables and fruits and ensuring their consumption by children, pregnant and lactating women. Nutritional education was also a thrust area. Kitchen gardening, poultry, bee-keeping etc. were also encouraged.

### **National Nutritional Anaemia Prophylaxis Programme**

The programme for Prophylaxis against nutritional anaemia was started in the year 1970, during the fourth 5-year plan (1969-74) by the Ministry of Health and Family Welfare to prevent nutritional anaemia in mothers and children. Distribution of the Iron-Folic Acid tablet (IFA tablets) to pregnant women and children under 12 years of age is an important component of this programme.

**Doses and Formulations** : Women (pregnant, lactating and family planning acceptors) are given one tablet of iron and folic acid containing 100mg elemental iron and 0.5mg folic acid. Children in the age group of 1 to 5 years are given one tablet iron containing 20 mg elemental iron (60 mg ferrous sulphate) and 0.1mg folic acid daily for a period of 100 days. Recently (2007) the government of India recommended that infants (6-12 months should also be included in the programme and a liquid formulation must be incorporated for children for easy dispensing for children between 6-60 months. Dispersible tablets must also be used, which are easy to use under the 'programme conditions'.

There is another recent recommendation to include school children (6 to 10 years of age) and adolescents (11 to 18 years of age) also in the programme. Children will be provided 30

mg elemental iron and 250 microgram folic acid for 100 days. Adolescents will be provided the same dose as that for adults. Adolescent girls will be given priority.

The distribution of the tablets is carried out through the Primary Health Centres, MCH Centers in Urban areas and the ICDS.

**Critique** : It is generally agreed that the programme has failed to make any impact on the anaemia scene in the country. The incidence of anaemia has hardly changed over the past decade, as is clear from the comparison of figures from NHFS II and III. Some of the important causes of the poor outcome of this programme are summarized in Box - 1.

<b>Box - 1 : Causes of Poor Outcome of National Nutritional Anaemia Prophylaxis Programme</b>
Poor perception of the problem (of anaemia) by the population.
Inadequate outreach of target population.
Poor compliance.
Medicine supply & stocks inadequate and poor quality.
Knowledge of functionaries and beneficiaries poor.
No attention given to educational and training components of programme.
Evaluation system not implemented.

**Achieving Control of Iron Deficiency** : The following actions are required to achieve control of iron deficiency :

1. Better appreciation of the problem by the community and care givers.
2. Better organisation of primary health services to effectively render iron supplementation.
3. Strengthening of the supplementation programme.
4. Nutrition education with respect to Do's and Dont's of iron natures.
5. Development of suitable fortificant and its effective implementation.
6. Active involvement of medical community especially the nutritionists, haematologists, internists, paediatricians, obstetricians and community medicine specialists to combat iron deficiency.
7. Joint action by the Government, NGOs, medical and biomedical scientists, agriculturists and planners.
8. Using biotechnology for enhancing iron and ferritin contents of foods like soyabean and other seeds.

The experience from other countries teaches that long term measures for control of anaemia are more effective. The most promising intervention is fortification of food items with iron over long periods. These food items can be as varied as salt, sugar, milk, cereals, etc. India has already perfected the technology of double fortification of salt with iodine and iron. Nutrition education is also another long term measure that is likely to change the face of anaemia if followed well.

### **National Programme for Prophylaxis against Blindness in Children due to Vitamin A Deficiency**

The deficiency of Vitamin A continues to be a public health

problem in India. Many surveys indicate the prevalence of Bitots spots to be higher than 0.5% and night blindness in the range of 0.7-2%. The solution is to supplement oral vitamin A to children. Vitamin A Prophylaxis Programme was started by the Ministry of Health and Family Welfare in 1970 with this aim. National Institute of Nutrition (NIN), Hyderabad rendered the necessary technical assistance.

The aim of the programme was to decrease prevalence of Vitamin A deficiency from the current 0.7% to less than 0.3%. The 10th five year plan had set a target to eliminate vitamin A deficiency as a public health problem and decrease prevalence of night blindness to below 1% and Bitots spots to less than 0.5% in children of 6 months to 6 years of age.

**Dosage** : Under this programme a total of 9 lakh IU of Retinol palmitate is administered orally in 5 doses. The first dose of 1 lac IU is given at 9 months, starting along with the measles vaccine followed by the second dose at 15 months of 2 lakh IU. This is followed by another 3 doses of 2 lakh IU at 6 monthly intervals, till the age of 3 years (ie 1 lakh IU at 9 months and 2,00,000 IU each at 15 to 18, 24, 30 and 36 months of age).

**Implementation** : The vitamin A doses are being administered by Anganwadi workers under the supervision of ANM. The programme is being implemented through the RCH programme.

**Critique** : This programme has significantly contributed to our endeavour of elimination of Vitamin A deficiency in India. The morbidity has steadily declined. Integration of vitamin A administration with RCH and immunization programme has made it logistically much simpler and practical to implement. Some episodes of deaths of children following vitamin A intake has brought the programme to disrepute. There is however no scientific explanation of mortality even after administration of double the recommended dose of vitamin A. The media must refrain from sensationalizing these news stories without solid scientific evidence. The health community too, must counter it through health education campaigns.

### **Iodine Deficiency Disorders (IDD) Control Programme**

National Goitre Control Programme was launched in 1962. In 1992 the programme was renamed as National Iodine Deficiency Disorders Control Programme. The components of the programme are :

- a) To conduct surveys to establish magnitude of the problem
- b) Provision of Iodized salt
- c) IDD monitoring
- d) Manpower training
- e) Health Education (IEC) activities

**Surveys** : Surveys have proved beyond doubt that it is not only the Sub Himalayan Goiter belt but almost all states of India are endemic for IDD. More than 200 million people are living at risk of IDD.

**Provision of iodized salt** : The orders on banning sale of non-iodized salt have not been consistent over the past few decades. The exact policy on ban has been fluctuating. Moreover it was at the convenience of the states to implement the order. As a result some states have been following a strict ban and others not. The Ministry of Health and Family Welfare again issued a notification banning the sale of non-iodized salt in November

2005 under the PFA Act, to be effective from mid 2006.

The quality control of iodized salt is also important. Testing kits for spot qualitative analysis of iodine in salt have been developed. The iodine content of salt at production and consumption levels should be 30 and 15 ppm respectively. Iodized salt has been introduced in the public distribution system of most of the states.

**IDD Monitoring** : Continuous monitoring of the IDD status is vital to observe the progression of the condition. This is carried out through various surveys. Iodine in salt and urinary iodine excretion are also monitored. IDD monitoring laboratories have been established at district levels in 17 states. A national reference laboratory has been set up at National Institute of Communicable Disease at New Delhi.

**Manpower Training** : Various institutions run courses for manpower training in various facets of IDD control. Workers are trained in goiter survey methodology and laboratory technology with respect to iodine level monitoring in urine and salt, etc.

**Health Education and IEC Activities** : Government provides fund to run IEC campaign to increase awareness on consumption of iodized salt intake. Endemic districts are under operation of IEC activities through 268 units of Directorate of Field Publicity. Doordarshan is also used for IEC campaigns. Global IDD day is celebrated on 21st Oct. The misconceptions regarding consumption of iodized salt are also managed through the IEC campaign.

**Critique** : It was conceived that universal iodization of salt will root out IDD. But that has not really happened, even after a decade of 'universal iodization'. It is primarily because of the fact that we have not been able to achieve universal immunization, which was the main pillar of the programme. The priorities and policies of the state governments have been varying, and in the bargain the iodization status of salt suffers, compromising the programme. There is a ban on the sale of un-iodized salt but the same has to be ensured through various administrative mechanisms of respective states.

The allocation of funds is very small in comparison to other national programmes, since the priority attributed to it is lower. There have been 'roadblocks' in the transportation of salt through the railways. These administrative problems have to be sorted to enable a smooth programme. Cost of iodized salt too is a constraint for poor society in India. Only a strong and committed political and bureaucratic will could help the programme succeed.

### **Midday Meal Programme**

It was Madras Presidency in the year 1923 that started the concept of providing cooked meals to children studying in corporation schools of Madras city. It was expanded to a larger scale in 1961, thus India became one of the first countries to have started the Midday Meal Programme, then called as the School Lunch Programme. Other states also joined in and programmes run by Gujarat and Kerala are also widely acclaimed. In 2001, a landmark decision was given by the honourable Supreme Court of India, which made it mandatory for all government primary schools to provide cooked meals. The primary aim of the programme was to provide at least



one nourishing meal to the school going children per day. The objectives were :

- It served as an incentive for the children to attend school.
- To reduce dropouts from school.
- To improve the nutritional status of the child

There are certain additional advantages of the programme too. It also serves as an opportunity to impart basic health / nutritional education to children. Moreover some local women get employment to cook food for the mid day meal.

It must be remembered that the programme provides a supplement, and not a substitute to the food eaten at home. This meal provides one third the total daily energy requirement and half the need of proteins (300Kcal and 8-12 g of proteins). The central government (Ministry of Education) supplies the full quota of grains to the states. Food that could be cooked easily, available locally and at low cost is preferable. To avoid monotony it is desirable to change the menu frequently.

**Critique :** The mid day meal concept was a noble one as it primarily serves the underprivileged rural primary children. The sustainability of the programme however depends on the political will, community participation and prudent running of the programme. The programme has to be saved from ill-publicity which it sometimes attracts through news of food-poisonings associated with the programme. The standards can be improved through a sustained improvement of quality of service.

### Integrated Child Development Services (ICDS)

The Integrated child development program (ICDS) was initiated by the government of India on 2nd October 1975 by the Ministry of Social Welfare. It is the world's largest early child development program. It was initially started in 33 blocks (1975) but now it encompasses 6500 blocks, employing more than 6 lakh Anganwadi Workers (AWW) and equal number of helpers. It is providing its outreach services to 33.2 million children and 6.2 million pregnant and lactating women. It is an inter-sectoral programme which seeks to directly reach out to children, below six years, especially from vulnerable and remote areas and provide early childhood education, health and nutrition along with the care of the women in the reproductive age group (women of 15-45 years, pregnant and lactating women). Currently, services under the scheme are being provided to about 562.18 lakh beneficiaries, comprising of about 467.18 lakh children (0-6 years) and about 95 lakh pregnant and lactating mothers through a network of about 7.48 lakh Anganwadi Centres.

#### Objectives of ICDS :

1. Lay the foundation for proper psychological development of the child
2. Improve nutritional & health status of children 0-6 years
3. Reduce incidence of mortality, morbidity, malnutrition and school drop-outs
4. Enhance the capability of the mother and family to look after the health, nutritional and development needs of the child
5. Achieve effective coordination of policy and implementation among various departments to promote child development

This programme has a major nutritional component :

- Supplementary nutrition to children below 06 years of age, nursing and pregnant mothers from low income families.
- Nutrition and health education to all women in age group of 15 - 45 years.
- Referral of serious cases of malnutrition or illness to hospitals.

**Services :** The Scheme provides many services in an integrated manner through community-based workers and helpers. The services are provided at a centre called the 'Anganwadi'. The Anganwadi, literally a courtyard play centre, is a childcare centre, located within the village. A package of following six services is provided under the ICDS Scheme :

1. Supplementary nutrition
2. Non-formal pre-school education
3. Immunization
4. Health Check-up
5. Referral services
6. Nutrition and Health Education

The three services namely immunization, health check-up and referral are delivered through public health infrastructure i.e. the Sub Centres, PHCs and CHCs under the MoHFW.

Target Groups & Service Provider		
Services	Target Group	Services Provider
Supplementary Nutrition	Children below 6 years; pregnant and lactating mothers	Anganwadi Workers (AWW) & Anganwadi Helper (AWH)
Immunization*	Children below 6 years; pregnant and lactating mothers	ANM/MO
Health Check-ups*	Children below 6 years; pregnant and lactating mothers	ANM/MO/AWW
Referral	Children below 6 years; pregnant and lactating mothers	AWW/ANM/MO
Pre-School Education	Children 3-6 years	AWW
Nutrition & Health Education	Women (15-45 years)	AWW/ANM/MO
* AWW assists ANM in identifying & mobilizing the target group to health-centres		

**Supplementary Nutrition :** This includes supplementary feeding and growth monitoring; and prophylaxis against vitamin A deficiency and control of nutritional anaemia. All families in the community are surveyed, to identify children below the age of six and pregnant and nursing mothers. They avail of supplementary feeding support for 300 days in a year. By providing supplementary feeding, the Anganwadi attempts to bridge the protein energy gap for the beneficiaries.

Growth Monitoring and nutrition surveillance are two important activities that are undertaken. Children below the age of three



years are weighed once a month and children 3-6 years of age are weighed every quarter. Weight-for-age growth cards are maintained for all children below six years. This helps to detect growth faltering and helps in assessing nutritional status. Besides, severely malnourished children are given special supplementary feeding and referred to health sub-centres, PHCs as and when required.

**Supplementary Nutrition Norms** : Nutritional supplements are provided to the extent indicated in Table - 1.

<b>Table - 1</b>		
<b>Beneficiaries</b>	<b>Calories (cal)</b>	<b>Protein (g)</b>
Children below 3 years	300	8-10
Children 3-6 years	300	8-10
Severely malnourished Children on medical advice after health check-up	600	16-20
Pregnant & Lactating (P&L) Mothers	500	20-25

**Non Formal Pre-School Education** : This component for the three-to six years old children in the Anganwadi is directed towards providing and ensuring a natural, joyful and stimulating environment, with emphasis on necessary inputs for optimal growth and development. The early learning component of the ICDS is a significant input for providing a sound foundation for cumulative lifelong learning and development. It also contributes to providing the child the necessary preparation for primary schooling and offering substitute care to younger siblings.

**Immunization** : Immunization services are delivered by the Ministry of Health and Family Welfare under its Reproductive Child Health (RCH) programme. The ICDS only tends to facilitate these services through a reiteration of the family to attend the immunization clinic at the relevant centre. In addition, the Iron and Vitamin "A" Supplementation to children and pregnant women is also facilitated.

**Health Check-ups** : This includes health care of children less than six years of age, antenatal care of expectant mothers and postnatal care of nursing mothers. These services are provided by the ANM/ Medical Officers from Sub-Centres and Primary Health Centres. The various health services include regular health check-ups, immunization, management of malnutrition, treatment of diarrhoea, de-worming and distribution of basic medicines etc.

**Referral Services** : During health check-ups and growth monitoring, sick or malnourished children, in need of prompt medical attention, are referred to the Primary Health Centre etc. The Anganwadi worker has also been oriented to detect disabilities in young children.

**Nutrition and Health Education** : Nutrition and Health Education is also an important element of the work of the Anganwadi worker. This enables women in the age group of 15-45 years to look after their own health, nutrition and development needs as well as that of their children and families in a better way.

**ICDS Staff** : Anganwadi Worker, a lady selected from the local community, is a community based frontline voluntary worker of the ICDS Programme. She is also an agent of social change, mobilizing community support for better care of young children, girls and women. She is assisted by Anganwadi helpers. She reports to the supervisor. Child Development Project Officers (CDPOs) and District Programme Officers (DPOs) are the officers directing the programme within a block. Besides the Medical Officers, the Lady Health Visitors (LHVs) and Auxiliary Nurse Midwife and Female Health Workers from nearby Primary Health Centres (PHCs) and Sub-Centres work in an integrated manner with the ICDS functionaries to provide health, medical, immunization and referral services.

#### Administration of the Scheme

**Location** : The administrative unit for the location of ICDS Project is the Community Development Blocks in rural areas, tribal blocks in tribal areas and ward(s) or slums in urban areas. For the purpose of working out the estimated number of beneficiaries, a rural/urban Project is assumed to have a population of 1 lakh and tribal project 35,000. One Anganwadi Centre normally caters to 1000 population in a rural/urban project and 700 population in a tribal project.

**Sparsely populated hilly/desert areas** : There is provision for setting up an Anganwadi in every village or hamlet having a population of 300 or more sparsely populated hilly/desert areas. Very small villages/ hamlets with a population of less than 300 are covered by the adjoining Anganwadi.

**Finances** : ICDS is a centrally-sponsored Scheme implemented through the State Governments/UT Administrations with 100% financial assistance for inputs other than supplementary nutrition which the States were to provide out of their own resources. From 2005-06, it has been decided to extend support to States up to 50% of the financial norms or 50% of expenditure incurred by them on supplementary nutrition, whichever is less.

**Mini-AWCs** : Mini-Anganwadis can be set up to cover the remote and low populated hamlets/ villages in tribal blocks having a population between 150 to 300.

**Anganwadi Workers** : Anganwadi Workers (AWWs) and Helpers (AWHs) are "honorary workers" from the local community who come forward to render their services, on part-time basis, in the area of child care and development. Anganwadi Workers & Helpers are the grass roots functionaries to implement the ICDS Scheme. AWWs & Helpers, being honorary workers, are paid a monthly honoraria as decided by the Government from time to time. At present the AWW get about Rs 938 to 1063 (depending on qualification and experience) and AWH gets Rs. 500 per month as honorarium.

**Critique** : The ICDS programme has largely been a successful endeavour of the government of India. Given the very large scope of the beneficiaries (about 6 crores) and about 15 lakh AWW and AWH working in extremely diverse environs of states with varied ideologies, diverse terrains and constraints, there has to be criticism of the scheme in some quarters. The aim of the scheme was to reduce the incidence of mortality, morbidity, malnutrition and school dropouts, which has been achieved to a great extent. There is a criticism that the beneficiaries only

visit the centre only during the meal timings. But provision of nutrition too has been an objective of the programme. Infant Mortality Rate (IMR) has declined from 110 in 1981 to 58 per thousand live birth in 2004. Similarly, under-5 mortality has declined from 161 in 1983 to 87 in 2003. Various surveys have revealed that there has been significant impact of the scheme. Many non-monetary benefits like insurance, incentives, preference in other jobs (teachers) have been given to the AWW and AWH. There is certainly a scope of enhancing the honorarium offered to these grass root workers.

## Summary

After independence the government of India took many initiatives to ensure food security for the country. National nutritional programmes were a firm step in that direction. Ministry of Social Welfare runs the ICDS programme, Balwadi nutrition programme and special nutrition programme. Ministry of Health and Family Welfare runs the programmes for prophylaxis against nutritional anaemia, vitamin A prophylaxis programme and the iodine deficiency disorders control programme. The mid day meal programme is run by the Ministry of Education. The programmes have achieved improvement in the nutritional status of the children, pregnant and lactating women. More specifically the ICDS programme that has a strong nutritional component can be termed as a successful programme.

## Study Exercises

**Long Question :** What are the objectives of the ICDS scheme? Discuss the benefits offered to various vulnerable groups under

the scheme.

**Short Notes :** (1) Mid day meal programme (2) Anganwadi worker (3) Iodized salt (4) Services under National Nutritional Anaemia Prophylaxis Programme (5) Supplementary Nutrition under ICDS

## MCQs

- Mid day meal programme offers (a) Half of daily protein and one third of calorie requirement (b) Half of daily protein and half of calorie requirement (c) One third daily protein and half of calorie requirement (d) One third of daily protein and one third of calorie requirement.
- To a child under 3 years of age, ICDS provides : (a) 300 Kcal energy and 8-10 g protein (b) 300 Kcal energy and 16-20 g protein (c) 500 Kcal energy and 8-10 g protein (d) 500 Kcal energy and 16-20 g protein.
- In rural areas, the administrative unit for the location of ICDS Project is (a) Gram Panchayat (b) Community Development Blocks (c) District head quarter (d) Primary Health Centre.
- Which of the following is not run by the Ministry of Health and Family Welfare (a) Prophylaxis against nutritional anaemia (b) Vitamin A prophylaxis programme (c) Iodine Deficiency Disorders Control programme (d) ICDS Programme.
- Which of these is not carried out at the Anganwadi centre (a) Supplementary nutrition (b) Non-formal pre-school education (c) Immunization (d) Nutrition and Health Education.

**Answers :** (1) a; (2) a; (3) a; (4) b; (5) c.

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## Nutritional Assessment and Surveillance of a Community

*Rajul K Gupta*

## Assessment of Nutritional Status of Individuals and Communities

### Aims of Assessment of Nutritional Status

The assessment of nutritional status is carried out with the following aims :

- To map out distribution and geography of nutritional disorders
- To identify high risk groups with respect to nutritional vulnerability
- To assess various epidemiological factors for nutritional deficiencies
- Make recommendations to rectify shortcomings leading to nutritional deficiencies
- To project for financial allocations and budget for food

materials at a large administrative level e.g. at the national level.

Various methods are available for the assessment of nutritional status. These are enumerated in Box - 1. These can be further sub-classified into direct and indirect methods of nutritional status assessment.

### Box - 1 : ABCD... of Nutritional Status Assessment

Anthropometry
Biochemical & lab methods
Clinical assessment
Diet survey
Ecological studies
Functional assessment
G - - Vital statistics

## Direct Assessment of Nutritional Status

The term 'direct assessment' refers to methods in which individuals or communities are investigated directly. The various methods that are available for the direct assessment are summarized in Box - 2.

Box - 2 : Direct Assessment of Nutritional Status	
Clinical signs	
Laboratory Tests	
<ul style="list-style-type: none"><li>Biochemical</li><li>Haematological</li><li>Parasitological</li></ul>	
Biophysical Methods	
Anthropometry	

**Assessment of Nutritional Status using Clinical Signs :** Clinical examination is a widely practiced direct method to assess the nutritional status of individuals and communities. Assessment of clinical signs is based on the examination for changes believed to be related to inadequate or excessive nutritional intake, that can be observed in superficial tissues (skin, eyes, hair, mouth) or in organs close to the surface (thyroid, skull).

**Caution with Clinical Examination :** The cheapness and the relatively easy organization of clinical examination for nutritional assessment, might sometimes lead to the assumption that the method is simple, can be quickly mastered by a beginner, and yield results that are quick to interpret. But this is not the case. This method has got its own limitations, advantages and disadvantages. Expertise is required to select it as a valid method in a given situation, to conduct it and to interpret the results obtained.

**Classification of Clinical Signs :** Based on their importance with regard to suggesting a nutritional etiology the clinical signs can be classified into three groups (1) :

**Group 1 - Potentially Nutritionally Significant (Signs 'strongly suggestive' of dietary deficiency or excess) :** Some signs are strongly suggestive of a particular nutritional deficiency or excess e.g. Bitot's spots (Vitamin A), Flag sign (PEM). A list of these is summarized in Table - 1.

**Group 2 - Signs that are of probable nutritional significance :** There are some signs that are of uncertain nutritional significance. These have to be appreciated and interpreted in correlation with the case. e.g. Xanthomata eye might indicate high blood cholesterol, Corneal scar (previous infection, trauma, malnutrition, avitaminosis A), Fissure tongue, recession of gums, transverse ridging of nails, etc.

**Group 3 - Signs that have no nutritional significance :** These signs are not nutritionally significant but required to be differentiated from other nutritionally relevant signs. e.g. pterygium (an insignificant sign) is to be differentiated from Bitot's spots, geographic tongue, pyorrhea.

**Assessment of Nutritional Status using Biochemical and Laboratory Methods :** We have seen previously that clinical signs are often non specific and develop rather late in the

disease process. Biochemical changes, on the other hand can be expected to take place prior to clinical manifestations. Hence tests that can be conducted on easily accessible body fluids (blood and urine), can help to detect disease at a sub-clinical level even in a community setting.

Table - 1 : Signs 'strongly suggestive' of dietary deficiency or excess	
Deficiency Sign	Suggested nutrient abnormality
Pale conjunctiva	Iron
Bitot's spots	Vitamin A
Angular stomatitis	Riboflavin
Spongy, bleeding gums	Vitamin C
Bilateral edema (young children)	PEM
Thyroid enlargement	Iodine
Bilateral epiphyseal enlargement of wrists	Vitamin D
Sign of Excess	Suggested nutrient abnormality
Mottled enamel	Fluoride
Dental caries	Sugar

**Available laboratory tests :** Three groups of laboratory tests are available, namely, haematological tests, parasitological tests and biochemical tests. The haematological tests include the commonly done hemoglobin estimation, parasitological tests would include stool examination for intestinal parasites and biochemical tests include many tests like the urine examination for albumin, sugar, etc. Advanced biochemical test are taken up for vitamin, minerals and enzyme estimations as well, that indicate nutritional status. Normal range of some of these tests is given in Table - 2.

**Assessment of Nutritional Status through Anthropometry :** Nutritional anthropometry is the measurement of human body at various ages and levels of nutritional status. It is based on the principle that appropriate measurements should reflect any morphological variation occurring due to a significant functional physiological change. For example, a low Fat Fold Thickness reflects a shift in energy balance. The advantages of anthropometry are that it is simple, quick to do, easy to reproduce and objective. In some cases it identifies even subclinical changes resulting from nutritional variations.

**Common Methods of Anthropometry :** The common anthropometric methods should be quick, simple and easy to reproduce. Minimum training should be required to conduct the measurement. The commonly used methods are : Height; Crown-heel length and standing height; body weight, mid upper arm circumference; and fat fold thickness. Head and chest circumference are measured for children under five years of age.

**Body Weight :** Body weight is the commonest and simplest anthropometric measure used for the evaluation of nutritional status. It is a reflection of total body mass comprising of all

body constituents. It is measured for both children and adults. Definite body weight standards are available to us. Body weight is an indicator of 'current' nutritional status of the individual, as weight fluctuates with nutrition. Unlike height which is irreversible, it reflects the nutrition state of the present day. It is therefore a useful indicator for acute disorders. Small illnesses like childhood diarrhoea is also good enough to alter the weight, it is thus a sensitive indicator.

**Measurement of Weight :** The ideal weighing instrument is the lever actuated balance or a beam balance. The balance must have a least count of not more than 100g. Balances using a 'spring' are not advisable as the spring loses its tension due to prolonged use and an error is inevitable. Commonly used bathroom scales are based on the 'spring' principle, thus they must be best avoided for scientific work. The balance which is in use must be calibrated frequently for best results. The precautions to be taken while measuring weight are given in the Box - 3.

**Height :** Height is an indicator of the linear growth of the individual. It is widely accepted that height is determined genetically. Environmental factors, most importantly nutrition and morbidity determine the extent to which the genetic potential will be harnessed, to achieve the maximum possible height. Growth retardation resulting from any environmental factors like infections, malnutrition, etc. result in a retarded height, resulting in stunting (or short stature). Height is

affected by long standing nutritional deprivation. A short or retarded height is thus indicative of chronic food insufficiency over a longer duration, unlike a reduced weight which indicates a short term nutritional deprivation or infection.

<b>Box - 3 : Precautions while measuring weight</b>
Use the right balance. Avoid bathroom scales.
Weight must be taken in minimum clothing.
Remove shoes before weight is recorded.
The zero-error must be checked and corrected before using a machine.
It is advisable to record weight in the morning (in basal conditions)
These precautions must be applicable in a standardized manner for all subjects (within a study group)

**Measurement of Height :** In young children, height is referred to as length or Crown-heel length in young children who cannot stand with ease (say up to 2 years of age). An infantometer is use to measure their recumbent 'length' (in lying position). In adults and older children, the height is measured using a vertical measuring rod, the Anthropometric rod.

The subject should remove his shoes and stand erect. He must keep his heels together and toes apart. He must look straight.

**Table - 2 : Normal range of some biochemical tests (2)**

Nutrient	Test	Normal (Acceptable)	Low (Medium risk)	Deficient (high risk)
Albumin (g/100ml) for age 6-17 yrs	Serum levels	>3.5	2.8-3.4	<2.8
Vitamin A (μg/dl)	Serum levels	>30	20-30	<20
Vitamin D (ng/ml)	Serum levels of 25-Hydroxy cholecalciferol	>10	05-10	<5
Vitamin E	Ratio of serum vitamin/total lipids	>0.8		
Vitamin K	*PIVKAS accumulation			If PIVKAS accumulates
	Prothrombin time			Delayed **
Thiamin	Urinary thiamin	100μg/24 hrs or 65μg/g creatinine		
Riboflavin	Urinary Riboflavin	80μg/g creatinine		
Niacin	2-Pyridone to NI-methyl nicotinamide ratio	1 to 4		<1
Vitamin B <sub>6</sub>	Vitamin B <sub>6</sub> urinary excretion			<20μg/g creatinine
	Pyridoxic acid excretion			<0.5mg/day
Folic Acid	Serum folate (ng/ml)	>6.0	3.0-5.9	<3
	RBC Folate (ng/ml)	>160	140-159	<140
Vitamin B <sub>12</sub>	Serum B <sub>12</sub> (pg/ml)			<80
Ascorbic acid	Plasma (mg/dl)	>15	08/15/09	<8

\* PIVKAS: Protein Induced by Vitamin K Absence. \*\* Prothrombin time is a functional test



He stands against the anthropometric rod kept at his back, placed perpendicular to the ground. The investigator standing to the left holds the subject's chin with his left hand and the occiput with the right little finger in the Frankfurt horizontal plane (an imaginary line joining the tragus of the ear to the eye). The moving head piece of the anthropometric rod is brought down and placed on the head with little pressure, in the sagittal plane. The reading is taken. Average of three readings is recorded. The disadvantage of height as a measure of nutritional status is that it doesn't indicate present nutritional status of the individual, but indicates only the past history of a chronic disease.

**Mid-Upper Arm Circumference (MUAC) :** Mid-upper arm circumference indicates the muscle development. Since poor muscle development is seen in PEM, the lower MUAC indicates poor nutrition. MUAC correlates well with weight, weight for height and clinical signs of malnutrition. It can be used to calculate the mid arm muscle circumference using a simple formula, if the value of fat fold at triceps is also estimated simultaneously. The mid calf circumference can also be used instead of MUAC.

The mid-upper arm circumference is measured on the non-dominant arm (left arm in case of right handed subjects and vice-versa) of the subject. The mid point between the tip of the acromion (of scapula) and olecranon process of ulna is located with the arm flexed at the elbow. It should be marked with a pen. The arm is now held hanging freely by the side of the subject and a fiberglass tape is placed gently but firmly embracing the arm without 'squeezing' the soft tissue, at the point marked in pen. The reading is taken to the nearest millimeter.

**Interpretation :** The usefulness of MUAC is based on the principle that MUAC remains almost constant between 1 to 5 years of age (increasing only approx 1.5 cm between 1 and 5 years of age). Thus fair degree of standardization can be achieved even if the age is not known in a preschool child. A cut off point of 12.5 cm is taken. MUAC of less than 12.5 cm is taken as low. To make the procedure of measurement even simpler and usable at the grassroot level, Shakir introduced a simple tricoloured tape in 1975, called as the Shakir's tape. The red colour in the tape (which fell in the less than 12.5 cm zone) marked Danger, yellow or white colour, fell in 12.5-14 cm zone marked Caution and green colour more than 14.0 cm is considered as OK or normal.

MUAC can be used as an efficient technique for screening large population of children for malnutrition. Children thus screened, can be subjected to further anthropometric measurements and other (Clinical/biochemical) tests for specific nutritional deficiencies.

The biggest advantage of using the MUAC is that it is easy to conduct and it is age independent till about 5 years of age. A modified tape (Shakir's Tape) can be used easily even by a village health worker.

**Body Fat :** Body Fat indicates reserve of energy in the body. The quantity of fat present subcutaneously at various sites indicates the gross nutritional status of the person. The thickness of fat can be correlated to the body content of fat. Fat distribution in and around the body varies with age, sex,

physiological, nutritional and health status of the individual.

#### *Anthropometric Measurement of Body Fat : Fat fold thickness*

Anthropometric measurement of body fat can be carried out at various subcutaneous sites. These sites are commonly undertaken : Two sites on the trunk namely sub scapular and supra-iliac and three sites on the extremities namely triceps, thighs and mid calf. Biceps fat fold is also done. The fat fold thickness at triceps is the most sensitive (to socioeconomic changes) and most reliable (indicator of obesity).

Fat fold at triceps is the commonest measure. It is carried out at the dorsal side at the same mid point where MUAC is measured. The skin fold is picked up between the thumb and the forefinger 1 cm above the midpoint, taking care not to include the underlying muscle. The tips of the skin fold calipers must be applied at the mid point at a depth equal to the skin fold. The skin fold is held gently in the left hand throughout the measurement. Average of two measurements must be taken.

**Head and Chest Circumference :** Head and chest circumferences are measures used in children. A neonate is born with a bigger head. The chest grows faster than the head in a normally nourished child in the 2<sup>nd</sup> and 3<sup>rd</sup> years of life. As a result, the chest circumference overtakes the head by about 1 year of age. In a child suffering from PEM, the chest grows at a lower rate and it remains smaller than the head even till 2 ½ to 3 years of age. This indicates a poor state of nutrition.

Head and chest circumferences are measured using a fiberglass tape. Head circumference is taken at the supraorbital ridges of the frontal bone (just above the eyes) in front and the most protruding point of the occiput in the back. The chest circumference is taken at the level of the nipples in mid inspiration.

#### **Classification of Nutritional Status Based on Anthropometric Parameters**

**Weight for age :** There are standard weights laid down for a particular age. Thus a given child's weight (for his particular age), is compared to the 'standard' weight of a 'normal' child. This standard is taken as per the 50th centile of the Boston standard. The Gomez classification is one of the commonest classifications used to classify malnourishment into various grades.

$$\text{Weight for age(\%)} = \frac{\text{Weight of child}}{\text{Weight of 'normal child' of same age}} \times 100$$

The grades as per Gomez classification are given in Table - 3.

<b>Table - 3 : Gomez Classification</b>	
<b>Malnutrition grade</b>	<b>Weight/Age (%) of normal</b>
Normal	>90%
Grade I (Mild)	75 – 89 %
Grade II (Moderate)	60 – 74 %
Grade III (Severe)	< 60 %

The Indian Academy of Paediatrics (IAP) classification on the other hand puts the degree of malnutrition into four grades (Table - 4). This classification is used by the ICDS in India.

<b>Table - 4 : Indian Academy of Paediatrics (IAP) Classification</b>	
<b>Malnutrition grade</b>	<b>Weight/Age (%) of normal</b>
Normal	> 80%
I Grade	70-80%
II Grade	60-70%
III Grade	50-60%
IV Grade	<50%

**Weight for height** : The weight for height classification doesn't take age into consideration. Weight is also related to height. Many a times age is not known. Weight for height is an age independent parameter. It is a good prognostic indicator of severe PEM and an index of current nutritional status. Weight for height of less than 80% of normal is considered to indicate wasting in preschool children.

**Wasting and Stunting** : In the Waterlow classification weight for height and height for age are used to classify children as normal, wasted, stunted and wasted and stunted. Children with low weight for height are considered as wasted and those with low height are 'stunted' (Table - 5).

<b>Table - 5 : Wasting and Stunting - Waterlow classification</b>			
<b>Weight for height</b>	<b>Height for age</b>	<b>Nutritional status</b>	<b>Interpretation</b>
Normal	Normal	Normal	Normal
Low	Normal	Wasted	Acute malnutrition
Normal	Low	Stunted	Nutritional dwarf
Low	Low	Wasted and stunted	Acute on Chronic malnutrition

**Body Mass Index (BMI)** : Body Mass Index (BMI) is the ratio of weight in Kg to square of height in metre.

$$BMI = \frac{\text{Mass (Kg)}}{\text{Height (m)}^2}$$

It gives an indication of the nutritional status, esp. obesity. Now-a-days in context of lifestyle diseases, BMI is taken as an indicator of risk of cardiovascular diseases as well.

BMI does not measure the body fat but relates well with the degree of obesity. The categories of obesity as pronounced by the WHO are depicted in Table - 6. A BMI of 25-30 is considered as a warning sign and may warrant intervention, especially in the presence of additional risk factors. A BMI of 30 or higher is generally considered the point at which some form of treatment is required. Obesity Class III i.e. BMI >40 or morbid obesity, is a medical condition that impairs a person's overall health and therefore requires medical attention.

**Table-6: Grades of obesity based on BMI (WHO, 1998) (3)**

<b>BMI</b>	<b>Classification</b>	<b>Risk of co-morbidities</b>
< 18.5	Underweight	Low
18.5-24.9	Healthy/normal weight	Average
25 – 29.9	Pre-obese (Overweight)	Mildly increased
30 – 34.9	Obesity Class I	Moderate
35 – 39.9	Obesity Class II	Severe
> 40	Obesity Class III	Very severe

The guidelines have been revised and made more stringent lately for Asians, considering the fact that Asians (esp. South East Asians including Indians) are more susceptible to metabolic syndrome. These are summarized in Table - 7.

**Table - 7 : Grades of obesity for Asians (5)**

<b>BMI</b>	<b>Classification</b>	<b>Risk of co-morbidities</b>
< 18.5	Underweight	Low
18.5-23	Normal weight	Increasing but acceptable
23 – 27.5	Pre-obese	Increased
>27.5	Obese	High

### Dietary Assessment for Nutritional Status

A nutritional survey is never complete without a diet survey. We may be able to find out that there is a nutritional deficit through clinical, laboratory or anthropometric methods, but in order to find out if this nutritional deficiency is because of diet and which particular diet/nutrient, we have to invariably resort to a diet survey. It is thus an integral part of nutritional survey. A diet survey objectively defines importance of diet in various health state and disease (2). Diet survey is nothing but the scientific assessment of food consumption, and using this data for various purposes including assessment of nutritional status.

**Methods** : Various methods are there to undertake diet surveys. These are appropriate in different settings (6) and are summarized in the Box - 4.

**Box - 4 : Methods of Diet survey**

Food balance sheet method
Inventory method
Weighment method
24 hr Recall method (Questionnaire method)
Dietary score method
Food Frequency Questionnaire method
Duplicate sample (chemical analysis) method

**Diet Balance Sheet Method** : This method is used when information regarding availability and consumption of food is required at a macro level like at the global, national, region or state levels. The total food supplies available and used up at a

given level are taken into account in this method. Effectively the difference between receipt (of food various sources) and expenditure over a given period of time gives the food consumed by population. The consumption per capita/day is worked out as :

$$\frac{\text{Food consumed by population}}{\text{Mid yr pop} \times 365}$$

These figures are used for various types of planning and budgeting, namely plans for agriculture, fertilizers, productions, imports and Public Distribution System (PDS). The method has got certain demerits. It is a gross method. Secondly the consumption of rich and poor is equated and averaged out when this method is used. It gives the consumption pattern but doesn't include purchasing power of the individual.

**Inventory Method :** As mentioned earlier the inventory method is carried out at an institutional level, on a homogenous group as present in a hostel, jail, mess, army barrack, orphanage etc. It is essentially done from books. Amounts of various food stuffs available as per records are taken into consideration. The balance of various food items is again checked after a reference point of say 7 days (one week).

$$\text{Individual consumption / day} =$$

$$\frac{\text{Stocks at beginning of week} - \text{Stocks at end of week}}{\text{No. of individuals} \times \text{No. of days}}$$

The Merits are that it is fast, much easier, less cumbersome and faster than the weighment methods. It is also fairly accurate. It may not indicate an accurate individual food consumption but is fairly satisfactory for the purposes of planning.

The Demerits are that it doesn't account for wastage. Secondly, it gives only the mean individual consumption but actual individual consumption is not reflected. Thirdly, the estimates are as good as the food records made available. Lastly, the results will be affected if the subjects are eating some food stuff obtained from any source other than the common kitchen under question.

**Weighment Method :** In this method the foods are actually weighed using a grocer's balance. Both raw and cooked food are weighed. In community surveys (at a family level), the raw food is weighed rather than the cooked food, since weighing cooked food is not acceptable to the families. In an institution however, the cooked food can also be weighed, since cooking is carried out at a central kitchen. While using weighment method at a family level the following points are important :

1. Convince the housewife of the need of the survey for the benefit of the family
2. Avoid holidays/fares/festivals/feasts as the dietary practice of these days does not reflect the actual dietary practices.
3. It should be carried out for 3 to 7 days consecutively.
4. At least two visits a day for lunch and dinner have to be made.
5. Two investigators should be available - one talks and weighs and the other records observations.
6. Any pets, breast fed children, guests etc. should be considered.

**The method :** Weigh the raw food before cooking. It is preferable to weigh the food again after cooking. A conversion factor is arrived at. For example let's assume that the weight of raw rice is 100 g. The weight of cooked rice becomes 400g. Thus a conversion factor of 100/400 or  $\frac{1}{4}$  is arrived at. In other words 1 g cooked rice represents  $\frac{1}{4}$  g of raw rice. Or if a person eats 400g cooked rice it is equivalent to 100g of raw rice. The nutrient contents of raw rice are extracted from standard Food Composition Tables. The same process is employed to estimate the nutrient contents of all food preparations.

Ideally both, raw and cooked foods must be weighed. But if it is not possible to weigh the cooked foods an approximate conversion factor can be taken. Obviously this will lead to some degree of error. Another alternative is to measure the volumes of raw and cooked foods and subject them to weight conversions. In practice measuring volumes of cooked portions actually eaten by the individuals is easier than weighing the portions eaten. The volumes can be converted into weights and subsequently into nutrients, through standard tables. The merits of this method are that it accounts for the non edible parts of food as well. The wastage is also taken into account. This method is more accurate than the inventory method. The demerit is that it is a very cumbersome, time consuming and tedious process as it involves weighing of all foods.

**24 hour Recall (or Questionnaire) Method :** The 24 recall (questionnaire) method is a relatively easy method based on the recall capabilities of the individual over a period of the past 24 hours. Since it is a short term retrospective method it is more prone to errors.

A set of cups and ladles standardized for volume are used. The housewife is asked about the types of food items prepared at the time of breakfast, lunch and dinner. The raw ingredients used for cooking each meal are noted. The cups are exhibited to the housewife. The cooked food items are noted in terms of these cups. The intake of each food item by the specific individual in the family is also assessed by using these cups.

The method is fairly accurate. It take lesser time than the weighment method. However, the disadvantage is that the method is based on recall capability of the respondent so there is a likelihood of 'inaccurate recall' and error in derivation of nutrients. A fair degree of cooperation is to be sought from the respondent. The process is a cumbersome.

**Food Frequency Questionnaire (FFQ) Method :** Food frequency questionnaire (FFQ) method is based on the principle as to how frequently an item is consumed over a period of time. It is an epidemiological technique used to study the meal patterns and dietary habits of people. It can be used to assess the specific dietary intakes during pregnancy, lactation, etc. It can even be conducted through post. For example a FFQ may read "In one week how often do you consume the following items...."

Item	Frequency (Consumption Per Week)			
Meat	1	2	3	4.....
GLV	1	2	3	4.....
Sprouts	1	2	3	4.....

This filled up questionnaire is then analysed, using pre-decided values of for nutrients for different food items.



## Nutritional Surveillance

It is clear from the earlier chapters that the state of nutrition of an individual or a community depends on a variety of (unrelated) factors. These could be as diverse as the 'health' of the crops, state of rainfall, GDP per capita income, efficiency of the public distribution system, availability of food and the health state of the community.

Given this dynamic and ever changing state of availability and use of food, it is vital to keeping a constant watch over all these factors concerning nutrition, in order to continuously assess the situation, give an early warning and take appropriate decisions that will lead to improvement in the nutritional status of population. This on-going process of constant scrutiny of the nutritional situation and factors influencing them and its application in the public health interest is termed as nutritional surveillance. The word was used first in 1974 with respect to drought relief, during a World conference in nutrition. A nutrition surveillance programme was developed for the developing countries 1976. The term has been used extensively by the UNO since 1980. The process of nutritional surveillance finds the following applications :

- It provides inputs for health and development planning
- It is useful for programme management and evaluation
- It provides timely warning and intervention to prevent (short term) food consumption crisis and plan for long term action

**Steps :** The various steps of nutritional surveillance are :

- Identify community/population
- Data collection
- Data transit
- Data processing
- Interpretation
- Responses and Planning
- Improvement
- Further implementation

**Methodology of Nutritional Surveillance :** The methodology of the nutritional surveillance can be outlined through answering the following basic questions :

- What is the problem? → Define & describe the type of nutritional problem e.g. malnutrition (acute or chronic), micronutrient deficiency, etc.
- Who is at risk? → Describe the population groups affected by area, socioeconomic status, biological/physiological status, etc.
- Why is this population at risk? → Identify the causal factors. These causes could be immediate (non availability of food, poor health, etc) or of long standing nature like unequal resource distribution, poor sanitation and infections.
- Where to get the data from? → Identify the data sources. These will depend on the purpose for which surveillance has been undertaken.

Purpose of surveillance	Data source
Health and development planning	Household survey
Data from records	Programme management and evaluation
Interviews and records	Timely warning and intervention programme
Rainfall, prices, employment	Health system surveys

- Define food supply system. The food can be obtained mobilizing the existing stores, through national and international aid, improving the agricultural production, etc.
- Obtain the data, analyse and provide feedback to decision makers. Finally, evaluate the nutritional surveillance system.

## Nutritional Rehabilitation

The cases of severe malnutrition are treated in a hospital setting. Such a treatment no doubt, does make the child survive; it doesn't guarantee that he will live a life free of malnutrition and disease in future. Besides only medical, additional inputs like those of social, physical, psychological and emotional rehabilitation have to go in, if the child is to live a life of positive health.

**Principle :** More often than not it is seen that after a short spell in the hospital, once the child returns back to the original social milieu, the condition recurs. The child either dies or becomes extremely vulnerable to subsequent infections, malnutrition, disease and death. The basic principle of nutritionally rehabilitating a child is not only to treat his malnutrition and related acute complications, but to prevent a recurrence of the condition.

**Methods :** The process of rehabilitation is to be dove-tailed with treatment. It can be undertaken at three levels, depending on the severity of the condition and the facilities available.

**(a) Hospital :** The child is hospitalized in severe cases or when he has concomitant complications. Special standardized dietary regimes (intensive feeding with high proteins and energy dense diets) are required to be instituted and continued for a long time to come. Systematic education of parents in food selection and cooking has also to be imparted. The standardized dietary regimes and specific nutritional education It is initiated in the hospital but is required to be followed up either at the day care centre or at home.

**(b) Day Care Centre :** A day care facility is an intermediate arrangement between the hospital and home. Children who are not required to be admitted to a hospital or those who have been discharged from the hospital are expected to visit the day care centre. This centre may be run by a health worker who is trained in preparation of special feeds for malnourished children and who could educate the mothers on preparation of special feeds suitable to the particular child (as discussed in last paragraph). Any health facility like an anganwadi centre, sub-centre or a PHC can be used as a day care centre. The advantage of a day care centre (over hospital) is that it



is cheaper; the mother can spend the day at the centre under supervision of a trained health worker, learn sufficient skills in specialized feeding and child-craft, in an informal setting, closest to her home environment and really imbibe it.

(c) **Domiciliary** : In case the child is not severely affected, after medical consultation, he can be treated at home. He could also be one who has been weaned off a hospital or a day care set-up. To maintain health of child it is important that the mother is trained in handling the 'special' nutritional needs of this child.

## Summary

The condition of the body resulting from intake, absorption and utilization of food and the effect of pathological factors is termed as nutritional status.

Nutritional status is assessed too map out distribution and geography of nutritional disorders, identify high risk groups and to assess various epidemiological factors for responsible for nutritional deficiencies. It is also an administrative tool used to allocate budget for food materials at a large scale. The important methods are anthropometry, biochemical and laboratory methods, clinical assessment, diet survey, ecological studies, functional assessment and indirect assessment from vital statistics data.

There are clinical signs that may be 'strongly suggestive' of dietary deficiency or excess (e.g. Bitot's spots), of probable significance (e.g. corneal scar) and those that are of no nutritional significance (e.g. pterygium). Clinical signs might develop rather late and are subjective and non specific.

Biochemical tests on the other hand give objective and quantitative indication of nutritional status, but these are costly and instrument intensive.

Anthropometry remains the sheet anchor of nutritional assessment. Weight, height, head and chest circumference, MUAC and fat fold thickness are the common anthropometric parameters used. Many derived parameters like the BMI, weight for age, weight for height, etc are also used in different situations.

Various methods of diet survey are used to ascertain as to what an individual or a group of people are eating. This indicates the deficiency of nutrients in the diet and thus appropriate measures can be suggested to improve it. The main methods Food balance sheet method are inventory method, weighment method, 24 hour recall method (Questionnaire method), dietary score method, food frequency questionnaire method and duplicate sample (chemical analysis) method. The inventory method, weighment method and 24 hour recall method are the most commonly used dietary survey methods.

Nutritional Surveillance is an on-going process to keep a constant watch over all the nutrition related factors, in order to continuously assess the situation, give an early warning and take appropriate actions.

Nutritional Rehabilitation aims at re-establishing the severely malnourished child medically, nutritionally and psychologically into the family and society. The aim is to prevent a recurrence

of acute malnourishment. This can be achieved through appropriate measures begun at the hospital. Subsequently the child may be managed at a day care centre or at home.

## Study Exercises

**Long Questions** : (1) Enumerate the various methods for nutritional assessment. Describe any one in detail. (2) What is nutritional surveillance? Outline the methodology of nutritional surveillance. (3) What are the various anthropometric techniques available to assess nutritional status of a 5 year old child? How can weight for age be useful to ascertain malnutrition in this child?

**Short Notes** : (1) Mid Upper Arm Circumference (2) 24 hour recall method (3) FFQ (4) Using BMI to assess CED in adults (5) Disadvantages of using clinical signs for nutritional status assessment

## MCQs

- All can indicate nutritional status except : (a) Fall in weight (b) Falling hair (c) Failure to gain height (d) Flag sign
- All are signs of PEM except (a) Flag sign (b) Unilateral pedal edema (c) Low weight for age (d) Dermatoses
- Stunting is \_\_\_\_\_ weight for height but \_\_\_\_\_ height for age : (a) Normal; Low (b) Low; Normal (c) Low; Low (d) High; low
- Acute malnutrition may be indicated by : (a) Stunting (b) Wasting (c) Stunting and wasting (d) All of the above
- Which of these is not true for nutritional surveillance : (a) It is an ongoing process (b) It can be used as a nutritional survey technique (c) It is a close scrutiny of events related to nutritional changes (d) It provides timely warning for action

Match the following

Age		Suitable anthropometric measure	
6.	New born	(a)	MUAC
7.	3 years	(b)	Weight
8.	42 years	(c)	BMI
9.	8 years	(d)	Head & chest circumference
10.	1 ½ years	(e)	Weight for age

**Answers** : (1) b; (2) b; (3) a; (4) b; (5) b; (6) b; (7) a; (8) c; (9) e; (10) d.

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### Food Processing

*Food processing* is the technique used to transform raw ingredients into food or to transform food into other forms for consumption. It can be done either at home or by the food processing industry.

**Aim of Food Processing** : Food processing is aimed at improving the colour, appearance, palatability, taste, texture, keeping quality and marketability of food. Food processing makes the food attractive and many a times makes it a long-life food product. Foods used in certain special situations can not be used without processing. Some of these situations can be space travel, high altitude expeditions, disaster aid situations, combat missions by soldiers, etc. Some common food processing techniques are enumerated in Box-1.

Processing helps to remove toxins, eases marketing and distribution of foods. In addition, it increases seasonal availability of many foods, enables transportation of delicate perishable foods across long distances and makes many kinds of foods safe to eat by de-activating spoilage and pathogenic micro-organisms. Food processing techniques are also used to add extra nutrients such as minerals and vitamins to food preparations.

**Disadvantages of Food Processing** : Food processing can sometimes lower the nutritional value of foods. Some vitamins are very sensitive to heat and are lost on cooking (e.g. vitamin C). Some water soluble vitamins can be lost on washing with water. Food additives such as colours, flavouring agents and preservatives, used while processing the foods, may be unhealthy. Some are known to be allergic or even carcinogenic. Processed foods (like junk foods) often have a higher ratio of calories to other essential nutrients than unprocessed foods, and may provide empty calories. Processing also increases the prices of food products.

### Food Additives

The concept of adding “non-food” substances to food products is not new. Pickling preserves the food articles such as mango, lime etc. for fairly long periods by the addition of salt and spices. Salt and spices were the traditionally used food additives. These can be considered as natural additives.

With industrialization, increasing demand of ‘ready to eat food’ and use of modern techniques, the food processing industry is relying heavily on chemical additives. The food additives improve taste, flavour, texture and colour. They also help increase the shelf-life of food. Now a days majority of the processed foods contain some food additive or the other. Some commonly used food additives are enumerated in Box - 2.

#### Box - 1: Some Common Food Processing Techniques

Peeling and skinning (fruits and vegetables)
Mincing (meat)
Liquefaction (fruit juice)
Fermentation (Soy, beer, cocoa)
Baking (cakes, pastries, bread)
Sprouting (cereals, pulses)
Steaming (rice)
Boiling (vegetables)
Carbonation (beer, soft drinks)
Packaging (most commercial foods)
Canning (juices, fruits, fish)
Sauce and ketchups (tomato)
Brewing (tea)
Chopping or slicing (vegetables)
Pureeing (vegetables and fruits)
Pickling (vegetables)
Emulsification
Cooking (most foods)
Frying (French fries, <i>pakorries</i> )
Grilling (chicken)
Pasteurization (milk)
Spray drying (milk powder)
Dehydration (fish, vegetables, soup powders)
Jam and jelly (fruit, vegetables)
Wines and ciders
Freeze drying (meat)

#### Box - 2 : Some Commonly Used Food Additives (Emulsifiers, Stabilizers, Thickeners and Gelling Agents) \* (1)

Name	Food
Lecithins	Chocolates, margarine, potato snacks
Citric Acid	Pickles, dairy products, baked products
Tartaric Acids	Baking powder
Alginic Acid	Ice creams, desserts
Agar	Ice cream, soups, tinned ham
Gums	Ice creams, soups, confectionery
Pectin	Jellies

\* A list of antioxidants and preservatives is given in the next section

**Definition** : Food additives are the non-nutritious substances added intentionally to food, generally in small quantity, to improve the basic properties of food like its appearance, flavour, texture etc.

Food additives can be classified into the following two broad categories :

**1. Additives deliberately added to food**

- a) Colouring agents e.g. saffron, turmeric.
- b) Flavouring agents e.g. vanilla essence
- c) Sweeteners e.g. saccharin, cyclamate
- d) Preservatives e.g. sorbic acid, sodium benzoate (details given in next section)
- e) Acidity imparting agents e.g. acetic acid etc.
- f) Thickening Agents e.g. alginate (from seaweed) and casein used in ice creams, cheese, yogurt etc.
- g) Emulsifiers: Keep water and oil mixed together. e.g. lecithin, monoglycerides and diglycerides are used in margarine, baked goods and ice cream.
- h) Anti-Oxidants : Prevent spoilage, flavor changes, and loss of color caused by exposure to air e.g. Vitamin C and Vitamin E.

These are generally considered safe for human consumption. However, certain preservatives such as nitrites and nitrates can lead to the production of toxic substances, e.g. nitrosamines that have been implicated in cancer etiology.

**2. Contaminants** : They get incorporated incidentally through packing, processing, farming practices (insecticides) or other environmental contaminants.

**Provisions of Law Applicable to Food Additives** : The use of food additives is subjected to government regulations throughout the world. In India two regulations viz. the Prevention of Food Adulteration Act (PFA Act) and the Food Products Order are in vogue. The PFA Act has been discussed separately. Use of food additives that are not permitted by law is considered to be an adulterant. In case the quantity of the food additive exceeds the permissible limit then also the food is considered adulterated. It is also required by law that the nature and quantity of the additive shall be clearly printed on the label that is affixed to the container. Whenever any extraneous colouring agent is added to a food article, the words 'Artificially Coloured' shall be printed on the label.

At the international level, FAO/WHO have established the Codex Alimentarius Commission as its principal organ. Protection of the health of consumers is the primary aim of this commission.

**Food Preservatives**

It is not possible to consume food immediately on production as we don't have access to farm fresh food all the time. If we can't consume the food quick enough, the food tends to get spoilt. As soon as a food is harvested or cooked, the process of food spoilage sets in. The enzymes and other chemicals (e.g. acids and alcohols) present in foods initiate the process of deterioration. Micro-organisms (bacteria and fungi) are the prime agents that cause spoilage under suitable conditions. Environmental factors like heat and humidity enhance the process of spoilage. Once spoilt the food no more remains fit for consumption and may lose its original nutritive properties as well. Preserving food therefore becomes imperative. Preservation is undertaken with the following aims:

- a) Increasing the keeping quality of food
- b) Preserving its nutritional characteristics

c) Preserving the appearance, colour and texture of food

**Methods of Food Preservation** : Preservatives are centuries old. Since ancient times, salt has been used to make pickles, cure meats and fish. Sugar has also been added to fruits to conserve them. Herbs, spices and vinegar have also served as preservatives for centuries. These early preservatives (sugar and salt) produce food environments of high osmotic pressure that deny bacteria the conditions needed by them to propagate. Jams and jellies are preserved as solutions of high sugar content.

The Modern Day Preservatives could either be natural or synthetic.

**Natural Food Preservation** : As discussed earlier salt and sugar are the commonest natural preservatives. Another group of natural preservatives target enzymes in fruits and vegetables that continue to metabolize even after they are cut. For instance lemon juice contains citric and ascorbic acids which inhibit the action of enzyme phenolase that turns cut surfaces of apples and potatoes brown.

**Anti-Oxidants** : Anti-Oxidants not only preserve foods through preventing spoilage but also limit flavour changes and loss of colour caused by exposure to air. Vitamin C and Vitamin E are used as antioxidants. Other antioxidant preservatives are compounds like BHA (Butylated Hydroxyanisole).

**Anti-microbial Preservatives** : Anti-microbial preservatives inhibit the growth of microbes. Benzoic acid, sulfur dioxide and ethanol have long been used as preservatives. Other common anti-microbial preservatives are calcium propionate, sodium nitrate, sodium nitrite, sulphites, sulphur di-oxide, sodium bisulphite, potassium hydrogen sulphite, disodium EDTA.

**Microbes as preservatives** : All microorganisms are not harmful. Some microbes are responsible for the production and preservation of certain foods. Microbial action is a part of the production of cheese and flavouring agents. Sauerkraut is both processed and preserved by lactobacilli. Yeast cells ferment sugars, producing alcohol and help to preserve them.

**Irradiation**: Food irradiation using radioactive rays or high-intensity X-rays or streams of electrons is a modern method of food preservation. It has the advantage of preserving food while in their packets. There is minimal person-to-food contact reducing the possibility of contamination. Food is not required to be exposed to chemical preservatives which may be harmful. Irradiation extends the shelf lives of foods such as strawberries, potatoes, onions, grains, etc. Irradiation does not make foods radioactive, but may cause changes in food colour or texture.

Some commonly used food chemical preservatives are enumerated in Box - 3.

**Health Concerns on Food Preservatives** : There have been health concerns with many chemical additives like colouring and flavouring agents. Preservatives are also not untouched with these fears. Some modern synthetic preservatives have become controversial because they have been shown to cause respiratory or other health problems. Sulfur dioxide (often used to preserve wines) is irritating to the bronchial tubes of persons who have asthma, and nitrites have been implicated as carcinogens. Some preservatives are known to cause allergic reactions including anaphylactoid reactions.

<b>Box - 3 : Commonly Used Food Preservatives (1)</b>	
<b>Preservative</b>	<b>Food</b>
<b>Antioxidants</b>	
Ascorbic acid	Beer, soft drinks, fruits, meat, powdered milk
Tocopherols	Vegetable oils
Gallates	Vegetable oils, fats, margarine
BHA and BHT	Fats, margarine in baked products
<b>Other Preservatives</b>	
Sorbic Acid	Cheese, yogurt, soft drinks
Acetic Acid	Pickles, sauce
Lactic Acid	Sauce, confectionery
Propionic acid	Bread, cakes, flour
Benzoic Acid	Soft drink, pickles, fruit products, jams
Sulphur dioxide	Soft drinks, fruit products, beer, cider, wine
Nitrites	Cured meats, cooked meats and meat products
Nitrates	Meat products, cheese

### Food Fortification

Food Fortification is the process by which a nutrient is added to commonly eaten foods to improve the quality of the food. WHO has defined food fortification as “the process whereby nutrients are added to foods in relatively small quantities to maintain or improve the quality of diet of a group, a community, or a population.” Fortification is the addition of nutrients at levels higher than those found in the original or in comparable foods. The food that carries the nutrient is referred to as the *food vehicle*; and the nutrient added is the *fortificant*.

Fortification of food is a public health measure aimed at reinforcing the usual dietary intake of nutrients with additional supplies to prevent/control some nutritional disorders. A food fortification program is usually undertaken when there is a widespread and consistent nutritional deficit in the population's diet. Food fortification has been commonly used as a method to control micronutrient deficiencies.

The term *food enrichment* is used for replacing nutrients lost in processing. It occurs with grains, as some vitamins and minerals are lost in the milling process.

**The Need for Fortification** : One of every four people in the world suffers from micronutrient deficiencies. Globally, the key micronutrient deficiencies are that of iodine, vitamin A and iron. These vitamins and minerals are referred to as micronutrients because the body needs them in minute quantities for normal growth and development. All these major micronutrient deficiencies can be overcome at a community level by the simple process of fortification. Some of the fortification programmes of demonstrated effectiveness are: iodization of salt for combating endemic goitre, fortification of vanaspathi ghee, butter and milk with vitamins A and D and fluoridation of water to prevent dental caries. Recently, technology has

been developed at the National Institute of India, Hyderabad in India for the twin fortification of salt with iodine and iron. Some initiatives taken by the Government of India on food fortification are given in Box - 4.

<b>Box - 4 : Some Facts on Fortification - Initiatives by the Government of India</b>
<b>Wheat flour (atta)</b> : In February 1970, the Government of India launched a programme in Bombay for fortification of atta with vitamins and minerals, and for increasing the protein content by admixture with edible groundnut flour.
<b>Edible oils</b> : Fortification of Vanaspathi (hydrogenated oil) with vitamin A has been made compulsory (2,500 IU of vitamin A and 175 IU, vitamin D per 100 g of Vanaspathi) by the Government of India.
<b>Common salt</b> : Under the PFA act common salt has to be fortified with iodine (commonly potassium iodate) in a dose of 30 ppm at production site and 15 ppm at consumer end.

**Choosing a Food Vehicle and a Fortificant** : While choosing an ideal food vehicle the following aspects are considered:

- The food should be consumed by all population groups that is at risk of the particular nutritional deficiency.
- The food should be used regularly and in consistent amounts by the entire population at risk.
- Taste, appearance and smell of the food should not change after fortification.
- The fortificant should remain stable under extreme conditions such as cooking, food processing, delivery and storage.
- The food should not be consumed in amounts that would present a risk of consumption at toxic levels of the fortificant.
- The food should not increase the cost of food.

### Benefits of Food Fortification

- It effectively prevents major micronutrient deficiencies at a small cost.
- Fortification does not require change in the dietary habits of the population.
- It can be implemented relatively quickly and can be sustained over a long period of time.
- It being a population based approach, benefits all.
- It is a very cost-effective approach.

### Food Adulteration and the Prevention of Food Adulteration Act (PFA)

Food is a substance consumed for eating or drinking (except for water and drugs). Unscrupulous traders use the practice of adulteration for their ulterior motives. Any material which could be used for adulteration is called as an adulterant. Commonly it is believed that adding a substandard stuff to food (e.g. water to milk) is adulteration, but as per the law the word adulteration has a much wider connotation.

The Prevention of Food Adulteration (PFA) Act was enacted by the parliament in 1954. The PFA Rules were framed by an expert body called the ‘Central Committee for Food Standards’ in 1955. Various amendments have been made in the act since then.



**Objective :** The PFA Act was enacted with the main objectives of :

- Ensuring pure & wholesome food
- Protecting against fraudulent & deceptive trade practices

### Adulteration

An article is deemed adulterated if 'it is not of the nature, substance or quality as demanded by the purchaser; if the food contains other substances that affect injuriously the nature, substance or quality of food; if the food is substituted by an inferior or cheaper substance; or if any constituent of the food has been abstracted; or if it contains any poisonous ingredient, the food is said to be adulterated' (PFA Act). Some common food adulterants are enumerated in Box - 5.

<b>Box - 5 : Some Common Food Adulterants</b>	
<b>Food Item</b>	<b>Adulterant</b>
Cereals	Mud, grit
Dal	Kesari dal, dyes
Dhania	Horse dung
Black pepper	Papaya seeds
Chilli	Brick powder
Tea	Gram husk
Milk	Water
Mustard seeds	Prickly poppy seeds
Sweets	Non permitted colours
Ghee	Vanaspati

As per the PFA Act the following acts amount to adulteration of food:

- If any article has been prepared, packed or kept under unsanitary conditions whereby it has become contaminated or injurious.
- If the article is filthy, putrid, rotten, decomposed or from a diseased animal or vegetables; or is insect infested or is otherwise unfit for human consumption.
- It is obtained from a diseased animal.
- Contains a non prescribed colouring matter or preservative.
- The mal-practices like mixing, substitution, concealing the quality, misbranding, selling decomposed food, adding toxicants, extracting food material or giving false labels also amount to adulteration.

**Process :** Whenever an instance of food adulteration comes to the notice, a food sample is collected from the site. The sample can be collected by a government functionary like the food inspector or even by the consumer (1986 amendment). The consumer/purchaser can get food analyzed, provided the vendor is informed of this intent and the purchaser pays fees to the designated laboratory to carry out the analysis.

**Sample collection, disposal and analysis :** The food inspector expresses his intent of collecting the sample and getting it analyzed under the PFA Act to the vendor in advance. The cost of food item (sample) is paid to the vendor. The signatures of

the shopkeeper / vendor are taken. In case the shopkeeper/ vendor refuses to put his signature, an independent witness is made to sign. In case the witness also refuses to sign, the food inspector endorses a certificate to this effect. The sample is divided into three parts, they are packed and sealed. The sample number one is submitted to public analyst under intimation to the local health authority (The local health authority is an officer appointed by the government through a gazette notification to be the in charge of health administration, in a given area. Generally this responsibility lies with the municipal/cantonment health administrators). The 2nd and 3rd samples are kept as reserve samples and are deposited with the local health authority for safe custody. Sample analysis is carried out by the local government public analyst. The report is submitted to the local health authority. In case the sample is found to be adulterated suitable action is taken by the court of law. The vendor can apply to the court, within 10 days to get the reserve sample, kept in the custody of the local health authority, analyzed at the relevant Central Food Laboratory, for confirmation. For the purpose of this reconfirmation four reference laboratories have been established and notified by the government of India. These labs have been allocated a zone of responsibility and certain predefined regions/states/ union territories are dependent on them. These laboratories are located at Mysore, Kolkata, Pune and Ghaziabad (Box - 6).

<b>Box - 6 : Central Food Laboratories (CFL) and States Dependent on them</b>	
<b>Central Food Laboratory</b>	<b>Dependent states</b>
Mysore	Gujarat, Himachal Pradesh, Haryana, Punjab, UP, Maharashtra
Kolkata	North Eastern states, Orissa, Andaman & Nicobar
Pune	AP, Delhi, J&K, Karnataka, Kerala, Rajasthan, Tamil Nadu
Ghaziabad	Bihar, Goa, MP, West Bengal

**Punishment :** Following the hearing, the court awards a sentence to the guilty. A minimum imprisonment of 6 month to a maximum of life imprisonment (in cases of grievous hurt or death) can be awarded. The court may also impose a fine of Rs 1000 to Rs 5000.

### Food Toxicants

Even today there is always a lurking fear that some antisocial elements might poison a source of water. While such acts are deliberate, a toxic or poisonous substance might be present as an integral component of a foodstuff. In a small dose it may not have any significant toxic effect, but in a larger dose or when consumed over a prolonged period it may even be fatal. Many possible toxic effects of foods are known. Table - 1 indicates the great variety of ill effects that natural food poisons might have.

**Table - 1 : Some Possible Toxic Effects of Common Foods (2)**

Food stuff	Active toxic ingredient	Effects on
Some bananas	5-Hydroxytryptamine, adrenaline, noradrenalin	Central or and Peripheral nervous systems
Some types of cheese	Tyramine	Blood Pressure
Almond, cassava	Cyanide	Tissue respiration
Some fish/meat	Nitrosamines	Cancers
Mustard oil adulterated with argemone oil	Sanguinarine	Epidemic dropsy
<i>Kesari dal</i> (Lathyrus)	Beta Oxalyl Amino Alanine and others	Neurolathyrism
<i>Brassica</i> species (seeds)	Glucosinolates, thiocyanate	Goitre
Green potato	Solanine	Gastrointestinal upset
Mushrooms ( <i>A muscaria</i> , <i>A phalloides</i> )	Various toxins	CNS effects
Groundnuts	Aflatoxin	Aflatoxicosis

### Lathyrus Toxin

The ancient Indian text '*Bhava Prakasham*' describes the *Kesari dal* and neurolathyrism. Hippocrates has also described it in the pre-Christian era. Lathyrus and related pulses ('tares') were poorly regarded even in the Biblical times, as is clear from a quote from the Bible.

Cantani coined the term lathyrism in Italy. In India too *Lathyrus sativus* is deliberately sown with wheat in the dry districts. If the rains are good, wheat overgrows the lathyrus (and it is not harvested), but if rain fails and there is poor crop of wheat, a reasonable crop of lathyrus is reaped. Lathyrus is a tasty and high protein pulse. If eaten in small quantities it probably does not cause toxicity. If consumed in larger amounts (providing more than 50% of energy) a severe disease of the nervous system may result, leading to spastic paralysis. Some landlords (*zamindars*) used to pay their labourers in kind, the form of *Kesari dal* and not in cash. In this situation *Kesari dal* used to become the staple diet for these poor people and a cause of neurolathyrism. Neurolathyrism is a crippling disease of the nervous system characterized by gradually developing spastic paralysis in lower limbs, occurring mostly in those consuming a pulse, *Lathyrus sativus* in large quantities. In animals a variant of the disease i.e. osteolathyrism affecting skeletal system is seen.

The disease is seen in some European, African and Asian countries. Cases are reported from Spain, Algeria, Ethiopia, Mexico, Afghanistan and India. In India it is seen in some districts of Madhya Pradesh, Maharashtra, UP, Bihar, Rajasthan, Assam and Gujarat. Old literature reports thousands of cases

of Neurolathyrism occurring in epidemic proportions in some given regions, but now no outbreaks are reported, only sporadic cases occur in certain areas.

**Lathyrus Sativus (Kesari dal)** : *Lathyrus sativus* is also referred to as *Teora dal*, *Lak dal*, *Batra*, *Matra*, etc. It looks like *Arhar dal* (*toor dal*) red gram or bengal gram. However its seeds are triangular in shape and greyish in colour. It is cheaper and a rich source of protein.

In 1962 a neurotoxin,  $\beta$ -N-Oxalyl Amino-L-Alanine (BOAA) was isolated from the common vetch (*Vicia Sativa*), which frequently grows as a weed in *Lathyrus sativus*. In 1963, another toxin  $\beta$ -N-oxalyl-L- $\alpha,\beta$  di-aminopropionic acid was isolated from the seeds of *Lathyrus sativus*. Both of these can cause neurological lesions in primates. These toxins are neuro-exitants and can be removed by soaking in hot water and rejecting it.

**Clinical Features** : If more than 30% energy is obtained from *Kesari dal* for more than six months, the signs and symptoms may appear in the form of spastic paralysis. The condition is known as Lathyrism. It is most commonly seen in men in the age group 15-45 years. The onset of Lathyrism is sudden, often preceded by exertion or exposure to cold. A patient may find himself paralyzed on getting up in the morning. Sometimes backache and stiffness of legs precede the paralysis of legs. The condition is spastic paralysis of lower limb.

The underlying pathology is the toxin induced degeneration of spinal motor tracts (pyramidal tracts) and sclerosis. The motor nerves to muscles of trunk, upper limbs and sphincter are spared. The sensory system is also not involved.

The patient may pass through progressive stages of severity. In the latent stage the patient may be apparently healthy. In the mild stage there is stiffness and weakness of legs, exaggerated knee and ankle jerks and clonus may follow. As the disease progresses the gait may be affected and the patient walks with bent knees on tiptoe. The legs may become crossed and patient may develop scissor gait. The patient may be able to walk only with one stick and later with two sticks. Later on when paraplegia develops, walking may become impossible. Later the patient has to support his body on his hands, buttocks and heels for moving about (crawling stage). In the most severe stage patient can only move on 'all fours', supported by his hands. Many patients might be left with no other alternative but to resort to beggary.

**Detection of Toxin** : The toxin can be detected through laboratory methods using the ninhydrin reaction, which gives a purple colour. Electrophoresis and biological methods (bioassay in animals) can also be used.

**Prevention** : The condition is preventable if pulse is removed from diet, at the earliest. Use of the legislation of Prevention of Food Adulteration act to limit the consumption of crop must be encouraged. In case the crop has to be consumed, the toxin can be removed by steeping. At the household level, steeping can be done by soaking the pulse in hot water for 2 hours. Water is then drained and pulse is dried in sun. The disadvantage of using this method is that the taste and nutrients are lost to an extent. At a large scale, parboiling can be done. The process is the same as used for parboiling rice. Soaking the pulse overnight in lime water and subsequently boiling or cooking it

also helps in removing the toxin.

High dose vitamin C (1000 mg/day) prophylaxis for few weeks is also found to be useful. Nutritional education in the form of abstaining from the use of crop or using it in the manner prescribed above would be useful in preventing the consumption of toxic crops. Bringing about social changes in the form of improving the socioeconomic status would also help people not to fall prey to the toxic dal.

### Aflatoxicosis

The first known outbreak of Aflatoxicosis probably occurred in England in 1960, among young turkeys. Turkeys fed on infested groundnut meal had hepatitis and enteritis. The groundnuts concerned were harvested, stored and processed in high humidity conditions. The toxic effects were produced by a fungus *Aspergillus flavus*, a mould contaminating the nuts. Human cases have not been rare since then.

**Causative Agent :** *Aspergillus flavus* or another species *Aspergillus parasiticus* are storage fungi that affects foods in poor storage conditions of high temperature (30-37°C) and high humidity, as is common in the rainy season and during floods and cyclones.

**Foods Infested :** The fungus infests improperly stored foods like maize, groundnut, soya, sorghum, rice, wheat, sunflower, tree nuts, spices and even milk and cheese.

**Toxins :** Brightly fluorescing furanocoumarin compounds known as the 'aflatoxins' are known to be responsible for the condition. *Aflatoxin B1* is the most potent known natural hepatocarcinogen. Another toxin *Aflatoxin G1* is also known. They are known to cause hepatitis (jaundice), ascitis, portal hypertension, liver cirrhosis and hepatocellular carcinoma.

### Ergotism

While aflatoxicosis is a storage fungus, *Claviceps fusiformis* and *Claviceps purpurea* are field fungi. Crops get infested in flowering or seeding stages. *Bajra*, rice, sorghum, wheat and *rye* get commonly affected. Ergotamine is the toxin responsible for the clinical symptoms of nausea, vomiting, abdominal cramps, muscular cramps, giddiness, burning, itching and gangrene of digits and limbs.

Epidemics of aflatoxicosis were known as St. Anthony's fire in France in the 11th century. The disease was referred to as 'fire' because of the intolerable burning pain in the limbs, which became black and shriveled (gangrenous) and eventually dropped off. The legend also goes to say that the condition used to improve when the patients visited the St Anthony's shrine located a distance away. The patients probably improved because of the discontinuation of consumption of ergot affected cereals, as they shifted to the new location (of the shrine).

Epidemics were common in many European countries like Germany, Poland, England and Russia till the late eighteenth century, when it was related to the consumption of fungus (*Claviceps purpurea*) infested rye. Besides the symptoms enumerated above, convulsions, palsies and discordant movements were also known, indicating the affliction of the nervous system. The *Claviceps fusiformis* infestation of *bajra* in India is a milder clinical entity as compared to the more severe classical European variant described above. This fungus

produces alkaloids of the clavine group that has milder toxicity than ergotamine. *Claviceps fusiformis* infestation leads to nausea, vomiting, abdominal cramps and drowsiness. The recovery is usually complete.

### Fusarium

*Fusarium incarnatum* is another field fungus affecting crops like sorghum, rice and maize. It is seen in the subtropical and temperate regions. The fungus produces toxins like deoxynivalenol and fumonisin which are responsible for certain clinical symptoms like vomiting and diarrhoea. The episodes of mouldy ragi poisoning in India (1929) and Alimentary Toxic Aleukia (haemorrhagic rash, bleeding nose, leucopenia) seen in Russia during the Second World War were due to fusarium.

**Detection of Mycotoxins :** Many sophisticated methods are available for the detection of Mycotoxins. Thin Layer Chromatography (TLC), Radio-immuno Assay (RIA) and ELISA tests are available. Several rapid kits are also available for detection of aflatoxicosis, etc.

**Prevention :** Four broad groups of steps should be taken (3):

1. **Plant Breeding :** Cultivating varieties of *rye*, *bajra*, millets, and wheat resistant to disease (ergotism) can radically minimize the problem.

2. **Good agricultural practices during pre and post harvest period :** Good pre-harvest agricultural practices like avoiding water stress, minimizing insect infestation, are effective in reducing aflatoxin contamination in groundnuts and maize. Good post harvest and storage conditions for grains and nuts are also of paramount importance. These foods must be stored under ideal humidity and temperature conditions. Appropriate drying, storage and reducing the chances of moisture entry in the stores also limit the probability of contamination with storage fungi. If contamination does occur the infested grains can be removed using the floatation method in which the grain is allowed to float in 20% salt water. The infested grains float and can be easily removed. Air floatation and hand picking techniques can also be used.

3. **Detoxification :** Ammonia process is being used to detoxify aflatoxin affected groundnuts and remove the mycotoxin. The detoxified product is available only for animal feeds and is not suitable for human consumption.

4. **Health Education:** The community must be educated about the ill effects of the conditions and the importance of the preventive measures described above.

### Epidemic Dropsy

Several cases of epidemic dropsy were reported from many states of India as recently as in the year 1996. Similar outbreaks have been occurring off and on in the past as well. It was discovered by Indian scientists in the early twentieth century that the condition is attributable to contamination of mustard oil with argemone oil. Subsequently the toxic alkaloid sanguinarine was isolated from argemone oil and was chemically analysed. It was also determined that sanguinarine interferes with the oxidation of pyruvic acid, which is responsible for the dropsy.

The Prickly poppy plant grows indiscriminately and wild in India. It has large prickly leaves and bright yellow flowers (some species have white flowers as well). *Argemone mexicana*

is the species most commonly incriminated. The argemone seeds closely resemble mustard seeds. They mature with the mustard crop and may be harvested together. Argemone seeds (or oil) can be mixed with mustard to deliberately adulterate it. The contamination may sometimes be accidental.

**Clinical Features :** As the name suggests, the patient gets generalized swelling manifested as bilateral pedal edema of sudden onset. Patient may get diarrhoea. In advanced stage patient gets dyspnoea and signs of congestive cardiac failure (CCF). If not treated death may ensue. A mortality rate of 5 to 50% has been reported.

#### Detection of Toxin :

**(a) Nitric Acid test:** When nitric acid is added to a sample of oil, a brown orange colour emerges, indicating the presence of argemone oil. The sensitivity of this test is low. It is positive only if at least 0.25% of argemone oil is present in the sample.

**(b) Paper chromatography:** Paper chromatography is a test with much higher sensitivity, detecting argemone oil even at 0.0001%.

**Prevention :** The growth of argemone plant must be discouraged and the plants must be weeded out. Unscrupulous traders deliberately adulterating argemone oil to mustard oil must be tried under the PFA Act. Early detection and institution of control measures must be encouraged to limit the severity and further spread of morbidity. Educating and making the public aware of the problem and likely solutions will also go a long way in preventing the condition.

### Summary

Food processing is the technique used to transform raw ingredients into food or to transform food into other forms for consumption. The basic aims of food processing are to improve the colour, appearance, palatability, taste, texture and keeping quality of food. Food processing includes various techniques like pickling, fermentation, baking, Pasteurization and canning. Loss of nutrients (in some cases) could be a major disadvantage of food poisoning.

Food additives are the non-nutritious substances added intentionally to food, generally in small quantity, to improve the basic properties of food like its appearance, flavour, texture, etc. Almost all processed foods contain food additives.

Food preservatives are used to increasing the keeping quality, preserving the nutritional characteristics, appearance, colour and texture of food. There are few natural food preservatives known. The synthetic ones include certain preservatives like antioxidants and other chemicals.

Food Fortification is the process whereby nutrients are added to foods in relatively small quantities to maintain or improve the quality of diet of a group, a community, or a population. Addition of iodine to salt is the most well known example of fortification.

### Study Exercises

**Long Question :** What is the role of the PFA Act? Describe as to how a food sample can be obtained from a shop and how is it dispatched.

**Short Notes :** (1) Fortificant (2) Neurolathyrism (3) Common mycotoxins (4) Epidemic dropsy (5) Aims of food processing

#### MCQs

1. Vanilla essence is a food : (a) Additive (b) Fortificant (c) Supplement (d) Toxicant
2. Which of the following is not a mycotoxin : (a) Aflatoxin (b) Sanguinarine (c) Deoxynivalenol (d) Fumonisin
3. PFA Act was enacted in the year : (a) 1950 (b) 1954 (c) 1962 (d) 1986
4. \_\_\_\_\_ can take a food sample under the PFA act : (a) Consumer (b) Health inspector (c) Anyone authorized under the gazette (d) Any of the above
5. \_\_\_\_\_ are not to be used for preservation of foods : (a) Irradiation (b) Bacteria (c) Antibiotics (d) Antioxidants

#### Match the following

Food item	Role
6. Papaya seeds	(a) Flavouring agent
7. Sanguinarine	(b) Adulterant
8. MSG	(c) Fortificant
9. Salt	(d) Toxicant
10. Iodine	(e) Vehicle

**Answers :** (1) a; (2) b; (3) b; (4) d; (5) c; (6) b; (7) d; (8) a; (9) e; (10) c.

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There might be certain situations wherein nutrition assumes special importance and has to be catered for in a different manner. The resources required may be different and those available may be limited, in that given situation. There may be many such states; few selected important situations are discussed in this chapter.

### Nutrition during Disaster Situations

History is replete with the instances of disasters and their inevitable implications on human nutrition. May it be the Bengal or the Irish famines (in which millions died of starvation) or even a prolonged military conflict, it is the common population that suffers the most and starves in extreme cases.

Unfortunately the epidemiology of the nutritional consequences of a disaster unfolds in a pathetic manner. Irish famine can be taken as a typical example (See Box - 1).

#### **Box - 1: A Peep into the Genesis of Nutritional Problems in a Disaster through the Irish Famine**

It was an unassuming fungal disease, the potato blight, which initiated the Irish famine, as "potato rotted in the ground, there was horrible stench all over", the poor farmers lost all and they had no money to buy food. They became idle and unemployed and out of work, since they subsisted only on the potato crop! Sanitation suffered and diseases like dysentery, diarrhoea and Scurvy took on. Cholera epidemics were a common place. Due to extreme cold and wet winter of 1846, and hardly any money to buy warm clothing, typhus and relapsing fever ("Famine fever"), compounded the problems. Starvation followed and millions died. They tried to migrate to the New World - America, but many died enroute in the ships, some overloaded ships sank killing scores of people on board. Those who reached were too rickety and miserable to work even in America...

Any disaster as such, leads to scarcity of food but other inevitable consequences of disaster lead to disease prone conditions like overcrowding, poor sanitation, natural vagaries, lack of water, and lack of health care. These multiple factors in turn, worsen the scarcity of food and malnutrition. Starvation and epidemics force people out of the town displacing them. There is panic and social disruption. People become helpless and may die in large numbers. They might have to be moved to relief camps, which too are not problem free.

#### **Importance of Nutrition in Disaster**

Nutrition assumes extreme importance in a disaster situation as food is a primary requirement for sustenance of life. Nothing depletes human morale more than the non availability of food. Micronutrient deficiency is a reality in the absence of food,

and so is death. Starvation and malnourishment are common. Malnutrition leads to infection esp. in children and this vicious cycle is deadly.

The effect of disaster is not the same on everyone. Vulnerability of people to disaster depend on the severity and duration of disaster, degree of preexisting poverty, failure of the population to get timely food, aid, work and wages. In case the prevailing disaster conditions like conflicts continue, the recovery can not be expected to occur. The physiological groups most vulnerable to the consequences of disaster in general and poor nutrition in particular are the young children, pregnant and lactating women, the sick, disabled, and the elderly.

The requirement of food during disaster depends on the number and age distribution of people, their mean heights and weights, physical activity levels, environmental temperatures and the malnutrition and (ill) health status (1,2). The energy requirements for disaster situation is summarised in Table - 1.

**Table - 1 : Energy requirements for disaster situation (2)**

Group	Age	Male (Kcal)	Female (Kcal)	Combined (Kcal)
Under 5s	0-4	1320	1250	1290
Children	5-9	1980	1730	1860
Adolescents	10-14	2370	2040	2210
Adolescents	15-19	2700	2120	2420
Adults	20-59	2460	1990	2230
Elderly	> 60	2010	1780	1890
Pregnant/lactating			285/500 (extra)	285/500 (extra)
Whole population		2250	1910	2080 (say 2100)

There is a general consensus that about 2100 Kcal per head should be catered for planning the energy requirements for a disaster situation. Proteins must contribute to 10-12% of the energy (about 52g of proteins per day). Fats must provide 17-20% of energy (46g of fat); half from invisible sources and half from visible fats (23g each). Critical micronutrients like iron, iodine, vitamin A and other vitamins (thiamine, niacin, vitamin C) must also be provisioned for, systematically. Ensuring the provision of locally available foods and maintaining their continuous supply would go a long way in disaster relief. At times, fortified foods and pharmaceutical supplements are also called for. A typical food survival ration is outlined in Table-2.

#### **Meeting Nutritional Requirements in a Disaster Situation**

Nutritional requirements in a disaster situation can be effectively met through being prepared all the time for a disaster and instituting sound interventions in the event of disaster.

##### **1. Be Prepared ... Disaster may Strike**

The community has to be taught to be always prepared for a disaster. Such preparations not only keeps the community confident that they can meet the 'unknown challenge effectively' but such a preparation can make the difference

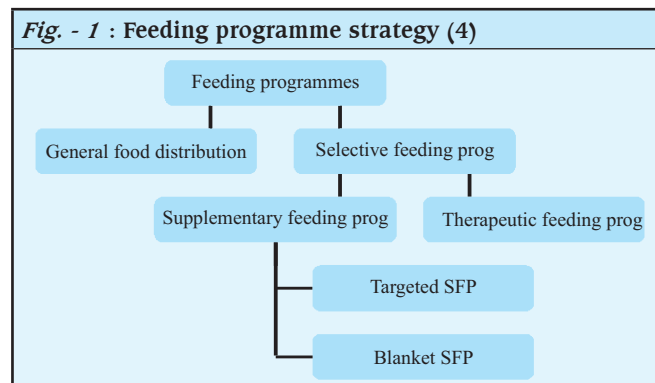
<b>Table - 2 : Typical food survival ration (3)</b>		
<i>(Quantity in g based on 2100 Kcal/person/day)</i>		
Item	Ration Option 1 (g)	Ration Option 2 (g)
Rice/Wheat flour	415	430
Pulses	45	0
Vegetable oil	25	25
Groundnuts	35	35
Canned fish	0	30
Sugar	15	15
Salt	5	5
Total	540	540

between life and death. Simple steps of storing food and water at vantage points and regularly replenishing them are some basic 'preparation' measures. The basic tips for storing water and food are summarised in Box - 2.

<b>Box - 2 : Be Prepared ... Disaster may Strike</b>
<b>Store Water</b> <ul style="list-style-type: none"> <li>For drinking - @ 2 lit / person / day</li> <li>For cooking - @ 2 lit /person /day</li> <li>At least for 3 days (2 weeks)</li> <li>If supplies run low, don't ration water</li> <li>Don't risk dehydration</li> <li>Store in a cool, dark place at home, office, vehicle</li> <li>Preferably in store-bought, factory-sealed water container</li> <li>Or in washed, rinsed food-grade containers</li> <li>Change every six months</li> </ul>
<b>Store Food</b> <ul style="list-style-type: none"> <li>That is eaten regularly</li> <li>Requires no refrigeration, preparation, cooking</li> <li>Include vitamin, mineral, protein supplements</li> <li>Store two weeks supply</li> <li>Canned food can be stocked</li> <li>Stock for infants – formula feed, pacifiers, medicines</li> <li>Wrap perishables and keep sealed</li> <li>Empty opened packages into screw-top / airtight jars</li> <li>Avoid fatty, high protein, salty foods</li> </ul>
<b>Don't forget</b> <ul style="list-style-type: none"> <li>Can opener, disposable cups, plates, knife, sugar, salt, plastic bags</li> <li>To replace water/foods at regular intervals</li> </ul>
<b>Replace at six monthly intervals</b> <ul style="list-style-type: none"> <li>Dry fruits, biscuits, infant formula</li> </ul>
<b>Replace at yearly intervals</b> <ul style="list-style-type: none"> <li>Canned meat</li> <li>Vegetable soups, fruit juices</li> <li>Jelly, butter, instant cereals, vitamins</li> </ul>
<b>Store indefinitely</b> <ul style="list-style-type: none"> <li>Some foods like dried corn, dry noodles instant coffee, tea, soft drinks, vegetable oils, salt, soybean, wheat and rice can be stored almost indefinitely.</li> </ul>

## 2. Interventions in the event of disaster

Rapid initial assessment will have to be undertaken to ascertain the origin of nutritional problem (failure of crops, war, drought, etc.), demographic profile of the affected population, baseline health data, factors affecting interventions like security, water, food and potential logistics constraints e.g. transport, roads, food supply, etc. Based on the above data the strategy for a particular feeding programme is chalked out. Many types of feeding programmes are available, depending on the situation. These are outlined in Fig. - 1. Various feeding programme strategies are described here in brief.



**General Food Distribution (GFD) :** The aim of the general food distribution strategy is to provide food to all for a basic level of survival. The limitations in this strategy are that the food might be insufficient to meet needs of all the people and the most vulnerable groups might be ignored. In any case it is a useful strategy esp. in the beginning of the disaster aid. It is done either through supplying cooked meal as an emergency measure or distributing dry ration when the situation has stabilized and people can cook in makeshift camps/shelters. The third option could be mass feeding the population with cooked meal. The principle is to provide energy dense foods on an immediate and urgent basis. 1 metric ton cereals can cater for the energy requirement of 1850 males for 1 day (5).

Presuming the individual consumption at a rate of 540g/person/day, the planning figures to determine food needs (in metric tons) has been worked out in Table - 3.

<b>Table - 3 : Planning figures to determine food needs (3)</b>						
<i>(Food quantity in metric tons @ 540g/person/day)</i>						
Popu-lation	1 day	1 month	3 months	6 months	1 year	
1,000	0.54	16.20	48.60	97.2	197.10	
5,000	2.70	81.00	243.00	486.0	985.0	
10,000	5.40	162.00	486.00	972.0	1971.0	
50,000	27.0	810.00	2430.00	4860.0	9855.0	
1 lakh	54.0	1620.0	4860.00	9720.0	19710.0	
(Basis of calculation: Requirement in metric tons = No. of persons per day x 0.540/1000 Kg)						

It must be remembered that any food that is offered should be culturally acceptable, as close to routine food, available for consumption in a digestible form, suitable to vulnerable groups and must contain adequate quantity of micronutrients.

**Organizing Mass Feeding :** Mass feeding can be undertaken in institutions and refugee camps. Local foods should be used as far as possible. The calculations for mass feeding are similar to the one shown above. Mass feeding must be undertaken in enclosed areas. Public kitchens have to be established under supervision of administrators. Timings must be fixed for meals. Distribution of cooked food can also be done through families. Some special feeding regimes have to be thought of, for the elderly, infants and pregnant women (6).

**Selective Feeding Programme :** Selective feeding programme have to be undertaken for vulnerable groups. It could be a supplementary feeding programme or therapeutic feeding programme. The aim of the supplementary feeding programme is to provide necessary nutrient supplements to the vulnerable groups like under fives children with malnutrition, pregnant and lactating women. This helps prevent deterioration of nutritional situation through correction of moderate malnutrition, prevention of severe malnourishment, infections like measles, pertusis, ARI, diarrhoea and chances of epidemics and mortality (7) The planning figures for supplementary feeding for typical daily rations (with monthly totals) providing 350 Kcal, 15 g protein/person/day) are given in Table - 4.

<b>Table - 4 : Planning figures: Supplementary Feeding (3)</b>					
<i>(Typical daily rations (with monthly totals) providing 350 Kcal, 15 g protein/person/day)</i>					
<b>Item (daily)</b>	<b>Amount (g)</b>	<b>Energy (Kcal)</b>	<b>Fat (g)</b>	<b>Protein (g)</b>	<b>Monthly (metric ton)</b>
Cereal	50	180	-	4	1.50
Veg oil	10	89	10	0	0.30
Wheat-soya	55	204	3	11	1.65
Salt	5	0	0	0	0.15
<b>Total</b>	<b>120</b>	<b>473</b>	<b>13</b>	<b>15</b>	<b>3.60</b>

**Therapeutic Feeding :** The aim of a therapeutic feeding programme is to help in medical and nutritional treatment of severely malnourished children (8) This is aimed to reduce infant and child deaths esp. because of severe PEM. Therapeutic feeding provides an intensively managed, carefully balanced medical regimen. It helps in the rehabilitation of severely malnourished children. It can be undertaken at a residential level wherein the mothers (along with the sick malnourished children) are admitted and treated with special focus on nutrition. An alternative approach is to take care of the children in the day care centres established for this purpose. The mothers visit such centres for day long period, get medical attention and learn the basic skills in child nutrition, care and disease prevention. Besides the severely malnourished young vulnerable children and adolescents, the low-birth-weight babies, orphan infants who lack inadequate traditional care are

also the prime focus of therapeutic feeding. Mothers of infants with lactational failure are also given such care.

**Conclusion :** It can be well appreciated that nutrition during a disaster situation is not merely providing a 'feed'. But it involves anticipating, preparing and training for disaster beforehand; assessing the disaster situation in terms of impact, demography and resources; making an immaculate plan; implementing the plan and learn from the mistakes. Infant feeding, nutrition for the elderly and nutrition for pregnant and lactating women remain special situations and need expert attention.

## Fairs and Festivals

India is a country of fairs and festivals. There is no month that doesn't have a festival or two. People tend to enjoy themselves during various festivals. Fairs and community feeding are integral to festivals. Fairs and festivals pose threat to public health as well, as people tend to congregate in large numbers in restricted spaces. The community is put to numerous risks; these could be as diverse as stampede, heat exhaustion, heat stroke, dehydration, infections, outbreaks, violence, terrorist threats, building collapse, fire, etc. The public health aspects pertaining to food in fairs and festivals are dealt with in brief, in the subsequent paragraphs. Mass feeding (during a festival) whether at the level of household or a community, poses threat to the people. The factors that make the community more vulnerable to food borne disease during mass feeding are:

- Large congregation of people
- Compromised food hygiene
- Scarcity of water
- Business interest of people that compromises basic hygiene
- Flies and other pests
- Indiscriminate littering of waste and poor waste disposal facilities
- Inadequate (hand, raw foods, utensils) washing facilities
- Inadequate toilets and wash rooms
- Participation of unspecified food handlers

## Responsibilities of Local Health Authority

It must be appreciated that the local health authority has a major role to play in managing health during fairs and festivals and ensuring proper measures to prevent disease. The local health authority is responsible for:

- Selecting the correct site for establishing the 'food centre'
- Selecting right agents/contactors providing food material (raw and cooked)
- Ensuring appropriate source of food
- Provision of safe drinking water
- Licensing the food shops and eateries
- Food hygiene and inspections
- Attending to complaints
- Food sampling as per the PFA act and follow up action
- Food and workplace safety
- Control of infectious disease and prevention of food poisoning
- Fly and pest control
- Educating the community on various aspects of food hygiene

The most common issues that must be ensured by the

administrators are :

- Adequate contingency planning and consistent procedures
- Communication between management and food handlers
- Adequate training, information, instruction and supervision for all
- Hazard analysis pertaining to feeding
- Recognition of potentially hazardous procedures.

### Responsibilities of the Community

The local health authority might make rules and try to enforce them, but it is the community that has to ensure their implementation in the right earnest, for its own benefit. The community must take the responsibility of adhering to the rules laid down by the health authority. The community must be aware of various aspects of food hygiene, food safety, foods to be consumed and foods to be avoided during mass gatherings. The importance of flies and pests, safe drinking water and basic procedures like hand washing and proper garbage disposal must be appreciated by the community. Unhygienic and unlicensed food vendors must be shunned and reported against. The community must co-operate in the efforts of the authorities in maintaining food hygiene.

### Role of Food Handlers

The responsibility of food handlers becomes even more important in the situation of fairs and festivals as they can transmit infection to numerous people. Their responsibilities have been discussed in detail in the chapter on food borne infections. Only the most salient points are repeated here. To prevent food borne infections hand-washing is of utmost importance. Hands must be washed with soap and water after visiting the toilet, handling rubbish, handling raw foods, putting hand over your nose or mouth and before starting work or after taking a break. Hands must be dried with clean towels. The nails must be clipped short; food handlers must be vaccinated against common diseases esp. typhoid. If the food handler is sick or has diarrhoea, it is best to refrain from kitchen duties.

### Taking Care of Food

Whenever a communal feeding is planned either at home or at a community centre the following simple points must be ensured:

- Once procured, the food must be cooked at the earliest but closest to the time of consumption
- Prepare and store raw and cooked food separately
- Expiry date must be checked for all packed foods
- Keep pets and pests away from food and food preparation surfaces
- Wash hands thoroughly before preparing food, and after going to the toilet
- Wash worktops and utensils
- Avoid food containing uncooked eggs
- Ensure food is piping hot
- Keep hot food hot and cold food cold
- Food handlers with diarrhoea / vomiting must be excluded
- Food freshly cooked is usually safe. Eating stale food (more than couple of hours old) constitutes greater risks of food borne disease
- Food has to be thoroughly cooked and must be hot when

served

- Uncooked food apart from fruits and vegetables that can be peeled must be avoided
- Foods exposed to flies and pests must be shunned

### Taking Care of Cleaning and Waste Management

Clean premises will reduce the risk of contamination, avoid pest infestations, provide a safe and pleasant environment to work. These simple guidelines must be observed:

- Always keep the premises clean
- A cleaning schedule must be followed. Staff must be nominated to clean a particular equipment or area, on a given day
- Keep all chemicals locked away from food
- Provide suitable dustbins with lids. Ensure their regular evacuation.
- Regularly clean refuse areas

### Taking Care of Drinking Water, Ice and Beverages

It must be ensured that only clean and safe drinking water is used. The source of water must be ascertained and safety ensured. If in doubt do not drink that water. Bottled or carbonated water might be safer! Water used for recreational purposes (such as swimming) is often contaminated and must not be consumed.

Commercial ice must be avoided unless one is sure that it is made from safe water and has not been contaminated by dirty hands, pests, or equipment. Ice-cream from unreliable sources may be contaminated and cause illness. If in doubt avoid it.

Beverages such as hot tea, coffee, beer, carbonated soft drinks or fruit juices are usually safe to drink. Expiry dates and seals must be checked. Avoid unpasteurised milk, cheese, paneer and other products.

### Specific Foods

Some food stuff must be viewed with suspicion and consumed only if one is sure of their safety, as there is a higher potential of food poisoning with them. Some of these are enumerated in the Box - 3.

To keep these foods safe ensure strict temperature control during the entire course of food processing: delivery, correct freezing, thawing, refrigeration, cooking and serving. They must be protected from contamination (bacterial and chemical). The entire supply line of the food product must be traced for hygiene.

<b>Box - 3 : Suspicious foods - Consume with care!</b>
Cooked meats and poultry
Milk, cream, artificial cream, cottage cheese ( <i>paneer</i> ) custards and dairy produce
Cooked eggs and products made with fresh shelled eggs (mayonnaise)
Fish and sea foods
Cooked rice
Ice
Salads, vegetables and fruit eaten raw
Sandwiches and filled rolls



## Duties of Health Officers

Health officers have the responsibility to ensure implementation of laid down health policies. They inspect premises for ensuring hygiene, correct cooking practices, storage and distribution of food, etc. They undertake surveillance to keep an eye on the cases reported as diarrhoea, vomiting and dysentery and rule out if they were food poisoning. They would also ensure taking samples from suspicious locations. Health officers can arrange to collect samples and have them examined at the Public Health Laboratory.

If a restaurant or food shop is implicated, the officer will carry out an inspection of the premises and take food samples for examination (if required). Mainly the officer looks for the bacterial risks arising from the type of food handled in the business and how food is stored, prepared, cooked and served. They investigate incidences of outbreaks of food poisoning in detail; recommend and take appropriate prevention and control measures.

## Community Feeding of Children

There are many instances when the community feeding of children has to be resorted to. It is commonly seen as part of certain national nutritional programmes. The Mid Day Meal Programme, Balwadi Programme and under the ICDS programme (Anganwadi), children are fed in groups ranging from a few dozens to thousands. While running such a programme is essential for the up-liftment of the nutritional status of children, such a mass feeding entails tremendous risk as well, given the large numbers involved. There have been occasional reports indicating food poisoning episodes in such congregations of children. This not only puts the lives of children at risk but also puts the very programme at stake of disrepute and rejection by the community. It is therefore imperative to take adequate measures to prevent such situations.

Infants and children are more vulnerable to infections owing to a poorly developed immune system and higher vulnerability to infections. For this reason it is important to take extra care when preparing food for infants and young children.

## Preparing food for infants and children

Some precautions that must be taken for preparing foods for infants and children are enumerated in Box - 4.

### Summary

Nutrition assumes extreme importance in a disaster situation as food is a primary requirement for sustenance of life. At an average energy requirement is 2100Kcal/person/day. It is best to be prepared for a disaster. Food and water must be stored at vantage points. After a disaster various feeding programmes namely a) General food distribution b) Selective food distribution can be resorted to. The latter can be applied either as a supplementary or a therapeutic feeding programme depending on the situation and the distribution of beneficiaries. Organizing a mass feeding programme for the disaster struck and refugees might pose a challenge to the authorities, so, sound administrative acumen is needed to make it a success, besides merely providing the relief material.

Mass feeding during fairs and festivals is a common and frequent feature in India. Large scale food preparation and distribution poses a serious public health threat if the same is not organized as per basic principles of hygiene. The local health authorities have to ensure implementation of relevant rules. Close monitoring and effective surveillance of health and hygiene during the feeding is indispensable. The community has a major role to play in maintaining health through following the rules laid down. Community must make effort to be aware of the basics of food hygiene and the dos and don'ts of eating in a large communal gathering. Cooks and food handlers must also realize their responsibilities to stop spread of infection.

Community feeding of children is often resorted to through various feeding programmes organized by the government, under the national programmes (Mid Day Meal, ICDS, etc). Special care in procurement, processing and distribution of food must be taken to prevent instances related to food poisoning. This can be achieved through immaculate kitchen hygiene, healthy food handlers and an aware community. We must strive to achieve these.

### Box - 4 : Guidelines for Preparing Food for Infants and Children

Raw food must be procured from authentic sources

Immaculate personal hygiene of cooks must be ensured

Dining area, tables, chairs, bibs must be thoroughly cleaned before and after every meal

Kitchen surfaces, floors, platforms, etc. must be immaculately clean

Avoid foods that are more likely to cause food poisoning e.g. cream, raw eggs, paneer, meat dishes, salad, etc.

Kitchen towels and cloths must be changed daily or more often

'Cook fresh and consume fresh' should be the rule

Avoid storing cooked food for another day

Discard left-overs

Children must wash their hands after visiting the toilet or touching pets.

## Study Exercises

**Long Question :** Discuss the nutritional interventions that could be undertaken in the event of an earthquake.

**Short Notes :** (1) Storing food for disaster (2) Therapeutic feeding programme (3) Community feeding of children (4) Post exercise feeding of athletes (5) Precautions with drinking water during fairs

### MCQs

1. At an average \_\_\_\_\_ Kcal/person should be catered for planning food aid during disaster: (a) 2100 (b) 1850 (c) 2400 (d) 2800
2. Water must be stored @ \_\_\_\_\_ lit for drinking and \_\_\_\_\_ lit for cooking (per day): (a) 1,1 (b) 2,2 (c) 2,3 (d) 3,2
3. Onemetricktonnegrainsaresufficienttofeed \_\_\_\_\_ males/day in a disaster situation : (a) 2100 (b) 1850 (c) 1000 (d) 1500
4. In a disaster situation the aims of therapeutic feeding includes all except (a) Medical treatment of severely malnourished (b) Nutritional treatment of severely malnourished (c) Reduce infant/child deaths (d) Treat cases of infections
5. Community feeding of children is undertaken in all except (a) ICDS programme (b) Mid day meal programme (c) Balwadi programme (d) School health programme

### Match the following

Act	Responsibility of
6. Take food samples	(a) Community
7. Lay down policy	(b) Local health authority
8. Report diarrhoea cases	(c) Food handler
9. Report own illness	(d) Local doctors
10. Maintain food hygiene	(e) Health officers

**Answers :** (1) a; (2) b; (3) b; (4) d (5) d; (6) e (7) b; (8) d; (9) c; (10) a.

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Rajul K Gupta

Table - 1 : Nutritive Value of Commonly Used Foods (per 100g) (1)

Food stuff	Proteins (g)	Fat (g)	Fibre (g)	Carbohydrates (g)	Energy (Kcal)	Iron (mg)
Wheat flour	12.1	1.7	1.9	69.4	341	4.9
Rice polished	6.8	0.5	0.2	78.2	345	0.7
Rice parboiled	6.4	0.4	0.2	79	346	1
<i>Bajra</i>	11.6	5	1.2	67.5	361	8
Maize dry	11.1	3.6	2.7	66.2	342	2.3
Bengal gram	17.1	3	3.9	60.9	360	4.6
Soya bean	43.2	19.5	3.7	20.9	432	10.4
<i>Rajmah</i>	22.9	1.3	4.8	60.6	346	5.1
Redgram	22.3	1.7	1.5	57.6	335	2.7
Beans	1.7	0.1	1.8	4.5	26	0.61
Spinach	2	0.7	0.6	2.9	26	1.14
Tomato	0.9	0.2	0.8	3.6	20	0.64
Carrot	0.9	0.2	1.2	10.6	48	1.03
Onion	1.2	0.1	0.6	11.1	50	0.6
Potato	1.6	0.1	0.4	22.6	97	0.48
Groundnut	25.3	40.1	3.1	26.1	567	2.5
Guava	0.9	0.3	5.2	11.2	51	0.27
<i>Amla</i>	0.5	0.1	3.4	13.7	58	1.2
Mango	0.6	0.4	0.7	16.9	74	1.3
Orange	0.7	0.2	0.3	10.9	48	0.32
Banana	1.2	0.3	0.4	27.2	116	0.36
Lime	1.5	1	1.3	10.9	59	0.3
Grape green	0.5	0.3	2.9	16.5	71	0.52
Grape blue	0.6	0.4	2.8	13.1	58	0.5
Papaya	0.6	0.1	0.8	7.2	32	0.5
Egg	13.3	13.3	-	-	173	2.1
Fish ( <i>Hilsa</i> )	21.8	19.4	-	2.9	273	2.1
Chicken	25.9	0.6	-	-	109	-
Milk, cow	3.2	4.1	-	4.4	67	0.2
Milk, buffalo	4.3	6.5	-	5	117	0.2
<i>Ghee</i>	-	100	-	-	900	-
Butter	-	81	-	-	729	-
Veg oils	-	100	-	-	900	-
Cheese	24.1	25.1	-	6.3	348	2.1
Curd	3.1	4	-	3	60	0.2
Jaggery	0.4	0.1	-	95	383	2.64

Table - 2 : Recommended Dietary Allowances for Indians (Infants, Children, Adults, Pregnant and Lactating women) (1)															
Group	Particulars	Body wt	Energy	Protein	Fat	Ca	Fe	Vitamin A	Thiamin	Ribo- flavin	Nicoti- nic acid	Pyri- doxin	Vit C	Folic acid	Vit B <sub>12</sub>
								Retinol	β carotene						
		Kg	Kcal/d	g/d	g/d	mg/d	mg/d	μg/ d	μg/ d	mg/d	mg/d	mg/d	mg/d	mg/d	μg/d
Man	Sedentary work		2425							1.2	1.4	16			
	Moderate work	60	2875	60	20	400	28	600	2400	1.4	1.6	18	2.0	40	100
	Heavy work		3800							1.6	1.9	21			
Woman	Sedentary work		1875							0.9	1.1	12			
	Moderate work	50	2225	50	20	400	30	600	2400	1.1	1.3	14	2.0	40	100
	Heavy work		2925							1.2	1.5	16			
	Pregnant woman	50	+300	+15	30	1000	.38	600	2400	+0.2	+0.2	+2	2.5	40	400
	Lactation														
	0-6 months	50	+550	+25	45	1000	30	950	3800	+0.3	+0.3	+4	2.5	80	150
	6-12 months		+400	+18						+0.2	+0.2	+3			
Infants	0-6 months	5.4	108/ Kg	2.05/ Kg		500				55μl Kg	65pgl Kg 710μgl Kg	0.1	25	25	0.2
	6-12 months	8.6	98/Kg	1.65/ Kg				350	1200	50μl Kg	60μg/Kg 650pgl Kg	0.4			
Children	1-3 years	12.2	1240	22			12	400	1600	0.6	0.7	8	0.9		30
	4-6 years	19.0	1690	30	25	400	18	400		0.9	1.0	11		40	40
	7-9 years	26.9	1950	41			26	600	2400	1.0	1.2	13	1.6		60
Boys	10-12 years	35.4	2190	54	22	600	34	600	2400	1.1	1.3	15	1.6	40	70
Girls	10-12 years	31.5	1970	57			19			1.0	1.2	13			
Boys	13-15 years	47.8	2450	70	22	600	41	600	2400	1.2	1.5	16	~.0	40	100
Girls	13-15 years	46.7	2060	65			28			1.0	1.2	14			
Boys	16-18 years	57.1	2640	78	22	500	50	600	2400	1.3	1.6	17	2.0	40	100
Girls	16-18 years	49.9	2060	63			30			1.0	1.2	14			



<b>Table - 3 : Major Contributors of Energy to Our Diet (Some raw foods and their energy content per 100g) (1)</b>			
Food stuff	Energy (Kcal)	Food stuff	Energy (Kcal)
<i>Cereals &amp; Millets</i>		<i>Non vegetarian foods</i>	
Wheat flour	341	Egg (hen)	173
Rice polished	345	Fish ( <i>Hilsa</i> )	273
<i>Bajra</i>	361	Chicken	109
Maize dry	342	Mutton (lean)	118
<i>Ragi</i>	328	Pork (muscle)	114
<i>Pulses &amp; Legumes</i>		<i>Milk &amp; milk products</i>	
Bengal gram	360	Milk, cow	67
Soya bean	432	Milk, buffalo	117
<i>Rajmah</i>	346	Milk, human	65
Redgram ( <i>Arhar</i> )	335	Butter	729
Greengram ( <i>Moong</i> )	334	<i>Ghee</i>	900
Lentil ( <i>Masoor</i> )	343	Cheese	348
Pea dry	315	Curd	60
<i>Fruits &amp; Vegetables</i>		<i>Nuts</i>	
Banana	116	Groundnut	567
Apple	59	Cashew nut	596
Grapes, pale green	71	Coconut, fresh	444
Custard apple	104	Miscellaneous	
Jack fruit	88	Jaggery	383
Raisins	308	Sugar	398
Potato	97	Veg oils	900

<b>Table - 4: Calorie Content of Selected Cooked Food Items (per serving) (2)</b>			
Food item	Kcal	Food item	Kcal
<i>Samosa</i> (1no.)	256	<i>Dalia</i> (1 plate)	80
<i>Masala dosa</i> (1no.)	360	<i>Khichri</i> (1 plate)	160
<i>Kachori</i> (2 no.)	500	Biscuits (4 no.)	150
Omelette (1egg)	236	<i>Poha</i> (1 plate)	120
<i>Puri</i> (4 no x 25g each)	320	Bread (2 slices)	125
Chapati with <i>ghee</i> (4 no.)	360	<i>Chapati</i> (2no x 35g each)	160
Cake (1small piece)	250	<i>Kheer</i> (1 <i>katori</i> )	120
Butter chicken (1 <i>katori</i> )	400	Cornflakes (1bowl)	190
Chicken <i>biryani</i> (200g)	400	Veg salad	50
<i>Malai paneer</i> (1 <i>katori</i> )	270	Butter milk (1 glass)	90
<i>Paratha</i> (2no x 50g each)	360	Jam (2tsp)	40
Ice cream (100ml)	250	<i>Dhokla</i> (2 pcs)	100
Pastry (1 no.)	290	Green leafy veg (1 <i>katori</i> )	130
Milk cake (1 piece)	300	<i>Idli</i> (2no x 55g each)	155
Butter (2 tsp)	180	<i>Dosa</i> (2no x 45g each)	250
Fried Cashew (50g)	375	Tinned cheese (2tbsp)	105

<b>Table - 5 : Signs 'Strongly Suggestive' of Dietary Deficiency or Excess (3)</b>	
<i>Sign of Deficiency</i>	<i>Suggested nutrient abnormality</i>
Pale conjunctiva	Iron
Bitot's spots	Vitamin A
Angular stomatitis	Riboflavin
Spongy, bleeding gums	Vitamin C
Bilateral edema (young children)	Protein and Energy
Thyroid enlargement	Iodine
Bilateral epiphyseal enlargement of wrists	Vitamin D
<i>Sign of Excess</i>	<i>Suggested nutrient abnormality</i>
Mottled enamel	Fluoride
Dental caries	Sugar

<b>Table - 6 : Normal Range of Some Biochemical Tests (4)</b>				
Nutrient	Test	Normal (Acceptable)	Low (Medium risk)	Deficient (high risk)
Albumin (g/100ml) for age 6-17 yrs	Serum levels	>3.5	2.8-3.4	<2.8
Vitamin A ( $\mu\text{g}/\text{dl}$ )	Serum levels	>30	20-30	<20
Vitamin D (ng/ml)	Serum levels of 25-Hydroxy cholecalciferol	>10	5-10	<5
Vitamin E	Ratio of serum vitamin/total lipids	>0.8		
Vitamin K	*PIVKAS accumulation			If PIVKAS accumulates
	Prothrombin time			Delayed **
Thiamin	Urinary thiamin	100 $\mu\text{g}/24$ hrs or 65 $\mu\text{g}/\text{g}$ creatinine		
Riboflavin	Urinary Riboflavin	80 $\mu\text{g}/\text{g}$ creatinine		
Niacin	2-Pyridone to NI-methyl nicotinamide ratio	1 to 4		<1
Vitamin B <sub>6</sub>	Vitamin B <sub>6</sub> urinary excretion			<20 $\mu\text{g}/\text{g}$ creatinine
	Pyridoxic acid excretion			<0.5mg/day
Folic Acid	Serum Folate (ng/ml)	>6.0	3.0-5.9	<3
	RBC Folate (ng/ml)	>160	140-159	<140
Vitamin B <sub>12</sub>	Serum B <sub>12</sub> (pg/ml)			<80
Ascorbic acid	Plasma (mg/dl)	>15	8-15	<8
* PIVKAS: Protein Induced by Vitamin K Absence				
** Prothrombin time is a functional test				

<b>Table - 7 : Approximate Fatty Acid Composition of Common Fats and Oils (g/100g) (5)</b>					
<b>Oil/Fat</b>	<b>Saturated</b>	<b>MUFA</b>	<b>Linoleic acid</b>	<b><math>\alpha</math>-linolenic acid</b>	<b>Predominant FA</b>
Coconut	90	7	2	<0.5	SFA
Palm kernel	82	15	2	<0.5	SFA
<i>Ghee</i>	65	32	2	< 1.0	SFA
<i>Vanaspatti</i>	24	19	3	<0.5	SFA (t-FA)
Red palm oil	50	40	9	<0.5	SFA + MUFA
Palm oil	45	44	10	<0.5	SFA + MUFA
Olive	13	76	10	<0.5	MUFA
Groundnut	24	50	25	<0.5	MUFA
Rape/Mustard	8	70	12	10	MUFA
Sesame	15	42	42	1.0	MUFA + PUFA
Rice bran	22	41	35	1.5	MUFA + PUFA
Cotton seed	22	25	52	1.0	PUFA
Corn	12	32	55	1.0	PUFA
Sunflower	13	27	60	<0.5	PUFA
Safflower	13	17	70	<0.5	PUFA
Soyabean	15	27	53	5.0	PUFA

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7

## Family Health



Section 7 : Family Health			
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A S Kushwaha

The health of women and children has always been an important social goal of all societies. Over the years, maternal and child health has evolved through various stages of conceptual approach, technological advances and social prioritization. The realization that, improved maternal and child health is the key to the ultimate objective of lifelong health in any society, has led to renewed interest and global focus towards this very important social health issue.

### Mother and Child: A Single Entity

Mother and child are often spoken of in one breath for a number of reasons. Health of the child and the mother are so closely linked that each has the capacity to influence the other. The outcome of pregnancy in terms of a healthy newborn is dependent on the physical, physiological, mental and nutritional state of the mother during pregnancy. Some specific health interventions jointly protect pregnant women and their babies e.g. tetanus toxoid immunization and nutrition supplementation. At childbirth, both mother and child are at risk for complications which can endanger their lives. The postpartum care of the mother is inseparable from newborn care, immunization and family planning advice, and this provides not only operational convenience but offers continuity of care as well.

### Important Sub Disciplines Related to MCH

There are a number of sub disciplines that have developed over the years in the field of maternal and child health. It is in this endeavour that disciplines like *social obstetrics, preventive pediatrics, community obstetrics, family health and family medicine* have originated. Various initiatives in child health include *essential newborn care, well baby clinics, under five clinics, Child guidance clinics and school health services*.

### Why So Much Attention to This Issue?

Firstly, together, mothers (women 15-45 years of age) and children (under 15 years of age) constitute 70-80% of the population. They also belong to the most vulnerable section of society in terms of death, disease, disability and discrimination. Women and Children represent economically dependent and least empowered section of the society. The falling sex ratio (from 972 in 1901 to 933 in 2001) is a grim reminder of the social disadvantage faced by women in India<sup>(1)</sup>. The issue also merits attention because of high morbidity and mortality faced by this group. Most of the deaths and illnesses in these groups are avoidable by cost effective interventions which are available to tackle them.

### Scenario of Maternal and Child Health

**Global Picture** : Of the estimated 211 million pregnancies that occur each year, about 46 million end in induced abortion. Attending to all of the 136 million births every year is one of the major challenges that is now faced by the world's health systems. Globally, huge toll on account of maternal deaths continues unabated. Often sudden, unpredicted deaths occur during pregnancy itself (as a consequence of unsafe abortion),

during childbirth, or after the baby has been born due to blood loss and infections. The 5,29,000 annual maternal deaths, including 68,000 deaths attributable to unsafe abortion, almost all of these are occurring in poor countries with only 1% in rich countries. Each year 3.3 million babies are stillborn, more than 4 million (neonatal deaths) are dying within 28 days of coming into the world, and a further 6.6 million young children die before their fifth birthday. Although an increasing number of countries have succeeded in improving the health and well-being of mothers, babies and children in recent years, in some countries the situation has actually worsened. Slow progress, stagnation and reversal are closely related to poverty, to humanitarian crises, and, particularly in sub-Saharan Africa, to the direct and indirect effects of HIV/AIDS. Over 300 million women in the world currently suffer from long-term or short-term illness brought about by pregnancy or childbirth. Programmes to tackle vaccine preventable diseases, malnutrition, diarrhoea, or respiratory infections still have a large unfinished agenda.

### India

**Health of Women** : The country has a falling low sex ratio of 933 female per thousand male. Early marriage in women and universality of marriage are important social issues. The median age at first marriage among women is 17.2 years. Almost half (46%) of women age 18-29 years got married before the legal minimum age of 18. Among young women age 15-19, 16 percent have already begun childbearing. Indians have poor knowledge about temporary contraceptive methods and this coupled with poor availability affects 'delaying the first and spacing the second child' doctrine adversely. Among the married women, 13 percent have unmet need for family planning. Less than half of women receive antenatal care during the first trimester of pregnancy, as is recommended. Three out of every five births in India take place at home; only two in five births take place in a health facility. Less than half of births took place with assistance from a health professional, and more than one third were delivered by a Traditional Birth Attendant. The remaining 16 percent were delivered by a relative or other untrained person. A Disposable Delivery Kit (DDK) is being used only in 20% of births taking place at home. Most women receive no postnatal care at all. Only 37 percent of mothers had a postnatal checkup within 2 days of birth. Every seven minutes an Indian woman dies from complications related to pregnancy and childbirth. The maternal mortality ratio in India stands at 300 per 100,000 live births. (Table - 1).

**Child Health** : Infant mortality is 77 per 1,000 for teenage mothers, compared with 50 for mothers age 20-29. Infant mortality in rural areas is 50 percent higher than in urban areas. Perinatal mortality, which includes stillbirths and very early infant deaths (in the first week of life), is estimated at 49 deaths per 1,000 pregnancies, that lasted 7 months or more. Less than half (44%) of children 12-23 months are fully vaccinated against the six major childhood illnesses: tuberculosis, diphtheria, pertussis, tetanus, polio, and measles. Although breast feeding is almost universal in India, only 46 percent of children under 6 months are exclusively breastfed. Many infants are deprived of the highly nutritious first milk (colostrum) as only 55 percent are put to the breast within the first day of life. Almost half

of children under age five are stunted or too short for their age. Anaemia is a major health problem in India, especially among women and children. Among children between the ages of 6 and 59 months, about 70 percent are anaemic including three percent who suffer from severe anaemia. More than half of women in India (55 percent) have anaemia with 17 percent of these have moderate to severe anaemia.

**Table - 1: Important Mortality indicators of Maternal and Child Health (Source-NFHS 3)**

Indicator	1994	2000	2001	2002	2003	2004	2005
IMR	74	68	65.9	64	60	58	58
NNMR	47.7	44	40.2	NA	37	37	37
PNMR	26	23	25.7	NA	23	21	22
PMR	42.5	40	26.2	NA	33	35	37
SBR	8.9	8	9.3	NA	9	10	9
MMR	327			301			

<b>IMR</b>	Infant Mortality rate
<b>NNMR</b>	Neonatal Mortality rate
<b>PNMR</b>	Post-Neonatal Mortality Rate
<b>PMR</b>	Perinatal Mortality Rate
<b>SBR</b>	Still Birth Rate
<b>MMR</b>	Maternal Mortality Ratio

### Challenges in MCH

The look at statistics in Table - 1 gives a picture of many unfulfilled promises in the field of maternal and child health despite a family welfare programme running since 1950s. The challenges include lack of universalisation of services, rural urban differential, poor status of women in society and lack of political will and acceptance of the issue as a social priority. The main challenge to child survival no longer lies in determining the proximate causes of or solutions to child mortality but in ensuring that the services and education required for these solutions reach the most marginalized countries and communities.

### Opportunities in MCH

**A new paradigm in MCH - Continuum of Care** : The continuum consists of a focus on two dimensions in the provision of packages of essential primary-health-care services:

**Time:** There is a need to ensure essential services for mothers and children during pregnancy, childbirth, the postpartum period, infancy and early childhood. The focus on this element was engendered by the recognition that the birth period – before, during and after – is the time when mortality and morbidity

risks are highest for both mother and child.

**Place:** Linking the delivery of essential services in a dynamic primary-health-care system that integrates home, community, outreach and facility-based care. The impetus for this focus is the recognition that gaps in care are often most prevalent at the locations – the household and community – where care is most required.

The continuum of care concept has emerged in recognition of the fact that maternal, newborn and child deaths share a number of similar and interrelated structural causes with undernutrition. The continuum of care also reflects lessons learned from evidence and experience in maternal, newborn and child health during recent decades. In the past, safe motherhood and child survival programmes often operated separately, leaving disconnections in care that affected both mothers and newborns. It is now recognized that delivering specific interventions at pivotal points in the continuum has multiple benefits. Linking interventions in packages can also increase their efficiency and cost-effectiveness. The primary focus is on providing universal coverage of essential interventions throughout the life cycle in an integrated primary-health-care system.

### Road Ahead

The NRHM and RCH are aimed at meeting this challenge and have set out their targets as envisaged under various policies and MDGs. (See Table - 2)

**Table - 2 : The Road Ahead (National targets for MCH)**

Indicator	10th Plan goals (2002-07)	RCH -2 (2004-09)	National Population Policy 2000 (by 2010)	MDGs (by 2015)
Infant mortality rate	45 per 1000 live births	35 per 1000 live births	30 per 1000 live births	-
Under 5 mortality rate	-	-	-	Reduce by 2/3rd
Maternal mortality ratio	200 per 1 lakh live births	150 per 1 lakh live births	100 per 1 lakh live births	Reduce by 3/4th

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### Risk as a Proxy for Need

In every society there are communities, families and individuals whose chances of future illness, accident and untimely death are greater than others; they are said to be vulnerable owing to peculiar set of characteristics they share. These characteristics could be biological, genetic, environmental, psychosocial or economic. Similarly there are others who have a chance to enjoy better health. Thus as an example we can see that pregnant, poor, very young children and elderly are vulnerable and young and affluent are not. Risk however has come to be associated with the vulnerability to disease or illness or death. A pregnant woman with high blood pressure is at risk of complications like eclampsia and this measured risk to her and the child is an expression of her need for medical help and intervention. The risk strategy utilizes these risk estimates as guide for action, resource allocation, coverage and referral care. The hypothesis, on which risk strategy rests, therefore, is that more accurately the risk is measured, the better is the understanding of the need.

The risk approach is a managerial tool based on the strategy for efficient utilization of scarce resources with more care for those in need and proportionate to the need.

### Tools of the Risk Approach

The characters shared by a cohort making them vulnerable are referred to as risk factors. The measure of association with the outcome is known as the relative risk and estimation of the adverse outcome if these risk factors are present and calculation of effect if these risk factors are removed have made our decisions in public health prioritization. *Risks, predictions and possible effects* are therefore the tools of the risk approach. By quantifying the risks to the health of a population group and their associated risk factors, it focuses attention on the need for prevention.

### Risk Approach Applied to MCH

The mothers and children are most susceptible to good or harmful influences that will permanently affect their health. The harm can be inflicted or the good can be promoted in a very short time. The preventive and promotive elements of primary health care will have greatest yield if applied by using risk approach in MCH.

### Definitions

**Risk** : It implies that the probability of adverse consequences is increased by the presence of one or more characteristics or factors. It is a measure of statistical chance of a future occurrence.

**Relative Risk** : It measures the strength of the association between risk factor and the outcome e.g. RR of an outcome due to a risk factor is 1.3, means a 30% excess risk in those with the risk factor.

**Attributable Risk** : This brings together three ideas - the frequency of the unwanted outcome when risk factor is present, frequency of the unwanted outcome when risk factor is absent, frequency of the occurrence of risk factor in the community. It indicates what might be expected to happen to the overall outcome in the community if the risk factor was removed.

**Risk Factors** : Risk factor is defined as any ascertainable characteristic or circumstance of a person or group of persons that is known to be associated with an abnormal risk of developing or being especially adversely affected by a morbid process. Risk factor is one link in a chain of association leading to an illness or an indicator of a link.

Risk factors can therefore be causes or signals but they are observable and identifiable. Risk factor could be related to individual, family, community or the environment. Examples include - first pregnancy, high parity, teenage pregnancies, malnutrition, rural area, birth attendance etc.

The significance of risk factors from the point of application and utility in practice of preventive community medicine can be judged by -

- (a) Degree of association with the outcome.
- (b) Frequency of the risk factor in the community.

### Combination of Risk Factors

The combination of two or more risk factors increases the probability of the outcome. For example in a pregnancy, the hypertensive disease and poor antenatal care are independent risk factors for perinatal mortality but when both factors are present, the probability of perinatal mortality is much higher than expected. This is because the risk factors may have an additive or multiplicative effect.

### Risk Factors and Causes

Not all significant associations between the risk factor and the outcome are part of a chain of causality. Associations are usually described as 'causal' if they can be seen to be directly related to pathological processes, even if the pathways are not fully understood. e.g. Maternal malnutrition and low birth weight, placenta praevia and foetal death from anoxia, rubella in first trimester and congenital malformation. The important attributes in such association are 'dose response relationship, specificity, consistency of association, time relationship and biological plausibility. The complex relationship between risk factor and outcome can be explained by an example of gastroenteritis in a child belonging to a poor family where the complex of poverty may include contributions to risk from large family size, crowding, early weaning, poor nutrition with infection of infant and neglect of early Diarrhoea for a variety of reasons. Thus it is more than clear that family poverty is a risk factor for gastroenteritis and death from gastroenteritis. The advantage of risk approach is the attention being given to all causes regardless of their medical, intersectoral, economic, political or social origins.

### Methodology in Risk Approach

The risk approach involves, first, decisions as to priority 'targets' or unwanted outcomes, measurement of association between risk factors and the outcome, and then intervention

planned. The risk approach has to be studied by research and then only applied over a wide population.

**Outcome, Risk and Measurement** : The risk approach seeks to use information about risk to prevent a variety of adverse outcome (illness, injury and death) through the application of a strategy at many levels of care.

**Outcomes** : This is the first information required. Collect details of morbidity and mortality rates which are our targets or priorities (prevalence and incidence, trends, distribution in geographical area and different groups).

**Risk Factors** : Collect information on the following :

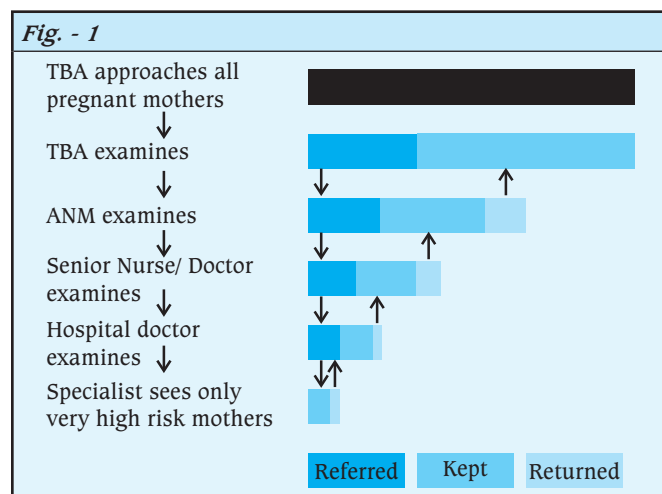
- Risk factors for each unwanted outcome.
- Risk factors or combinations of risk factors for each group of unwanted outcome.
- For all risk factors -
  - Prevalence and incidence and trends in the population
  - Relative risk of unwanted outcomes associated with each risk factors or combinations
  - Attributable risk associated with each risk factors
  - Predictive power of each risk factor
  - The ease, accuracy and acceptability of screening for the presence of risk factor in communities and individuals.

**Priorities among Outcomes** : This will depend upon many variables like -

- Community priority and preference
- Prevalence or frequency of occurrence
- The seriousness of the problem (fatality rate)
- Degree of preventability
- Rising frequency or upward trend of the problem (emerging issues)

#### Steps

- Identifying the risk factors and the populations and the individuals at risk
- Selection of risk factors
  - Optimum grouping
  - Usefulness in terms of proposed intervention
  - Strength of association / cause - effect relationship
  - Ease of modification (intervention)
  - Ease and accuracy of identification (test)
- Who should do the screening? (Fig - 1)



To give an example, if it was the Perinatal and maternal mortality (Outcome) then the identification of risk factors will involve screening at various levels for different risk factors depending upon the complexity of identification and infrastructure available and training of the health worker.

These decisions to refer or to keep are based on some form of risk scoring system. For example, while doing above exercise, suppose there is a risk scoring from 0 - 5, the scheme would look like (See Table - 1).

Table - 1 : Risk Scoring System					
Health level	Func - tionary	Exam - ines	Keeps	Refers	Returns
I	TBA	0, 1, 2, 3, 4, 5	0	1, 2, 3, 4, 5	-
II	ANM	1, 2, 3, 4, 5	2	3, 4, 5	1
III	Senior Nurse	3, 4, 5	3	4, 5	2
IV	Doctor	4, 5	4	5	3
V	Specialist	5	5	-	4

#### Issue of False Positives and False Negatives

When screening populations, some of the difficulties faced are related to the issues of false positive and false negatives. The value of risk factors at predicting outcomes is gauged by proportion of the true association. There are examples where the cases of gastroenteritis deaths may be seen in breastfed infants (though less likely) while some of the bottle fed infants may not suffer from gastroenteritis (less likely). The issue of false positives and false negatives may make decisions for interpreting and introducing screening tests difficult.

#### Risk Scoring

Scores must accurately reflect the risk to the mother and children which in itself is a proxy for the need for care. Scoring attempts to provide simple, easy to use index of the urgency, seriousness and complexity, of the future threat to health. The risk scores are a good managerial tool. Sources of scores are -

- Ad hoc - e.g. tall or short, poor or not poor, well fed or malnourished
- Points or score based on experience - For example, while scoring for poor outcome of pregnancy, 3 points for poor obstetric history, 3 for high parity, 2 for maternal age, 1 for birth interval, family income, poor education etc.
- Absolute risk
- Relative risk
- Attributable risk

Most scoring systems use the relative risk.

**Trade off** : While deciding the cut off for continuous risk factor there is a compromise between yield and resources by trade off between false positive and false negatives. This decision is arrived at by weighing how many more false positive can be afforded by the community for the desired reduction in the false negatives.

### Basic information needed for planning the use of Risk Approach

1. Age and sex distribution and geographical distribution by community and household
2. Mortality by age, sex and cause
3. Local cultural factors, occupations, religion and attitude to health and disease
4. Services likely to have most impact from risk approach
5. Information on environmental risk factors
6. Local community organizations, groups
7. Local health care services including personnel and infrastructure
8. Present way to deal with the MCH problems
9. Information about traditional systems of medicine and their acceptance

**Intervention at different levels of care :** This is used to define the main point of impact of an intervention within the health care system. Risk approach can be applied at all levels from self and home to intersectoral policy.

### Uses of the Risk Approach

1. Self & Family
  - (a) Improved ability to recognize health priorities and health lifestyle and behavior.
  - (b) Informed surveillance of self and family.
  - (c) Earlier self and family referral.
2. Local community - village groups, self help groups, women's group.
3. Application within the health care system - resource allocation.
4. Increasing coverage - e.g. Universal immunization, essential maternal and newborn care.
5. Improved referral - better facilities, technology and skills.
6. Regional and National level - for defining and planning priorities, capacity and staffing, design referral chain, resource allocation and evaluation.
7. Intersectoral collaboration is the key to planning, designing and executing any health intervention.

### Selecting Interventions : Steps involved are -

- (a) Potential for change in health care - managerial, avoid authoritarian approach, no conflict with local, regional and national interest, local values and religious customs (MTP, Contraception).
- (b) Criteria for selection - importance, feasibility, acceptability.
- (c) Local priorities for action - Maternal mortality, Infant deaths, Perinatal mortality. Local priorities to be specific and well defined for application of risk approach.
- (d) Local resources - people (trained and trainable), institutions, facilities and technology, managerial skills, health information systems, funds. Most important resources are time, commitment, enthusiasm and cooperation.
- (e) National priorities
- (f) Decision pathway

**Modifying Risk Factors :** Individual risk factors capable of modification are exemplified by some taboos and cultural practices (difficult to change), malnutrition, dwarfing, inadequate family planning services, lack of concern for environmental hazards, unsatisfactory personal hygiene,

negligent or dangerous work pattern and numerous intercurrent illnesses. Some can be modified without delay, some will have to wait till next pregnancy while yet others will only be changed in the next generation. Modification of the community risk factors is probably the most important potential achievement of the risk approach.

**Selecting Target Health Problems :** Among many health problems of mothers and children, it is usually a simple matter to choose the most important. This choice is often coloured by opinions. Most important health problems are not always the best targets for prevention. A method of rating scale which balances the factors like prevalence, seriousness, preventability, trends in time and local concern (Table - 2) is shown as an example.

Health Problem	Criterion	Max rating	Rating accorded
Maternal mortality	Extent	10	3
	Seriousness	10	10
	Preventability	10	8
	Local concern	10	10
	Time trend	10	2
Neonatal tetanus	Extent	10	8
	Seriousness	10	10
	Preventability	10	10
	Local concern	10	4
	Time trend	10	5
Childhood RTAs	Extent	10	3
	Seriousness	10	10
	Preventability	10	5
	Local concern	10	7
	Time trend	10	8

The relative importance of each criterion is also given its weight e.g. say on a five point scale, if we rate, extent and seriousness are given 5/5, preventability and local concern is given 3/5, time trend is given 2 out of 5. A simple matrix will set the health problems in the order of priority as seen in the Table - 3.

The order of priority in the above example is: first neonatal tetanus, second maternal mortality and third childhood RTAs.

### Lessons from the Risk Approach -

1. Application to the whole field of Primary Health care is limited due to shortage of support from evaluative research. Need to develop health system research.
2. Impediments and Barriers are related to Ethical (No research without service), Sociological (not in sync with local culture), Problems of human motivation, Political, managerial and technical problems and Shortage of skilled human resources.

The risk approach in MCH is a very useful tool and can help

in maximizing the output from the limited resources available especially in the developing countries. The risk approach helps to ease the pressure on the limited beds and facilities at the hospital level and also saving the expert human resources and sophisticated equipment for those who need it most. The risk approach also helps in developing health auxiliaries at the periphery providing the basic care in MCH close to home to the clientele within acceptable socio - cultural milieu. The policies and principles of care under NRHM using ASHA are an example of this approach.

Table - 3 : Selecting a problem by rating/scoring						
Criteria and Relative weightage						
Health problem	Extent (weight 5)	Seriousness (weight 5)	Preventability (weight 3)	Local concern (weight 3)	Time trend (weight 2)	Total score
Maternal mortality	3x5	10x5	8x3	10x3	2x2	123
Neonatal tetanus	8x5	10x5	10x3	4x3	5x2	142
Childhood RTAs	3x5	10x5	5x3	7x3	8x2	117

## Summary

The risk strategy utilizes the risk estimates as guide for action, resource allocation, coverage, referral and care. Therefore the more accurately the risk is measured the better is the understanding of the need for efficient utilization of scarce resources with more care for those in need and proportionate to the need. Risk, predictions and possible effects are the tools

of the risk approach. The preventive and promotive elements of primary health care will have greatest yield if applied by using risk approach in MCH. Risk factors could be related to the individual, family, community and environment and their significance can be judged by their frequency and the degree of their association with the outcome. The risk approach involves prioritizing targets, measuring associations and the interventions to be applied. Info about the risk factors can be obtained through prevalence, incidence, trends, relative risk of unwanted outcomes and attributable risk associated with each risk factors and predictive power of risk factors. Prioritization will depend upon community priority, prevalence, fatality rates, degree of preventability and rising trend. Risk scoring (most of them use relative risk) if used must reflect the risk to the mother and the child.

Increased coverage, improved referral, risk factor modification, local, national and regional reorganization and training are the some of the uses of risk approach. The risk approach in MCH is a very useful tool maximizing the output with the limited number of tools available in addition to developing the health auxiliaries at the periphery.

## Study Exercises

**Long Question :** Risk approach in MCH

**Short Notes :** (1) Basic information needed for planning the use of risk approach (2) Risk scoring (3) Uses of risk approach within and outside the health care system (4) Steps for selecting interventions.

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## Maternal Health Care

AS Kushwaha

All mothers and newborns, not just those considered to be at particular risk of developing complications, need skilled maternal and neonatal care. Maternal health care includes Antenatal, Intranatal care and Postnatal care, Quality intranatal care is critical to achieve the aim of a healthy mother and a healthy baby at the end of a pregnancy. This particular period (perinatal) though constitutes, only a small fraction in terms of its share (0.5 %) in the maternity cycle, but is probably, the most crucial.

## Definitions

**Maternal Death :** Maternal death is defined as death of a woman, while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of pregnancy, from any cause related to or aggravated by pregnancy or its management but not from accidental or incidental causes. (ICD-10)

**Direct Obstetric Deaths :** The deaths resulting from obstetric complications of the pregnant state (pregnancy, labour and the puerperium), from interventions, omissions, or incorrect treatment, or from a chain of events resulting from any of the above are called direct obstetric deaths.

**Indirect Obstetric Deaths :** Those resulting from previous existing disease or disease that developed during pregnancy and



that was not due to direct obstetric causes but was aggravated by the physiological effects of pregnancy.

**Late Maternal Death** : Late maternal death is death of a woman from direct or indirect obstetric causes, more than 42 days but less than one year, after termination of pregnancy.

**Pregnancy Related Death** : To facilitate the identification of maternal death in circumstances in which cause of death attribution is inadequate, ICD-10 introduced a new category, that of “pregnancy-related death” which is defined as : the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the cause of death.

**Skilled Birth Attendant** : Skilled Birth Attendants are people with midwifery skills (e.g. doctors, midwives, nurses) who have been trained to proficiency in the skills necessary to manage a normal delivery and diagnose and refer obstetric complications. This includes capacity to initiate the management of complications and obstetric emergencies, including life-saving measures where needed. Ideally skilled attendants live in, and are part of the community they serve.

### Measurement of Maternal Mortality

There are three main measures of maternal mortality- the maternal mortality ratio, the maternal mortality rate and the lifetime risk of maternal death.

**Maternal Mortality Ratio** : This represents the risk associated with each pregnancy, i.e. the obstetric risk. It is calculated as the number of maternal deaths during a given year per 100,000 live births during the same period. This is usually referred to as rate though it is a ratio.

*The appropriate denominator for the Maternal Mortality Ratio would be the total number of pregnancies (live births, foetal deaths or stillbirths, induced and spontaneous abortions, ectopic and molar pregnancies). However, this figure is seldom available and thus number of live births is used as the denominator. In countries where maternal mortality is high denominator used is per 1000 live births but as this indicator is reduced with better services, the denominator used is per 1,00,000 live births to avoid figure in decimals.*

**Maternal Mortality Rate**: It measures both the obstetric risk and the frequency with which women are exposed to this risk. It is calculated as the number of maternal deaths in a given period per 100,000 women of reproductive age (usually 15-49 years). From the year 2000, the SRS (Sample Registration System) has introduced this method of verbal autopsy called RHIME (Representative, Re-sampled, Routine Household Interview of Mortality with Medical Evaluation).

### Lifetime Risk of Maternal Death

This parameter takes into account both the probability of becoming pregnant and the probability of dying as a result of the pregnancy cumulated across a woman's reproductive years. *Lifetime risk can be estimated by multiplying the maternal mortality rate by the length of the reproductive period (around 35 years). This is also approximated by the product of the Total Fertility Rate and the Maternal Mortality Ratio.*

### Antenatal Care

The care of women during pregnancy is called antenatal care. This begins soon after conception. The ultimate objective is

to have a healthy mother and a healthy child at the end of pregnancy. *Antenatal care* includes visit to antenatal clinic, examination, investigations, immunization, supplements (Iron, Folic acid, Calcium, Nutritional) and interventions as required. This is a comprehensive approach to medical care and psychosocial support of the family that ideally begins prior to conception and ends with the onset of labour. *Preconception care* refers to physical and mental preparation of both parents for pregnancy and childbearing in order to improve the pregnancy outcome (Refer Box - 1). Antenatal (Prenatal) care formally begins with the diagnosis of pregnancy and includes ongoing assessment of risk, education and counselling and identifying and managing problems if they arise (Box - 2).

#### Box - 1 : Indications for Preconception Care

Advanced maternal (>35 years) or paternal (>55 years)age
History of neural tube defects in family or previous pregnancy
Congenital heart disease, hemophilia, thalassemia, sickle cell disease, Tay-sach's disease, cystic fibrosis, Huntington chorea, muscular dystrophy, Down's syndrome.
Maternal metabolic disorders
Recurrent pregnancy loss (>3)
Use of alcohol, recreational drugs or medications
Environmental or occupational exposures

#### Box - 2 : Objectives of Antenatal Care

To promote, protect and maintain health of the mother
To detect 'at risk' cases and provide necessary care
To provide advise on self care during pregnancy
To educate women on warning signals, child care, family planning
To prepare the woman for labour and lactation
To allay anxiety associated with pregnancy and childbirth
To provide early diagnosis and treatment of any medical condition/ complication of pregnancy
To plan for “Birth” and emergencies / complications (where, how, by whom, transport, blood)
To provide care to any child accompanying the mother

**Frequency** : Under optimal conditions a women should undergo regular antenatal health check once a month during first seven months, twice a month for 8th month and every week thereafter till delivery. However, a minimum of four visits are essential.

**Essential Antenatal Care**: Under CSSM program three antenatal visits have been recommended as minimum acceptable level of antenatal care. Early registration by 12-16 weeks followed by visits at 20, 32 and 36 weeks is recommended during any pregnancy. At least one home visit by health worker must be made. Essential Antenatal Care also includes immunization with tetanus toxoid and Iron Folic Acid supplements for 100 days. Deworming with mebendazole in areas endemic for hook

worm may be provided during 2nd/3rd trimester. Under RCH a minimum of three visits are to be made.

**History Taking and Examination** : During history taking important points to be covered are detailed medical, psychosocial and immunization history followed by careful physical examination and certain relevant laboratory tests.

Physical examination should include measurement of height, weight, pelvimetry (not very important). Important laboratory tests include hemoglobin, urinalysis, PAP smear, VDRL and any other test as warranted by the concerned physician. There is an opportunity for health promotion like cessation of tobacco, alcohol, manage pre-existing medical disorders, appropriate immunization and pregnancy planning.

**First Visit** : The patient is registered and antenatal card is initiated. First visit should be made at the earliest possible after pregnancy is suspected, ideally at 8 weeks of gestation but not later than 12-16 weeks. This is important for determining accurate EDD, evaluation of risk and to provide essential patient education. The functions of this visit are-

- (a) Confirmation of pregnancy
- (b) Screening for high risk pregnancy
- (c) Baseline investigations
- (d) Initiation of Iron and Folic Acid supplementation
- (e) Immunization with Tetanus toxoid (if visit in 2nd trimester)
- (f) Education of the mother on pregnancy and childbirth

#### Identification of “High Risk” Pregnancies

The identification of high risk pregnancies involves meticulous history taking, careful examination and relevant investigations. The identification of these high risk pregnancies should follow needful referral and care. History should cover all aspects as outlined for preconception care. The ‘at risk’ pregnancies can be identified as under-

#### Maternal Factors

- (i) Age- <18 years or > 35 years (especially in primigravida)
- (ii) Multiparity (> 4)
- (iii) Short stature ( < 140 cms )
- (iv) Weight < 40 Kg / weight gain < 5 Kg
- (v) Rh negative

#### Bad Obstetric History

- (i) Recurrent abortions ( 2 x1st trimester or 1 mid-trimester)
- (ii) Intrauterine death or intrapartum death/ stillbirth
- (iii) Prolonged labour, birth asphyxia , early neonatal death
- (iv) Previous caesarean section / scar dehiscence
- (v) Postpartum haemorrhage, manual removal of placenta
- (vi) Baby which is LBW, SFD or large for date, congenitally malformed
- (vii) Malpresentation, instrumental delivery, ectopic pregnancy
- (viii) Twins, hydramnios, pre-eclampsia

#### Medical Disorders

- (i) Cardiac (RHD, CHD, Valve defects), Renal, Endocrine (Thyroid) or Gastrointestinal disease.
- (ii) Infections - TB, Leprosy, Malaria etc.
- (iii) Hypertension, Diabetes, IHD and Seizures
- (iv) Anaemia

Besides the above, the pregnancy at any stage can be classified as high risk if any of the following conditions/ complications

appear -

- (a) Bleeding PV at any point ( Antepartum haemorrhage)
- (b) Excessive vomiting ( Hyperemesis gravidarum)
- (c) Hypertension, proteinuria
- (d) Severe anaemia
- (e) Abnormal weight gain
- (f) Multiple pregnancy, hydramnios, oligohydramnios
- (g) Abnormal presentation in 9th month
- (h) Preterm Labour, PROM
- (i) Pre-eclampsia, eclampsia

#### Health Education

This is one of the most important and often neglected functions of antenatal care. This is also called prenatal advice. The communication between the mother and the service provider should be free and encompass the issues concerning not only pregnancy but should spillover to childbirth and childcare. The family planning issues like spacing and sterilization are better received at this time. Important issues that need to be deliberated are given below.

- (a) Diet & Rest
- (b) Personal Hygiene and Habits
- (c) Sexual intercourse
- (d) Drugs
- (e) Exercise
- (f) Travel
- (g) Care of Breasts
- (h) Weight Gain

**Warning signs** : Besides education on common symptoms and their management, the woman should be educated on warning signs during pregnancy which should not be ignored. She should report to health facility in case she has any of the warning signs. The warning signs are-

- (i) Swelling of feet
- (ii) Convulsions/ unconsciousness
- (iii) Severe headache
- (iv) Blurring of vision
- (v) Bleeding or discharge per vaginum
- (vi) Severe abdominal pain
- (vii) Other unusual symptom

#### Pregnancy & HIV Infection

This situation is likely to be encountered in states where HIV prevalence amongst antenatal cases is high. This will require special handling. The urgency of preventing mother-to-child transmission (PMTCT) of HIV is clear. Without treatment, half of the infants born with the virus will die before age two. Significant reductions in mother-to-child transmission, however, can occur through implementation of basic but critical actions, such as identifying HIV-infected pregnant women by offering routine HIV testing, enrolling them in PMTCT programmes, ensuring that health systems are fully able to deliver effective antiretroviral regimens both for prophylaxis and for treatment, and supporting women in adhering to optimal and safe infant feeding. The counselling of women early in pregnancy on risk of transmission to the baby and testing of spouse is mandatory. AZT 300 mg every 12 hours is given from 36 weeks of pregnancy till onset of labour and thereafter 300mg every 3 hours. Alternatively, Nevirapine 200 mg single dose as early

as possible in labour and 50 mg in oral solution form to the newborn within 72 hours is recommended to prevent mother to child transmission. After delivery, this also helps to make required adaptations in infant feeding. Replacement feeding using principles of AFASS (acceptable, feasible, affordable, safe and sustainable) is a viable solution to prevent transmission of infection through breast feeding.

### Planning for Birth (Birth Plan)

This is an important function of the prenatal care. The planning for birth and emergencies is very important as it can take care of many unforeseen complications which may endanger life of both mother and the child and may arise at any point of time without any prior warning in an otherwise normal pregnancy. Plans made early for emergencies during pregnancy and labour will result in favourable outcomes. The birth plan helps to tide over the uncertain and sudden nature of complications of labour. The delivery will take place at hospital or home must be decided (See Box - 3).

<b>Box - 3 : Institutional delivery is a must if there is-</b>	
	Mild pre-eclampsia
	PPH in the previous pregnancy
	More than 5 previous births or a primi
	Previous assisted delivery
	Maternal age less than 16 years
	H/o third-degree tear in the previous pregnancy
	Severe anaemia
	Severe pre-eclampsia/eclampsia
	APH
	Transverse foetal lie or any other Malpresentation
	Caesarean section in the previous pregnancy
	Multiple pregnancies
	Premature or pre-labour rupture of membranes (PROM)
	Medical illnesses such as diabetes mellitus, heart disease, asthma, etc.

In case of delivery at home what arrangements are there to overcome any unanticipated complication? The arrangement

for vehicle, money and blood can be difficult to make if not already planned and can be crucial for the life of both mother and child. Institutional delivery should be encouraged. Institutional delivery should be advocated as it is the right of every pregnant woman.

## Intranatal Care and Postnatal Care

### Objectives of Intranatal Care - (AMC-N)

1. Thorough Asepsis ("The Five Cleans" - clean hands, surface, blade, cord, tie)
2. Minimum injury to mother and child
3. To deal with any Complications during labour
4. Care of the Newborn

### The Postpartum Care

The Postpartum Care is aimed at achieving a Puerperium which is free of any complications and to ensure a healthy newborn. (Box - 4)

<b>Box - 4 : Objectives of Postpartum care</b>	
1.	Restoration of mother to optimum health
2.	To prevent complications of puerperium
3.	Provide basic postpartum care & services to mother and child
4.	Motivate, educate and provide family planning services
5.	To check adequacy of breast feeding

**The Postpartum Visits :** The first 48 hours following delivery are the most important. The next most critical period is the first week following delivery. The mother is asked to pay another visit on day 3rd and day 7th, or the ANM in charge of that area should pay a home visit during this period. The second postpartum visit should be planned within 7-10 days after delivery. A visit at 6 weeks is mandatory to see that involution of uterus is complete. Further visits can be once a month for 6 month and thereafter every 2-3 months till the end of one year. Efforts to organize 3 - 6 visits must be made. If the woman misses her postpartum visits, she should be informed regarding the danger signs which if appear she should report back (Box - 5).

**Complications of the Puerperium :** The postpartum period is often neglected after having a successful parturition. Sadly,

<b>Box - 5 : Danger Signs in Puerperium</b>			
<b>Advise the woman and her family to go to an FRU immediately, day or night, WITHOUT WAITING</b>		<b>Advise the woman that she should visit the PHC as soon as possible, if . . .</b>	
(i)	Excessive vaginal bleeding, i.e. soaking more than 2 or 3 pads in 20-30 minutes after delivery, or bleeding increases rather than decreases after the delivery	(i)	Fever
(ii)	Convulsions	(ii)	Abdominal pain
(iii)	Fast or difficult breathing	(iii)	The woman feels ill
(iv)	Fever and weakness; inability to get out of bed	(iv)	Swollen, red or tender breasts, or sore nipples
(v)	Severe abdominal pain	(v)	Dribbling of urine or painful micturition
		(vi)	Pain in the perineum or pus draining from the perineal area
		(vii)	Foul-smelling lochia

neglected postnatal period can be the cause of significant mortality in mother and the newborn. The infections and haemorrhage are two serious dangers of Puerperium. Besides these UTIs, thrombophlebitis and psychiatric disorders are also seen (Box - 6).

<b>Box - 6 : Common Complications of the Puerperium</b>	
1.	Puerperal sepsis
2.	Urinary tract infections
3.	Breast infections
4.	Venous thrombosis
5.	Pulmonary thromboembolism
6.	Puerperal haemorrhage
7.	Incontinence of urine
8.	Psychiatric disorders

## Maternal Mortality

### Global Burden

Maternal mortality is currently estimated at 5,29,000 deaths per year, a global ratio of 400 maternal deaths per 100,000 live births (1). There are immense variations in maternal death rates in different parts of the world (See Table - 1). Only a small fraction (1%) of these deaths occurs in the developed world. Maternal mortality ratios range from as high as 830 per 100,000 births in some African countries to as low as 24 per 100,000 births in European countries. Of the 20 countries with the highest maternal mortality ratios, 19 are in sub-Saharan Africa. In sub-Saharan Africa, the lifetime risk of maternal death is 1 in 16, (See Table 1) compared with 1 in 2800 in rich countries (2). Rural populations suffer higher mortality than urban dwellers, rates can vary widely by ethnicity or by socio-economic status, and remote areas bear a heavy burden of deaths. Such deaths often occur suddenly and unpredictably. Between 11% and 17% of maternal deaths happen during childbirth itself and between 50% and 71% in the postpartum period (3-7). The fact that a high level of risk is concentrated during childbirth itself, and that many postpartum deaths are also a result of what happened during birth, focuses attention on the hours and sometimes days that are spent in labour and giving birth. The postpartum period - despite its heavy toll of deaths - is often neglected. Within this period, the first week is the most prone to risk. About 45% of postpartum maternal deaths occur during the first 24 hours, and more than two thirds during the first week (3).

<b>Table - 1 : Life Time Risk of a Woman</b>		
Continents	Losing a Neonate	Of dying due to Maternal cause
Africa	1 in 5	1 in 16
Asia	1 in 11	1 in 132
Latin America	1 in 21	1 in 188
Developed countries	1 in 125	1 in 2976

Breakdowns of access to skilled care due to war, strife and HIV may rapidly result in an increase of unfavourable outcomes, as in Malawi or Iraq. Malawi is one country that experienced a significant reversal in maternal mortality: from 752 maternal deaths per 100,000 live births in 1992 to 1120 in 2000 due to rise in HIV prevalence. Fewer mothers gave birth in health facilities: the proportion dropped from 55% to 43% between 2000 and 2001. The quality of care within health facilities deteriorated in Iraq as sanctions during the 1990s severely disrupted previously well-functioning health care services, and maternal mortality ratios increased from 50 per 100,000 in 1989 to 117 per 100,000 in 1997 (12).

### Scenario in India

Every seven minutes an Indian woman dies from complications related to pregnancy and childbirth. The maternal mortality ratio in India stands at 300 per 100,000 live births. It has some high performing states like Kerala with MMR of 110 and poorly doing states like Uttar Pradesh with MMR of 517 (13). The highlight is that most of the states recording unfavourable maternal mortality rates are the ones with the highest number of birth rates and huge population bases with poor health infrastructure. There are a number of reasons India has such a high maternal mortality ratio. Marriage and childbirth at an early age, lack of adequate health care facilities, inadequate nutrition and absence of skilled personnel, all contribute to pregnancies proving fatal. The common causes of maternal mortality in India are anaemia, haemorrhage, sepsis, obstructed labour, abortion and toxemia. Maternal morbidities are the anaemias, chronic malnutrition, pelvic inflammations, liver and kidney diseases. In addition, the pathological processes of some preexisting diseases, such as chronic heart diseases, hypertension, kidney diseases and pulmonary tuberculosis are aggravated by pregnancy and childbirth.

### 'Delay' Model Leading to Maternal Death

The maternal deaths can be explained by this model of delay which is due to:

- Delay in seeking care
- Delay in transport to appropriate health facility
- Delay in provision of adequate care

### Causes of Maternal Mortality

Maternal deaths result from a wide range of indirect and direct causes (See Fig. 1 & 2). Maternal deaths due to indirect causes represent 20% of the global total. They are caused by diseases (pre-existing or concurrent) that are not complications of pregnancy, but complicate pregnancy or are aggravated by it. These include malaria, anaemia, HIV/AIDS and cardiovascular disease. Their role in maternal mortality varies from country to country, according to the epidemiological context and the health system's effectiveness in responding.

The lion's share of maternal deaths is attributable to direct causes. Direct maternal deaths follow complications of pregnancy & childbirth or are caused by any interventions, omissions, incorrect treatment or events that result from these complications, including complications from unsafe abortion.

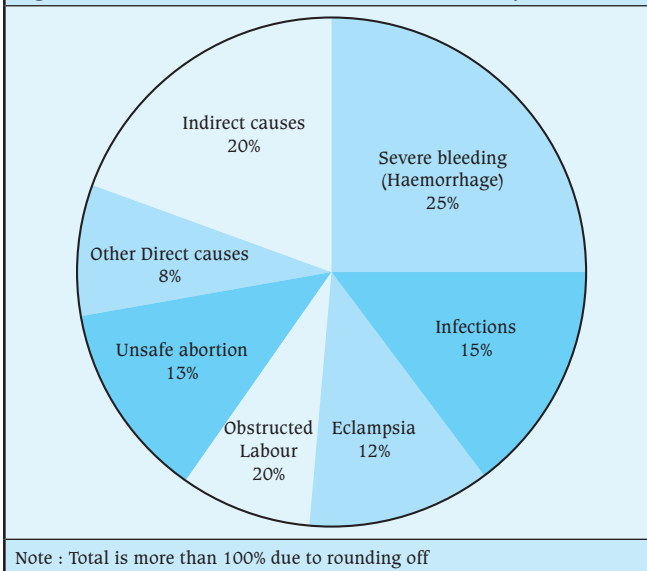
The four major direct causes of maternal loss are-

- Haemorrhage

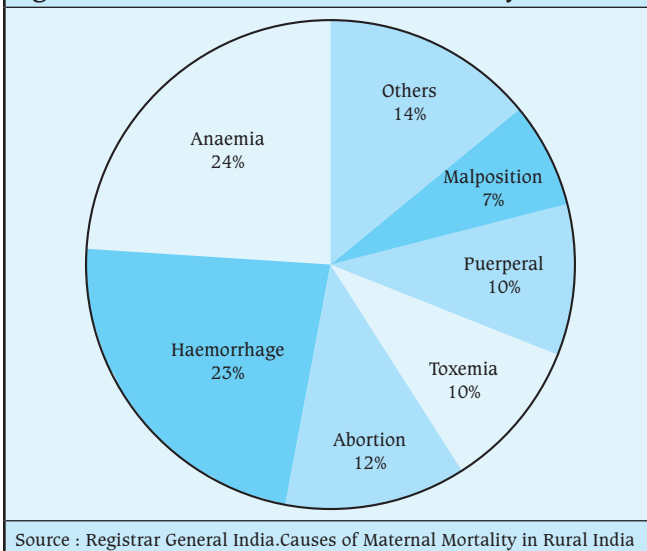


- (b) Infection (sepsis)
- (c) Eclampsia
- (d) Obstructed Labour

**Fig. - 1 : World - Causes of Maternal Mortality**



**Fig. - 2 : India - Causes of Maternal Mortality**



**Haemorrhage** : The most common cause of maternal death is severe bleeding, a major cause of death in both developing and developed countries (14,15). Postpartum bleeding can kill even a healthy woman within two hours, if unattended. It is the quickest of maternal killers. An injection of oxytocin or ergometrine given immediately after childbirth is very effective in reducing the risk of bleeding. In some cases a fairly simple - but urgent - intervention such as massage of the uterus, removal of clot or manual removal of the placenta may solve the problem. Other women may need a surgical intervention or a blood transfusion, both of which require hospitalization with appropriate staff, equipment and supplies. The proportion

needing hospital care depends, to some extent, on the quality of the first-level care provided to women; for example, active management of the third stage of labour reduces postpartum bleeding. The proportion that dies depends on whether appropriate care is provided rapidly and with the degree of skill with which it is provided.

**Infection** : The second most frequent direct cause of death is sepsis, responsible for most late postpartum deaths. This is often a consequence of poor hygiene during delivery. The introduction of aseptic (clean delivery) techniques brought a spectacular reduction of its importance in the developed world. However, sepsis is still a significant threat in many developing countries.

**Eclampsia** : Classic complications of pregnancy include pre-eclampsia and eclampsia which affect 2.8% of pregnancies in developing countries and 0.4% in developed countries leading to many life-threatening cases and over 63 000 maternal deaths worldwide every year accounting for 12 % of the maternal deaths (17).

**Obstructed Labour** : The prolonged or obstructed labour accounts for about 8% of maternal deaths. This is often caused by fetopelvic disproportion or by malpresentation (transverse lie, mentoposterior, brow presentation). Disproportion is more common where malnutrition is endemic, especially among populations with various traditions and taboos regarding the diets of girls and women. It is worse where girls marry young and are expected to prove their fertility, often before they are fully grown.

**Abortions** : More than 18 million induced abortions each year are performed by people lacking the necessary skills or in an environment lacking the minimal medical standards, or both, and are therefore unsafe resulting in 68000 deaths (18, 19). Almost all take place in the developing world. With 34 unsafe abortions per 1000 women, South America has the highest ratio (19). Unsafe abortion is particularly an issue for younger women. Around 2.5 million, or almost 14% of all unsafe abortions in developing countries, are among women under 20 years of age. The proportion of women aged 15-19 years in Africa who have had an unsafe abortion is higher than in any other region.

**Others** : Haemorrhage following placental abruption or placenta praevia affects about 4% of pregnant women. Less common, but very serious complications include ectopic pregnancy and molar pregnancy. Maternal malnutrition is a huge global problem, both as protein-calorie deficiency and as micronutrient deficiency. Anaemia is an important indirect cause of maternal death due to cardiovascular deaths but also is an important underlying factor in many direct causes like haemorrhage and sepsis.

### Factors underlying the medical causes

**Socio-Economic** : The factors underlying the direct causes of maternal deaths operate at several levels. The low social and economic status of girls and women is a fundamental determinant of maternal mortality in many developing countries including India. Low status limits the access of girls and women to education and good nutrition as well as to the economic resources to pay for health care or family planning services.

Lack of decision making power in terms of family planning puts them to repeated childbearing. Excessive physical work coupled with poor diet leads to poor maternal outcomes. Many deliveries in rural areas are either conducted by relatives or traditional birth attendant or at times none. In India three out of every five births take place at home; only two in five births take place in a health facility. However, the percentage of births in a health facility has increased steadily.

**Nutritional** : Poor nutrition before and during pregnancy contributes in a variety of ways to poor maternal health, obstetric problems and poor pregnancy outcomes. Stunting predisposes to cephalopelvic disproportion and obstructed labour. Anaemia may predispose to infection during pregnancy and childbirth, obstetric haemorrhage and are poor operative risks in the event if surgery is required. Severe vitamin A deficiency make women more vulnerable to obstetric complications. Iodine deficiency increases the risk of stillbirths and spontaneous abortions. Lack of dietary calcium appears to increase the risk of pre-eclampsia and eclampsia during pregnancy.

### Impact of Maternal Deaths (India)

Maternal death has implications for the whole family and an impact that rebounds across generations. The complications that cause the deaths and disabilities of mothers also damage the infants they are carrying. The impact is summarized as under-

- (a) Children who lost their mothers are more likely to die within two years of maternal death.
- (b) 10 times the chance of death for the neonate.
- (c) 7 times the chance of death for infants older than one month.
- (d) 3 times the chance of death for children 1 to 5 years.
- (e) Enrolment in school for younger children is delayed and older children often leave school to support their family.

Significant reduction in infant mortality can be achieved by improving the access to care during labour, birth and the critical hours immediately afterwards.

### Measures to Reduce Maternal Mortality

#### What is known about Reducing Maternal Mortality?

The countries that have successfully managed to make motherhood safer have three things in common.

- (a) First, policy-makers and managers were informed: they were aware that they had a problem, knew that it could be tackled, and decided to act upon that information.
- (b) Second, they chose a common-sense strategy that proved to be the right one: not just antenatal care, but also professional care at and after childbirth for all mothers, by skilled midwives, nurse-midwives or doctors, backed up by hospital care.
- (c) Third, they made sure that access to these services - financial and geographical - would be guaranteed for the entire population.

Where strategies other than that of professionalization of delivery care are chosen or where universal access is not achieved, positive results are delayed. This explains why many developing countries today still have high levels of maternal mortality. To provide skilled care at and after childbirth and to deal with complications is a matter of common sense - it is

also what mothers and their families ask for. Putting it into practice is a challenge that many countries have not yet been able to meet.

**Training of Traditional Birth Attendant - A Failed Experiment!** : In the 1970s, training of traditional birth attendants (TBAs) to improve obstetric services became widespread in settings where there was a lack of professional health personnel to provide maternity care, and where there were not enough beds or staff at hospital level to give all women access to hospital for their confinement. TBAs already existed and performed deliveries (for the most part in rural areas), they were accessible and culturally acceptable and they influenced women's decisions on using health services. While WHO continued to encourage this strategy until the mid-1980s but evidence emerged that training TBAs has had little impact on maternal mortality.

**Actions for Safe Motherhood** : Countries vary widely in terms of the situations and challenges they face and their capacity to address these. However, it is seen that to reduce maternal mortality requires coordinated, long term efforts. Actions are needed within families and communities, in society as a whole, in health systems, and at the level of national legislation and policy.

**Legislative & Policy actions** : Long term political commitment is an essential prerequisite. This leads to adequate resource allocation and policy decisions are taken. A supportive social, economic and legislative environment allows women to access the healthcare. (transport, money, social barriers limit the access)

**(a) Family planning** : To avoid pregnancies that are too early, too late or too frequent.

**(b) Adolescents** : To encourage late marriage and childbearing by increasing educational opportunities. To improve their nutritional status by supplementary nutrition (e.g. *ICDS-Kishori Shakti Yojna*). Education of adolescents on reproductive health and empowerment of women to control fertility and reproduction.

**(c) Barriers to access** : Provision of skilled health worker at village level health facility to overcome problems of distance and transport. These workers to be adequately trained in midwifery and paid adequately and to be provided with adequate supplies and at minimal cost.

**(d) Develop protocols** : Aimed at providing both routine maternal care and referral facilities for obstetric complications. (e.g. IMNCI, 2005-Guidelines on pregnancy by MCH Division of Ministry of Health & Family Welfare)

**(e) Decentralization and delegation** : Decentralized facilities available close to people's homes together with written policies and protocols to allow delegation of certain functions at lower levels.

**(f) Abortion** : Availability of safe abortion services and policy to discourage illegal and unsafe abortions.

**Society and Community Interventions** : The long term commitment of politicians, planners and decision makers to programmes on safe motherhood depends on popular support from community and religious leaders, women's groups, youth

groups etc. National, regional and district safe motherhood committees can be set up. Health facility and community committee can investigate maternal deaths and implement strategies for improvement in areas such as referral, emergency transport, deployment and support of health care providers and cost sharing.

**Health Sector Actions :** The role of health sector is to ensure availability of good quality essential services to all women during pregnancy and childbirth. It is clear that certain pregnancy complications can be prevented but large number of these which occur around the time of childbirth/labour can neither be prevented nor predicted. Therefore, presence of a skilled birth attendant is crucial for early detection and management of such complications.

**First Level Maternal and Newborn Care :** First-level care does save lives and manage emergencies. It does so by controlling conditions before they become life threatening (e.g. treating anaemia) by avoiding complications (e.g. active management of the third stage of labour). A midwife or other professional with midwifery skills also actually deals with a range of emergencies on the spot, such as by administering vacuum extraction in case of foetal distress or by arranging emergency referral for caesarean section or other back-up care.

First-level maternal and newborn care should preferably be organized in midwife led birthing centres, combining cultural proximity in a non-medicalized setting, with professional skilled care, the necessary equipment, and the potential for emergency evacuation. Decentralization for easy access obviously has to be balanced by the need to concentrate the staff and equipment necessary to be available 24 hours a day, something more easily done in birthing centres with a team of several skilled attendants than in solo practices.

Health workers who provide first-level care need back-up when a problem occurs that they are unable to deal with as it goes beyond their competence or beyond the means they have at their disposal.

Back-up maternal and newborn care encompasses emergencies (such as a LSCS, hysterectomy or treatment of neonatal tetanus or meningitis) as well as non-emergency interventions (such as treatment of congenital syphilis). Back-up is ideally provided in a hospital where doctors - specialists, skilled general practitioners or mid-level technicians with the appropriate skills - can deal with mothers whose problems are too complex for first-level providers. To make the difference between life and death, the required staff and equipment must be available 24 hours a day, and the links between the two levels of care should be strong.

**Rolling out Services Simultaneously :** First-level maternal and newborn care and the referral hospital services that should provide back-up have to be rolled out in parallel.. The challenge of simultaneous roll-out has striking similarities to the one that led the primary health care movement to opt for the health districts, with both health centres and a district hospital, linked by referral mechanisms, and organized to ensure a continuum of care.

### Initiatives in India

India has a history of starting Family planning programme

since 1952 which focused mainly on limiting family size. This was later made more client oriented and allowed voluntary acceptance of these services and came to be called as family welfare from 1977 onwards. The focus on maternal and child services was program centric without involving client. It was in 1992, that a comprehensive approach to ensure survival of children and safe motherhood was implemented in the form of CSSM programme. It was later realized, that the overall improvement in the reproductive health was the key to achieve the overall aim of lifelong health and thus, the approach was changed and RCH program was launched. Various initiatives that have been taken are spelt out in the succeeding paragraph. The MDGs and launching of NRHM have provided the necessary impetus to the issue of safe motherhood which is the right of every woman.

**All India Hospital Postpartum Programme :** The Post Partum Programme, a maternity centered hospital based approach to Family Welfare Programme was begun in 1969 with 54 participating hospitals, the program had 122 hospitals by 1971-1972. 90% of these were attached to medical colleges. With a view to provide maternal, child health and family welfare services in semi-urban/ rural areas, the Post Partum Programme has been extended to sub-district level hospitals also by covering 50 institutions during 1980-81. Subsequently the programme was extended in a phased manner and by the end of 1988-89, 1075 Sub-district Level Hospitals were covered. The training of medical students and graduates in the techniques of birth control is an important aspect of the program. The major purpose of the program is to convince maternity and abortion patients to adopt birth control practices while they are in the hospital and also to interest others who hear about the program by word of mouth. Contraceptive services, including sterilization, are available to all friends, relatives, and neighbors of the confined women. Rural areas are reached through the medical colleges and attached hospitals which have responsibility for the area. Educational programs are a significant part of the program and are carried out in many parts of the hospitals and clinics.

**Essential Obstetric Care (EOC) :** This is the minimum obstetric care that must be made available to all pregnant women.

- (a) Registration of pregnancy in the first 12-16 wks of pregnancy.
- (b) At least 3 prenatal check ups by ANM or in dispensary.
- (c) Assistance during delivery. (Skilled Birth Attendant)
- (d) At least 3 postnatal check ups.

**Emergency Obstetric Care (EmOC) :** This is the service provided to cater for any unforeseen complication that may arise in any pregnancy at any stage. EmOC is an intervention for preventing maternal morbidity and mortality. Early detection and management of complications such as anaemia, haemorrhage, obstructed labour and sepsis can substantially reduce maternal mortality & morbidity. This requires competent supervision and check ups by ANM during antenatal, intranatal & post natal period. ANM should refer all cases having complications during pregnancy or at the time of delivery to PHCs / FRUs.

**Inputs :** A total of 1748 FRUs have been identified & equipped under CSSM programme. Some of the FRUs are lacking in manpower or infrastructure. Under RCH programme, a



provision has been kept for strengthening these FRUs through provisioning of drug kits, laparoscope, blood transfusion and employing contractual staff like PHN/ANM/Lab Asst and anaesthesiologist.

**24 Hour Delivery Services at PHCs/CHCs :** Under RCH program, arrangements have been made that a doctor on call duty, a nurse and cleaning staff are available beyond normal working hours to encourage people to seek deliveries in PHCs/CHCs. For this doctor could be paid Rs 200/- per delivery & other staff could be hired on contractual basis.

**Referral Transport to Indigent Families through Panchayats :** In category C districts of eight weakly performing states, communication infrastructure is weak and economic status of families in remote villages is poor. Because of this, even if there is a complication identified during pregnancy or delivery, the women have the delivery conducted in the village and frequently through untrained Dais. This is one of the causes of high maternal mortality and morbidity. This has been addressed by providing financial assistance to Panchayats through District Family Welfare Officers.

**Blood Supply to FRUs/PHCs :** Dept of family welfare will be taking up pilot projects with the assistance of European Commission under the RCH programme for setting up of regular and reliable supply of blood to PHCs/CHCs by linking them with the nearest blood bank

**MTP services :** MTP by untrained or experienced persons is responsible for high maternal mortality and morbidity. Therefore, increasing and improving facilities for MTP is an important component of the RCH programme at PHC level.

#### Inputs

- Need based training in MTP by NIHFW.
- Supply of MTP equipment to District Hospitals, CHCs & PHCs where trained staff is available.
- Assistance for engaging doctors trained in MTP to the PHCs once a week on fixed days for performing MTP (Pay Rs 500/- day). These doctors will also provide ANC and PNC services to patients during their visit.
- Supply of MTP equipment to Private clinics if they have OT & trained doctors.

#### Janani Suraksha Yojna (Maternal Safety Scheme)

Janani Suraksha Yojana (JSY) is a safe motherhood intervention under the National Rural Health Mission (NRHM) being implemented with the objective of reducing maternal and neo-natal mortality by promoting institutional delivery among the poor pregnant women. The Yojana, launched on 12th April 2005, is being implemented in all states and UTs with special focus on low performing states. JSY is a 100 % centrally sponsored scheme and it integrates cash assistance

with delivery and post-delivery care. The success of the scheme would be determined by the increase in institutional delivery among the poor families

The Yojana has identified ASHA, the accredited social health activist as an effective link between the Government and the poor pregnant women in 10 low performing states, namely the 8 EAG states and Assam and J&K and the remaining NE States. In other eligible states and UTs, wherever, AWW and TBAs or ASHA like activist has been engaged in this purpose, she can be associated with this Yojana for providing the services.

Role of ASHA or other link health worker associated with JSY would be to:

- Identify pregnant woman as a beneficiary of the scheme and report or facilitate registration for ANC,
- Assist the pregnant woman to obtain necessary certifications wherever necessary,
- Provide and / or help the women in receiving at least three ANC checkups including TT injections, IFA tablets,
- Identify a functional Government health centre or an accredited private health institution for referral and delivery,
- Counsel for institutional delivery,
- Escort the beneficiary women to the pre-determined health center and stay with her till the woman is discharged,
- Arrange to immunize the newborn till the age of 14 weeks,
- Inform about the birth or death of the child or mother to the ANM/MO,
- Post natal visit within 7 days of delivery to track mother's health after delivery and facilitate in obtaining care, wherever necessary,
- Counsel for initiation of breast feeding to the newborn within one-hour of delivery and its continuance till 3-6 months and promote family planning

The scheme focuses on the poor pregnant woman with special dispensation for states having low institutional delivery rates namely the states of Uttar Pradesh, Uttaranchal, Bihar, Jharkhand, Madhya Pradesh, Chhattisgarh, Assam, Rajasthan, Orissa and Jammu and Kashmir. While these states have been named as Low Performing States (LPS), the remaining states have been named as High performing States (HPS).

**Tracking Each Pregnancy :** Each beneficiary registered under this Yojana should have a JSY card along with a MCH card. ASHA/AWW/ any other identified link worker under the overall supervision of the ANM and the MO, PHC should mandatorily prepare a micro-birth plan. This will effectively help in monitoring Antenatal Check-up, and the post delivery care.

**Disbursement of Cash Assistance :** As the cash assistance to the mother is mainly to meet the cost of delivery, it should be

<i>Eligibility for Cash Assistance</i>	
LPS States	All pregnant women delivering in Government health centres like Sub-centre, PHC/CHC/ FRU / general wards of District and state Hospitals or accredited private institutions
HPS States	BPL pregnant women, aged 19 years and above
LPS & HPS	All SC and ST women delivering in a government health centre like Sub-centre, PHC/CHC/ FRU / general ward of District and state Hospitals or accredited private institutions



disbursed effectively at the institution itself.

<b>Scale of Cash Assistance for Institutional Delivery</b>						
Category	Rural Area		Total Rs.	Urban Area		Total Rs.
	Mother's Package	ASHA's Package		Mother's Package	ASHA's Package	
LPS	1400	600	2000	1000	200	1200
HPS	700		700	600		600

**Cash assistance for Referral transport :** This assistance is given to go to the nearest health centre for delivery. The state will determine the amount of assistance (should not less than Rs.250/- per delivery) depending on the topography and the infrastructure available in their state. It would, however, be the duty of the ASHA and the ANM to organize or facilitate in organizing referral the transport, in conjunction with gram pradhan, Gram Sabha etc.

*Note : This assistance is over and above the Mother's package.*

**Cash Incentive to ASHA :** This should not be less than Rs.200/- per delivery in lieu of her work relating to facilitating institutional delivery. Generally, ASHA should get this money after her postnatal visit to the beneficiary and that the child has been immunized for BCG.

**Transactional cost (Balance out of Rs.600/-) :** It is to be paid to ASHA in lieu of her stay with the pregnant woman in the health centre for delivery to meet her cost of boarding and lodging etc. Therefore, this payment should be made at the hospital/ health institution itself.

All payments to ASHA would be done by the ANM only. In this case too, a voucher scheme be introduced in such a manner that for every pregnant woman she registers under JSY, ANM would give two vouchers to ASHA, which she would be able to encash on certification by ANM.

#### Special Dispensation for LPS States

- Age restriction removed
- Restricting benefits of JSY up to 2 births removed
- No need for any marriage or BPL certification

**Subsidizing cost of Caesarean Section or management of Obstetric complications :** Generally PHCs/ FRUs / CHCs etc. would provide emergency obstetric services free of cost. Where Government specialists are not available in the Govt's health institution to manage complications or for Caesarean Section, assistance up to Rs. 1500/- per delivery could be utilized by the health institution for hiring services of specialists from the private sector. If a specialist is not available.

**Assistance for Home Delivery:** In LPS and HPS States, BPL pregnant women, aged 19 years and above, preferring to deliver at home is entitled to cash assistance of Rs. 500/- per delivery. Such cash assistance would be available only upto 2 live births and the disbursement would be done at the time of delivery or around 7 days before the delivery by ANM/ASHA/ any other link worker.

**Strategy :** While the scheme would create demand for institutional delivery, it would be necessary to have adequate number of 24x7 delivery services centre, doctors, mid-wives,

drugs etc. at appropriate places. Mainly, this will entail -

- (a) Linking each habitation (village or a ward in an urban area) to a functional health centre- public or accredited private institution where 24x7 delivery service would be available,
- (b) Associate an ASHA or a health link worker to each of these functional health centre,
- (c) It should be ensured that ASHA keeps track of all expectant mothers and newborn. All expectant mother and newborn should avail ANC and immunization services, if not in health centres, at least on the monthly health & nutrition day, to be organised in the Anganwadi or sub-centre:

**Micro-Birth Plan for JSY Beneficiaries :** Inform the mother and the family about 4 Is, namely

- (a) *Inform* dates of 3 ANC & TT Injection(s) & ensure these are provided
- (b) *Identify* the health centre for all referral
- (c) *Identify* the Place of Delivery
- (d) *Inform* expected date of delivery

#### Vande Mataram Scheme

The scheme is continuing under Public Private Partnership with the involvement of Federation of Obstetric and Gynaecological Society of India and Private Clinics. The aim of the scheme is to reduce the maternal mortality and morbidity of the pregnant and expectant mothers by involving and utilizing the vast resources of specialists/trained work force available in the private sector. The scheme intends to provide free antenatal and postnatal check, counselling on nutrition, breast feeding, spacing of birth etc. through public private partnership.

This is a voluntary scheme wherein any Obstetric and Gynaecologist, maternity home, nursing home can volunteer themselves in joining the scheme. Any lady doctor/MBBS doctor providing safe motherhood services can also volunteer to join this scheme. The enrolled 'Vandemataram' doctors will display 'Vandemataram' logo in their clinic. Iron and Folic Acid Tablets, oral pills, TT injections etc. will be provided by the respective District Medical Officers to the 'Vandemataram' doctors/clinics for free distributions to beneficiaries. The cases needing special care and treatment can be referred to the Government Hospitals and institutes, who have been advised to take due care to the patients coming with Vandemataram cards.

#### Challenges in Maternal Health

**(a) Establishing data base on maternal mortality :** The maternal mortality continues to be a problem in rural, remote, inaccessible and tribal areas where there is hardly any health service available and even if available it is inadequate and in this setting the deaths in childbirth are either not recorded or recorded incorrectly due to causes other than pregnancy or childbirth. There is a need to record each and every maternal death to ascertain the correct magnitude of this public health problem.

**(b) High Risk Pregnancy Behaviour - Too Early, Too Many, Too Close :** The social customs like universality of marriage, early marriage, social pressure for early childbearing, son preference, lack of education and poor social status of women in decision making, all lead to consequences of pregnancies that are early, repeated and frequent leading to maternal

depletion and debility and even death.

**(c) Urban-Rural Divide** : The rural urban divide is a major social issue and a challenge for the public health administrators as most of the women who need the most care continue to be deprived of the same. The rural urban divide is marked not only by unequal distribution of health services but all the social and cultural factors which add up to the negative milieu for maternal health and survival.

**(d) Poor Rate of Institutional Deliveries** : Even after the facilities are made available, the uptake of these services continue to be poor because of various factors like lack of adequate manpower, infrastructure and facilities in the PHC/CHC, preference to deliver at home due to cultural reasons and inability to afford the cost of maternity in a civil or private health care setting.

**(e) Lack of Skilled Care at Birth** : The care available to mothers at birth continues to be by TBAs or midwives who are neither trained nor adequately equipped to handle complicated situations and thus either there is delay in diagnosing, transportation and referral to a FRU.

**(f) Lack of Women Empowerment** : This social aspect of women empowerment for a lady to take decisions for her own safety and health is still lacking where her in laws are making these decisions for her. The women are still not having the right to decide their age at marriage, pregnancy, spacing and contraception and even their maternity care.

**(g) Poor Implementation of Programs** : There has been a family welfare programme running in the country since last six decades but the services available for maternal health and survival at primary level is still inadequate with poor results. The reasons are many. The core intervention of providing a skilled care at birth by a midwife and backed by a referral service has still not materialized. There is a proposal for such services under NRHM as part of RCH programme.

### Ten Action Messages for Safe Motherhood

These ten action messages were identified at the Sri Lanka Technical Consultation on Safe Motherhood in 1999, which marked the tenth anniversary of the Safe Motherhood Initiative.

- (1) Advance Safe Motherhood Through Human Rights
- (2) Empower Women: Ensure Choices
- (3) Safe Motherhood is a Vital Economic and Social Investment
- (4) Delay Marriage and First Birth
- (5) Every Pregnancy Faces Risks
- (6) Ensure Skilled Attendance at Delivery
- (7) Improve Access to Quality Reproductive Health Services
- (8) Prevent Unwanted Pregnancy and Address Unsafe Abortion
- (9) Measure Progress
- (10) The Power of Partnership

To provide skilled care at and after childbirth and to deal with complications is a matter of common sense - it is also what mothers and their families ask for. Putting it into practice is a challenge that many countries have not yet been able to meet. It is time to ensure that each pregnancy receives its due care with a view to prevent loss of lives in the form of maternal

deaths which are preventable to a large extent. India has an enormous task ahead to make assured services available at its health institutions and universalize the coverage of all women including those marginalized & underserved sections of society to realize the goal of safe motherhood. RCH and NRHM provide the necessary direction and opportunity to achieve this goal.

### Summary

Maternal health includes Antenatal care, Intranatal care and Postnatal care. The Intranatal period constitutes only 0.5% of maternal cycle and but it is probably the most crucial.

Maternal death is defined as death of a women while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of pregnancy, from any cause related to or aggravated by pregnancy or its management but not from accidental or incidental cause. There are three main measures of Maternal mortality which are maternal mortality ratio, maternal mortality rate and life time risk of maternal death.

Antenatal care is the care of women during pregnancy. Its ultimate objective is to have a healthy mother and healthy child at the end of pregnancy. Antenatal care includes visit antenatal clinic, examination, investigations, immunization, supplements and interventions as required. Pre-conceptional care is indicated in some cases like maternal age more than 35 yrs and paternal age more than 55 years, history of congenital defects in family, recurrent pregnancy loss and use of alcohol.

Prenatal care should start as early as 8 weeks but not later than 12-16 weeks with registration of patient and initiation of antenatal card. This is important for determining exact EDD, evaluation of risk and essential health education of the patient. The at risk pregnancies are age less than 18 or more than 35, multiparity, short stature, Rh negative, bad obstetric history, medical disorders for eg IHD, Diabetes, seizures, hypertension, tuberculosis, anaemia etc. Health education or prenatal advice includes issues like diet, rest, personal hygiene, sexual intercourse, drugs, exercise, travel and care of breasts. Women should also be educated about the warning signs which should not be ignored like convulsions, severe headache, blurring of vision and bleeding or discharge per vaginum.

Birth planning is an important function of prenatal care. It takes care of complications which may arise suddenly and can be dangerous to the life of both mother and the child. Institutional delivery should be advocated but it is a must in many conditions which should be identified.

Objectives of Intanatal care are asepsis (The five cleans- clean hands, surface, blade, cord, tie), minimum injury to mother and child, to deal with complications during labour and the care of newborn.

The first 48 hours following delivery are the most important followed by first week following delivery. The mother should give postpartum visit at 3rd, 7th day and 6 weeks after delivery to see that involution of uterus is complete. Mother should be educated about danger signs and advised to report to hospital if they appear. Infections, haemorrhage, UTI, thrombophlebitis, and psychiatric disorders are common complications of puerperium.

The global burden of maternal mortality is 400 maternal deaths per 100000 live births. The burden is very high in developing countries as compared to developed countries where it is low.

Rural population, low socio-economic status and remote areas bear a heavy burden of deaths. About 45% of maternal deaths occur in occur during the first 24 hours and more than two-thirds during first week. The maternal mortality ratio in India is 300 per 100,000 live births. The common causes in India are Anaemia, Haemorrhage, Sepsis, Obstructed labour, Abortion and Toxaemia. The 4 major direct causes of Maternal mortality are Haemorrhage, Infection, Eclampsia & Obstructed labour.

Actions for safe motherhood include legislative and policy decisions, society and community interventions, and health sector actions. Initiatives in India started since 1952 as Family planning programme. This was made more client oriented and voluntary since 1977 and called as Family welfare. In 1992 comprehensive approach was started in the form of CSSM programme. It was later realized, that the overall improvement in the reproductive health was the key to achieve the overall aim of lifelong health and thus, the approach was changed and RCH program was launched. Other programmes are All-India Hospital post-partum programme, Janani Suraksha Yojana (Maternal Safety Scheme) and Vande Matram Scheme.

The main challenges in Maternal Health are establishing data base on maternal mortality, high risk behavior, urban-rural divide, poor rate of institutional deliveries, lack of skilled care at birth, lack of women empowerment and poor implementation of programmes.

## Study Exercises

**Long Question :** Describe in details the Programmes in India directed towards Maternal Health Care.

**Short Notes :** (1) Causes of Maternal mortality (2) Maternal Mortality Rate (3) All India Hospital Post-Partum Programme (4) Janani Suraksha Yojana

### MCQs :

- Which of the following is not included in 'Cleans' in conduct of delivery : (a) Clean hands (b) Clean Perineum (c) Clean cutting and care of the cord (d) Clean surface of delivery
- In India, majority of deliveries take place at: (a) Hospital (b) Primary Health Centre (c) Private clinics (d) Home
- Ante-natal care includes: (a) Genetic counselling for prospective parents (b) Spacing of births (c) Ensuring adequate maternal nutrition (d) All of the above
- Janani Suraksha Yojana has been started under: (a) CSSM (b) NRHM (c) MCH (d) ICDS
- Iron/Folic acid tablets are distributed to private doctors for free distribution under which scheme: (a) NRHM (b) CSSM (c) Janani Suraksha Yojana (d) Vande Mataram Scheme
- Following are high risk ante-natal cases except: (a) Elderly Primi (b) Pre-eclampsia (c) Twin pregnancy (d) None
- Minimum number of Antenatal visits during pregnancy is: (a) Two (b) Three (c) Five (d) Six
- MMR in India is: (a) 300 per lakh (b) 400 per lakh (c) 200 per lakh (d) 500 per lakh

**Answers :** (1) b; (2) d; (3) d; (4) b; (5) d; (6) d; (7) b; (8) a.

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## 143 Care of Infants

A S Kushwaha

Infancy is the first year of life and this is marked by the greatest threat to survival and therefore is a good measure of the progress in the fields of socio-economic, medical and healthcare development in a country. It is customary to divide infancy into various time periods for convenience of planning service. The determinants of health are also different in these phases.

Infancy is sub-divided into following four distinct phases or periods

- Perinatal period
- Early neonatal period
- Late neonatal period
- Post-neonatal period

### Definitions

**Perinatal Period** : Perinatal period extends from 28th weeks of gestation to less than 7 days of life, after birth.

**Neonate** : A child in 1st month [under 4 weeks of age (<28 days)]. Early Neonatal Period- First week of life (<7days or <168 hours). Late Neonatal period extends from 7th to 28th day.

**Post-Neonatal period** : Period of infancy from 28 days to under 365 days (<1 year)

**Live born** : A live born neonate is a product of conception, irrespective of weight or gestational age, that after separation from the mother, shows any evidence of life such as breathing, heart beat, pulsation of umbilical cord or definite movement of the voluntary muscle.

**Still birth** : A foetal death is a product of conception that after separation from the mother does not show any evidence of life. The WHO has recommended that within any country the term stillbirth be applied to a foetus born dead and weighing >500gm which is associated with a gestation of 22 weeks. For international comparisons a weight of 1000gm is to be used which frequently measures to 28 weeks of gestation. Still birth rate is the number of foetal deaths (>1000gm weight at birth) occurring in a year per 1000 total births (live births + stillbirths).

**Pre-term Baby** : Any neonate born before 37 completed weeks (<259 days) of gestation irrespective of the birth weight.

**Term baby** : A neonate born between 37 and 42 weeks of pregnancies (259-294 days) irrespective of the birth weight.

**Low Birth Weight (LBW)** : Any neonate weighing less than 2500 gm at birth irrespective of gestational age.

**Very Low Birth Weight baby (VLBW)** : Any neonate weighing less than 1500 gm at birth irrespective of gestational age.

**Extremely Low Birth Weight baby (ELBW)** : Any neonate weighing less than 1000 gm at birth irrespective of gestational age.

**Perinatal Mortality Rate** : This includes both late foetal deaths

(stillbirths) and early neonatal deaths. The important thing to consider is the weight 1000gm and more at birth or a gestation of 28 weeks if birth weight is not available and if both weight and gestation are not available, body length (Crown to heel) of at least 35 cm should be used.

The preferred criterion is birth weight. The denominator used in calculation of perinatal mortality is 1000 live births (suits nations with poor recording of still births) but for more precise comparison the denominator includes all live births weighing 1000 gm or more. Perinatal mortality is a sensitive indicator of essential maternal and newborn care provided at childbirth. The factors responsible for stillbirths and early neonatal deaths are often similar. This indicator also assumes importance in view of the fact that many of the early neonatal deaths are recorded as stillbirth in developing nations thereby inflating figures for stillbirths but showing figures for early neonatal deaths lower than the factual. This anomaly is taken care of by Perinatal Mortality Rate. The Perinatal period comprises just 0.5 % of the average lifespan but has more deaths in this period than next 30-40 years of life.

Babies continue to be very vulnerable throughout their first week of life, after which their chances of survival improve markedly. The conditions causing newborn deaths can also result in severe and lifelong disability in babies who survive.

**Infant Mortality Rate** : The ratio of infant deaths registered in a given year to the total number of live births registered in the same year, usually expressed per 1000 live births.

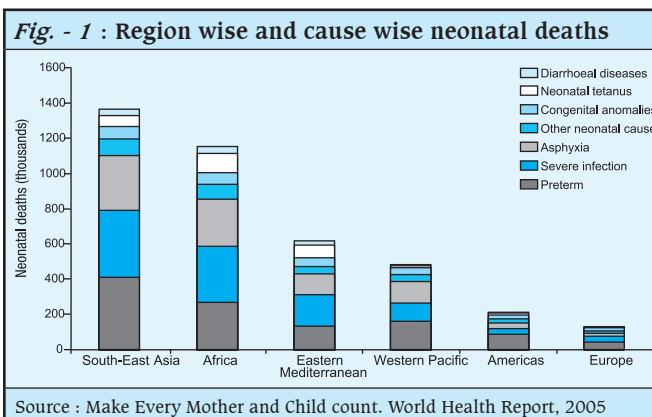
The infants who survive early neonatal period then face the dangers of Malnutrition, Diarrhoea and ARI and certain vaccine preventable diseases like measles.

Infant mortality has a special significance as -

- Single category with largest age specific mortality.
- Measure of health status and level of living of a community
- Deaths are due to specific causes different from those that affect adults.
- Indicates social measures directed towards mother and child in a country. The importance of IMR can be gauged from the fact that it is one of the parameters for calculating Physical Quality of Life Index (PQLI). Various programs and policies have included reduction of Infant mortality as an important objective in the progress towards health for all.

**Global Scenario** : Each year, about four million newborns die during neonatal period across the world. Almost all (98%) of these deaths occur in developing countries. Newborn deaths now contribute to about 40% of all deaths in children under five years of age globally, and more than half of infant mortality. Rates are highest in sub-Saharan Africa and Asia. Two thirds of newborn deaths occur in the two WHO Regions (Fig. - 1), Africa (28%) and South-East Asia (36%). The average IMR for world is 54 per 1000 live births (2004). The lowest infant mortality rates in developed nations are under 10 with Japan recording an IMR of 3 per 1000 live births. The figures of IMR in underdeveloped nations are as high as 90 and above. The highest rates of IMR are recorded in Sierra Leone (165), Afghanistan (165), Mali (121) and Mozambique (104).



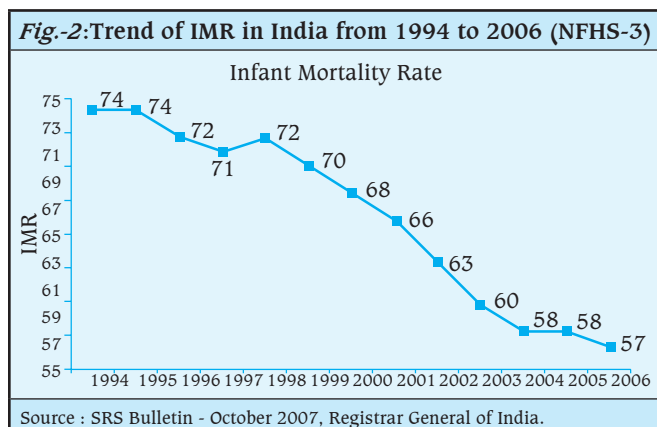


**Progress :** Consecutive household surveys from developing countries show that most have experienced a decline in neonatal mortality in recent decades. Much of the progress in survival has been made in the late neonatal period, with little improvement in the first week of life. Reductions in infant and child mortality in many countries are at least partly driven by socioeconomic development: improvements in women's education and literacy, household income, environmental conditions (safe water supply, sanitation and housing), along with improvements in health services and child nutrition

**Scenario in India :** The infant mortality has been declining steadily over the years but the decline has been slower than desirable (Table - 1). The progress over the last decade is given in Fig. - 2.

**Table-1 : Mortality indicators of infancy: India (1994-2006)**

Indicator	1994	2000	2006
Infant Mortality Rate	74	68	57
Neonatal mortality rate	48	44	37
Post-neonatal mortality rate	26	23	22
Still birth rate	9	8	9



The deaths in the 1st year of life account for 18.7 % of total deaths in the country. Of these infant deaths, >60% occur during the 1st month of life (Neonatal deaths). Of this 40% of

neonatal deaths occur in the 1st week of life (Perinatal deaths). Risk of death is highest during first 24-48 hours of life.

Girls in India face a higher mortality risk than boys. Children born to mothers under age 20 or over age 40 are more likely to die in infancy than children born to mothers in the prime childbearing ages. Infant mortality is 77 per 1,000 for teenage mothers, compared with 50 for mothers aged 20-29 yrs. Infant mortality in rural areas is 50 percent higher than in urban areas. Children whose mothers have no education are more than twice as likely to die before their first birthday as children whose mothers have completed at least 10 years of school. In addition, children from scheduled castes and scheduled tribes are at greater risk of dying than other children. Infant mortality rates are highest in Uttar Pradesh, Chhattisgarh and Madhya Pradesh, where about 70 children in 1,000 die in their first year of life, and lowest in Kerala and Goa, with 15 infant deaths per 1,000 live births.

### Causes

Infant mortality is due to combination of various factors operating at different stages and are related to issues which may range from maternal, foetal, environmental and social. The causes differ during the neonatal and post neonatal phases of infancy. The factors operating in perinatal period do not have much relative impact in late neonatal part of infancy. Low birth weight (57%), respiratory infections (17%), diarrhoeal diseases (4%), congenital malformations (5%), Birth injury (3%) are the major causes of infant mortality in India. A list of causes is given in the Table - 2.

**Table - 2 : Causes of Infant Mortality**

Neonatal Mortality	Post neonatal Mortality (1-12 months)
Low birth weight & prematurity	Diarrhoeal diseases
Birth injury & difficult labour	Acute respiratory infection
Sepsis	
Congenital anomalies	Other communicable diseases-measles, malaria
Haemolytic diseases of newborn	
Conditions of placenta & cord	Malnutrition
Diarrhoeal diseases	Congenital anomalies
Acute respiratory infections	Accidents
Neonatal tetanus	

**Factors Underlying Infant Mortality :** The factors as discussed earlier vary in the Perinatal, neonatal and post neonatal phases of infancy. Perinatal mortality and neonatal mortality in particular accounts for nearly half of the infant mortality. Perinatal mortality is linked to a gamut of factors operating in the prenatal, intranatal and postnatal period.

#### (a) Prenatal

- Maternal factors-age (teenage, elderly), diseases like hypertension (toxemia), cardiovascular, diabetes, anaemia etc.
- Anatomical - uterine and cervical defects
- Blood incompatibilities

- Malnutrition, anaemia
- Antepartum haemorrhage
- Foetal- congenital defects

(b) Intranatal

- Birth trauma
- Birth asphyxia
- Prolonged or difficult labour
- Obstetric complications

(c) Postnatal

- Preterm baby/ Low birth weight
- Respiratory distress syndrome
- Congenital anomalies
- Infections

The causes operating in perinatal period are related to the maternal, foetal factors and care during delivery to the mother and the newborn. Factors like birth trauma, sepsis, asphyxia, prolonged labour and obstructed labour arise and operate due to lack of skilled care during delivery. The factors in the neonatal period are mainly 'endogenous' like prematurity, low birth weight and gestational age and congenital anomalies. This part of the infant mortality is the most difficult to tackle. Factors causing Post neonatal mortality are mainly social and environmental related. In developed countries the congenital anomalies is the main cause.

### Prevention

The preventive strategy will be based on some direct and indirect measures as under -

**Direct** : These measures if taken can modify the problem of Infant mortality pretty quickly. These measures act both at primary and secondary prevention levels.

- Safe and clean delivery with skilled birth attendant
- Essential Care of the newborn at birth
- Newborn resuscitation
- Infection control measures
- Exclusive Breast feeding
- Early diagnosis and management of complications
- Special care for the preterm and premature infants
- ORT and antibiotics for Diarrhoea and ARI respectively
- Immunization

**Indirect** : These factors though intangible but have a role of immense importance and operate at the level of family, community, health care and society at large. These factors are mostly acting at promotion and primary prevention levels.

- Family planning - timing, spacing births, limiting family size
- Prenatal nutrition of mothers
- Education of the mother on pregnancy and child care
- Antenatal care
- Growth monitoring of child
- Prevention of malnutrition- weaning practices
- Breast feeding
- Vit A prophylaxis
- Improved Sanitation and safe water
- Access to primary health care
- Overall socio-economic development

### Essential Newborn Care

Care of the newborn at birth is primarily aimed at helping the newborn to adapt to the extra-uterine environment. Physiological adaptation includes initiation of respiration and oxygenation of the arterial blood, temperature adaptation and initiation of breast feeding. Box - 1 shows the actions at birth.

<b>Box - 1 : Actions at birth</b>
Note timing of birth
Note sex of the baby and show to mother
Cleaning the airway
Cleaning and drying the baby
Put a identification mark / tag
Transfer the baby
APGAR score at 1 and 5 minutes
Take birth weight, length
Rule out any major congenital anomaly, birth injury

### Routine Care at Birth

Over 90% of newborns do not require any active resuscitation at birth. Efforts are directed to maintain asepsis, prevent infection and hypothermia, and to keep the airway patent.

<b>Advise the mother to return immediately if the young Infant has any of these signs</b>
Breast feeding or drinking poorly
Becomes sicker
Develops a fever or feels cold to touch
Fast breathing
Difficult breathing
Blood in stool

### Examination of the Newborn

A complete physical examination is an important part of newborn care. Each body system is carefully examined for signs of health and normal function. The physician also looks for any signs of illness or birth defects. The newborn baby at birth is 50 cm long & weighs >2.5 kg with a head circumference of 34 cm.

### Risk Identification in the Newborn

An important task of the attending MO in the labour room is the identification of newborns at high risk for morbidity and mortality. These newborns would need special care, either at the PHC where the delivery took place (if the facilities and trained personnel exist) or at the FRU where these babies should be referred to.

#### **Guidelines to detect these newborns at risk :**

Danger Signs in a Newborn

- Convulsions
- Fast breathing (60 breaths per minute or more)
- Severe chest indrawing

- Nasal flaring
- Grunting
- Bulging fontanelle
- 10 or more skin pustules or a big boil
- Severe Jaundice
- Axillary temperature 37.5°C or above (or feels hot to touch) or temperature less than 35.5°C (or feels cold to touch)
- Lethargic or unconscious
- Less than normal movements
- Blood in the stools
- Not able to feed
- Not sucking at all
- No attachment at all

### Referring the Newborn to an FRU

Check on the arrangement for referral. A newborn will benefit from referral to a higher centre only if it is properly ventilated and kept warm during transport. Two people are needed to escort a newborn who requires ventilation: one person will continue to ventilate the baby while the other will assist with other tasks. If possible, transfer for the mother should also be arranged alongside.

### Stopping Resuscitation

Despite complete and adequate resuscitation efforts, some newborns may undergo brain death if the heart rate is absent at 15 minutes. Therefore, an absent heart sound, even after 15 minutes, is an absolute indication to stop resuscitation. If there is no gasping or breathing at all even after 20 minutes of effective ventilation (and cardiac massage, if required), stop ventilation.

### Jaundice

In mild or moderate levels of jaundice, by 5 to 7 days of age the baby will take care of the excess bilirubin on its own. If high levels of jaundice do not clear up, phototherapy may be prescribed. The other modalities like exchange transfusion and suspension of breast feeding temporarily may be used if required depending on the cause.

### Common Birth Injuries

A difficult birth or injury to the baby can occur because of the baby's size or the position of the baby during labour and delivery.

### Breast feeding

**Feeding of the Newborn** : After birth, breast feeding should be initiated as early as possible (within 1 hour) unless there is a contraindication. The benefits of early and exclusive breast feeding must be explained to the mother. The baby should be fed on demand, both day and night. The mother should be advised that she SHOULD NOT-

- Force the baby to feed.
- Interrupt a feed before the baby is done
- Use the artificial teats or pacifiers
- Give the baby any other food or drink for the 1<sup>st</sup> six months of life.

**Colostrum** : During the first few days after delivery a woman produces special milk that is thick, sticky and yellowish or clear in colour. This special milk is called colostrum.

- Colostrum contains large quantities of protective

substances and growth factors and has more protein and Vitamins A and K than mature milk.

- It enhances the development and maturation of the baby's gastro-intestinal tract.
- The anti-infective proteins and white cells provide the first immunization against the diseases that a baby encounters after delivery.
- Although colostrum is secreted in small quantities (30-90 ml), it is sufficient to meet the caloric needs of a normal newborn in the first few days of life.
- Colostrum also has a mild purgative effect, which helps to clear baby's gut of meconium (the first, very dark stools) and helps to prevent jaundice by clearing the bilirubin from the gut.
- It stimulates the baby's immature intestine to develop in order to digest and absorb milk and to prevent the absorption of undigested protein.

Initiate breast feeding as soon as the baby is ready to suckle or as soon as the mother's condition permits. If breast feeding has to be delayed due to maternal or newborn problems, teach the mother to express breast milk as soon as possible and ensure that this milk is given to the newborn. The BFHI promotes, protects, and supports breast feeding through The Ten Steps to Successful Breast feeding for Hospitals, as outlined by UNICEF/WHO are given in Box - 2.

Box - 2 : BFHI : Ten steps to successful breast feeding	
1	Maintain a written breast feeding policy that is routinely communicated to all health care staff
2	Train all health care staff in skills necessary to implement this policy.
3	Inform all pregnant women about the benefits and management of breast feeding
4	Help mothers initiate breast feeding within 1 hour of birth.
5	Show mothers how to breast feed and how to maintain lactation, even if they are separated from their infants.
6	Give infants no food or drink other than breast milk, unless medically indicated
7	Practice "rooming in"-- allow mothers and infants to remain together 24 hours a day.
8	Encourage unrestricted breast feeding
9	Give no pacifiers or artificial nipples to breast feeding infants
10	Foster the establishment of breast feeding support groups and refer mothers to them on discharge from the hospital or clinic

Objective of Breast feeding is "Exclusive breast feeding of the first six months of life" to be propagated as it has the following benefits:

- It is the ideal method of infant feeding.
- It is the single most cost effective intervention for reduction of infant mortality.
- Delays return to fertility in the mother and hence acts as a natural contraceptive.

The Infant Milk Substitute (IMS) Act is being implemented and following initiatives have been taken-

- Baby Friendly Hospital Initiative
- Lactation Clinics
- Peer Counselling

**Weaning (Complementary Feeding)** : The complementary feeding means giving the child other nutritious foods in addition to breast milk. Weaning literally meant taking the child away from the breast and nourishment by other means. Breast feeding alone is sufficient to take care of the requirements in 1<sup>st</sup> six months. Thereafter, concentrated energy dense complementary foods are essential to maintain adequate velocity of growth for the infant. Weaning if not carried out properly, may lead to malnutrition and illness.

### Small Babies (LBW)

Neonates weighing <2500 gm at birth are classified as low birth weight. One third of the births in India are estimated to be LBWs. These LBWs can be of two broad groups- Preterm and SFA (small for gestational age) term infants. Most of these LBWs are SFA in developing countries while they are mostly pre-term in developed world. These LBWs face many risks at birth and are prone to many conditions like infections, respiratory difficulty and metabolic disturbances. Problems of each category are summarized in the Table - 3.

Table - 3 : Hazards of Low Birth Weight (LBW) Infant	
Preterm (<37 weeks)	Small for Age (SFA)
Birth asphyxia	Birth asphyxia
Hypothermia	Hypothermia
Infections	Infections
Metabolic acidosis	Meconium aspiration
Hyperbilirubinemia	Hypoglycemia
Apneic spells	Polycythemia
Respiratory distress (Hyaline membrane disease)	

**Health Risk of being LBW** : The low birth weight child begins with a disadvantage at birth and this may even have long term implications. The hazards of being born low birth weight are-

**Survival** : The mortality in infancy is much higher amongst those born with weight <2500 gm. This is due to several factors like physiological immaturity of respiratory, CNS system, liver; predisposition to hypoglycemia, hypothermia and infections, malnutrition etc.

**Growth and development** : Since LBWs are starting poorly at birth, they are likely to lag behind those born with normal weight. They have delayed milestones and grow poorly. The so called 'catch up growth' is seen more in preterm babies who are otherwise appropriate for their age.

**Syndrome X** : This metabolic syndrome is more common amongst those born with a poor weight at birth. Due to genetic programming (thrifty gene hypothesis) they develop tendency for accumulation of fat when nutrition is adequate and suffer the ill effects of this condition with increased likelihood of IHD, hypertension and diabetes.

**The Causes of LBW** : The causes of the LBW have been studied and they have inter-related multiple factors acting simultaneously in the setting of poverty (Table - 4). The famous triad of 'Malnutrition, Infection and Unregulated fertility' operates to produce this unfavourable outcome.

Table - 4 : Causes of Preterm and SFA infants		
Preterm infants		SFA Infants
Maternal	Incompetent cervix	Short stature
	Medical diseases	Undernutrition
	Infections	Primi, grand multipara Smoking, tobacco
Placental	Placenta previa, APH	Abruptio placentae, infarction, anomalies
Foetal	Multiple pregnancy	IUGR, multiple pregnancy
	Congenital malformation	congenital malformation, intrauterine infections
Medical Conditions / complications	Uncontrolled diabetes	Hypertension, toxemia
	Hypertension, toxemia	Cardiac illness
	Cardiac illness	Foetal distress
	Foetal distress	Rh isoimmunisation
	Rh isoimmunisation	Anaemia
	Severe IUGR	Malaria
Iatrogenic	Improper assessment of maturity	-

### Principles of Management of LBWs

- Care at Birth - All 'at risk' pregnancies for LBW babies must take place at a place where optimal facilities exist. Being prone to hypothermia, adequate precautions must be taken by maintaining a '**Warm chain**'. All arrangements for resuscitation of newborn should be available.
- Appropriate place of care - Depending on the birth weight the LBW can be cared for at home (>1800 gm) and if <1800, at the hospital till the child gains weight and if <1500 gm, these babies will need tertiary level care.
- Thermal protection - As outlined elsewhere by delaying bathing, maternal contact by Kangaroo mother care and external heat source if required.
- Fluids and feeds - Breast feeding, expressed breast milk, nasogastric feeding and IV fluids if required.
- Monitoring for early detection and management of complications like respiratory difficulty, metabolic disturbances, infections etc.
- Kangaroo Mother Care



**Kangaroo Mother Care (KMC)** : This concept was first presented by Rey and Martinez in Colombia. It has been particularly advised in small, preterm and LBW babies but applies well in all babies. In this the key features are as under :

- Early, continuous and prolonged skin-to-skin contact between the mother and the baby
- Exclusive breast feeding
- It is initiated in hospital and continued at home
- Small babies can be discharged early
- Mothers at home require adequate support and follow up

It was developed as an alternative to inadequate and insufficient incubator care for those preterm newborn infants who had overcome initial problems and required only to feed and grow. It has been shown to be effective for thermal control, breast feeding and bonding in all newborn infants. The support binder is the only special item required for KMC. The baby is placed between the mother's breasts in an upright position, chest to chest. The position allows mother with both hands free and ability to move around.

#### **Preventive Strategies to Tackle the Problem of LBW**

##### **Direct**

- Maternal nutrition- by improving the pre-pregnancy weight and maternal nutrition during pregnancy, birth weight of the infant can be improved.
- Good antenatal care
- Prevention of infection in the mother
- Early diagnosis and management of maternal factors like anaemia, malaria, hypertension etc.

##### **Indirect**

- Delayed marriage and childbearing
- Adequate spacing
- Family planning
- Improved socio-economic status
- Women empowerment

**Infection Prevention in the Newborn** : This is an important component of every sphere of newborn care. Newborns are more susceptible to infection because of immature immune system. This is still more relevant to preterm and low birth weight infants.

##### **General Principles**

- Consider every person (including staff and the baby) as potentially infectious
- Wash hands or use hand rub (alcohol based) before handling a baby and after
- Wear protective clothing like gown, mask, gloves
- Observe aseptic techniques in all procedures
- Routine cleaning of the ward and all equipment
- Isolation of babies with infections
- Routine care of newborn

##### **Early Childhood**

Children are more likely to survive, to grow in a healthy way, to have less disease and fewer illnesses, and to fully develop thinking, language, emotional and social skills when well nurtured and cared for in their earliest years. Frequent illness, unsanitary environments and poor nutrition steal a child's potential.

It is a child's right to have every chance to survive and thrive. Moreover, ensuring optimal conditions for a child's early years is one of the best investments that a country can make if it is to compete in a global economy based on the strength of its human capital. The growth monitoring, correct feeding practices, immunization, responsive health care system, legal provisions, sensitive society, management during sickness and providing protection to these children can help in improving the lot of this important group of vulnerable population. The concept of well baby clinic, under five clinic and mother and child clinics are steps in this direction. The growth and development (Growth and Development) and care of sick children (IMNCI) are described in different chapters.

##### **Community Based Health Care Interventions**

UNICEF and WHO, have agreed on 12 key household practices for neonates and infants that can help to promote child survival, health and nutrition in communities:

- (1) *Exclusive breast feeding* from birth to six months.
- (2) *Complementary feeding* : Starting at about six months old, feeding children energy - and nutrient-rich complementary foods while continuing to breast feed for at least two years could prevent more than 10 per cent of deaths from diarrhoea and acute respiratory infections, particularly pneumonia; and increase resistance to measles and other illnesses.
- (3) *Micronutrient Supplementation* : Improving the intake of vitamin A through diet or supplements in communities where it is deficient could reduce mortality among children aged 6 months to five years by 20 per cent.
- (4) *Hygiene* : Better hygiene practices, particularly hand washing with soap (or ashes) and the safe disposal of excreta could reduce the incidence of diarrhoea by 35%.
- (5) *Immunization* : Vaccination against measles for children under age one could prevent most of the measles - related deaths each year. Caregivers should make sure children complete a full course of immunization (Bacille Calmette-Guérin; diphtheria, pertussis and tetanus vaccine; oral polio vaccine; and measles vaccine) before their first birthday.
- (6) *Malaria prevention* : The use of insecticide-treated mosquito nets in households in malaria-endemic areas could lower malaria-related child deaths by as much as 23 per cent.
- (7) *Psychosocial care and development*: Promote mental and social development by responding to a child's need for care and by talking, playing and providing a stimulating environment.
- (8) *Feeding and fluids for sick children*: Continue to feed and offer more fluids, including breast milk, to children when they are sick.
- (9) *Home treatment*: Give sick children appropriate home treatment for infections.
- (10) *Care seeking*: Recognize when sick children need treatment outside the home, and seek care from appropriate providers.
- (11) *Appropriate practices*: Follow the health worker's advice about treatment, follow-up and referral.
- (12) *Antenatal care*: Every pregnant woman should have adequate antenatal care.

Further important practices that protect children include - providing appropriate care for those who are affected by HIV and AIDS, especially orphans and vulnerable children; protecting children from injury and accident, abuse and neglect; and involving fathers in the care of their children. Many of these practices can be undertaken by community health workers or by community members themselves, given the appropriate support and distribution of products and services. The direct involvement of the community is perhaps most appropriate for those aspects of health care and nutrition that most closely affect members on a daily basis. These include infant and young child feeding, other caring practices, and water and sanitation.

### Special Child Survival Initiatives in India

**CSSM** : The Child Survival and Safe Motherhood Programme jointly funded by World Bank and UNICEF was started in 1992-93 for implementation up to 1997-98. The Child Survival and Safe Motherhood Programme was implemented in a phased manner covering all the districts of the country by the year 1996-97. The objectives of the programmes were to improve the health status of infants, child and maternal morbidity and mortality. The programmes seek to sustain high coverage levels achieved under the Universal Immunisation Programme (UIP) in good performance areas and strengthen the immunisation services of poor performing areas. The programme also provides for augmenting various activities under the Oral Rehydration Therapy (ORT) Programme, universalising prophylaxis schemes for control of anaemia in pregnant women & control of blindness in children and initiating a programme for control of Acute Respiratory Infection (ARI) in children. The Programme yielded notable success in improving the health status of pregnant women, infants and children & also making a dent in IMR, MMR and incidence of vaccine preventable diseases.

**UIP** : Universal Immunization Programme against six preventable diseases, namely, diphtheria, pertussis, childhood tuberculosis, poliomyelitis, measles and neonatal tetanus was introduced in the country in a phased manner in 1985, which covered the whole of India by 1990. Significant progress was made under the Programme in the initial period when more than 90% coverage for all the six antigens was achieved. The UIP was taken up in 1986 as National Technology Mission and became operational in all districts in the country during 1989-90. UIP became a part of the Child Survival and Safe Motherhood (CSSM) Programme in 1992 and Reproductive and Child Health (RCH) Programme in 1997. Under the Immunization Programme, infants are immunized against tuberculosis, diphtheria, pertussis, poliomyelitis, measles and tetanus.

**ORT** : The diarrhoeal disease control programme was started in the country in 1978. The main objective of the programme was to prevent death due to dehydration caused by diarrhoeal diseases among children under 5 years of age due to dehydration. Health education aimed at rapid recognition and appropriate management of Diarrhoea has been a major component of the CSSM. Under the RCH programme ORS is supplied in the kits to all sub-centres in the country every year.

**RCH** : The initiatives under RCH for newborn and infant care

are as under-

### Infant & Child Health

- Reduction of new-born deaths, infant deaths and child deaths by providing continuous health care and strengthening of new-born care infrastructure facilities.
- Organizing counselling sessions for the mothers.
- Implementing integrated management of neonatal and childhood illness as a pilot initiative in selected districts.
- Operationalising infant death/stillbirth verbal autopsy.
- Addressing the issue of female infanticide and foeticide

**IMNCI** : Integrated Management of Neonatal and Childhood Illness (IMNCI)

Integrated Management of Childhood Illness (IMCI) strategy, which has already been implemented in more than 100 countries all over the globe, encompasses a range of interventions to prevent and manage five major childhood illnesses i.e. Acute Respiratory Infections, Diarrhoea, Measles, Malaria and Malnutrition. It focuses on preventive, promotive and curative aspects, i.e. it gives a holistic outlook to the programme. The details on the care of sick children are given in the chapter on IMNCI.

### Home Based Care of Newborns and Mothers - (SEARCH) A Project

In the Gadchiroli district of India, Drs. Abhay and Rani Bang and colleagues at the *Society for Education, Action & Research in Community Health* (SEARCH) have developed a remarkable approach to home-based health care that benefits both newborns and their mothers. It had to be home-based because 83 percent of births in rural India occur at home, and these villagers have virtually no access to health facilities. After two years of research, SEARCH introduced neonatal care through trained village health workers and trained birth attendants, who provide health education to new mothers, support breast feeding and maintenance of body temperature, and recognize danger signs in mothers and babies. By the third year of the program, which tracked results in 39 intervention villages and 47 control villages, SEARCH had recorded a 62 percent reduction in the neonatal mortality rate for the intervention areas as well as a significant reduction in various neonatal and maternal morbidities. This strategy has been recognized as a valuable option for the districts with high infant mortality.

Tackling infant mortality is largely an issue of addressing the perinatal mortality. Perinatal mortality improves by universal coverage of all deliveries with skilled attendance at birth and essential maternal and newborn care coupled with effective referral mechanism and back up FRU facilities. Post neonatal mortality is amenable to known interventions and is easiest to tackle by launching child survival methods like ORT, treating pneumonia, breast feeding, supplementary feeding, weaning practices and immunization. The infant survival is related largely to clean delivery practices, correct feeding practices, immunization and availability, adequacy and timely health care during sickness especially due to Diarrhoea, ARI and measles. The malnutrition is one single factor which touches all of these and determines the survival of the infant. The core interventions for child survival are given in Box - 3.

**Box - 3 : Core Interventions to Improve Child Survival**

**Skilled attendance during pregnancy Child birth and the immediate postpartum period** : Nurturing newborns and their mothers.

**Infant feeding** : Exclusive breast feeding during the first six months of a child's life, with appropriate complementary feeding from six months and continued breast feeding for two years or beyond, with supplementation with vitamin A and other micronutrients as needed.

**Vital vaccines** : Increased coverage of measles and tetanus vaccines, as well as immunization against common vaccine-preventable diseases.

**Combating diarrhoea** : Case management of diarrhoea, including therapeutic zinc supplementation and antibiotics for dysentery.

**Combating pneumonia and sepsis** : Case management of childhood pneumonia and neonatal sepsis with antibiotics.

**Combating malaria** : Use of insecticide-treated bednets, intermittent preventive malaria treatment in pregnancy, and prompt treatment of malaria.

**Prevention and care for HIV** : Treatment, care, infant feeding counselling and support for HIV-infected women and their infants.

## Summary

Infancy is the first year of life and is marked by greatest threat to survival and therefore is a good measure of the progress of a country. It is sub-divided into Perinatal, Early neonatal, Late neonatal and Post neonatal period. Babies are very vulnerable during their first week of life and also when they are weaned. Infant Mortality Rate (IMR) has special significance because it is a single category with highest age-specific mortality, measure of PQLI. Deaths are due to causes different from adults and hence IMR indicates measures directed to mother and child in a country.

Each year, 4 million children die during neonatal period worldwide. Neonatal deaths contribute to 40% of deaths in Under-5 children and more than half of infant mortality worldwide. Rates are highest in Sub-saharan Africa and Asia. The average IMR is 54 per 1000 for the world (2004). The highest rates of IMR are in Sierra Leone and Afghanistan and lowest in Japan. Consecutive household surveys in developing countries have shown a reduction in neonatal mortality rates of which maximum reduction is in late neonatal period.

In India the infant mortality rate is declining steadily over the years but the decline has been slower than desirable. IMR in 2006 for India was 57. The deaths in the first year of life account for 18.7% of total deaths in the country. Of these Infant deaths more than 60% occur in neonatal period. Of these neonatal deaths 40% occur in first week of life (Early neonatal period). The greater mortality risk is associated with girl child, children of mothers aged less than 20 and more than 40, children born in rural areas, children of mothers with no formal education, children of scheduled castes and tribes. In India IMR is highest in Uttar Pradesh, Chattisgarh and Madhya Pradesh and lowest

in Kerala and Goa. Major causes of Infant mortality in India are Low birth weight(57%), Respiratory infections(17%), Congenital malformations(5%), Diarrhoeal diseases(4%) and Birth injury(3%).

Infant mortality can be due to prenatal, intranatal and postnatal causes. Prenatal causes are Maternal age (teenage and elderly), Maternal diseases like hypertension, cardiovascular, diabetes and anaemia, Uterine and cervical defects, Blood incompatibilities, Malnutrition, Ante-partum haemorrhage and Feto-congenital defects. Intranatal causes are Birth trauma, Birth asphyxia, Prolonged or difficult labour and Obstetric complications. Postnatal causes are Preterm or low birth weight baby, Respiratory distress syndrome, congenital anomalies and Infections.

Preventive strategies for reducing Infant mortality are divided into direct and indirect methods. Direct methods are Safe and clean delivery by skilled birth attendant, Essential care of newborn, Newborn resuscitation, Infection control measures, Exclusive breast feeding, Early diagnosis and management of complications, Special care for preterm and premature infants, ORT and antibiotics for Diarrhoea and ARI respectively and Immunization. Indirect methods are Family planning, Prenatal nutrition of mothers, Education, Antenatal care, Growth monitoring of child, Prevention of malnutrition, Vit A prophylaxis, Improved water and sanitation, Access to primary health care and overall socio-economic development.

Care of newborn at birth is primarily aimed at helping the newborn to adjust to extra-uterine environment. Physiological adaptations include initiation of respiration and oxygenation of the arterial blood, temperature adaptation and initiation of breast feeding. The Baby Friendly Hospital Initiative (BFHI) promotes, protects and supports breast feeding through the ten steps to successful breast feeding for hospitals as outlined by UNICEF/WHO. Objective of breast feeding is Exclusive breast feeding for the first six months of life. The Infant Milk Substitute (IMS) act is being implemented and the initiatives are Baby friendly hospital initiative, Lactation clinics and Peer counselling.

Over 90% of newborns do not require active resuscitation at birth. In these cases the mother is advised to return to hospital immediately if infant is breast feeding or drinking poorly, becomes sicker, develops fever or feels cold to touch, difficult breathing and blood in stools. In case of Jaundice the child is taken to hospital if Jaundice is noted during first 24 hours or baby develops a fever over 100°F or colour deepens after day 7 or Jaundice does not disappear after day 15 or baby is not gaining sufficient weight.

Complementary feeding or weaning means giving the child other nutritious foods in addition to breast milk and is done after 6 months. In this, complementary energy dense foods, which are locally available and are inexpensive, easily digestible and culturally acceptable are given.

Neonates weighing less than 2500 grams at birth are classified as low birth weight. They can be divided into Pre-term babies and Small for Gestational Age (SFA) babies. The health risks of being low birth weight are decreased survival, delayed milestones, poor growth and development and increased



chances of Syndrome X later in life. The famous triad causing LBW babies include Malnutrition, Infection and Unregulated fertility. Principles of management of LBW babies include care at birth, appropriate place of care, thermal protection, fluids and feed, monitoring for early detection and management of complications and Kangaroo Mother Care (KMC).

The preventive strategies to tackle the problem of LBW are improving maternal nutrition, good ante-natal care, prevention of infection of the mother, early diagnosis and treatment of anaemia or hypertension or malaria etc., delayed marriage or childbearing, adequate spacing, family planning, improved socio-economic status and women empowerment.

UNICEF and WHO has agreed on 12 key household practices for neonates and infants that can help promote child survival, health and nutrition in communities. These are Exclusive breast feeding for six months, complementary feeding, micronutrient supplementation, hygiene, immunization, malaria prevention, psychosocial care and development, feeding and fluids for sick children, home treatment, care seeking appropriate practices and ante-natal care.

The important special child survival initiatives in India include CSSM (Child Survival and Safe Motherhood Programme), UIP (Universal Immunization Programme), RCH, IMNCI (Integrated Management of Neonatal and Childhood Illness).

Initiatives under RCH for newborn and infant care include reduction of newborn deaths, infant deaths and child deaths by providing continuous health care and strengthening of newborn care infrastructure facilities, organizing counselling sessions for the mothers, implementing IMNCI as a pilot project in selected districts, operationalising infant death/still birth verbal autopsy and addressing the issue of female infanticide and foeticide.

IMNCI strategy encompasses a range of interventions to prevent and manage five childhood illnesses i.e. ARI, Diarrhoea, Measles, Malaria and Malnutrition. It promotes on preventive, promotive and curative aspects i.e. it gives a holistic attitude to the programme.

## Study Exercises

**Long question :** Discuss various causes of high IMR in developing countries and strategies to prevent it.

**Short notes :** (1) BFHI (2) IMR and its trend in India (3) Causes of Infant mortality (4) Essential newborn care (5) Breast feeding (6) Weaning (7) LBW (8) Kangaroo mother care

## MCQs :

1. Premature infant is one which is born: (a) Before 40 weeks (b) Before 38 weeks (c) Between 28-37 weeks (d) Between 28-42 weeks
2. All are true of colostrum except: (a) Rich in proteins and minerals (b) Rich in anti-infective factors (c) Rich in fats (d) Secreted for first few days
3. Breast feeding should be started \_\_\_\_\_ hours after birth: (a) Within 1 hour (b) 2 hours (c) 24 hours (d) 48 hours
4. LBW baby is one whose weight is below: (a) 2200 grams (b) 2000 grams (c) 1500 grams (d) 2500 grams
5. Exclusive breast feeding is sufficient for \_\_\_\_\_ months after birth: (a) 1 month (b) 2 months (c) 6 months (d) 9 months
6. Low birth weight child is due to all except: (a) Maternal malnutrition (b) Infections (c) Unregulated fertility (d) Previous caesarean section
7. Single most important factor determining survival chances of newborn is: (a) Birth order (b) Multiple gestation (c) Intrauterine infection (d) Low birth weight
8. Adverse factor for child health is : (a) Birth order 5 or more (b) Maternal malnutrition (c) Teenage mother (d) All of the above
9. Perinatal period is: (a) 20-32 weeks of gestation (b) 37-42 weeks of gestation (c) 28 weeks of gestation to 1 week postnatal period (d) 28 weeks of gestation to 1 week postnatal period (d) 32 weeks of gestation to 2 week postnatal period
10. Perinatal mortality includes: (a) Stillbirths (b) Neonatal deaths (c) Stillbirths and Early neonatal deaths (d) Stillbirths and Neonatal deaths
11. Infant mortality rate in India in 2006 was: (a) 64 (b) 67 (c) 54 (d) 57
12. The denominator in IMR is: (a) Total no of live births (b) Total no of live and still births (c) Total no of still births (d) Total population

**Answers :** (1) a; (2) c; (3) a; (4) d; (5) c; (6) d; (7) d; (8) d; (9) c; (10) c; (11) d; (12) a.

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*A S Kushwaha*

Accumulated evidence has suggested that an integrated and syndromic approach is needed for efficient management of sick children to improve outcomes. On analysis of the major causes of mortality in childhood and evidence based data, an approach called IMCI (Integrated Management of Childhood Illnesses) was developed by WHO. This encompasses a range of interventions to prevent and manage *five* major childhood illnesses i.e. *Acute Respiratory Infections*, *Diarrhoea*, *Measles*, *Malaria* and *Malnutrition*. It focuses on the preventive, promotive and curative aspects of the disease management with participation of the mother also in the process, i.e. it gives a comprehensive and holistic outlook to the programme.

As part of Millennium Development Goals (MDGs), Goal 4 and Target 5 are to reduce by two third, the mortality in the children under five. India is a signatory to the MDGs adopted in 2000 as part of the Millennium Declaration. A Core Group was constituted which included representatives from Indian Academy of Pediatrics (IAP), National Neonatology Forum of India (NNF), National Anti Malaria Program (NAMP), Department of Women

and Child Development (DWCD), Child-in-Need Institute (CINI), WHO, UNICEF, eminent Paediatricians and Neonatologists, and the representatives from Ministry of Health and Family Welfare, Government of India. The Adaptation Group developed Indian version of IMCI guidelines and renamed it as Integrated Management of Neonatal and Childhood Illness (IMNCI).

### Approach

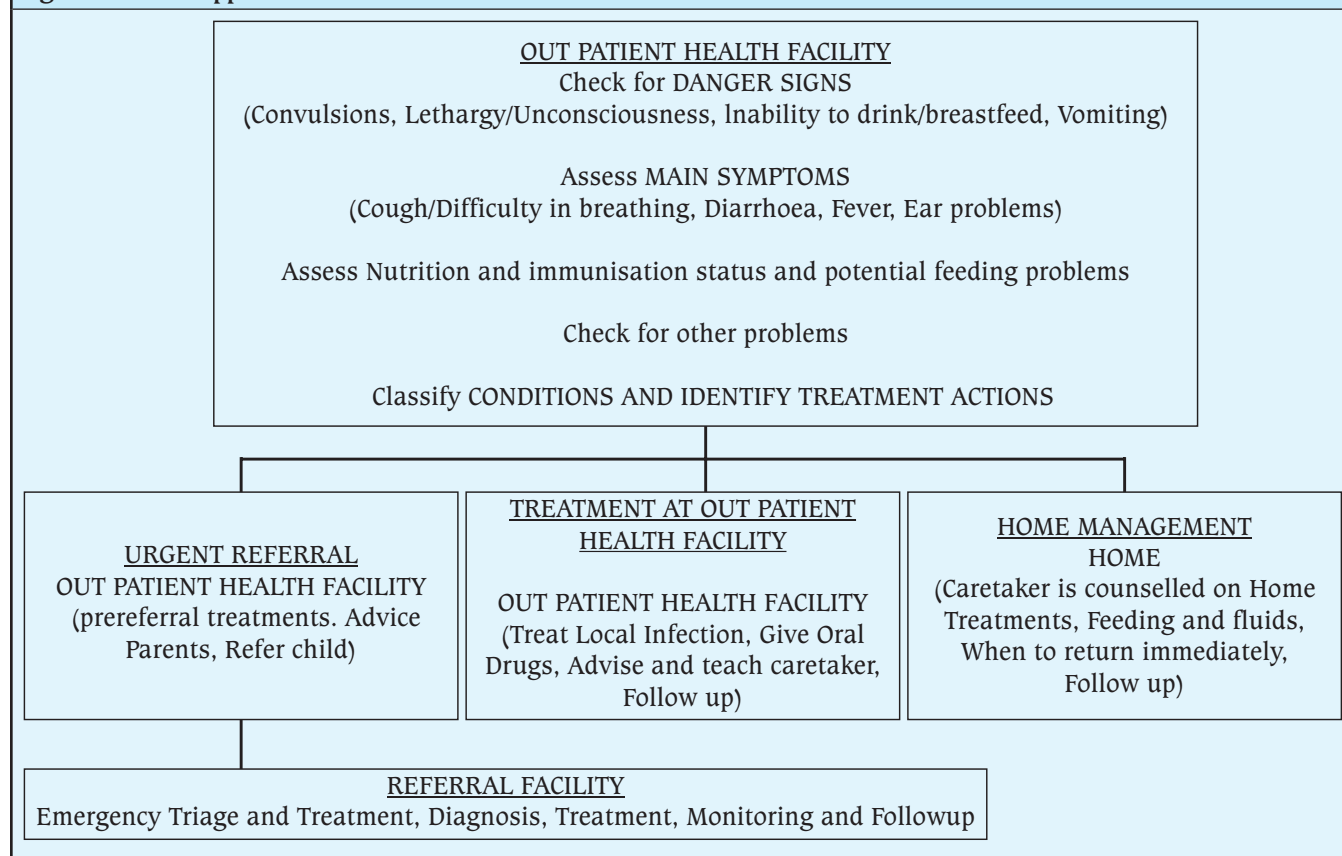
The IMNCI approach has some distinct features which are given as under-

**(a) Syndromic Approach** : Mostly the children suffer from a constellation of symptoms and need to be treated as a whole. Many sick children present with overlapping signs and symptoms of illnesses, and a single diagnosis may not be feasible or appropriate, especially in a primary care level with scarce resources. The Syndromic approach gives the advantage of not missing out on co-existing conditions while presenting with a particular condition.

**(b) Holistic Approach** : This means that taking care of all the factors that determine the health of the child. While treating for diarrhoea, the immunization and nutritional factors are also addressed.

**(c) Triage** : Management is planned after triage of the patient into those needing emergent, early treatment, referral or care at home.

**Fig. - 1 : IMNCI Approach**



(d) **Standardized Case Management** : Standardized case management based on the classification / severity of illness

(e) **Primary Health Care Model** : Based on primary health care model and referral to a facility when required.

(f) **Community Participation** : The IMNCI approach gives due importance to the role of the mother in the whole process of prevention, early diagnosis and management of the case at home by providing counselling to the caretaker.

### Components of IMNCI

The major components of this strategy are:

- (a) Strengthening the skills of the health care workers
- (b) Strengthening the health care infrastructure
- (c) Involvement of the community

The first two components are the facility based IMNCI and the third is the community based IMNCI in which mother is actively involved in the care of child in health and disease.

### Steps in Management

(ACT- assess, classify and treat) (See Fig. - 1)

The basic steps in the management of the sick children are as under-

- (a) Assess the child for group of symptoms
- (b) Classify the severity of disease
- (c) Treat as per the laid out plan
- (d) Counsell the mother
- (e) Follow up care

### Age Categories

Depending on the age of the child, various clinical signs and symptoms differ in their degree of reliability, diagnostic value and importance and even the principles of management also differ. The IMNCI guidelines therefore recommend case management procedures based on two age categories:

- (a) Young infants (age up to 2 months)
- (b) Children (2 months up to 5 years)

**Young Infants (Age Up to 2 Months)** : Neonates and infants below 2 months of age are considered as a special group for several reasons. They become sick rapidly and can die quickly due to serious bacterial infections. Certain general signs in these infants such as low body temperature, fever or less body movements may be the only manifestation of illness. On the other hand, a finding such as mild chest in-drawing is normal in them due to a soft chest wall. Therefore the assessment and classification process is different from that in an older infant or child.

#### Assessment (Assess for BCD IF Hypothermic)

- (a) For serious **B**acterial infection or local infection
- (b) For jaundice (Colour of skin)
- (c) For **D**iarrhoea
- (d) Checking the **I**mmunization status
- (e) For **F**eeding problem or malnutrition and breast feeding
- (f) For low body temperature (**H**ypothermic)

**1. Serious Bacterial Infection** : Suspect possible serious bacterial infection if there is - (remember STING BALL CM)

- (a) **S**kin pustules (10 or more)
- (b) **T**achypnoea (60 breaths per minute or more)
- (c) Severe chest **I**n-drawing

(d) **N**asal flaring

(e) **G**runting

(f) **B**ulging Fontanelle

(g) **A**bnormal **A**xillary temperature (more than 37.5°C or less than 35.5°C)

(h) **L**arge Boil on the skin

(j) **L**ethargy or **U**nconsciousness

(k) History of **C**onvulsions

(l) Less than normal **M**ovements

If any one of these criteria is present, the infant is classified as having possible serious bacterial infection. Infant is to be *referred to hospital urgently* for admission. The pre-referral treatment consists of administering first dose of antibiotics (intramuscular ampicillin 100 mg/Kg and gentamicin 5mg/Kg) ; giving expressed breast milk (or appropriate animal milk orally or by nasogastric tube) to prevent hypoglycemia and providing warmth by skin to skin contact (kangaroo care) to avoid hypothermia.

**2. Local Infection** : The infant has local bacterial infection if there is redness of umbilicus, pus discharge from ear or less than 10 skin pustules. All such cases are given oral antibiotic - (cotrimoxazole 6 mg/kg/day of trimethoprim or amoxicillin 30 mg/kg/day) for 5 days. The mother is taught to apply gentian violet and dry the ear by wicking. Ear is dried at least 3 times daily. Clean absorbent cloth or soft, strong tissue paper is rolled into a wick and placed in the young infant's ear. It is removed when wet. Replace the wick with a clean one and repeat these steps until the ear is dry. To treat skin pustules or umbilical infection, gentian violet paint is applied twice daily. The mother should gently wash off pus and crusts with soap and water. Dry the area and paint with gentian violet 0.5%. To treat thrush (ulcers or white patches in mouth) the mother should wash hands and then wash mouth of the child with clean soft cloth wet with salt water wrapped around the finger. After cleaning, the mouth is painted with gentian violet 0.25%. The infant is followed up after 2 days.

**3. Jaundice** : (a) Jaundice in a neonate appearing at less than 24 hrs or after 14 days or associated with yellow discolouration of palms and soles is classified as severe jaundice. Infant requires urgent referral to the hospital after giving pre-referral treatment which includes oral expressed breast milk, skin to skin contact and advising mother to keep the infant warm en route to hospital.

(b) If the infant has jaundice but palms and soles are not yellow, mother is reassured and the infant is reviewed after 2 days. It is important to advise the mother to return immediately if the infant develops any signs of serious bacterial infection or jaundice on palms and soles.

**4. Low Body Temperature** : In every sick young infant, Axillary temperature should be recorded. If it is 35.5 - 36.4°C, the infant is said to have low body temperature. Such an infant is warmed by skin to skin contact for one hour and reassessed. If there is no improvement, he is referred to hospital, while feeding expressed breast milk to prevent hypoglycemia.

**5. Diarrhoea** : If the stools have changed from the usual pattern and have increased in number and watery (more water than fecal matter), infant is said to have Diarrhoea. The normally

frequent or loose stools of a breast fed baby are not considered as Diarrhoea. Duration of Diarrhoea and history of blood in the stool are important questions in the history. Assess for presence and severity of dehydration.

**Severe dehydration** : If the young infant has two of the following three signs, the dehydration is severe :

- (a) Lethargic or unconscious
- (b) Sunken eyes
- (c) Skin pinch goes back very slowly (> 2 seconds)

If such an infant has low weight or any other severe classification, he is referred urgently to hospital. The pre-referral treatment includes first dose of IM antibiotics (ampicillin and gentamicin), giving frequent sips of ORS on the way, continuing breast feeding and keeping the infant warm. If the infant does not have low weight or another severe classification, fluids are administered for severe dehydration as per *plan C* and he is then referred to hospital after rehydration. The ORS should be continued. If IV fluids cannot be given, fluids by nasogastric tube could be given. If none of this is feasible refer to a hospital.

**Some dehydration** : If the young infant has two of the following three signs he is classified to have some dehydration. Oral rehydration is the mainstay.

- (a) Restless, irritable
- (b) Sunken eyes
- (c) Skin pinch goes back slowly.

If the infant has low weight or another severe classification, first dose of IM antibiotics (ampicillin and gentamicin) are given and urgent referral to hospital is done, with mother giving frequent sips of ORS on the way, continuing breast feeding and keeping the infant warm. If the infant does not have low weight or another severe classification; fluids are administered for some dehydration as per *plan B*. The mother is told to give more if child asks. If the child vomits wait for 10 minutes and then resume. Reassess after 4 hours and re-classify. Breast feeding should be continued. The mother is counselled to return immediately if not improving, not accepting fluids and has blood in stools. Follow up visit in 2 days is recommended or earlier if danger signs develop.

**No dehydration** : If there are not enough signs to classify as some or severe dehydration, the infant has no dehydration and is given fluids to treat Diarrhoea at home as per *plan A*. The follow up is done in 5 days and mother is also advised when to return immediately.

**Severe persistent diarrhoea** : Severe persistent Diarrhoea is Diarrhoea lasting 14 days or more and the infant with this classification is referred to hospital. Give inj Ampicillin or gentamicin if the child has low weight, Diarrhoea or any other severe classification, keep the child warm and treat to prevent hypoglycemia as part of pre-referral treatment.

**Severe Dysentery** : If there is blood in the stool, the young infant has severe dysentery and is similarly referred to hospital. Administer same pre-referral treatment as above before sending to hospital in the presence of any criteria of severe classification.

## 6. Feeding Problems and Malnutrition

**(a) Weight** : The present weight and birth weight should be noted. Using the reference growth charts, the infant is classified as very low weight for age, low weight for age or not low weight for age.

**(b) Feeding** : Feeding should be assessed immediately if the infant feeds less than 8 times in 24 hours, receives no other foods or drinks, or is low weight for age and has no indications to refer urgently to hospital. The infant should be put to the breast and observed for attachment and effective suckling. Blocked nose, oral thrush and breast or nipple problems (flat or inverted nipples, sore nipples, engorged breasts or breast abscess) should be looked for. If the young infant is not able to feed, has no attachment at all, is not sucking at all or is very low weight for age, he has a life threatening problem and needs urgent admission to hospital after administering pre-referral treatment. If there are other feeding problems or the infant is low weight for age, counselling of the mother is done about correct position during breast feeding, increasing frequency of feeds, treatment of breast and nipple problems and treatment of thrush. The infant is followed up after 2 days for feeding problem and after 14 days for low weight for age.

**7. Checking the Young Infant's Immunization Status** : Check whether OPV, BCG, DPT-1 and Hep B-1 vaccines have been administered in every sick young infant. An infant who is not sick enough to be referred to hospital should be given the necessary immunization before being sent home.

## 2 Months to 5 Years

A sick child aged 2 months to 5 years may present to the primary health care facility with common ailments like pneumonia, Diarrhoea, fever or an ear infection. The child in addition may also have malnutrition and anaemia. Irrespective of the presenting complaints the child is assessed in a comprehensive manner as under-

### Steps of Initial Assessment

- (a) Ask the mother about the child's problem.
- (b) Check for general danger signs.
- (c) Ask the mother about the four main symptoms: (**CDEF**)
  - (i) Cough or difficult breathing
  - (ii) Diarrhoea
  - (iii) Ear problem
  - (iv) Fever.
- (d) If one of the four above mentioned symptoms is present:
  - (i) Assess the child further for signs related to the main symptom
  - (ii) Classify the illness according to the signs which are present or absent.
- (e) Check for signs of malnutrition and anaemia
- (f) Check the child's immunization status
- (g) Assessing for any other problems.

**Look for General Danger Signs** : A sick child brought to the primary health care facility may have signs that point towards a specific problem. However, some children may present with serious, non-specific signs called "*General Danger Signs*" that may not point to a particular diagnosis. For example, a child who is having convulsions or is unconscious may be suffering from any of the diseases like meningitis, epilepsy or cerebral

malaria. It may be simply febrile convulsions. Presence of these general danger signs suggest that a child is severely ill and needs urgent attention. The following general danger signs are routinely checked in all children : (*VICU*)

- (a) Repeated Vomiting
- (b) Inability to drink or breast feed
- (c) Convulsions
- (d) Lethargy or Unconsciousness

If a child has any one or more of these signs, he is considered *seriously ill and should be referred*. In order to start treatment for severe illnesses without delay, the child should be quickly assessed for the most important causes of serious illness and death - acute respiratory infection (ARI), Diarrhoea, and fever (especially associated with malaria and measles). A rapid assessment of nutritional status is also essential.

**Check for Four Major Symptoms (Remember CDEF)** : After checking for general danger signs, the health care provider must check for the following main symptoms:

- (a) Cough or difficult breathing
- (b) Diarrhoea
- (c) Ear problems
- (d) Fever

#### Diagnosis & Management

**(A) Cough or Difficult Breathing** : Any child with cough or difficult breathing is assessed by respiratory rate, chest in-drawing and presence of stridor.

- (a) Respiratory rate: A child's age cut-off rate for fast breathing that suggests pneumonia is:
  - (i) 2 months up to 12 months: 50 breaths per minute or more
  - (ii) >12 months up to 5 years : 40 breaths per minute or more
- (b) Lower chest wall in-drawing
- (c) Stridor

Based on the above clinical signs, children presenting with cough or difficult breathing are classified in to one of the three categories:

- (a) Severe pneumonia or very severe disease
- (b) Pneumonia
- (c) No pneumonia (i.e. cough or cold).

**Severe Pneumonia / Very severe disease** : The child is classified as severe pneumonia /very severe disease if any general danger sign or chest in-drawing or stridor in an otherwise calm child is present. This child needs urgent attention and should be referred to a hospital by quickest means available, after administering the first dose of injectable antibiotic (IM Chloramphenicol 40mg/kg/dose) or if not possible, give oral amoxicillin 15mg/kg/dose.

**Pneumonia** : If only fast breathing is present without any stridor or chest in-drawing and there are no general danger signs, the child is classified as having pneumonia and is managed by oral antibiotics, cotrimoxazole (trimethoprim 8 mg/kg/day) for 5 days. Additional symptomatic treatment to soothe the throat and a safe cough remedy for children older than 6 months may be given. The mother is advised to return for follow up after 2 days. However if danger signs develop or the child becomes sicker, the mother should be asked to return

immediately.

**No Pneumonia - Cough or Cold** : If there are no signs of pneumonia, the classification is no pneumonia. The child is suffering from minor bout of cough or cold which can be managed symptomatically at home and does not warrant antibiotics. Such a child is followed up after 5 days if not improving, or immediately if any of the danger signs develop or the child deteriorates.

**(B) Diarrhoea** : A child presenting with Diarrhoea should first be assessed for general danger signs and the child's caretaker should also be asked if the child has cough or difficult breathing.

A child with Diarrhoea may have three *potentially lethal* conditions:

- (a) Acute watery Diarrhoea (including cholera)
- (b) Dysentery (bloody Diarrhoea)
- (c) Persistent Diarrhoea (Diarrhoea that lasts 14 days or more).

All children with Diarrhoea should be checked to determine the duration of Diarrhoea, if blood is present in the stool and if dehydration is present.

**Check Dehydration** : Based on a combination of the following clinical signs, children presenting with Diarrhoea are classified into the three categories of severe dehydration, some dehydration and no dehydration and appropriate treatment is to be given. Main clinical signs are used to determine the level of dehydration

**Severe Dehydration (Plan C)** : Presence of at least *two of the following signs* classifies the child as having severe dehydration.

- (a) Lethargic or unconscious
- (b) Sunken eyes
- (c) Not able to drink or drinking poorly
- (d) Skin pinch goes back very slowly

Child should be managed in the primary health care facility with fluids. Re-assess every 1-2 hours and if required, fluid can be repeated once. The ORS should be continued. If IV fluids cannot be given, fluids by nasogastric tube could be given. If none of this is feasible refer to a hospital. However if the child has any other severe classification, he should be urgently referred to hospital. Oral doxycycline (5 mg/kg/day) should be administered if cholera is prevalent in the area.

**Some dehydration** : Look for the signs of dehydration-

If two or more of the signs are present the, classification is some dehydration. The child should be treated as per *Plan B*.

Such a child is followed up after 5 days if not improving. Mother is counselled to return immediately if child has any of the following signs:

1. Not able to drink or breast feed
2. Becomes sicker
3. Develops fever
4. Passes blood in stool

**No dehydration** : The child is classified as if there are not enough signs to classify into some or severe dehydration. Treatment is given at home with fluids and feeds as per *Plan A*. The mother is advised to return after 5 days or immediately



if above danger signs develop like not able to drink or breast feed, becomes sicker, develops fever or passes blood in stool.

**Dysentery** : A child is classified as having dysentery if the mother or caretaker reports blood in the child's stool. This should be treated with oral cotrimoxazole (8mg/kg/day of trimethoprim in 2 divided doses) for 5 days. The child is followed up after 2 days.

**Persistent Diarrhoea** : All children with Diarrhoea lasting for 14 days or more are said to have persistent Diarrhoea. If dehydration is present, the child is classified as severe persistent Diarrhoea and should immediately be sent to hospital. If dehydration is not present, the child is given a single dose of vitamin A and oral zinc sulphate 20 mg daily for 14 days and the mother or caretaker is given counselling on feeding of the child. If still breast feeding, give more frequent, longer breast feeds, day and night. If taking other milk replace with increased breast feeding OR replace with fermented milk products, such as yoghurt OR replace half the milk with nutrient-rich semisolid food. Add cereals to milk (Rice, Wheat, Semolina). The child is followed up after 5 days.

**(C) Fever** : Children are considered to have fever if the body temperature is above 37.5°C axillary (38°C rectal). In the absence of a thermometer, children are considered to have fever if they feel hot or there is a history of fever. Body temperature should be checked in all sick children brought to an outpatient clinic. A child presenting with fever should be assessed for common serious causes like malaria, meningitis and measles. The following information is important:

- (a) Risk of malaria based on the geographic area endemic for it
- (b) Presence of bulging fontanelle or stiff neck suggesting very severe febrile illness such as meningitis
- (c) Presence of running nose, conjunctival congestion or generalized rash suggestive of measles

**Serious Febrile Illness** : A child with fever is classified as having serious febrile illness if there is any general danger sign or stiff neck or bulging fontanel. He requires urgent referral to hospital. Pre-referral required to be given to the child is a dose of IM quinine (10 mg/kg/dose) after making a blood smear; first dose of IV or IM chloramphenicol (40 mg/kg/dose or if not possible oral amoxicillin 15 mg/kg/dose), feeding to prevent hypoglycemia and one dose of paracetamol (15 mg/kg) for high fever (temp. 38.5°C or above).

**High Malaria Risk area** : Children with fever but without any danger sign or stiff neck or bulging fontanel are classified as Malaria and should be treated with antimalarials after making a blood smear. The antimalarials given are as follows:

*Presumptive treatment -*

- (i) Oral chloroquine 10 mg/kg single dose on Day 1, 10 mg/kg single dose on Day 2 and 5 mg/kg single dose on Day 3.
- (ii) In areas of high chloroquine resistance, give oral sulphadoxine (25 mg/kg) plus pyrimethamine (1.25 mg/kg) single dose.

*Radical treatment* : if *P. vivax* is positive on blood smear - Oral primaquine 0.25 mg/kg daily for 5 days.

**Low Malaria Risk Area** : Children with fever but without any danger sign / stiff neck / bulging fontanella are classified as

Malaria there are no symptoms of runny nose, measles or any other cause of fever. The antimalarials given after making a blood smear are as follows:

*Presumptive treatment*

- (i) Oral chloroquine 10 mg/kg single dose on Day 1
- (ii) In areas of high chloroquine resistance, give oral sulphadoxine (25 mg/kg) plus pyrimethamine (1.25 mg/kg)

*Radical treatment* in Smear positive Pf case

- (i) Oral chloroquine 10 mg/kg single dose
- (ii) Oral primaquine 0.75 mg/kg single dose

*Radical treatment* in Smear positive Pv case

- (i) Oral chloroquin 10 mg/kg single dose
- (ii) Oral primaquine 0.25 mg/kg daily for 5 days

In a child being treated for malaria, the mother should be advised to return immediately if the child becomes sicker or is unable to drink or breast feed. The child should be followed up after 2 days if fever persists or recurs within 14 days. If fever persists every day for 7 days the child should be referred for assessment.

**Measles** : A child with fever is assessed for signs of measles such as generalized rash with cough, runny nose and red eyes.

- If the child has measles or has had measles within the last 3 months, and there is any general danger sign or clouding of cornea or deep / extensive mouth ulcers, the classification is Severe complicated measles. This child should be urgently referred to hospital after giving first dose of oral vitamin A, chloramphenicol IM and tetracycline eye ointment application.
- If the child has measles now or has had measles within the last 3 months, and there is pus draining from eye or mouth ulcers are present, he is classified to have measles with eye or mouth complications, and given first dose of vitamin A, tetracycline eye ointment and gentian violet for mouth ulcers. Follow up is done after 2 days.
- If the child has measles now or has had measles within the last 3 months, with none of the above signs, only first dose of vitamin A is given.

**(D) Ear Infections** : Any sick child should be assessed for ear problems such as ear pain or ear discharge. If there is a tender swelling behind the ear, the child has mastoiditis. He should be given first dose of IM chloramphenicol and urgently referred to hospital. If there is pus discharge or ear pain, the classification is acute ear infection and oral antibiotic (cotrimoxazole) should be given for 5 days. Dry the ear at least 3 times daily. Roll clean absorbent cloth or soft, strong tissue paper into a wick. Place the wick in the young infant's ear. Remove the wick when wet. Replace the wick with a clean one and repeat these steps until the ear is dry.

**(E) Malnutrition** : Every sick child should be weighed and assessed for visible severe wasting and oedema of both feet.

- If there is visible severe wasting or oedema, the child is said to have severe malnutrition and given a single dose of vitamin A, kept warm and urgently referred to hospital.
- If the child has very low weight (malnutrition grade II, III or IV), the mother is counselled for feeding. The child

is followed up in 5 days if there is a feeding problem or otherwise after 30 days.

**(F) Anaemia :** Palmar pallor is looked for in every sick child presenting to primary health care.

- If there is severe palmar pallor, the child has severe anaemia and should be urgently referred to hospital.
- If some palmar pallor is present, the child has anaemia and should be given iron and folic acid therapy in a single dose daily for 14 days (elemental iron 3-6 mg/kg/day and folic acid 100-200 mcg/day).
- All other sick children older than 6 months should be given prophylactic iron and folic acid (20 mg elemental iron + 100 mcg folic acid) for a total of 100 days in a year after the child has recovered from the acute illness.

### Immunization

Immunization status of every sick child should be checked. Those being referred to hospital should not be immunized. All other children should be immunized as per schedule on the same day.

### Assess Other Problems

Although the IMNCI guidelines focus on the main symptoms as enumerated above, every sick child should be assessed for other complaints, which can lead to severe or acute illness. In addition, the health of the caretaker should be also be addressed. Case recording form for management of the sick child age 2 months up to 5 years is given on subsequent pages.

### Counselling of the Mother

- (a) Advise mother on home care for infant-The mother should be counselled on breast feeding the child and keeping the baby warm.
- (b) Advise mother when to return- To return immediately if the infant is
  - (i) Breast feeding or drinking poorly
  - (ii) Becomes sicker
  - (iii) Develops a fever or feels cold to touch
  - (iv) Fast breathing
  - (v) Difficult breathing
  - (vi) Yellow palms and soles ( if infant has jaundice)
  - (vii) Diarrhoea with blood in stool
- (c) Counsell the Mother about her own health
  - If the mother is sick, provide care for her, or refer her for help.
  - If she has a breast problem (such as engorgement, sore nipples, breast infection), provide care for her or refer her for help.
  - Advise her to eat well to keep up her own strength and health.
  - Give iron folic acid tablets for a total of 100 days.
  - Make sure she has access to:
    - Family planning, Counselling on STD and AIDS prevention

### Summary

WHO developed an approach called IMCI (Integrated Management of Childhood Illnesses) which encompasses a range of interventions to combat 5 major childhood illnesses i.e.

Acute Respiratory Infections, Diarrhoea, Measles, Malaria and Malnutrition. The Adaptation group developed Indian version of IMCI guidelines and renamed it as Integrated Management of Neonatal and Childhood Illnesses (IMNCI).

IMNCI approach has some distinct features i.e. It is based on syndromic and holistic approach, involves Triage and it works on Standardized case management and Primary health care model with community participation. The major components are strengthening the health care infrastructure, strengthening the skills of health care workers and community participation in which mother is actively involved. The basic steps in management are assess, classify, treat and follow up care of the child and counselling of the mother. The IMNCI guidelines recommend case management procedures separately for age up to 2 months and 2 months to 5 years.

For young infants aged up to 2 months the assessment and classification process is different from older infants and children. Assessment in young infants includes Serious bacterial infections or local infections, Jaundice, Diarrhoea, Low body temperature, Feeding problems or malnutrition and Immunization status. In case any sign of severe bacterial infection is present the child is given first dose of parenteral antibiotic and referred to hospital. If local infection present the infant is given oral antibiotics and advised home care. Jaundice in a neonate appearing in less than 24 hours or after 14 days or associated with yellow discolouration of palms and soles is classified as severe jaundice and urgent referral after initial treatment is done. Every sick young infant should be examined for low body temperature and managed accordingly. If Diarrhoea is present then assessment of dehydration should be done. If dehydration is present with low weight or any other severe classification, child is referred after giving first dose of IM antibiotics and frequent sips of ORS. If dehydration is present without low weight or any other severe classification, child is treated based on severity of dehydration. If Diarrhoea is present without signs of dehydration then child is treated at home with oral fluids. Weight and feeding of infant should also be assessed. Immunization status should also be checked and if feasible immunization should be carried out before discharging to home.

A sick child aged 2 months to 5 years may present with common ailments like Pneumonia, Diarrhoea, Fever, Ear infection, Malnutrition and Anaemia. Firstly the general danger signs should be looked for i.e. Lethargy or unconsciousness, Convulsions, Repeated vomiting and Inability to drink or breast feed. If a child has any one of these signs he is considered seriously ill and immediately referred. After examining for danger signs four major symptoms are looked for. These are Cough or difficult breathing, Diarrhoea, Fever and Ear problems. Any child with cough or difficult breathing is assessed by Respiratory rate, Chest-indrawing and Presence of stridor. Based on these signs children are classified into Severe pneumonia, Pneumonia and No pneumonia and treated accordingly. A child with severe pneumonia is referred to a hospital by quickest means after administering first dose of injectable antibiotics. A child classified as having pneumonia is treated with oral antibiotics at home for 5 days after giving necessary instructions to mother. A child with no pneumonia is treated

without antibiotics at home. A child presenting with Diarrhoea should be first assessed for danger signs and then assessed for dehydration. Based on dehydration status child is classified into Diarrhoea with severe dehydration, some dehydration or no dehydration. A child with severe dehydration is treated with intravenous fluids and reassessed every 1-2 hours. If signs of severe classification are present child is immediately referred to hospital. If a child has some dehydration treat with ORS and reassess after 4 hours. If a child has no dehydration treat at home with oral fluids. A sick child should be checked for fever and if present should be assessed for common serious causes like Malaria, Meningitis and Measles. A child with fever is classified as having serious febrile illness if there is any danger sign or stiff neck or bulging fontanellae and requires parenteral antibiotics and quinine and urgent referral to hospital. If a child is classified as having Malaria than appropriate treatment is given. A child with fever is also assessed for signs of Measles. Any sick child should also be assessed for Ear infections, Malnutrition and Anaemia. Immunization status of every sick child should be checked. Mother should also be counselled for child care and her own health.

## Study Exercises

**Long Question :** Describe in detail the IMNCI guidelines for management of Neonatal and Childhood illnesses.

**Short Notes:** (1) Components of IMNCI (2) IMNCI guidelines for Management of Pneumonia (3) IMNCI guidelines for Management of Diarrhoea (4) General danger signs in a sick child

## MCQs

- General danger signs in a sick child include all except: (a) Convulsions (b) Unconsciousness (c) Inability to Breast feed (d) Vomiting

- Which of the following is not true of dehydration: (a) Mild to moderate dehydration can be corrected at home by ORS (b) ORS Solution should be made fresh daily (c) Breast feeding should be delayed till dehydration is corrected (d) Patient should be given as much ORS as he wants
- Young infants in IMNCI guidelines are up to the age of: (a) 6 months (b) 1 year (c) 2 months (d) 3 months
- For young infants assessment is basically done for all except: (a) Jaundice (b) Hypothermia (c) Diarrhoea (d) Measles
- IMNCI recommendations are up to the age of: (a) 10 years (b) 8 years (c) 7 years (d) 5 years
- Severe Jaundice in a neonate are all except: (a) Less than 24 hours (b) More than 7 days (c) More than 14 days (d) Yellow discolouration of palms and soles
- In a 6 month old child breathing rate \_\_\_\_\_ or more suggests pneumonia: (a) 40 per minute (b) 50 per minute (c) 60 per minute (d) 70 per minute
- Signs for classifying a child as having severe dehydration are all except: (a) Dry tongue (b) Sunken eyes (c) Not able to drink (d) Lethargic or unconscious
- A case of Simple Pneumonia is treated with: (a) Parenteral antibiotics (b) Oral antibiotics (c) Referred to hospital (d) Parenteral antibiotics and Referral
- IMCI approach developed by WHO encompasses following childhood illnesses except: (a) Measles (b) Malaria (c) Diarrhoea (d) Chickenpox

**Answers :** (1) d; (2) c; (3) c; (4) d; (5) d; (6) b; (7) b; (8) a; (9) b; (10) d

## References

- Concept and strategy Framework- Integrated Management of Neonatal and Child illnesses (IMNCI) - Government of India, State Governments, UNICEF and WHO) - February, 2004.
- WHO and UNICEF, 2003. Integrated management of neonatal and childhood illness. Assess and classify the sick young infant age up to 2 months. Ministry of health and Family Welfare, Government of India, New-Delhi, 2003

## **CASE RECORDING FORM FOR MANAGEMENT OF THE SICK YOUNG INFANT AGE UP TO 2 MONTHS**

Name: \_\_\_\_\_ Age: \_\_\_\_\_ Weight: \_\_\_\_\_ kg Temperature: \_\_\_\_\_ °C Date: \_\_\_\_\_

ASK: What are the infant's problems? \_\_\_\_\_ Initial visit? \_\_\_\_\_ Follow up Visit? \_\_\_\_\_

**ASSESS** (Circle all signs present)

**CLASSIFY**

### **CHECK FOR POSSIBLE BACTERIAL INFECTION / JAUNDICE**

- Has the infant had convulsions?
  - Count the breaths in one minute. breaths per minute
  - Repeat if elevated \_\_\_\_\_ Fast breathing?
  - Look for severe chest indrawing.
  - Look for nasal flaring.
  - Look and listen for grunting.
  - Look and feel for bulging fontanelle.
  - Look for pus draining from the ear.
  - Look at the umbilicus. Is it red or draining pus?
  - Look for skin pustules. Are there 10 or more pustules or a big boil?
  - Measure axillary temperature (if not possible, feel for fever or low body temperature):
    - 37.5°C or more (or feels hot)?
    - Less than 35.5°C ?
    - Less than 36.5°C but above 35.4°C (or feels cold to touch)?
  - See if young infant is lethargic or unconscious
  - Look at young infant's movements. Less than normal?
  - Look for jaundice. Are the palms and soles yellow?

### **DOES THE YOUNG INFANT HAVE DIARRHEA?**

Yes \_\_\_\_ No \_\_\_\_

- For how long? \_\_\_\_\_ Days?
- Is there blood in the stool?
  - Look at the young infant's general condition. Is the infant:
    - Lethargic or unconscious?
    - Restless and irritable?
  - Look for sunken eyes.
  - Pinch the skin of the abdomen. Does it go back:
    - Very slowly (longer than 2 seconds)?
    - Slowly

### **THEN CHECK FOR FEEDING PROBLEM & MALNUTRITION**

- Is there any difficulty feeding? Yes \_\_\_\_ No \_\_\_\_ . • Determine weight for age. Very low \_\_\_\_ Low \_\_\_\_ Not Low \_\_\_\_
- Is the infant breastfed? Yes \_\_\_\_ No \_\_\_\_
  - If Yes, how many times in 24 hours? \_\_\_\_\_ times
- Does the infant usually receive any other foods or drinks? Yes \_\_\_\_ No \_\_\_\_
  - If Yes, how often?
- What do you use to feed the infant?

**If the infant has any difficulty feeding, is feeding less than 8 times in 24 hours, is taking any other food or drinks, or is low weight for age AND has no indications to refer urgently to hospital:**





## CASE RECORDING FORM FOR MANAGEMENT OF THE SICK CHILD AGE 2 MONTHS UP TO 5 YEARS

Name: \_\_\_\_\_ Age: \_\_\_\_ Weight: \_\_\_\_\_ kg Temperature: \_\_\_\_\_ °C Date: \_\_\_\_\_

ASK: What are the child's problems? \_\_\_\_\_ Initial visit? \_\_\_\_ Follow-up Visit? \_\_\_\_  
ASSESS (Circle all signs present) CLASSIFY

**CHECK FOR GENERAL DANGER SIGNS**  
NOT ABLE TO DRINK OR BREASTFEED  
VOMITS EVERYTHING  
CONVULSIONS

LETHARGIC OR UNCONSCIOUS

General danger sign present?  
Yes \_\_\_\_ No \_\_\_\_

Remember to use danger sign  
when selecting classifications

**DOES THE CHILD HAVE COUGH OR DIFFICULT BREATHING?** Yes \_\_\_\_ No \_\_\_\_

- For how long? \_\_\_\_ Days
- Count the breaths in one minute  
\_\_\_\_ breaths per minute. Fast breathing?
- Look for chest indrawing.
- Look and listen for stridor. \_\_\_\_\_

**DOES THE CHILD HAVE DIARRHEA?** Yes \_\_\_\_ No \_\_\_\_

- For how long? \_\_\_\_ Days
- Is there blood in the stool?
- Look at the child's general condition. Is the child:  
Lethargic or unconscious?  
Restless and irritable
- Look for sunken eyes.
- Offer the child fluid. Is the child:  
Not able to drink or drinking poorly?  
Drinking eagerly, thirsty?
- Pinch the skin of the abdomen. Does it go back:  
Very slowly (longer than 2 seconds)?  
Slowly?

**DOES THE CHILD HAVE FEVER?** (by history/feels hot/ temperature 37.5°C or above) Yes \_\_\_\_ No \_\_\_\_

Decide Malaria Risk: High \_\_\_\_ Low \_\_\_\_

- Fever for how long? \_\_\_\_ Days
- If more than 7 days, has fever  
been present every day?
- Has the child had measles within  
the last 3 months?
- Look or feel for stiff neck.
- Look and feel for bulging fontanelle.
- Look for runny nose
- Look for signs of MEASLES:
- Generalized rash
- One of these: cough, runny nose, or red eyes

**If the child has measles now  
or within the last 3 months:**

- Look for mouth ulcers  
If Yes, are they deep and extensive
- Look for pus draining from the eye.
- Look for clouding of the cornea.

**DOES THE CHILD HAVE AN EAR PROBLEM** Yes \_\_\_\_ No \_\_\_\_

- Is there ear pain?
- Is there ear discharge?
- If Yes, for how long? \_\_\_\_ Days
- Look for pus draining from the ear.
- Feel for tender swelling behind the ear.

**THEN CHECK FOR MALNUTRITION**

- Look for visible severe wasting.
- Look for oedema of both feet.
- Determine weight for age.  
Very Low \_\_\_\_ Not Very Low \_\_\_\_

**THEN CHECK FOR ANEMIA**

- Look for palmar pallor.  
Severe palmar pallor? Some palmar pallor? No pallor?

**CHECK THE CHILD'S IMMUNIZATION, PROPHYLACTIC VITAMIN A & IRON-FOLIC ACID STATUS** Return for next  
Circle immunizations and Vitamin A or IFA supplements needed today. immunization or  
vitamin A or IFA  
supplement on:

BCG \_\_\_\_ DPT 1 \_\_\_\_ DPT 2 \_\_\_\_ DPT 3 \_\_\_\_ DPT( Booster)DT \_\_\_\_

OPV 0 \_\_\_\_ OPV 1 \_\_\_\_ OPV 2 \_\_\_\_ OPV 3 \_\_\_\_ OPV IFA \_\_\_\_



### Plan A : Treat Diarrhoea at Home

Counsel the mother on the three rules of home treatment: Give extra fluids, continue feeding, return if child worsens

**Give extra fluids ( as much as the child will take)**

**Tell the mother :**

- If exclusively breast fed, breast feed frequently and for longer at each feed. If passing frequent watery stools: For less than 6 months age, give ORS and clean water in addition to breast milk. If 6 months or older, give one or more of the home fluids in addition to breast milk.
- If the child is not exclusively breast fed: give one or more of the following home fluids: ORS solution, yoghurt drink, milk, lemon drink, rice or pulse based drink, vegetable soup, green coconut water or plain clean water.

**It is especially important to give ORS at home when :**

- The child has been treated with plan B or Plan C during the visit
- The child cannot return to a clinic if the diarrhea gets worse

**Teach the mother how to mix and give ORS. Give the mother 2 packets of ORS to use at home.**

**Show the mother how much fluid to give in addition to the usual fluid intake:**

- Up to 2 years: 50 to 100 ml after each loose stool
- 2 years or more: 100 to 200 ml after each loose stool

**Tell the mother to :**

- Give frequent small sips from a cup
- If the child vomits, wait for 10 minutes. Then continue, but more slowly.
- Continue giving extra fluids until the diarrhea stops

### Plan B : Treat Some Dehydration with ORS

**Give recommended amount of ORS over a 4 hour period**

Determine the amount of ORS to give during next 4 hours as follows:

Age	Up to 4 months	4 months to 12 months	12 months up to 2years	2 years up top 5 years
Weight	< 6kg	6<10 kg	10 - <12 kg	12-19 kg
In ml	200-400	400-700	700-900	900-1400

- The approximate amount of ORS required (in ml) can also be calculated by multiplying the child's weight (in kg) times 75
- If a child wants more ORS than shown, give more.
- For infants who are not breast fed, also give 100-200 ml clean water during this period

**Show the mother how to give ORS:**

- Give frequent small sips from a cup
- If the child vomits, wait for 10 minutes. Then continue, but more slowly
- Continue breast feeding whenever the child wants

**After 4 hours**

- Reassess the child and classify for dehydration
- Select the appropriate plan and continue treatment
- Begin feeding the child in the clinic

**If the mother must leave before completing the treatment**

- Show her how to prepare ORS solution at home
- Show her how much ORS to give to finish 4 hour treatment at home
- Give her enough ORS packets to complete rehydration. Also give her two packets as recommended in plan A.

**Explain the 3 rules of home treatment:**

- Give extra fluids
- Continue feeding
- Return if child worsens, does not pass urine or refuses to drink



### Plan C : Treatment of Severe Dehydration

#### If you can give IV fluid immediately

- If the child can drink, give ORS by mouth while drip is set up.
- Give 100 ml/kg Ringers lactate solution or Normal saline as follows

Age	First give 30 ml/kg in :	Then give 70 ml/kg in:
Infants( up to 12 months)	1 hour ( repeat once if radial pulse is still very weak or not detectable)	5 hours
Children (12 months – 5 years)	30 minutes( repeat once if radial pulse is still very weak or not detectable)	2 ½ hours

- Reassess child every 1-2 hours. If hydration status is not improving, give the IV fluid more rapidly.
- Also give ORS (about 5 ml/kg/hour) as soon as the child can drink, usually after 3-4 hours(infants) or 1-2 hours( children)
- Reassess an infant after 6 hours and a child after 3 hours. Classify dehydration. Then choose the appropriate plan(A,B, or C) to continue

#### If you cannot give IV fluids immediately and IV treatment is available nearby (within 30 min)

- Refer urgently to hospital for IV treatment
- If the child can drink, provide the mother with ORS solution and show her how to give frequent sips during the trip \





#### If IV treatment is not available immediately and you are trained to use nasogastric tube for rehydration

- Start rehydration by tube (or mouth) with ORS solution: 20 ml/kg/hour for 6 hours (total of 120 ml/kg)
- Reassess the child every 1-2 hours
  - If there is repeated vomiting or increasing abdominal distension, give the fluid more slowly
  - If the hydration status is not improving after 3 hours, send the child for IV therapy
- After 6 hours, reassess the child. Classify dehydration. Then choose the appropriate plan (A, B, C) to continue treatment.

#### If IV treatment is not available immediately ( within 30 min), you are not trained to use nasogastric tube and the child cannot drink

- Refer urgently to hospital for IV or Nasogastric tube treatment

### Feeding recommendations during sickness and health

<p><b>Up to 6 Months of Age</b></p>  <p>Breastfeed as often as the child wants, day and night, at least 8 times in 24 hours.</p> <ul style="list-style-type: none"> <li>• Do not give any other foods or fluids not even water</li> </ul> <p><u>Remember:</u></p> <ul style="list-style-type: none"> <li>• Continue breastfeeding if the child is sick</li> </ul>	<p><b>6 Months up to 12 Months</b></p>  <ul style="list-style-type: none"> <li>• Breastfeed as often as the child wants.</li> <li>• Give at least <u>one katori serving*</u> at a time of :           <ul style="list-style-type: none"> <li>- Mashed roti/ rice /bread/biscuit mixed in sweetened undiluted milk OR</li> <li>- Mashed roti/rice/bread mixed in thick dal with added ghee/oil or khichri with added oil/ghee. Add cooked vegetables also in the servings OR</li> <li>- Sevan/dalia/halwa/kheer prepared in milk or any cereal porridge cooked in milk OR</li> <li>- Mashed boiled/fried potatoes</li> <li>- Offer banana/biscuit/ cheeko/ mango/ papaya</li> </ul> </li> </ul> <p><sup>*</sup>3 times per day if breastfed; 5 times per day if not breastfed.</p> <p><u>Remember:</u></p> <ul style="list-style-type: none"> <li>• Keep the child in your lap and feed with your own hands</li> <li>• Wash your own and child's hands with soap and water every time before feeding</li> </ul>	<p><b>12 Months up to 2 Years</b></p>  <ul style="list-style-type: none"> <li>• Breastfeed as often as the child wants.</li> <li>• Offer food from the family pot</li> <li>• Give at least <u>1½ katori serving*</u> at a time of :           <ul style="list-style-type: none"> <li>- Mashed roti/rice/bread mixed in thick dal with added ghee/oil or khichri with added oil/ghee. Add cooked vegetables also in the servings OR</li> <li>- Mashed roti/ rice /bread/biscuit mixed in sweetened undiluted milk OR</li> <li>- Sevan/dalia/halwa/kheer prepared in milk or any cereal porridge cooked in milk OR</li> <li>- Mashed boiled/fried potatoes</li> <li>- Offer banana/biscuit/ cheeko/ mango/ papaya</li> </ul> </li> </ul> <p><sup>*</sup> 5 times per day.</p> <p><u>Remember:</u></p> <ul style="list-style-type: none"> <li>• Sit by the side of child and help him to finish the serving</li> <li>• Wash your child's hands with soap and water every time before feeding</li> </ul>	<p><b>2 Years and Older</b></p>  <ul style="list-style-type: none"> <li>• Give family foods at 3 meals each day.</li> <li>• Also, twice daily, give nutritious food between meals, such as: banana/biscuit/ cheeko/ mango/ papaya as snacks</li> </ul> <p><u>Remember:</u></p> <ul style="list-style-type: none"> <li>• Ensure that the child finishes the serving</li> <li>• Teach your child wash his hands with soap and water every time before feeding</li> </ul>
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#### Feeding Recommendations For a Child who Has PERSISTENT DIARRHOEA

- If still breastfeeding, give more frequent, longer breastfeeds, day and night.
- If taking other milk:
  - replace with increased breastfeeding OR
  - replace with fermented milk products, such as yoghurt OR
  - replace half the milk with nutrient-rich semisolid food.
  - Add cereals to milk (Rice, Wheat, Semolina)
- For other foods, follow feeding recommendations for the child's age.

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### Global Scenario

In 2006, for the first time since mortality data have been gathered, annual deaths among children under five dipped below 10 million to 9.7 million. This represents a 60 per cent drop in the rate of child mortality since 1960. Most deaths among children under five years are still attributable to just a handful of conditions and are avoidable through existing interventions (Fig. - 1). Six conditions account for 70% to over 90% of all these deaths. These are acute lower respiratory infections, mostly pneumonia (19%), diarrhoea (18%), malaria (8%), measles (4%), HIV/AIDS (3%), and neonatal conditions, mainly preterm birth, birth asphyxia, and infections (37%).

### India

**Table - 1 : Child Health - India**

1	IMR	57 / 1000 live births
2	Under Five Mortality	74 / 1000 live births
3	Children <3 yrs who are underweight	42.5 %
4	Breast feeding initiation in 1 hour	24.5 %
5	ORS given to children with diarrhoea	26 %
6	Children (12-23 months) with completed immunization	43.5%
7	% of newborn babies LBW	30 %

### Definitions

**Child Death rate (1-4 Year Mortality Rate)** : Child death rate is the number of deaths of children aged 1 to 4 years per 1000 children in the same age group in a given year. It therefore excludes infant mortality. This is a more refined indicator of the social situation in a country than infant mortality rate. It reflects the adverse environmental health hazards faced by the children including factors like malnutrition, poor hygiene and sanitation, infections and accidents caused due to social, economic, cultural characteristics of the community. This measure of child health excludes the perinatal and endogenous factors operating in the infancy. The second year of life is the one which poses greatest risk to life and accounts for nearly half of all deaths in the 1-4 years age children. The infectious diseases like measles, diphtheria, ARI, diarrhoea affect this age most. The 1-4 years child mortality rate in developed countries is negligible and quite high in the developing and underdeveloped nations. The countries also show a great interstate variation. The developed countries have home accidents as the leading cause in developed countries while infections predominate in the developing nations.

**Under Five Mortality Rate (U5MR) (Child Mortality Rate)**: This is defined as the number of deaths in children under five

years of age expressed as rate per 1000 live births. This rate measures the probability of dying between birth and exactly five years of age. This indicator is considered as the single best indicator of social development and well being. The global figure stands at 72 while India has a rate of under five mortality at 74 per 1000 live births. There has been a declining trend in under five mortality but still continues to be very high in African countries especially Sub-Saharan countries. Child mortality is a sensitive indicator of a country's development and telling evidence of its priorities and values. It has several advantages as a barometer of child well-being in general and child health in particular. First, it measures an 'outcome' of the development process rather than an 'input', such as per capita calorie availability or the number of doctors per 1,000 population - all of which are means to an end. Second, the U5MR is known to be the result of a wide variety of inputs: the nutritional status and the health knowledge of mothers; the level of immunization and oral rehydration therapy; the availability of maternal and child health services (including prenatal care); income and food availability in the family; the availability of safe drinking water and basic sanitation; and the overall safety of the child's environment, among other factors. Third, the U5MR is less susceptible to the fallacy of the average than, for example, per capita gross national income (GNI per capita). This is because the natural scale does not allow the children of the rich to be 1,000 times as likely to survive, even if the human made scale does permit them to have 1,000 times as much income. In other words, it is much more difficult for a wealthy minority to affect a nation's U5MR, and it therefore presents a more accurate, if far from perfect, picture of the health status of the majority of children (and of society as a whole).

**Child Survival Index** : This indicator is calculated by subtracting the under five mortality rate from 1000 and dividing this figure by 10. The child survival is a measure of social development and the attention given to the care of under five children. The child survival index of developed countries is 99 and above approaching 100 and developing countries like India have a much lower survival index but it is improving steadily.

### Evolution of Under Five Child Health Services

**1. Primary Health Care Model** : During the 1970s, socioeconomic development and improved basic living conditions like clean water, sanitation and nutrition were seen as the keys to improving child health. Primary health care stood for universal access to care and coverage on the basis of need. Along with intersectoral action for health, community involvement and self-reliance, much of the primary health care strategy was designed with the health of children as the priority of priorities.

**2. Vertical Programmes-Model** : At the end of the 1970s, the economic recession did not allow for such a development of primary health care system. Child health and particularly child survival was such an obvious emergency that by the early 1980s, many countries shifted their focus from primary health care systems to vertical, "single-issue", programmes that promised cheaper and faster results. Child health continued to constitute a 'silent' emergency, as close to 15 million children were still dying annually before their fifth birthday.

In the late 1970s, two scientists, Julia Walsh and Kenneth Warren, published '*Selective Primary Health Care* : An interim strategy for disease control in developing countries' - a milestone paper that proposed an alternative strategy for rapidly reducing infant and child mortality at a reasonable cost. After breaking down the relative role of each major cause of child mortality and listing the existing interventions proved to be effective in addressing them, they concluded that a small number of causes (diarrhoea, malaria, respiratory diseases and measles, among others) were responsible for the vast majority of under-five deaths and that these deaths could be easily prevented by immunization oral rehydration therapy, breast feeding and antimalarial drugs(1). The Child Survival Revolution of the 1980s, spearheaded by the United Nations Children's Fund (UNICEF), and built around a package of interventions grouped under the acronym GOBI (growth monitoring, oral rehydration therapy for diarrhoea, breast feeding, and immunization) soon gained currency.

**3. Preventive Model (EPI)** : Expanded Programme on Immunization of the mid-1970s, and programmes for Control of Diarrhoeal Disease and Acute Respiratory Infections became the successful strategy in which at country level, these vertical programmes successfully tackled a number of priority diseases. The Expanded Programme on Immunization started in 1974 and widened the range of vaccines routinely provided, from smallpox, BCG and DTP to include polio and measles. It set out to increase coverage in line with the international commitment to achieve the universal child immunization goal of 80% coverage in every country.

**4. Breast feeding initiatives (BFHI)** : Baby-Friendly Hospital initiative to support promotion of breast feeding in maternities was launched in 1992. In 1990, less than one fifth of mothers gave exclusive breast feeding for four months; by 2002 that figure had doubled to 38%.

**5. Integrated and Syndromic Approach to a Sick Child (IMCI)**: A feverish and irritable child that has difficulty eating can be suffering from a single illness, such as dysentery, or from a combination of diseases, such as malaria and pneumonia. Single-issue programmes were not designed to provide guidance on how to deal with such situations. There was clearly a need for a more comprehensive view of the needs of the child, one that would correspond to problems as they were encountered in the field (4) and would offer a wider range of responses than the existing programmes. The response to this new situation was to package a set of simple, affordable and effective interventions for the combined management of the major childhood illnesses and malnutrition, under the label of "Integrated Management of Childhood Illness" (IMCI). Details are covered in chapter on IMNCI, the Indian adapted version of IMCI.

**6. Child Health - An issue of Rights for the Children** : The MDGs have made it binding on all countries to move forward on issues of child health focusing on survival, growth, development and protection. The children of the world are subjected to many violations of their rights like child labour, abuse and exploitation, neglect, early marriage and even sexual abuse and violence against them. The UNICEF with many NGOs are focusing on these issues.

## Under Five's Clinic

### History

Dr. Morley while working in rural areas of Nigeria developed the concept of growth chart popularly known as '*Road to Health*' chart (2-6). He highlighted the problem facing child health services throughout the developing world and especially malnutrition which was at the core of all other childhood problems. He emphasized the role of growth monitoring through under-fives 'clinic to quickly identify and combat malnutrition. These two measures have subsequently been adopted by many developing countries. Careful emphasis was placed on the social, economic, cultural and ethical considerations which were ignored by most doctors but also nurses and other health workers. Morley emphasized low-cost health services, within the means of the people involved, and the need to make extensive use of auxiliaries and villagers themselves. The concept of 'Well Baby clinics' is being practised with emphasis on preventive services mainly immunization and promotive growth monitoring.

### Under Fives - A special group

1. They constitute about 15 % of the total population.
2. They suffer high rates of mortality and morbidity.
3. The effects of malnutrition and other diseases have a role in later life.
4. The majority of the deaths are preventable through available interventions.
5. This is a period of growth and development.
6. Brain growth is completed during 1<sup>st</sup> five years.
7. Most causes of morbidity are preventable by immunization.
8. Health of children under five years and family health are inter-related.
9. Likely to be neglected in the face of poverty and unregulated fertility.

### Cause of Death in Children

The various causes of death in children are shown in Fig. - 1.

**1. Pneumonia** : Pneumonia kills more children than any other disease (19%), more than AIDS, malaria and measles combined. It is a major cause of child deaths in every region. Undernourished children, particularly those who are not exclusively breastfed or have inadequate zinc intake, or those with compromised immune systems, run a higher risk of developing pneumonia. Child suffering from other illnesses, such as measles, or those living with HIV, is more likely to develop pneumonia. Environmental factors, such as living in crowded homes and being exposed to parental smoking or indoor air pollution, may also play a role in increasing children's susceptibility to pneumonia and its consequences.

**2. Diarrhoea** : Diarrhoea is most common in children between 6 months and 2 years with highest incidence in the 6-11 months age when weaning occurs. The mortality is estimated at 4.9 children per 1000 per annum due to Diarrhoea in children under five in the developing regions. The ORS has reduced the burden of childhood mortality to a great extent.

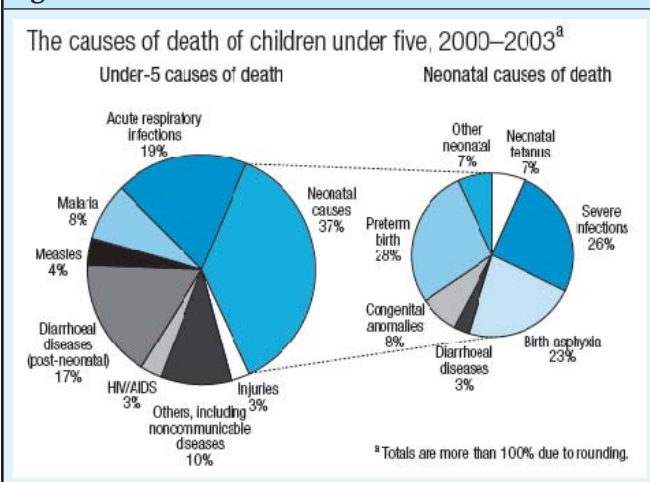
**3. Malaria** : This is a major cause of death in Sub-Saharan Africa where it causes 25% of childhood mortality. It kills

about 1 million children accounting for 80% of all deaths due to malaria. It also contributes indirectly to deaths from ARI, anaemia, diarrhoea and malnutrition.

**4. Measles :** In India, measles is a major cause of morbidity and a major contributor to child mortality. It affects children between 6 months and 3 years. It tends to be severe in malnourished children. It weakens children's immunity to other life-threatening diseases and conditions, including pneumonia, diarrhoea and acute encephalitis, and remains one of the leading causes of vaccine preventable deaths among children.

**5. HIV/AIDS :** This is an emerging cause of childhood deaths especially in Sub-Saharan Africa. This accounts for 3% of all under five deaths.

**Fig. - 1 : Causes of death in Under Five Children**



## Goal

The overall goal of the Under-Fives Clinic is to provide comprehensive health care to young children in a separate specialized facility.

The under five clinic is represented by traditional logo of a triangle with four internal triangles and an outer enveloping triangle as shown in the Fig. - 2.

## Objectives

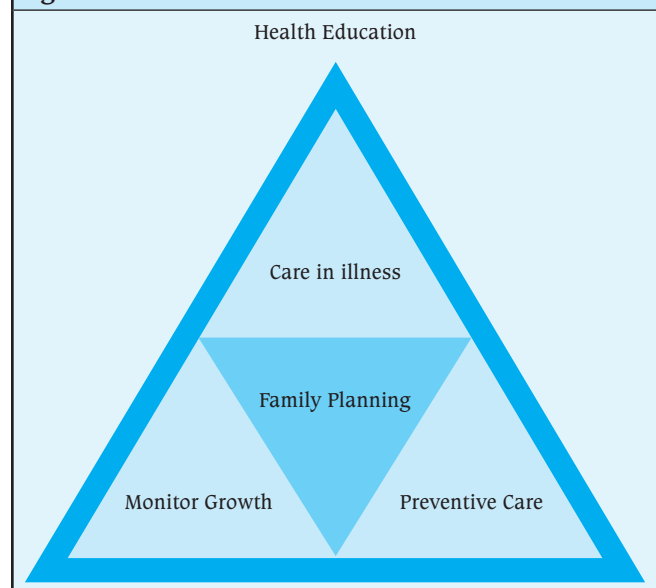
1. Care in illness
2. Growth monitoring
3. Preventive care
4. Family Planning
5. Health education

## Features

Under Five Clinics are specifically designed to serve children under the age of five in developing nations. It is important for the clinics to be as close to the residential areas as possible and for home visits to be a part of the services provided. Clinic visits also need to be kept as short as possible. The majority of the staff should be locally trained health care workers, nurses and auxiliary staff, who provide most of the care. The doctors on staff should be primarily responsible for training, diagnosis, and treatment of more complex conditions. When consultation with a senior staff person is necessary, the nurse

or auxiliary worker should be present and treated as an equal colleague. This procedure will encourage mothers to have more confidence in the skills of the locally trained worker. Mothers need education and support to institute practices that will minimize illness and promote health. Oral rehydration, breast feeding, and growth monitoring are all effective practices. Community health workers can also provide services, such as weighing, right in the residential areas. These workers should try to communicate with the key decision-makers in the child's family - mother, father and grandparents, to inform them of the child's nutritional needs.

**Fig. - 2 : Under Five's Clinic**



## Functions

**(a) Care in Illness :** This is the felt need of the mother and child for which any child is brought to the clinic. The usual illnesses encountered in children under five are fever, diarrhoea, ARI, infections of the skin and helminthiasis. The facility should provide for essential laboratory investigations and X-ray facilities. The Clinic should be backed by an effective referral mechanism.

**(b) Growth Monitoring :** This is one of the most important functions of the clinic. The child is weighed periodically - every month during the first year, every 2 monthly from 1 to 3 years of age and every 3 monthly in 4<sup>th</sup> and 5<sup>th</sup> years. Besides weighing, measuring height, mid arm circumference can also be carried out depending upon the availability of trained manpower and equipments. The growth is plotted on the growth chart and any faltering in the growth is detected and suitable action initiated. The milestones are also recorded and any delay in achieving milestone is evaluated.

**(c) Preventive Care :** This involves primarily the immunization services during the 1<sup>st</sup> five years of life and vitamin A supplementation (1 lac IU at 18 months, 2 lac IU at 6 month interval thereafter upto 3 years of age) and administration of Iron supplementation and antihelminthic treatment to prevent anaemia. The preventive care also provides for regular health



check up, nutritional surveillance and use of ORS during Diarrhoea to prevent dehydration from developing.

**(d) Family Planning** : Family planning is central to any program directed towards women and children. The mothers are more receptive to family planning during early Puerperium and lactation. Mother is counselled on the various options available, their merits and de-merits so that she can make an informed choice.

**(e) Health Education** : The opportunity should be made use to educate the mother on issues of child care, breast feeding, nutrition, growth monitoring, immunization and hygiene of safe water and food preparation.

## Child Health Programmes in India

In 1951, India was the first country in the world to launch a family planning programme. Since then approaches aimed at reducing population growth have taken a variety of forms. Till 1977, the major health activity was family planning which was changed into Family welfare programme with Maternal and Child Health becoming an integral part of family planning programme with the vision that reduction in birth rate has a direct relationship with reduction in infant and child mortality.

### (a) The Diarrhoeal Disease Control Programme

This programme was started in the country in 1978. The main objective of the programme was to prevent death due to dehydration caused by diarrhoeal diseases among children under 5 years of age due to dehydration. Health education aimed at rapid recognition and appropriate management of Diarrhoea has been a major component of the CSSM. Under the RCH programme ORS is supplied in the kits to all sub-centres in the country every year.

### (b) ICDS ( Integrated Child Development Scheme)

The ICDS scheme was initiated by the then Ministry of Social and Women's Welfare on 02 Oct 1975, in pursuance of the National Policy for children. The Ninth Five Year Plan aimed to universalise ICDS, i.e. cover the whole country.

#### The beneficiaries of ICDS are -

- (i) Children below 6 years
- (ii) Pregnant and lactating women
- (iii) Women in the age group of 15-44 years
- (iv) Adolescent girls in selected blocks

The ICDS seeks to lay a solid foundation for the development of the nation's human resource by providing an integrated package of early childhood services. These consist of

- Supplementary nutrition
- Immunization
- Health check-up
- Medical referral services
- Nutrition and health education for women
- Non-formal education for children up to the age of 6 years
- Care of pregnant and nursing mothers

### (c) Universal Immunization Programme

UIP against six preventable diseases, namely, diphtheria, pertussis, childhood tuberculosis, poliomyelitis, measles and neonatal tetanus was introduced in the country in a phased

manner in 1985, which covered the whole of India by 1990. Significant progress was made under the Programme in the initial period when more than 90% coverage for all the six antigens was achieved. The UIP was taken up in 1986 as National Technology Mission and became operational in all districts in the country during 1989-90. UIP became a part of the Child Survival and Safe Motherhood (CSSM) Programme in 1992 and Reproductive and Child Health (RCH) Programme in 1997. Under the Immunization Programme, infants are immunized against tuberculosis, diphtheria, pertussis, poliomyelitis, measles and tetanus. Universal immunisation against six Vaccine Preventable Diseases (VPD) by 2000 was one of the goals set in the National Health Policy (1983).

### (d) The ARI Control Programme

ARI control programme was started in India in 1990. It sought to introduce scientific protocols for case management of pneumonia with co-trimoxazole. A review of the health facility done in 1992 revealed that although 87% of personnel were trained and the drug supply was regular yet there were problems in correct case classification and treatment. Since 1992 the Programme was implemented as part of CSSM and later with RCH. Cotrimoxazole tablets are supplied as part of drug kit for use by different category of workers for managing cases of Pneumonia. Under RCH-II activities are proposed to be implemented in an integrated way with other child health interventions.

### (e) The Child Survival and Safe Motherhood (CSSM) Programme

This Programme jointly funded by World Bank and UNICEF, was started in 1992-93 for implementation up to 1997-98. The Child Survival and Safe Motherhood Programme was implemented in a phased manner covering all the districts of the country by the year 1996-97. The objectives of the programmes were to improve the health status of infants, child and maternal morbidity and mortality. The programme provided for augmenting various activities under the Oral Rehydration Therapy (ORT) Programme, universalising prophylaxis schemes for control of anaemia in pregnant women & control of blindness in children and initiating a programme for control of acute respiratory infection (ARI) in children. Under the safe motherhood component, training of traditional birth attendants (TBA), provision of aseptic delivery kits and strengthening of first referral units to deal with high risk and obstetric emergencies were taken up. Programme yielded notable success in improving the health status of pregnant women, infants and children & also making a dent in IMR, MMR and incidence of vaccine preventable diseases.

### (f) Reproductive Child Health (RCH) Programme

Government of India during 1997-98 launched the RCH Programme for implementation during the 9th plan period by integrating Child Survival and Safe Motherhood (CSSM) Programme with other reproductive and child health (RCH) services. In addition, a new component for management of Reproductive Tract Infection (RTI) and Sexually Transmitted Infection (STI) has also been incorporated. The RCH Programme is partly funded by World Bank, UNICEF, UNFPA and European Commission. The program follows a differential strategy with

inputs under the program linked to the needs of the area coupled with the capacity for implementation. The details on the RCH are covered under separate chapter on RCH.

### **(g) IMNCI (Integrated Management of Neonatal and Childhood Illnesses)**

This programme has been introduced on the principles of integrating all the services for management of sick children under 5 years of age. This is based on the fact that children have to be assessed as a whole for the entire important symptom complex and to be provided care and treatment involving the caregiver. Integration has different meanings at different levels. At the patient level it means case management. At the point of delivery it means that multiple interventions are provided through one delivery channel - for example where vaccination is used as an opportunity to provide vitamin A and insecticide-treated bednets during "EPI-plus" activities, boosting efficiency and coverage. At the system level integration means bringing together the management and support functions of different sub-programmes, and ensuring complementarity between different levels of care.

Childhood is the foundation of World's future. There has been a definite progress in improving the child survival, development and protection. The World must make more sustained, collective and focused efforts to realize the dream of 'World Fit for Children' and fulfill the promise of safe and healthy childhood for every child. The Millennium Development Goals, ratified by all UN member states, provide the world's governments with clear and tangible targets to combat poverty and raise the standard of living for the world's people by 2015. Early Childhood Development contributes to the achievement of the goals. Seven of the eight goals directly relate to child survival, growth and development. Research has shown that the most effective interventions to improve human development and break the cycle of poverty occur most in children's earliest years. Prevention is more cost-effective than treating a problem later. The important issues are ensuring positive gender socialization, supporting parents and families and developing standards and indicators for effective planning, monitoring and documentation of the progress in Early Childhood development.

### **Summary**

Childhood is the foundation of world's future. Only six conditions account for 70% to over 90% of the total deaths in under 5 age group. Child death rate excludes infant mortality rate and is a better indicator of social situation in a country than the IMR where as under 5 mortality rate is considered to be the single best indicator of social development and well being. It measures the outcome of the development process and is a result of various inputs. Child survival index is calculated by subtracting under 5 mortality rate from 1000 and dividing this figure by 10. Its a measure of the social development and the attention given to the care of under 5 children. Evolution of the under 5 child health services passes through various models like primary health care model, vertical programmes model,

preventive model, breast feeding initiative, IMCI. Under fives is a special group with pneumonia, diarrhoea, malaria, measles and HIV/AIDS being attributed as the major killers in this age group. For this reason the under five clinics were established in developing nations with five major objectives of care in illness, growth monitoring, preventive care, family planning, health education. In 1951 India was the first country in the world to launch a family planning programme and in 1977 it was changed to family welfare programme with maternal and child health becoming an integral part of it. Various child health programmes have been launched namely the diarrhoeal disease control programme (1978), ICDS (2 Oct 1975), Universal Immunization Programme (1985), the ARI control programme(1990), the child survival and safe motherhood programme (1992-93), Reproductive child health programme(1997-98), IMNCI which has been incorporated in RCH programme. Seven of the eight Millennium Development Goals directly relate to child survival, growth and development.

### **Study Exercises**

**Long Question :** Discuss various child health programmes.

**Short Notes :** (1) Child death rate (2) Under 5 mortality rate (3) Child survival index (4) Under 5 clinics

**Fill in the blanks**

- 1) Child death rate involves \_\_\_\_\_ age group
- 2) Child mortality rate involves \_\_\_\_\_ age group
- 3) CSSM was launched in year \_\_\_\_\_
- 4) Maximum number of children die because of \_\_\_\_\_ among the five major causes of mortality in under 5
- 5) IMR in India is \_\_\_\_\_ and Under 5 mortality in India is \_\_\_\_\_
- 6) The single best indicator of social development of a country is \_\_\_\_\_

**Answers :** (1) 1-4 yrs; (2) Less than equal to 5 yrs; (3) 1992; (4) Pneumonia; (5) 57/1000,74/1000 live births; (6) Under 5 mortality rate.

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A S Kushwaha

School is a setting that plays an important role in the physical, emotional, social and mental development of children. Schools present an extraordinary opportunity to help millions of young people to acquire health supportive knowledge, values, attitudes and behavior. They can influence health behavior of other children, their families and community. School health services provide an opportunity to improve health of the students and promote healthful behavior through health education.

### History

In India, the history of school health service can be traced back to 1909, when medical examination of school children was started in Baroda. This important issue of social value has been raised repeatedly in various forums but continues to be a neglected aspect of Community Health service till date. Bore committee in 1948 emphasized the need to put in place an organized system of school health service but this is still an unfulfilled dream. In 1953, Secondary Education Committee recommended medical examination and feeding of all school children to promote positive health early in the life as key to a healthy nation. The "National School Health Council" has been established since 1963 to plan and organize school children's health care. Provisions have been made in the municipal, cantonment and state regulations for organization and maintenance of a school health service.

The concept of school health service has undergone change from mere health check up to become a comprehensive service with elements of preventive, promotive, curative and rehabilitative services.

### Global School Health Initiative (GSHI)

WHO's Global School Health Initiative was launched in 1995. The initiative is designed to improve the health of students, school personnel, families and other members of the community through schools.

### Goal

The goal of GSHI is to increase the number of schools that can truly be called "Health-Promoting Schools".

### Health Promoting School

WHO defines a health promoting school as one that is constantly strengthening its capacity as a healthy setting for living, learning and working.

### Components of Comprehensive School Health Policy

- School environment that is safe and promotes health
- A sequential health education curriculum
- A sequential physical education curriculum
- Nutrition services programme
- School Health Service programme
- A counselling, psychological & social service programme
- Integrated family and community involvement activities
- Staff health promotion policy

### School Health Service

The objectives of the school health care are as follows:

- Help children in this critical period of their physical and mental growth.
- Maintaining working efficiency at a high level and improving mental assimilating power by:
  - Ensuring congenial working conditions.
  - Keeping them physically and mentally fit at all times.
  - Improving the general nutrition of the children.
  - Reducing absenteeism and thus increasing average study hours/days.
  - Prevent spread of infections, reduce and detect minor ailments.
  - Imparting health education and physical training to children.
  - Providing special arrangement for the education of handicapped children.

### Healthful School Environment

The environment at the school has an important influence on the health of the school children. The following points should be kept in mind as regards school premises.

#### 1. School premises

- The school should be located in areas free from crowded surroundings, away from market, butcheries, factories, disposal grounds for waste matters, public sanitary areas or enclaves, and such other places which may create a health nuisance.
- There should be sufficient open space around the buildings.
- Enough playgrounds should be provided. Free muscular activity reduces mental boredom and strain and provides a stimulus for growth.
- There should not be any water collections for mosquito or fly breeding places around the school area.
- Traffic should be restricted to the minimum so as to avoid noise, smoke and dust nuisance and mainly accidents.
- Accidents should be prevented not only on roads around school but also on the playgrounds and in class rooms. First aid should be taught to all.

**2. Seating Arrangement :** These should be such as to allow adequate space, permitting freedom of movement for children on the bench so as to enable them to work without strain.

**3. Drinking Water :** It should be procured from an authorized clean source. Arrangements for central storage and safety must be provided. Ladles should be provided to take out water if taps are not possible.

**4. Sanitary arrangements :** A minimum of one urinal for 60 students and one latrine per 100 students should be provided. These should be maintained regularly and kept clean at all times. Adequate water supply should be arranged for sanitary block. Toilet facilities should be separate for boys and girls.

**5. Nutrition services (Mid-day meal) :** These should provide about one third of the total daily requirements of calories, proteins, vitamins 'A' and 'B' complex and calcium. They should provide about 20-30 g of fat, 20 g of protein of which one third should be of animal origin. Inclusion of milk in the



meals will ensure this requirement. The school meals not only aim at supplementing the nutritional requirement but also at inculcating healthy food and eating habits.

**6. Canteen Facility** : All schools have some facilities which provide eatables. This canteen must observe cleanliness and hygiene of food preparation. Selling of junk food items at canteen must be prohibited.

**7. Vaccination** : School settings provide suitable conditions for spread of communicable diseases droplet infections and gastrointestinal diseases. All diseases amenable to prevention by vaccination should be covered. Children should be immunized against typhoid group of fevers, diphtheria and tetanus as a routine. If and when facilities exist, immunization against poliomyelitis and tuberculosis by BCG should be carried out.

**8. Health Check up** : All children should be thoroughly examined at least once a year or three times during the curriculum in addition to the one carried out at the time of entry. Results are recorded in the health record card and parents should be advised regarding remedial action. There should be a permanent register and health cards with column for remarks against examination of each system. The card is meant to be transferred to the institution the child may go after leaving one institution. A monthly, quarterly and annual report must be sent to the coordinating authority and medical authorities. The special points, to look for during any check up, are given below:

- (a) Eyes for trachoma and vision (including tests for acuity of vision).
- (b) Ears for perforated drums, otitis media & hearing acuity.
- (c) Teeth for caries, non-alignment, mottling, gingivitis and so on.
- (d) Nose & throat for adenoids and enlarged/infected tonsils.
- (e) Chest for lungs, cardiac anomalies (congenital).
- (f) Abdomen for enlarged spleen, liver and any palpable lymph nodes.
- (g) Genitalia for phimosis, undescended testis or patent inguinal canal.
- (h) Lower limbs for skeletal & muscular defects/deformities.
- (i) Spine for any deformity.
- (j) Skin for ring worm, scabies & any de-pigmented patches.
- (k) Hair for pediculosis, dandruff.
- (l) Weight and height for age and sex and nutritional profile (anthropometry).
- (m) Any abnormal curvatures/postures, delicate health, nutrition etc.

**9. Sick Reporting Facility** : This should be provided and children are encouraged to report sick whenever they feel unwell. It not only helps to reduce minor ailments from developing into major ailments or disabilities but also helps to detect any other major ailments or disabilities undetected in the incipient or early stages. A trained staff is designated to provide necessary assistance whenever required. Availability of commonly required medications must be ensured at all times.

**10. Referral Facilities** : Facilities for reference of children to a specialist for investigation of ailments and their treatment/ hospitalization should be ensured. There should be arrangements for emergency transport and referral in case of

an emergency. The telephone number of the clinic or hospital should be known to the staff.

**11. Physical Training** : It is a major item of a school curriculum and should be insisted upon. Physical Training Instructors (PTI) should be appointed. Besides this if possible yoga trained teacher may also be appointed.

**12. Health Education** : This should be part of the curriculum. It can be imparted either as an integrated part of curriculum or otherwise. Health education is also incidentally acquired by children through the experiences and observation of healthy school life as described above.

**13. School Health Committee** : All schools must have a school health committee. It should consist of the Headmaster or Principal as the Chairman and class teacher, health educator, school nurse, physical training instructor and the school medical officer as its members. They should meet once a month or at least once in a quarter. A few parents should also be invited to attend these health committee meetings.

### **Management of Children with “Scholastic backwardness”**

Once a child starts struggling with his studies, the school environment turns ‘hostile’ to him. He gets punished by the teachers and friends make fun of him. The young child is clueless as to why he cannot score like his classmates, in spite of effort. He reacts to all these the way children do - either, turn defiant and fight back, or swallow the insults and give up. A sensitive Teacher, sensitized to the various causes of poor school performance can turn out to be his saviour and guardian angel. She can identify the cause of this particular child’s failure and institute an appropriate remedial strategy. After ruling out visual impairment and hearing problems and mental and psychological deficiency, the child should be considered to be evaluated for learning disorders. It may first appear as behaviour problems : Attention deficit, Hyperactivity, naughtiness, defiance, aggression, addiction to TV or computer, forging progress reports, Tics, Obsessive disorders, Anxiety, Depression, School phobia etc. A Schematic algorithm for evaluation of a child with poor scholastic performance is given in Fig. - 1.

#### **Notes :**

1. Many normal children display some of these symptoms.
2. Not all LD children display all pointers.
3. Severe problems need multidisciplinary assessment.
4. LD - Learning Disorder; ADHD - Attention Deficit Hyperactive Disorder.

### **Educating ‘Special’ children**

#### **Categories of Disabilities**

1. Physical Disability
2. Mental Disability
3. Developmental Disability
4. Learning Disability
5. Hearing Disability
6. Visual Impairment
7. Emotional Disability

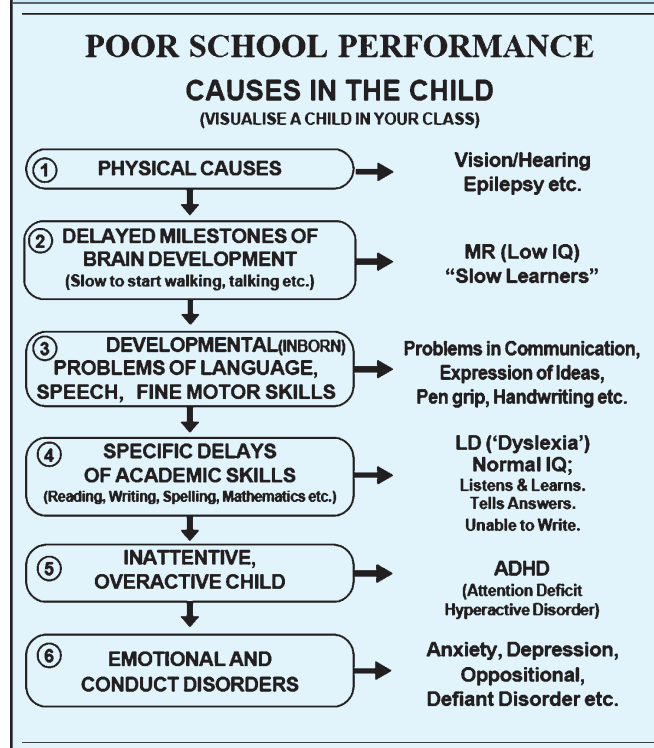
#### **Common disabilities**

1. ADD/ADHD



2. Autism
3. Cerebral Palsy
4. Down Syndrome
5. Multiple Sclerosis
6. Muscular Dystrophy
7. Seizure Disorders

**Fig. - 1 : A Schematic algorithm for evaluation of a child with poor scholastic performance**



**Special Schools in India :** Along with other parts of the world, India too, witnessed the emergence of special schools for people with disabilities. The first school for the deaf was set up in Bombay in 1883, and the first school for the blind at Amritsar in 1887. There was rapid expansion in the number of such institutions. Today, there are more than 3200 special schools throughout India. However, these special schools have certain disadvantages which became evident as the number of these schools increased. These institutions reached out to a very limited number of children, largely urban, and they were not cost effective. But most important of all, these special schools segregated CWSN from the mainstream, thus developing a specific disability culture.

### Integrated Education

The emergence of the concept of integrated education in India during the mid 1950s began by the Royal Commonwealth Society for the Blind, and the Christopher Blind Mission. The Ministry of Education, too, launched a comprehensive scholarship scheme in 1952, a rudimentary beginning of the integrated education initiative by the Government.

**Integrated Education for Disabled Children (IEDC) :** Consequent to the success of international experiments in

placing children with disabilities in regular schools, the Planning Commission, in 1971, included in its plan a programme for integrated education. The Government launched the IEDC scheme in December 1974.

*The aim of IEDC is to :*

- Provide educational opportunities to CWSN in regular schools.
- Facilitate their retention in the school system.
- Place children from special schools in common schools.

The scope of the scheme includes pre-school training, counselling for the parents, and special training in skills for all kinds of disabilities. The scheme provides facilities in the form of books, stationery, uniforms, and allowances for transport, reader, escort etc. Similar Scheme in US is known as 504 Plan, which is a legal document falling under the provisions of the Rehabilitation Act of 1973, designed to plan a program of instructional services to assist students with special needs who are in a regular education setting.

**Project Integrated Education for the Disabled (PIED):** Under PIED, there has been a significant increase in the number of not only mildly disabled, but also severely disabled children, with the number of orthopaedically handicapped children far outstripping other disabled children. All these perform at par with non - disabled children; in fact their retention rate is higher than that of non - disabled children and absenteeism is low. PIED has also had a positive impact on the attitudes of the teachers, the heads of schools, as well as parents and the community in general. Also, the interaction between the disabled and the non - disabled children is good.

DPEP estimates clearly showed that there were a large number of disabled children in the relevant age group. Gradually realization dawned that UPE could not be achieved unless children with special needs were also brought under the ambit of primary education. This led to more concrete planning and strategization of providing resource support and remedial assistance to children with special needs. As the programme progressed, many models of service delivery evolved with the sole aim of providing supportive learning environment to children with special needs. The thrust was on imparting quality education to all disabled children.

The steps needed for implementation of IED under SSA (*Sarva Shiksha Abhiyan*) are classified under three headings:

1. Direct Services to Children.
2. Support Services.
3. Monitoring and Evaluation.

This is an important aspect for assessing progress and providing improvement in the process.

### Summary

School plays an important role in the physical, emotional, social and mental development of children. The medical examination of school children was started in Baroda in 1909. The "National School Health Council" has been established since 1963 to plan and organize school children's health care. WHO's Global School Health Initiative (GSHI) was launched in 1995. The goal of GSHI is to increase the number of schools that can truly be called "Health-Promoting Schools". The

concept of school health service has undergone change from mere health check up to become a comprehensive service with elements of preventive, promotive, curative and rehabilitative services that must include elements of safety, health education, physical education, nutrition and counselling and social service programme. A healthful school environment should be provided with due consideration to premises, seating arrangement, drinking water, sanitary arrangement, mid day meal, canteen, vaccination, sick reporting with referral facilities, physical education and health education which are to be monitored and supervised by a school health committee. Management of the children with scholastic backwardness should be proper as per algorithm for the evaluation of a child with poor scholastic performance. The Planning Commission, in 1971, included in its plan a programme for integrated education of disabled children in regular schools. The Government launched the IEDC scheme in December 1974. The steps needed for implementation of IED under SSA (Sarva Shiksha Abhiyan) are classified under three headings namely direct services to children, support services, monitoring and evaluation. School health services can influence health behaviour of other children, their families and community.

## Study Exercises

**Long Question :** School health services in India

**Short Notes:** (1) GSHI (2) Healthful school environment (3) Causes of poor scholastic performance in school children (4) IEDC

### MCQs & Fill in the blanks

- 1) National School Health Council was established in \_\_\_\_\_
- 2) Global School Health Initiative was launched in \_\_\_\_\_
- 3) The first school of deaf in India was setup in (a) Bombay (b) Calcutta (c) Delhi (d) Bangalore
- 4) The first school of blind in India was setup in (a) Bombay (b) Calcutta (c) Delhi (d) none
- 5) IEDC scheme was launched in India in the year \_\_\_\_\_
- 6) The medical examination of school children was started in \_\_\_\_\_ In the year \_\_\_\_\_

**Answers :** (1) 1963; (2) 1995; (3) a; (4) d; (5) December 1974; (6) Baroda, 1909.

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Adolescence is a critical period of life marked by biological, social and psychological changes for an individual. These are formative years for behaviour patterns and activities relevant to health. It is a period of major transition during which adolescents learn to become adults. They can benefit from guidance in respect of vital issues of human biology, health, disease and behavioural adaptation. Recent discoveries in biological, behavioural, clinical and epidemiological research have clarified the concepts of this transition. The lifestyle and behaviour developed during adolescence has an impact on the health not only during adolescence but even in later life. In fact, the bulk of morbidity and mortality in adulthood is due to the health related behaviours (smoking, alcohol, exercise and diet) developed during the adolescence. The major issues concerning adolescents are growth and development, STDs and RTIs, drug, alcohol and tobacco abuse, teenage pregnancy, abortion, RTAs, suicide, homicide and issues of behavioural problems. HIV is

the latest addition to the multiple dimensions of adolescent health with huge implications on their health. Unfortunately, the special needs of adolescents' have not been addressed by the educational, health, and family welfare programs in India so far.

### Definition of Adolescence

The word 'Adolescent' has been derived from Latin word '*Adolescere*' which means 'to grow to maturity'. Adolescent is considered to be, no longer a child, and not yet an adult. The definitions vary as to the exact range of age for this period. Most cultures relate the beginning of adolescence to the onset of puberty, but differ on specifying the end of adolescence. Different cultures define the roles, responsibilities and prerogatives of adults differently and thus the above variation. Thus in certain societies, an individual may have attained biological maturity but may not have attained full adult status. The chronological definition of adolescence has been kept broad so that it can be used in a variety of socio-cultural and health settings. WHO defines Adolescence as 10-19 years old, 'Youth' as 15-24 years old and 'Young People' as 10-24 years old. The adolescence has been divided into two phases: 'early' (10-14 years) and 'late' (15-19 years).

The need to focus on Adolescent Health is because

- (a) Adolescents face serious health challenges
- (b) Adolescent health and development affect economic prosperity
- (c) Investing in youth helps to break cycle of poverty
- (d) Health is a key element of overall youth development
- (e) Young people have a right to health

### Adolescents : A special group with special needs

The need to focus on adolescent health exists for a number of reasons. (See Box 1)

<b>Box - 1 : Why Adolescents are a special group?</b>
Because of their number: they constitute more than 22% of the population.
Adolescence is the period of rapid physical growth, sexual and psychological changes.
Habits and behaviour picked up during adolescence (risk taking behaviour, Substance abuse, eating habits, conflict resolution) have lifelong impact.
Adolescence is the last chance to correct the growth lag and malnutrition.
Many adolescent boys and girls are sexually active but lack information and skill for Self- protection.
They have simple but wide pervading crucial reproductive health needs - Menstrual hygiene, contraception (including emergency contraception) safety from STI and HIV.
Communication gap exists with parents and other adults.

### Some Basic Physiological & Psychological Needs

**1. Growth and Development** : The early part of adolescence is characterized by rapid physical growth, changes in psychological functions and organ systems of the body and completion of sexual development. During adolescence marked morphological changes occur and hypothalamic-pituitary-gonadal system becomes mature. The ovaries and testes produce enough steroid hormones which result in the growth of genital organs and appearance of secondary sex characters. The body composition changes and there is increased strength and efficiency of body energy production. In adolescence these variations are exceedingly large within the same individual and between different individuals. This aspect needs to be understood by the adolescents, their families, health professionals in particular and society in general. The puberty in females is earlier as compared to males. Many adolescent boys and girls are sexually active but lack information and skills for self-protection (low level of information on Family Planning, low contraception use). They have simple but wide ranging crucial reproductive health needs- menstrual hygiene, contraception (including emergency contraception) safety from STI and HIV.

**2. Nutritional and Psychosocial Needs** : The adolescents in developing countries may suffer from malnutrition and dietary imbalance while those in developed countries may have problems of obesity. Adolescents have greater nutritional requirements because of rapid growth and physical activity

level. During this period that adolescents gain up to 50% of their adult weight, more than 20% of their adult height and 50% of their adult skeletal mass. In under-nourished children rapid growth during adolescence may increase the severity of under-nutrition. Iron is deficient in almost all age groups. Naturally the shortfalls create more vulnerability for adolescent girls. The factors that may interfere with nutrition are inadequate food supplies in quantity and quality, psychological factors affecting appetite, food fads and cultural attitudes and infections and parasitosis.

Adolescence is a period of change and, consequently, one of stress, characterized by uncertainties in regard to identity and position in the peer group, in the family, in the society at large and in the context of one's own responsibilities as an adult. The compulsions of parental approval often encounter the emerging aspirations for independence. Their behaviour is guided by an intense desire for independence and identity. In the process, adolescents undergo intense psychological stress and personality change.

**3. Socio-Cultural Factors Affecting the Development** : In most parts of the world, especially developing world, girls are deprived of nutrition, access to health care, and opportunities for education and employment. They are taken out of schools when they reach menarche. In most traditional societies, from the very beginning of life, girls are groomed to accommodate the male-dominated, patriarchal society. With the rising proportion of children attending school and ever increasing functions of education, opportunity to facilitate healthy development of adolescents has opened up in many developing countries. Increasing urbanization, globalization, cosmopolitan type of population, explosion of information technology, pervasive scientific attitude and changing social and cultural values in the evolving society affect the psychological development of an adolescent.

### Health Problems of Adolescence

Though adolescence is a relatively healthy period in the life of an individual with lowest age specific mortality (NFHS-3); however, it has certain characteristics that put them at risk to health hazards specific to this age group. The health problems of the adolescents relate to a large extent to their growth and development, sexual maturation, psychological changes. These issues are not discussed with the parents and health professionals due to lack of privacy and confidentiality and thus remain either unresolved or attempts are made through peers and available media which may not always be helpful and appropriate. The adolescent, because of rapid biological-psychosocial changes, is prone to impulsivity, emotional and risk taking type of behaviour putting them at risk to problems like STDs/RTIs, accidents, drug and substance abuse and psychological and mental health disorders.

The health care system have provided for health of the children and adults but adolescents have been left out, without any specific health programmes directed towards them especially in developing nations where resources are scarce. However, of late this special group of population has been given some attention in the post HIV period as the adolescents constitute highly vulnerable group



## Behaviour Related Health Problems

**Alcohol, Smoking and Drugs :** The adolescents tend to experiment with alcohol, smoking and other drugs. The use of tobacco and alcohol is widespread in both developing and developed nations. 30-50% of high school students in USA consider use of marijuana as an accepted way of life. In Sweden, drug dependence reaches its peak in the age group 12-20 years. The factors responsible for smoking in young people are peer pressure, following example of sibling and parents and employment outside the home.

**Dietary Habits :** Inappropriate dietary habits in adolescence are also commonplace. They tend to consume junk food and imbalanced diet more than any other age group. They may also develop habit of compulsive eating at one end and anorexia nervosa at the other end of spectrum.

**Sexual Behaviour :** Sexual indiscretion, lack of education on skills of responsible sexual behaviour and urge for experimentation can lead to myriad of problems ranging from unplanned pregnancy, STDs, HIV, unwed mothers, illegal abortions, psychological breakdowns and complex social problems.

**Risk Taking Behaviour :** Adolescent males tend to challenge difficulties without taking the danger into account to the extent that most adults would. This impulsive risk taking behaviour has implications for health of the adolescents, whether the activity is driving a vehicle, sports, any work or various health related behaviours like drugs, alcohol or sexual urge.

## Adolescence - A Stressful Transition Period

The world in which adolescents of today live is marked by vastness as far as mobility is concerned and rapid technical and social changes. This demands a great degree of adjustments and adaptation by the adolescents who are undergoing rapid biological-social-psychological transition. The adolescents tend to explore actively in seeking information on new situations, new roles and future difficulties.

## Adolescent Health : Global Scenario

The health of the adolescents can be measured by studying age specific morbidity, mortality, prevalence of behavioural disorders and DALYs. This relatively healthy phase of life must also be seen in the light of barriers to health seeking behaviour and under-reporting of adolescent related data in the developing countries. However, DALYs has been found to be most suitable indicator for the purpose of international comparison. More than 33 percent of the disease burden and almost 60 percent of premature deaths among adults can be associated with behaviours or conditions that began or occurred during adolescence - for example, tobacco and alcohol use, poor eating habits, sexual abuse and risky sexual behaviour (WHO 2002). Adolescence-related risk factors are a greater problem in wealthier countries, largely because of the relatively greater impact of smoking and diet-related risks in those countries, though the prevalence of these risks is expanding rapidly in many low - and middle-income countries.

## Indian Scenario

**Awareness on Common Health Issues :** There is a lack of knowledge and awareness amongst adolescents about

important health issues and problems that affect them. An Indian Council of Medical Research (ICMR) study showed that knowledge and awareness about puberty, menstruation, physical changes in the body, reproduction, contraception, pregnancy, childbearing, reproductive tract infections, Sexually Transmitted Infections (STIs), and HIV was low among boys and girls, especially in younger adolescents (ages 10-14). The study reported, however, that older adolescents (ages 15-19) had better knowledge. About 80 percent had knowledge of STIs, including HIV.

**Education :** Only 83 percent of primary-school age children (6-10 years) attend school. School attendance drops to 75 percent for children aged 11-14 years and is only 41 percent for children age 15-17 years. Education is linked to delayed marriage and childbearing and better outcomes besides decreased fertility.

**Marriage, Sex & Reproductive health :** The importance of reproductive health of adolescents is receiving increased attention due to multiple factors- they are almost  $\frac{1}{4}$  of the population, they are going to be parents of the next generation and HIV has provided the necessary impetus to this important issue. The fall in age at menarche and increased age at marriage coupled with changing social-cultural values and attitudes has increased the potential of pre-marital sexual activity. The effect of increased urbanization, migration, economic independence and declining family influence has provided suitable conditions for increased exposure of the young people to risky sexual behaviour.

High fertility rates, high rates of teenage pregnancy, high risk of STI/HIV and poor nutritional status are the main health problems among the adolescent population in India (4,5). The median age at first marriage among women is 17.2 years. Among young women aged 15-19 years, 16 percent have already begun childbearing. Of those who seek medical termination of pregnancy, 8-10% are teenage mothers and unmarried girls.

## Public Health Implications

The public health implications of adolescent health are far reaching and have intergenerational effects as well. (See Box - 2)

<b>Box - 2 : Public Health Implications of Adolescent Health</b>
<b>Mortality in Adulthood :</b> The 70% of the mortality in adulthood is linked to habits picked up during adolescence (risk-taking behaviour, substance abuse, eating habit and conflict resolution.)
<b>Intergenerational Effects :</b> Prevailing malnutrition, anaemia, stunting and lack of immunization have adverse impact on MMR, IMR and morbidity.
<b>Adolescent Sexuality :</b> Leads to adolescent pregnancy, unsafe abortion, RTI, STI/HIV and social problems.
<b>Adolescent Pregnancy :</b> In this the risk of adverse outcome (IMR, MMR LBW babies) is higher.
<b>Risk Taking Behaviour :</b> Lack of "connectedness" with parents and other adults prevents transmission of health messages and crucial skills leading to adoption of risky behaviour, substance abuse, early sexual debut and STI, HIV etc.



## Interventions

Improving the health of young people is a complex and difficult issue. Programs will have to seek multi-sectoral solutions that link health sector interventions with other types of interventions delivered through other sectors, either at the program level or at the policy level. Research has created international consensus over a multi-pronged intervention approach based on the following principles (Box - 3).

<b>Box - 3 : Principles of Health Programming for Adolescents</b>
Recognize the <i>diversity</i> of the youth age group.
<i>Involve</i> young people.
Design <i>comprehensive</i> programs
Make health services <i>Youth Friendly</i> .
<i>Address gender inequality</i> of Women.
<i>Address the needs of boys</i> .
Address <i>non-health factors</i> that influence health
Address underlying <i>risk and protective factors</i> .

**(a) Life-Skills and Health & Sexuality Education in Schools:** Well designed, well-implemented sexuality and reproductive health education can provide young people with a solid foundation of knowledge and skills to enable them to engage in safe and responsible sexual behaviour.

**(b) Peer Education :** Peer education programs are especially appropriate for young people who are not in school and for hard-to-reach, at-risk subsets of the youth population including, sex workers and street children.

**(c) Mass Media and Community Mobilization :** Mass media and community mobilization efforts that engage influential adults, such as parents, teachers, community and religious leaders, and music and sports stars, can help normalize positive adolescent behaviours and gender roles as well as direct young people to appropriate health services.

**(d) Youth Development Programs :** Youth development programs typically address a range of key adolescent needs, including life skills, education, jobs, and psychosocial needs. Programs with a voluntary community service component have successfully improved key reproductive health behaviours, but no evidence is available for developing countries.

**(e) Clinical Health Services :** Although some young people seek care through the formal health system, many others are deterred by the often judgmental attitudes of health workers, particularly when seeking care and advice on matters related to sexuality.

**(f) Social Marketing :** This approach involves the use of public health messages to promote healthy behaviours and the use of condoms and other health products and services. Effective programs bring products and services to places in the community that young people frequent, such as shops, kiosks and pharmacies.

**(g) Workplace and Private Sector Programs :** Programs that reach young people do so at their places of work and through

private channels, such as pharmacies and for-profit medical services, where many young people prefer to seek care.

## Initiatives in India for Health and Development of Adolescents

The Government of India has identified “*Survival, Protection, and Development*” as a major theme, focusing on gender-specific needs. This was a conscious effort to ensure equitable rights, opportunities, benefits, and status to girl children as part of National Plan for the SAARC decade of the Girl child.

Realizing for the first time, the importance of this population sub group, the Planning Commission has set up a Working Group for the Welfare and Development of Adolescents, to provide inputs into the Tenth Five Year Plan. Most importantly, policies and programmes need to cover the entire range of health and related problems of adolescents and not confined to education and service delivery for reproductive health alone. The Working Group proposed an allocation of at least Rs.112 crore for the Tenth Five Year Plan for the schemes for adolescents to be implemented by the nodal Ministry (Ministry of Youth Affairs & Sports). The adolescents have been recognized as valuable human resource with certain rights.

The initiatives taken under inter-related issues concerning adolescents under various schemes are given as under-

### 1. National Policy on Education (1986 modified in 1992):

The main emphasis in the National Education Policy is on the eradication of illiteracy and universalization of primary education. Education helps to develop adolescent health by delaying marriage, childbearing while generating positive health behaviour.

**2. National Population Policy :** They are specifically referred to in the sections on information, nutrition, contraceptive use, STDs and other population-related issues. There is a special mention about developing a health package for adolescents and enforcing the legal age at marriage.

**3. National AIDS Prevention and Control Policy :** Since unprotected sex is a major source of AIDS and adolescents form a significant portion of the sexually active population, they should form a special focus group under the Policy. While the policy talks about programmes for adolescents like University Talk AIDS and NYKs, surprisingly, the policy does not specifically mention adolescents. One can say that even without specifically mentioning adolescents, the policy is crucially relevant to them and aims at addressing their needs.

**4. National Nutrition Policy (1983) :** The National Nutrition Policy has focused on adolescent girls and that too only in relation to the importance of their role as mothers and housewives. Adolescent boys do not find any mention in the policy. The need for the well being of adolescents, as a group has not been recognized. ICDS is providing supplementary nutrition to adolescent girls (Kishori Shakti yojna) but the coverage is abysmally low (3%). The 10th Five Year Plan and Nutritional Policy proposed a nutritional program for girls weighing less than 35 Kg and for pregnant women weighing less than 45 Kg and below poverty line, who would get ration of Rs 6/- per month in the form of wheat or rice, through the Public Distribution System. The adolescent girls need

appropriate nutrition, education, health education, training for adulthood, training for acquiring skills as the base for earning an independent livelihood, training for motherhood, etc. Similarly on the other side their potential to be a good community leader has to be realized. A scheme for adolescent girls in ICDS was launched by the department of Women and Child Development, Ministry of Human Resource Development in 1991.

All adolescent girls in the age group of 11-18 years receive the following common services:

- (a) Immunization
- (b) General health check up once in every six months
- (c) Training for minor ailments
- (d) Deworming
- (e) Prophylactic measures against anaemia, goiter, vitamin deficiency, etc.
- (f) Referral to PHC/District hospital in case of acute need
- (g) Watch over menarche

**5. National Policy for the Empowerment of Women (2001) :** The policy has recognized the girl child as a separate category and adolescent girls seem to be covered there under. The policy relates to their nutrition, education, holistic approach to health, violence against them, sexual abuse of them and the rights of the girl child.

**6. Reproductive & Child Health :** The special package of interventions for adolescents under RCH are-

- (a) One booster dose of TT at the age of 16 & immunization of girls against Rubella.
- (b) Sex education to promote responsible and healthy reproductive & sexual behaviour.
- (c) Prevention of STD/HIV and AIDS.
- (d) Adult Literacy especially among women.
- (e) Vocational training.
- (f) Pre marital counselling.
- (g) Gender equality.
- (h) Family life education.

It will be seen from the above that the present policies address specific sectors like education, health, family welfare, nutrition, HIV/AIDS, sports etc. or address certain population groups like women, children and youth. None of the policies however take an integrated and holistic view of adolescents. Adolescents in difficult circumstances like adolescents with disabilities, learning disorders, adolescent sex workers or children of sex workers and street children need much more visibility in policies.

### Specific Programs on Adolescents

Brief of some specific programs initiated by governmental and non-governmental organization directed towards adolescents in India is given below-

**1.Kishori Shakti Yojana :** To improve the health and nutritional status of girls by supplementary nutrition, anaemia prophylaxis under ICDS. Poor coverage of the target population is the limitation of this programme.

**2.Balika Samridhi Yojana, 1997:** This scheme works to raise the status of girl children born in families below the poverty line by providing financial help to these families. Some specific

criteria have been laid down to provide financial assistance to the mother of a newborn girl child in the form of grants and investments through a postal financial instrument to be applied toward the education and economic independence of that child. The deposit will mature and be paid to the girl if she remains unmarried until she reaches 18 years of age. This helps to delay the age of marriage.

**3.National Service Scheme (NSS) :** NSS was launched in 1969 with a primary focus on students' personality development and community service. NSS involved more than 1.6 million student volunteers from more than 175 universities and 22 senior secondary councils. The scheme's programs include "regular activities" and "special campaign programs."

**4.Bharat Scouts and Guides :** It is the third largest youth organization in the world. Scouting and guiding movements aim to develop boys' and girls' characters with the goal of making them good citizens of India. It inculcates in them a spirit of patriotism and promotes balanced physical and mental development.

**5. Child Labour Projects :** The Ministry of Labour is running 76 national Child Labour Projects in the country.

**6. Integrated Program for "Street Children" :** The Ministry of Social Justice and Empowerment has been implementing this program since 1992-93. One of the important initiatives under the program's revision in 1998 was the establishment of the Child Help Line Services in a number of cities. The Child Help Line provides emergency assistance to children.

**7. Population Council :** The Population Council has supported initiatives on adolescent transition in different states in collaboration with several NGOs. The Population Council supported programs on adolescence run by Mahila Samakhya in Karnataka and Andhra Pradesh and in the state of Haryana, *Apni Beti Aapna Dhan* and services in the areas of personality development, education, health, reproductive health, economic participation, and life skills training.

**8. International Centre for Research on Women (ICRW):** ICRW is coordinating a multi-site intervention and research program to develop effective programs for adolescent sexual and reproductive health and development in India. The studies confirmed that a lack of power, decision making opportunity, autonomy, and access to resources underlie the reproductive health risks faced by adolescents, particularly adolescent females, and those who are unmarried.

**9. Centre for Development and Population Activities (CEDPA) :** CEDPA, An international NGO with operations in Delhi, in collaboration with local NGOs, UNFPA, UNESCO and USAID, has adapted "Choose a Future: Issues and Options for Adolescent Boys" to the Indian cultural context and is currently implementing programs in 11 states.

**10. Planned Parenthood Federation :** Planned Parenthood has promoted four major projects with the help of local NGOs:

**(a) Improving the Reproductive Health of Young Women and Men :** The goal of the project is to improve the lives of adolescents and youth by providing contraceptive services and sexuality education in 20 rural villages in a district in West Bengal with a local NGO.

**(b) Couple to Couple :** The project employs peer couples to work with groups of newlyweds and other young couples to motivate them to increase gender awareness, encourage supportive relationships, and plan for their new families together.

**(c) Improving the Reproductive Health of Adolescents and Youth :** Located in Jharkhand state, the project aims to increase young people's knowledge and understanding about sexuality and reproductive health and help them develop communication and decision-making skills so that they may lead healthy reproductive lives.

**(d) Reproductive Health Through Advocacy and Services:** The project is a part of a larger program to improve the reproductive health and rights of adolescents and youth in the Indian states of Bihar and West Bengal.

### National Youth Policy, 2003

The National Youth Policy, 2003 reiterates the commitment of the entire nation to the composite and all-round development of the young sons and daughters of India. This Policy covers all the young people in the country in the age group of 13 to 35 years. The age group is, therefore divided into two broad sub-groups viz. 13-19 years and 20-35 years.

#### Strategy

##### 1. Youth empowerment

- Attainment of higher educational levels and expertise by the youth, as per their abilities and aptitudes, and access to employment opportunities accordingly.
- Adequate nutrition for the full development of physical and mental potential and the creation of an environment which promotes good health.
- Protection from disease agents and unwholesome habits.
- Development of youth leadership.
- Equality of opportunity.

**2. Gender Justice :** The Policy recognizes that prevailing gender bias is the main factor responsible for the poor status of health and economic well-being of women in our society. The Policy enunciates that:

- Every girl child and young woman will have access to education and would also be a primary target of efforts to spread literacy.
- Women will have access to adequate health services and will have full say in defining the size of the family.
- Domestic violence will be viewed not only as violation of women's freedom but also as that of human rights.
- All necessary steps should be taken for women's access to decision-making process, to professional positions and to productive resources and economic opportunities.
- Young men, particularly the male adolescents shall be properly oriented, through education and counselling to respect the status and rights of women.

**3. Inter-Sectoral Approach :** The Policy recognizes that an inter-sectoral approach is a pre-requisite for dealing with youth-related issues.

**4. Information & Research Network :** The Rajiv Gandhi National Institute of Youth Development (RGNIYD) will serve as the apex Information and Research Centre on youth development issues. There is a crying need to have valid data

on health of adolescents in India. Priority Target Groups under the policy are given in Box - 4.

<b>Box - 4 : Priority Target Groups</b>
<ul style="list-style-type: none"> <li>• Rural and Tribal Youth</li> <li>• Out-of-school Youth</li> <li>• Adolescents particularly female</li> <li>• Youth with disabilities</li> <li>• Adolescents under special circumstances like victims of trafficking; orphans and street children.</li> </ul>

**Implementation Mechanism :** The Union Ministry of Youth Affairs & Sports (with the guidance of this Committee) will be the Nodal Ministry for all such programmes and schemes and will oversee the implementation of the provisions of this Policy. A National Youth Development Fund will be created through contributions, including from Non-Governmental Organizations, which would be utilized for youth development activities.

#### Life Skills Education

Life skills have been defined by World Health Organization as *'the abilities for adaptive and positive behaviour that enable individuals to deal effectively with the demand and changes of everyday life'*. Life skills are abilities that help to promote mental well being and competency of young people to face the challenges of life. Effective acquisition of life skills can influence the way one feels about oneself and others and can enhance one's productivity, efficacy, self-esteem and self-confidence. Life skills can also provide the tools and techniques to improve interpersonal relations.

There are three kinds of life skills : *Thinking skills, social skills and negotiating skills*. Thinking Skills include problem solving, thinking critically, processing information and exercising choice, making informed decisions and setting goals. Social skills include appreciating/validating others; building positive relationship with peer groups and family; listening and communicating effectively; taking responsibility; and coping with stress. Negotiating skills include self realization that enables an individual to understand ones values, goals, strengths and weaknesses. Thus, negotiating skills need to be enhanced at two levels - within oneself and with others. *Adolescents need to learn to be assertive, including learning to say "no" to adopt risky and harmful behaviour like drug use or casual sex before marriage*. During adolescence, life skills development is an active process. Despite superior intellectual abilities, the adolescent's behaviour is occasionally influenced by emotions rather than by rational thinking. Frequently the adolescent is in an emotional dilemma of wanting to be guided by parents, yet wishing to be free from them, and more aligned to their peers. They also have the need to exercise skills to indicate and establish their individuality and independence. This becomes complex, as an adolescent has multiple situations to deal with. Many critical issues arise during adolescence like - puberty, dealing with sexuality and gender issues, tackling emotional upheaval, finishing education, need to make future career choices, facing responsibilities as an adult, etc. Hence, Life Skills Development is of immense value to the adolescents



in managing their lives. It is recommended that 30 to 45 day 'Life Skills Development Programmes' be organized by NGOs/NYKs/other community groups for both school going and out of school adolescents. Adolescents who go through such a training programmes could thereafter be used as peer educators. Education of adolescents on family life is an important exercise as they are the parents of tomorrow. It is defined as "an educational process designed to assist young people in their physical, social, emotional and moral development as they prepare for adulthood, marriage, parenthood, ageing as well as their social relationship in their socio cultural context of the family and society" (UNESCO).

### Counselling

Counselling is a process of enabling and empowerment to help a person in problem solving and crisis management. This may be required at different stages of life. One of these stages is the period of adolescence when adolescents are usually either in school or college or out of school as 'drop-outs' and 'left-outs', and therefore the need and importance of counselling is highest during this period and for these groups.

### Adolescents in Difficult Circumstances

Adolescents in difficult circumstances are those who belong to special groups like drug addicts, adolescents with AIDS and adolescents with parents afflicted by AIDS, adolescent prostitutes and children of the same, juvenile delinquents and adolescent victims of crime, street adolescents, neglected juveniles and adolescents who are physically and mentally challenged. Any intervention to address adolescents must also keep in mind the environment in which adolescents live - their families and society. It is equally essential for any intervention aimed at adolescents in difficult circumstances, to address the parents and families of these adolescents. Needless to say a holistic and integrated approach has to be adopted.

### Juvenile Delinquency

It refers to a large variety of behaviour of children and adolescents which the society does not approve of and for which some kind of admonishment, punishment or preventive and corrective measures are justified in public interest.

- Juvenile- '*Juvenis*'- young - boy who has not attained 16 yrs, girl aged less than 18
- Delinquent - "*delinquere*"
  - A child who has committed an offence
  - All deviations from normal youthful behaviour

This includes all children who are incorrigible, ungovernable and habitually disobedient and who desert their homes, with behavioural problems and anti-social practice. The term 'juvenile' has been defined in clause (h) of Section 2 of the Juvenile Justice Act, 1986, as a boy who has not attained the age of sixteen years or a girl who has not attained the age of eighteen years. Offence under clause (n) of Section 2 of the above Act means an offence punishable under any law for the time being in force which includes the Narcotics Drugs and Psychotropic Substances Act, 1985 and the Terrorist and Disruptive Activities (Prevention) Act, 1987.

A child becomes a criminal through the interaction of many causes, social and individual, familial, psychological and economic. In order to rehabilitate the juvenile delinquent as

a healthy member of society, it is necessary to understand all these causes and remove them through improving family life, proper schooling, reducing harmful peer influences, and social welfare services. Under the Juvenile Justice Act, 1986, separate provisions have been laid down for the neglected and uncontrollable juveniles. They are dealt with by the Juvenile Welfare Boards and not by Juvenile Courts.

### Common Problems seen in Juvenile Delinquents

1. Behavioural problems e.g. lying, stealing, gambling aggressiveness, destructiveness, disobedience, over activity.
2. Learning disabilities.
3. Emotional problem e.g. depression, school refusal, fears, timidity, shyness.
4. Adjustment reactions e.g. school related problem, grief.
5. Development disorder e.g. autism, bedwetting & soiling.
6. Intellectual deficit.
7. Psychosomatic disorders.
8. Bizarre and abnormal behaviours.
9. Relationship (including parent-child, sibling and marital) problem.
10. Socio-legal issues and problem e.g. child custody assessment, sexual offences, child abuse and head injuries.
11. Other e.g. eating and sleep disorders, sexual problems in adolescence, tics (movement disorder) & stress reaction.

### Prevention & Management of Juvenile Delinquency

- Improvement of family life
- Life Skills development
- Schooling
- Social welfare services - Child guidance clinics, juvenile court, Child placement (Orphanages, Foster homes, Borstals, Remand home)

### Child Guidance Clinic (CGC)

The concept originated in USA when Child Guidance Clinic was started in 1909 in Chicago. These were originally intended to deal with juvenile delinquency. Now the concept has been widened to also deal with those children who are not adjusted with their environment. The basic objective of these clinics is to prevent children from becoming neurotics, psychotics, criminals in later life by offering a gamut of services provided by a team which may include-

- Psychiatrist
- Clinical psychologist
- Educational psychologist
- Psychiatric social worker
- Public health nurse
- Pediatrician
- Speech therapist
- Neurologist

The composition of the team is variable depending on the need and the resources available.

The clinic offers a number of services for these children. Psychotherapy is central to all other services provided.

### Services

- Psychotherapy- core of services
- Physical health



- Children's One-Stop Psycho-Educational Services (COPES)

#### Treatment

- Medical treatment
- Individual psychotherapy
- Family and marital therapy
- Behavioural / Cognitive therapy
- Occupational therapy
- Group therapy
- Play therapy
- Social case work

**Prevention** : The preventive measures are based on the belief that juvenile delinquents are shaped by the socio-economic-cultural influences on a vulnerable child. A stable, emotionally fulfilling and healthy family environment is the best vaccine against this disorder. School plays an important role in shaping the behaviour of a child and healthy interaction with teachers and peers will result in a child who is emotionally balanced and mentally healthy. The role of developing life skills and family life education cannot be overemphasized.

### Juvenile Justice (Care and Protection of Children) Act (2000)

#### Background

1. The constitution in Articles 15, 39, 45 & 47 has imposed on the state a primary responsibility of ensuring that all the needs of children are met and that their basic human rights are fully protected.
2. Convention on the rights of the Children adopted by UN general assembly in 1989.
3. Government of India ratified the convention in 1992.
4. United Nations Standard Minimum Rules for the administration of Juvenile Justice, 1985 (Beijing rules) and UN rules for the protection of juveniles deprived of their liberty (1990).
5. Juvenile Justice Act 1986.

Earlier the Children Act, 1960 amended in 1977 laid down that delinquent children needed to be provided with care, education, maintenance, training and rehabilitation. This covered victimized, uncontrollable, ungovernable, destitute and delinquent children. The Juvenile justice Act 2000 has removed all the inadequacies of the children act and has made the care more comprehensive and encompassing. The Act has been published in "The Gazette of India" No.70: The Juvenile Justice (Care & Protection of Children) Act 2000 (No. 56 of 2000) published by the Legislative Department of Ministry of Law, Justice and Company Affairs after receiving the assent of the President of India on 30 December 2000.

#### The salient features of the Act are given below

**(a) Child Welfare Committee** : The State Government may, by notification in Official Gazette, constitute for every district or group of districts, specified in the notification, one or more Child Welfare Committees for exercising the powers and discharge the duties conferred on such Committees in relation to child in need of care and protection under this Act. The Committee shall consist of a Chairperson and four other members as the State Government may think fit to appoint, of whom at least one shall be a woman and another, an expert on matters concerning children. The Committee shall have

the final authority to dispose of cases for the care, protection, treatment, development and rehabilitation of the children as well as to provide for their basic needs and protection of human rights. Where a Committee has been constituted for any area, such Committee shall, notwithstanding anything contained in any other law for the time being in force but save as otherwise expressly provided in this Act, have the power to deal exclusively with all proceedings under this Act relating to children in need of care and protection.

**(b) Juvenile Justice Board** : State Government may, by notification in the Official Gazette, constitute for a district or a group of districts specified in the notification, one or more Juvenile Justice Boards for exercising the powers and discharging the duties conferred or imposed on such Boards in relation to juveniles in conflict with law under this act. A Board shall consist of a Metropolitan Magistrate or a Judicial Magistrate of the first class, as the case may be, and two social workers of whom at least one shall be a woman, forming a Bench and every such Bench shall have the powers conferred by the Code of Criminal Procedure, 1973 (2 of 1974), on a Metropolitan Magistrate or, as the case may be, a Judicial Magistrate of the first class and the Magistrate on the Board shall be designated as the principal Magistrate. No Magistrate shall be appointed as a member of the Board unless he has special knowledge or training in child psychology or child welfare and no social worker shall be appointed as a member of the Board unless he has been actively involved in health, education, or welfare activities pertaining to children for at least seven years.

**(c) Children Homes** : The State Government may establish and maintain either by itself or in association with voluntary organizations, children's homes, in every district or group of districts, as the case may be, for the reception of child in need of care and protection during the investigation of any pending inquiry and subsequently for their care, treatment, education, training, development and rehabilitation. The State Government may, by rules made under this Act, provide for the management of children's homes including the standards and the nature of services to be provided by them, and the circumstances under which, and the manner in which, the certification of a children's home or recognition to a voluntary organization may be granted or withdrawn.

**(d) Rehabilitation** : The rehabilitation and social reintegration of a child shall begin during the stay of the child in a children's home or special home and the rehabilitation and social reintegration of children shall be carried out alternatively by-

- (i) Adoption
- (ii) Foster care
- (iii) Sponsorship
- (iv) Sending the child to an aftercare organization

**(e) Special Juvenile Police Unit** : Special juvenile police unit, to handle juveniles or children may be created in every district and city to co-ordinate and to upgrade the police treatment of the juveniles and the children.

#### Child Placement

**1. Orphanages** : These are for the children who have no home, no parents or single parents or parents too poor to care for them. The concept is not very favourable to the overall wellbeing of

the child as it does not provide emotional and social warmth required for their development.

**2. Foster Home :** This is a setting which provides all that is available in a family setting but a home other than their original family.

**3. Borstals :** These are institutions somewhere between a certified school and an adult prison for the children 16 years and above who have some social adjustment pathology.

**4. Remand Homes :** This is for those children who have been arrested by the police in some situation which warrants them to be taken care of like immoral trafficking, prostitution etc.

## Summary

WHO defines *Adolescence* as 10-19 years old, *Youth* as 15-24 years old and *Young people* as 10-24 years old. The adolescence has been divided into two phases: early (10-14 years) and late (15-19 years). The need to focus on adolescent health exists for many reasons. They constitute 23.1% of Indian population. It is the period of rapid physical growth, sexual maturation and psychological changes. Habits and behaviours picked up during this period (risk taking behaviour, substance abuse, eating habits and conflict resolution) have long lasting impact. Adolescence provides the last chance to correct the growth lag and malnutrition of childhood.

There are various health problems related to the period of adolescence. The adolescent because of rapid biological and psychosocial changes, is prone to impulsivity, emotional and risk taking type of behaviour putting them at risk to problems like STDs/RTIs, accidents, drug and substance abuse and psychological and mental health disorders. Inappropriate sexual behaviour may lead to unplanned pregnancy, STDs, HIV, unwed mothers, illegal abortions, psychological breakdowns and complex social problems. An unfavourable family environment in the form of poverty, marital discord between parents, and alcoholic parent puts the adolescent at risk of Delinquency and prone to psychological problems. Adolescence is also a stressful transitional period. The transitions include educational, occupational, marriage, pregnancy/parenthood and migration related to education and employment.

The health of the adolescents can be measured by studying age specific morbidity, mortality, prevalence of behavioural disorders and DALYs. DALYs have been found to be the most suitable indicator for international comparisons..

In India there is lack of knowledge and awareness among adolescents about important health issue problems that affect them according to an ICMR study. High fertility rates, high rates of teenage pregnancy, high risk of STI/HIV, and poor nutritional status are important problems in adolescents in India. The median age at first marriage in India is 17.2 years.

Improving the health of young people is a complex problem. A multi-pronged intervention approach which should include life-skills and health and sexuality education in schools, peer education, mass media and community mobilization, youth development programs, clinical health services, social marketing and work place and private health sector programs.

The Government of India has identified Survival, Protection and Development as a major theme, focusing on gender

specific needs. The initiatives have been taken under inter-related issues concerning adolescents under various schemes. The notable ones are National policy on education (1986 modified in 1992), National population policy, National AIDS prevention and control policy, National nutrition policy (1983), National policy for empowerment of women and Reproductive and child health policy. These policies address specific sectors like education, health, family welfare, nutrition, HIV/AIDS, sports etc. or address certain population groups like women, children and youth. There are specific programs initiated by governmental and non-governmental organization directed towards adolescents. National Youth Policy, 2003 reiterates the commitment of the entire nation to the composite and all-round development of the young sons and daughters of India. This policy covers all young people in the country in the age group of 13 to 35 years. The strategies are Youth empowerment, Gender Justice, Inter-sectoral approach and Information and research network. The areas of focus are General health, Mental health, Spiritual health, AIDS and STDs, Population education/Family life education/Reproductive health and Tobacco/Substance abuse. The implementation is by Union Ministry of Youth Affairs and Sports.

Life-skills has been defined by WHO as 'the abilities for adaptive and positive behaviour that enable individuals to deal effectively with the demands and changes of everyday life'. Effective acquisition of life skills can influence the way one feels about oneself and others and can enhance one's productivity, efficacy self esteem and self confidence. There are three kinds of life skills- Thinking skills, Social skills and negotiating skills. Adolescents need to be assertive, including learning to say "no" to adopt risky and harmful behaviour like drug use or casual sex before marriage.

Juvenile Delinquency refers to a large variety of behaviour of children and adolescents which the society does not approve of and for which some kind of admonishment, punishment or preventive and corrective measures are justified in public interest. Juvenile is a boy who has not attained the age of 16 years or a girl less than 18 years. The common problems seen in Juvenile delinquents are Behavioural problems like stealing or lying or gambling or aggressiveness or destructiveness or disobedience, Learning disabilities, Emotional problems, Adjustment problems, Development disorder, Intellectual deficit, Psychosomatic disorders, Bizarre and abnormal behaviours, Relationship problems and Socio-legal issues and problems. Prevention and management of Juvenile delinquency includes improvement in family life, life skill development, schooling and social welfare services (child guidance clinics, juvenile courts, orphanages, foster homes, borstals and remand homes).

Child Guidance Clinics (CGC) started in USA in 1909, deals with children who are delinquents and also those who are not adjusted to their environment. The Juvenile Justice (Care and Protection of Children) Act 2000 (No. 56 of 2000) was published by the Legislative Department of The Ministry of Law, Justice and Company Affairs on 30 December 2000. The salient features of the Act include Child welfare committee, Juvenile Justice Board, Children homes, Rehabilitation and Special Juvenile Police Unit. The various Child placement institutions are Orphanages, Foster homes, Borstals and Remand homes.

## Study Exercises

**Long Question:** Describe various adolescent health problems in India and Programs directed against them.

**Short Notes:** (1) Specific programs on adolescents in India (2) National Youth Policy 2003 (3) Life skills education (4) Juvenile Delinquency (5) Child Guidance Clinic (6) Children Homes

### MCQs

1. The concept of Child Guidance Clinic was started in (a) India (b) USA (c) Russia (d) France
2. Median age at first marriage among women in India is (a) 18.5 years (b) 17.2 years (c) 16.2 years (d) 19.5 years
3. The Population Council supported program on adolescents 'Apni Beti Aapna Dhan' is running in (a) Punjab (b) Haryana (c) Himachal Pradesh (d) Uttar Pradesh
4. A Juvenile boy is one who is under \_\_\_\_\_ years of age (a) 17 years (b) 18 years (c) 16 years (d) 15 years
5. Child Guidance Clinics deals with (a) Juvenile Delinquents (b) Children who are not adjusted to their environment (c) Both (d) None
6. A 13 year old with no father, runs from school and caught in a theft should be kept in (a) Foster home (b) Prison (c) Orphanage (d) Remand home
7. Which of the following closely resembles Juvenile Delinquency (a) Bedwetting (b) School failure (c) Speech problem (d) Destructiveness
8. The main service of Child guidance Clinic is (a) Career counselling (b) Management of Orphans (c) Psychotherapy (d) Recreation facilities
9. Children with parental disharmony are more prone to: (a) Mental retardation (b) Epilepsy (c) Delinquency (d) Accidents

10. All of the following are problems antisocial in nature except (a) Lying (b) Gambling (c) Unsociability (d) Destructiveness
11. The percentage of adolescents among total population in India is (a) 27.3% (b) 18.7% (c) 21.2% (d) 23.1%
12. According to WHO adolescents are \_\_\_\_\_ years of age (a) 10-19 (b) 11-18 (c) 10-17 (d) 12-21

**Answers :** (1) b; (2) b; (3) b; (4) c; (5) c; (6) d; (7) d; (8) c; (9) c; (10) c; (11) d; (12) a

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A S Kushwaha

*"We are guilty of many errors and many faults, but our worst crime is abandoning the children, neglecting the foundation of life. Many of the things we need, can wait. The child cannot. Right now is the time his bones are being formed, his blood is being made and his senses are being developed. To him we cannot answer "Tomorrow". His name is "Today"."*

- Gabriela Mistral, 1948

The early years of life are crucial. When well nurtured and cared for in their earliest years, children are more likely to survive, to grow in a healthy way, to have less disease and fewer illnesses, and to develop thinking, language, emotional and social skills.

## State of Children in India

UNICEF 2005 Report on the state of the world's children was published under the title *"Childhood under Threat"*. Speaking about India, the report states that millions of Indian children are equally deprived of their rights to survival, health, nutrition, education and safe drinking water. A girl child is the worst victim as she is often neglected and is discriminated against because of the preference for a boy child. In India, children's vulnerabilities and exposure to violations of their protection rights remain spread and multiple in nature. The manifestations of these violations are various, ranging from child labour, child trafficking, to commercial sexual exploitation and many other forms of violence and abuse. With an estimated 12.6 million children engaged in hazardous occupations (2001 Census); for instance, India has the largest number of child labourers under the age of 14 in the world. The lack of available services, as well as the gaps persisting in law enforcement and in rehabilitation schemes also constitute a major cause of concern.



## Child Protection Against Exploitation

An estimated 300 million children worldwide are subjected to violence, exploitation and abuse including the worst forms of child labour in communities, schools and institutions; during armed conflict; and to harmful practices such as female genital mutilation/cutting and child marriage. Millions more, not yet victims, also remain without adequate protection.

Protecting children from violence, exploitation and abuse is an integral component of protecting their rights to survival, growth and development. UNICEF advocates and supports the creation of a protective environment for children in partnership with governments, national and international partners including the private sector, and civil society. National child protection systems, protective social practices and children's own empowerment coupled with good oversight and monitoring are among the elements of a protective environment and enable countries, communities and families to prevent and respond to violence, exploitation and abuse.

The UN Convention on the Rights of the Child states that all children are entitled to the same rights, regardless of the child's, or their parent's or legal guardian's race, colour, sex, language, religion, political or other opinion, national, ethnic or social origin, property, disability, birth or other status. However, discrimination is a daily reality for millions of the world's children. There are numerous forms of discrimination. The most common include:

- (a) Gender
- (b) Disability
- (c) Ethnicity and race
- (d) Caste
- (e) HIV/ AIDS
- (f) Birth status

### Actions to Provide Protective Environment to Children

Building a protective environment for children that will help prevent and respond to violence, abuse and exploitation involves the following essential components as defined by UNICEF:

1. Strengthening government commitment and capacity to fulfill children's right to protection.
2. Promoting the establishment and enforcement of adequate legislation addressing harmful attitudes, customs and practices.
3. Encouraging open discussion of child protection issues that includes media and civil society partners.
4. Developing children's life skills, knowledge and participation.
5. Building capacity of families and communities.
6. Providing essential services for prevention, recovery and reintegration, including basic health, education and protection.
7. Establishing and implementing ongoing and effective monitoring, reporting and oversight.

**UNGASS (UN General Assembly Special Session on Children):** The UN held its 27th special session on children in May 2002. This was to review the progress made since 1990 when World Summit for Children (Convention on the Rights of

the Child) was held. The commitment to promote and protect rights of children was reaffirmed. The aim is to create a 'World Fit for Children' through following principles (See Box-1).

<b>Box - 1 : World Fit for Children</b>
Put children first
Eradicate poverty: Invest in children
Leave no child behind
Care for every child
Educate every child
Protect children from harm and exploitation
Protect children from war
Combat HIV/ AIDS
Listen to children and ensure their participation
Protect the Earth for children

### Initiatives on Child Rights

**(a) National Policy on Children, 1974 :** India is a party to the UN declaration on the Rights of the Child 1959. In 1974, the Government of India adopted a National Policy for Children, declaring the nation's children as 'supremely important assets'. The policy reaffirmed the constitutional provisions for adequate services to children, both before and after birth and through the period of growth to ensure their full physical, mental and social development. This policy lays down recommendations for a comprehensive health programme, supplementary nutrition for mothers and children, nutrition education for mothers, free and compulsory education for all children up to the age of 14, non-formal preschool education, promotion of physical education and recreational activities, special consideration for the children of weaker sections of the population like the scheduled castes and the schedule tribes, prevention of exploitation of children and special facilities for children with handicaps. The policy provided for a National Children's Board to act as a forum to plan, review and coordinate the various services directed toward children. The Board was first set up in 1974.

**(b) The Department of Women and Child Development :** This was set up in the Ministry of Human Resource Development in 1985. The Department, besides ICDS, implements several other programmes, undertakes advocacy and inter-sectoral monitoring catering to the needs of women and children.

**(c) Convention on the Rights of the Child (CRC), 1990 :** The Government of India ratified the CRC on 12 November 1992. By ratifying the Convention on the Rights of the Child, the Government is obliged "to review National and State legislation and bring it in line with provisions of the Convention". The Convention re-validates the rights guaranteed to children by the Constitution of India. The Ministry of Women and Child Development has the nodal responsibility of coordinating the implementation of the Convention. Since subjects covered under the Articles of the Convention fall within the purview of various departments/ ministries of the Government, the Inter-Ministerial Committee set up in the Ministry with representatives from the concerned sections monitor the implementation of the



Convention. In pursuance of this, the Department formulated a National Plan of Action for Children in 1992.

**(d) National Plan of Action for Children, 1992** : India is a signatory to the World Declaration on the Survival, Protection and Development of Children. In pursuance of the commitment made at the World Summit, the Department of Women and Child Development under the Ministry of Human Resource Development has formulated a National Plan of Action for Children. Most of the recommendations of the World Summit Action Plan are reflected in India's National Plan of Action-keeping in mind the needs, rights and aspirations of children in the country. The priority areas in the Plan are health, nutrition, education, water, sanitation and environment. The Plan gives special consideration to children in difficult circumstances and aims at providing a framework, for actualization of the objectives of the Convention in the Indian context.

**(e) Education - Right of every Child, 2002** : The Constitution (86th Amendment) Act was notified on 13th December 2002, making free and compulsory education a Fundamental Right for all children in the age group of 6-14 years.

**(f) National Charter for Children, 2004** : The National Charter for Children, adopted on 9th February 2004, emphasizes Government's commitment to children's rights to survival, development and protection. It also stipulates the duties for the State and the community towards children and emphasizes the duties of children towards family, society and the Nation.

**(g) National Action Plan for Children, 2005** : In recognition of the fact that 41% of India's population is below 18, constituting a significant national asset, The National Plan of Action for Children, 2005 re-affirms the Nation's commitment to wisely, effectively and efficiently invest its national resources to fulfill its commitments to children. This plan commits itself to ensure all rights to all children up to the age of 18 years. The guiding principles of the action plan are given in the Box - 2.

**Box - 2 : The Guiding Principles of the National Plan of Action for Children, 2005**

To regard the child as an asset and a person with human rights.
To address issues of discrimination emanating from biases of gender, class, caste, race, religion and legal status in order to ensure equality.
To accord utmost priority to the most disadvantaged, poorest of the poor and least served child in all policy and programmatic interventions.
To recognize the diverse stages and settings of childhood, and address the needs of each.

The National Plan of Action for Children, 2005 is divided into following four sections; and all categories of rights apply to all age groups, including before birth.

- (i) *Child Survival*
- (ii) *Child Development*
- (iii) *Child Protection*
- (iv) *Child Participation*

The Plan has identified twelve key areas keeping in mind

priorities and the intensity of the challenges that require utmost and sustained attention in terms of outreach, programme interventions and resource allocation, so as to achieve the necessary targets and ensure the rights and entitlements of children at each stage of childhood. Key result areas of the action plan are given in the Box - 3.

**Box - 3 : Key Result Areas of the National Action Plan for Children 2005**

Reducing Infant Mortality Rate.
Reducing Maternal Mortality Rate.
Reducing Malnutrition among children.
Achieving 100% civil registration of births.
Universalization of early childhood care and development and quality education.
Complete abolition of female feticide, female infanticide and child marriage.
Improving Water and Sanitation coverage both in rural and urban areas.
Addressing and upholding the rights of Children in Difficult Circumstances.
Legal and social protection from all kinds of abuse, exploitation and neglect.
Complete abolition of child labour
Monitoring, Review and Reform of policies, programmes and laws
Ensuring child participation and choice

**(h) National Commission for Protection of Child Rights, 2006** : In order to ensure child rights practices and in response to India's commitment to UN declaration to this effect, the Government of India set up a National Commission for Protection of Child Rights. The Commission is a statutory body notified under an Act of the Parliament on December 29, 2006. Besides the chairperson, it will have six members from the fields of child health, education, childcare and development, juvenile justice, children with disabilities, elimination of child labour, child psychology or sociology and laws relating to children. The Commission has the power to inquire into complaints and take *suo motu* notice of matters relating to deprivation of child's rights and non-implementation of laws providing for protection and development of children among other things.

**(j) Constitutional Provisions** : India's commitment to children is clearly manifested in its Constitution wherein several articles are dedicated to children (See Box - 4).

**National Plan of Action for Children, 2005 : GOALS**

The National Plan of Action for Children 2005 has set out goals related to various fields of child welfare, exploitation, abuse and their right to health. The salient goals are laid out in Box - 5 to 9.

The ultimate objective of the entire international, regional, national and sub-national effort is to create a society where children will get the most favourable conditions to survive,

grow and develop into healthy adults. This in other words can happen only in a *Child Friendly Society* that promotes survival, protection, development of children ensuring their protection against all forms of exploitation with their participation.

There has been a lot of progress in the field of child health in terms of not only improved child health indices but also with respect to global focus towards this very vital social issue. The Convention on the Rights of Children to a healthy childhood is a milestone in this endeavor. However, it is disturbing to note uneven progress not only in different regions and countries but also country to country variation and rural urban differential not only continue to exist but widening as well. The global pledge to address these child health issues by adopting MDGs is a ray of hope for the children of the world. The society has a moral duty to give every child a right to survival, growth, development and protection so that they can achieve their full potential. The ultimate aim of all initiatives towards rights and protection of children is to develop a child friendly society.

#### **Box - 4 : Constitutional Provisions to Children**

**Article 14** : Equality before the law or the equal protection of laws

**Article 15** : The State shall not discriminate against any citizen. Nothing in this Article shall prevent the State from making any special provisions for women and children.

**Article 21 A** : The State shall provide free and compulsory education to all children of the age of 6-14 years in such manner as the State may, by law, determine.

**Article 23** : Traffic in human beings and beggar and other forms of forced labour are prohibited and any contravention of this provision shall be an offence punishable in accordance with the law.

**Article 24** : No child below the age of 14 years shall be employed to work in any factory or mine or engaged in any other hazardous employment.

**Article 45** : The State shall endeavour to provide early childhood care and education for all children until they complete the age of six years.

**Article 243 G read with Schedule 11** : Provide for institutionalization of child care by seeking to entrust programmes of Women and Child Development to Panchayat (Item 25 of Schedule 11)

#### **Box - 5 : Child Health Goals (NAP 2005)**

To reduce Infant Mortality Rate to below 30 per 1000 live births by 2010.

To reduce Child Mortality Rate to below 31 per 1000 live births by 2010.

To reduce Neonatal Mortality Rate to below 18 per 1000 live births by 2010.

To explore possibilities of covering all children with plan for health insurance.

#### **Box - 6 : Care and Education Goals (NAP 2005)**

To universalize early childhood services to ensure children's physical, social, emotional and cognitive development.

To ensure that care, protection and development opportunities are available to all children below 3 years.

To ensure integrated care and development and pre-school learning opportunities for all children aged 3 to 6 years.

To provide day care and crèche facilities to parents in rural and urban areas.

#### **Box - 7 : Children in Difficult Circumstances Goals (NAP 2005)**

To ensure that best interest of the child is upheld in all policies, plans, programmes, interventions and in strategies for children in difficult circumstances.

To create and uphold a safe, supportive and protective environment for all children within and outside the home.

#### **Box - 8 : Protection Against Sexual Exploitation And Child Pornography Goal (NAP 2005)**

To protect all children, both girls and boys, from all forms of sexual abuse and exploitation.

To prevent use of children for all forms of sexual exploitation, including child pornography.

To develop new and strengthen existing legal instruments to prevent sexual abuse and exploitation of children.

#### **Box - 9 : Combating Child Labour Goals (NAP 2005)**

To eliminate child labour from hazardous occupations by 2007, and progressively move towards complete eradication of all forms of child labour.

To protect children from all kinds of economic exploitation

## **Summary**

The early years of life are the most crucial years. Violations of the basic rights of children ranging from child labour, child trafficking, to commercial sexual exploitation may lead to various problems in the future. An estimated 300 million children worldwide are subjected to violence and many others remain without adequate protection. The lack of available services with India having the largest number of under 14 child labourers in the world is a major cause of concern especially with India being a signatory to UN declaration on the Rights of the Child, 1959. UNGASS in its 27th special session in May 2002 aims to create a 'World Fit for Children' through certain laid out principles. As a initiative to child rights, India adopted National Policy on Children in 1974 and a number of conventions and departments were setup followed by National Action Plan for Children, 2005 as a recognition of the fact that 41% of India's population is below 18. It has set out various goals related to various fields of child welfare, exploitation, abuse and their right to health. India's commitment to children is clearly manifested in its several articles which are dedicated

to children. The ultimate aim is to develop a Child Friendly Society.

## Study Exercises

**Long Questions:** India's initiatives on Child Rights.

**Short Notes :** (1) National Action Plan for Children, 2005  
(2) Constitutional provisions relating to child's rights

**MCQs and Fill in the blanks :**

- 1) UNGASS stands for \_\_\_\_\_
- 2) India adopted the National Policy on Children in the year \_\_\_\_\_
- 3) Free and compulsory education is a fundamental right of the children in the age group (a) 7-12 yr (b) 6-8 yr (c) 6-12yr (d) 6-14 yr
- 4) National action plan for children was launched in \_\_\_\_\_
- 5) At present \_\_\_\_\_% of population is under 18 years of age
- 6) Free and compulsory education is a fundamental right of the children according to the article (a) 14 (b) 15 (c) 24 (d) 21A

- 7) No child will be employed in any factory or mines according to Article \_\_\_\_\_
- 8) Infant mortality rate should be brought down to below \_\_\_\_\_ by 2010 according to child health goals
- 9) Child labour from all hazardous occupations should be eliminated by \_\_\_\_\_ according to child health goals
- 10) The department of women and child development was set up under the Ministry of \_\_\_\_\_

**Answers:** (1) United Nations General Assembly Special Session; (2) 1974; (3) d; (4) 2005; (5) 41; (6) d; (7) 24; (8) 30/1000 live births; (9) 2007; (10) HRD

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## Growth and Development of Children

A S Kushwaha

### Early Childhood

When well nurtured and cared for in their earliest years, children are more likely to survive, to grow in a healthy way, to have less disease and fewer illnesses, and to fully develop thinking, language, emotional and social skills. Although it is never too late to improve the quality of a child's life, the first three years are the most crucial for their survival and thriving. Frequent illness, unsanitary environments and poor nutrition steal a child's potential.

When they enter school, their prospects for performing well are improved, and as adolescents, they are likely to have greater self-esteem. Later in life, they have a greater chance of becoming creative and productive members of society. It is a child's right to have every chance to survive and thrive. Moreover, ensuring optimal conditions for a child's early years is one of the best investments that a country can make if it is to compete in a global economy based on the strength of its human capital. The growth monitoring, correct feeding practices, immunization, responsive health care system, legal

provisions, sensitive society, management during sickness and providing protection to these children can help in improving the lot of this important group of vulnerable population. The concept of well baby clinic, under five clinic and mother and child clinics are steps in this direction.

### Definitions

**Growth and Development :** Growth is the progressive increase in the size of a child. Development is progressive acquisition of various skills (abilities) such as head support, speaking, learning, expressing the feelings and relating with other people. Growth and development go together but at different rates.

**Importance :** The assessment of growth and development is very helpful in finding out the state of health and nutrition of a child. Continuous normal growth and development indicate a good state of health and nutrition of a child. Abnormal growth or failure to thrive (growth failure) is a symptom of disease. Hence, measurement of growth is an essential component of the physical examination.

**Factors affecting growth and development :** Each child's pattern of growth and development is determined by its genetic and environmental influences. The genetic factors determine the potential and limitations of growth and development. If favourable, the environmental factors, such as adequate nutrition, facilitate the achievement of the genetic potential of growth and development. Unfavourable factors, acting singly or



in combination, slow down or stop the growth and development. Some of the unfavourable factors are malnutrition, infections (prenatal and postnatal), congenital malformations, hormonal disturbances, disability, lack of emotional support, lack of play, and lack of language training. To promote optimum growth, these environmental factors can be removed or minimized. Once they are removed, infant follows a period of catch up growth. During this period the growth rate is greater than normal. This growth rate continues until the previous growth pattern is reached. Then the growth rate is reduced to the normal rate determined by the individual's genetic factors.

A child genetically determined to be tall grows slightly more rapidly than a child genetically determined to be short. Socio-economic factors, emotional and cultural factors too exert their influence on the growth and development of children.

**Laws of growth :** Growth and development is a continuous and orderly process and follows a particular pattern over a period of time termed as sigmoid curve. There are periods of rapid growth and slower growth. Growth pattern of each child is unique. Each organ system and body part also has its characteristic pattern of growth. The body, brain and gonads grow in a different manner in different phases of childhood. The children grow in 3 different types of physical patterns of growth, ectomorphs, endomorphs and the mesomorphs.

**1. Somatic growth (Body size) :** This is rapid during foetal life, 1st 2 years of life and after onset of puberty. This follows a sigmoid curve pattern.

**2. Brain growth :** The brain enlarges rapidly during latter months of foetal life and early months of postnatal life. At birth head size is 65-70% of the expected head size of the adult. It reaches 90% by the age of two years.

**3. Gonadal growth :** Gonadal growth is dormant in childhood with rapid growth during puberty. The growth spurt during puberty is attributed to neuro-hormonal stimulation of the hypophysis by the hypothalamus.

**4. Lymphoid growth :** This is most notable in mid-childhood and may be even larger than in an adult.

**Weight :** Body weight represents the sum of protein, fat, water, and bone mineral mass, and does not provide any information on relative changes in these four chemical components.

Weight for age in children from 6 months to 7 years of age is an index of acute malnutrition, and is widely used to assess protein energy malnutrition and over nutrition, especially in infancy when the measurement of length is difficult. A major limitation of it as an index of PEM is that it does not take into account height differences. As a result children with low weight for age are not necessarily wasted. To interpret a single measurement of weight in relation to the reference data, the exact age of the child must be known. The average birth weight in Indian children is around 2.6 Kg and 3 kg in developed countries. After losing 10% weight in 1st week, the infants regain their weight by the second week. They gain weight at an approximate rate of 25-30 gm per day for 3 months. The gain in weight in next 9 months is @ 400 gm per month. An infant doubles weight by 5 months and triples by one year of age and becomes 4 times his birth weight by end of 2 years. At 3 years

the weight becomes 5 times the birth weight. On an average child gains 2 kg per year in 3-7 years age and 3 kg after that till puberty.

**Head Circumference (HC) :** HC is important because it is closely related to brain size. It can be used as an index of chronic protein energy nutritional status during the first two years of life. Chronic malnutrition during the first few months of life, or intrauterine growth retardation, may decrease the number of brain cells and result in an abnormally low head circumference.

Beyond the age of two years, growth in HC is slow and its measurement is no longer useful.

The head circumference is measured by encircling the head with an unstretchable tape measure, or a piece of string in the absence of a tape measure. This is passed over the most prominent part of the occiput posteriorly and just above the supra-orbital ridges anteriorly to obtain the greatest distance around the head. At birth HC is 35 cm, at 3 months 40 cm, 45 cm at 1 year and reaches 48 cm by second year and 52 by 3rd year. Crown rump length (CRL) is always <HC in 1st year of life.

**Mid Upper Arm Circumference (MUAC) :** Arm contains subcutaneous fat and muscle. A decrease in MUAC may therefore reflect a reduction in muscle mass, a reduction in subcutaneous tissue or both. In developing countries, where the amount of subcutaneous fat is frequently small, a change in MUAC tend to parallel changes in muscle mass and hence is particularly useful in the diagnosis of PEM or starvation. Changes in MUAC can also be used to see progress during nutritional therapy. MUAC changes are easy to detect and require a minimal amount of time and equipment. Some investigators claim that MUAC can differentiate normal children from those of PEM as reliably as weight for age. MUAC changes very little from 1-5 years of age and it can be used as an age-independent measurement.

Low MUAC has been shown to be a sensitive indicator of risk of death in children.

The mid upper arm circumference is measured using a tape or string in the absence of a tape. The tape or string is placed around the upper arm, midway between the olecranon and acromion processes. Care is taken not to pull the tape or string too tightly. The mid upper arm circumference increases fairly rapidly to about 16 cm by the age of one year. In the period 1 to 5 years, the mid upper arm circumference increases by only 1 cm. So, irrespective of age, the mid upper arm circumference of well nourished children ranges 16 -17 cm in the period 1-5 years. Conversely, if the mid upper arm circumference of a child of 1 to 5 years of age is less than 16 cm, that child has malnutrition and corrective intervention should be carried out.

**Length / Height :** The length of a child is measured in the first 3 years and the height is measured after 3 years of age. The length is measured using a horizontal measuring board put on the ground or on a table. The child is laid on his back with the head against the fixed head board. A helper holds the child's head so that the eye angle- external ear canal line is vertical and also keeps the body straight. With one hand of the health worker, the child's knees are pressed down to straighten the child's legs fully while, with the other hand, the sliding foot



board is placed to touch the child's heels firmly. With the foot board in place, the child's length is read on the metre scale. To measure the height, a bare foot child stands with the feet together. The heels, the buttocks and the occiput lightly touch the measuring device. The head is aligned so that the external eye angle- external ear canal plane is horizontal. The child is told to stand tall and is gently stretched upward by pressure on the mastoid processes with the shoulders relaxed. The sliding head piece is lowered to rest firmly on the head. The height is read and recorded. An average term baby is 50 cm long. The length increases by 50% in the first year. In the second year, the average height growth is about 12 cm. The birth length doubles by 4 years of age. After the second year of age, the annual height growth averages 5-6 cm until the beginning of the adolescent growth spurt. Height growth stops at about the age of 18 years in girls and at the age of about 20 years in boys. After plotting the child's height or length on a height chart, you should determine whether the growth pattern is normal. A normal growth pattern is parallel to the printed percentile lines.

**Chest circumference :** The chest circumference is 3 cm less than the head circumference at birth. They become equal by end of 1st year and thereafter chest circumference exceeds the head circumference.

**Tooth eruption :** Tooth eruption is an important part of growth. In general, teething in infants usually starts at about 6 months of age, but some start later than 6 months. A new tooth appears approximately every month so that by 2 - 2½ years of age the baby will have 20 primary teeth. This makes the number of teeth roughly equal to age in months minus 6.

A parent should only start to worry about tooth eruption if a child has not yet started teething by 13 months. This is because at this age the child should be eating solid foods. Teething may cause excessive salivation, irritability, disturbed sleep and some pain. Sometimes it also causes Diarrhoea. At the age of about 6 years, the shedding of the primary teeth starts and continues through to the age of 12 years. Eruption of permanent teeth starts at about 6 years of age.

## Development

Development is defined as the progressive acquisition of various skills (abilities) such as head support, speaking, learning, expressing the feelings and relating with other people. Each child follows a unique path in growth and development that is laid down from the beginning of life by what he has inherited from both parents. Unfortunately, many factors may change the genetically determined path of growth and development. These things include, for example, infections, lack of care, psychological trauma, bad education, and malnutrition, to mention just a few. The normal well-fed infant who is protected from infections develops quickly, particularly during the first 3 months. It is very important to know the age ranges when most children acquire certain skills. The various skills the baby and a young child learn are called *milestones* (Table - 1). In monitoring development, we notice at what age the child achieves various milestones, such as smiling at the mother, sitting without support, grasping objects with his/her hands, standing, walking and talking. You should record at what

age the child has achieved the various milestones. Still, it is important to remember that every child develops at his/her own rate or pace. Some walk early, others late.

Infant development occurs in an orderly and predictable manner that is determined intrinsically. It proceeds from cephalic to caudal and proximal to distal as well as from generalized reactions to stimuli to specific, goal-directed reactions that become increasingly precise. Extrinsic forces can modulate the velocity and quality of developmental progress.

Table - 1 : Important Developmental Milestones		
Age range	Motor Development	Language and social development
Birth	When prone turns head to one side to avoid suffocation	Cries
3-6 Months	Good head control	Can follow an object with eyes, plays with hands
6-9 Months	Can sit unsupported	Grasps actively, makes loud noises
9-12 Months	Able to stand	Understands a few words, tries to use them
9-18 Months	Able to walk	Grasps small objects with thumb and index finger
15-30 Months	Able to run around as much as he wants	Can say several words or even some sentences
3 Years	Plays actively, is able to jump and climb	Starts talking a lot, is curious and asks many questions

Each developmental domain must be assessed during ongoing developmental surveillance within the context of health supervision. Generalizations about development cannot be based on the assessment of skills in a single developmental domain (i.e. one cannot describe infant cognition based on gross motor milestones). However, skills in one developmental domain do influence the acquisition and assessment of skills in other domains.

Speech delays are the most common developmental concern. A sound understanding of the distinction between an isolated speech delay (usually environmental and often can be alleviated) and a true language delay (a combined expressive and receptive problem that implies more significant pathology) will help the clinician refer appropriately for precise diagnosis and appropriate management.

It is essential to understand normal development and acceptable variations in normal developmental patterns to recognize early patterns that are pathologic and that may indicate a possible developmental disability. Assessment of the quality of skills and monitoring the attainment of developmental milestones are essential to early diagnosis of developmental disabilities and expedient referral to early intervention programs.

**Theories of Development :** Developmental theory has been shaped by the persistent debate of whether nature (intrinsic forces) or nurture (extrinsic forces) is the predominant

influence. Earlier theories centered on the role of nature. By mid 20th century, theories that stressed the importance of nurture began to prevail. Pavlov (1930s), Watson (1950s), and Skinner (1960s) promoted the view that development was a function of learning. Operant conditioning (positive and negative reinforcements through social interactions or environmental changes) promoted learning and shaped the child's development. During the second half of the century, the name of Piaget became almost synonymous with child development. Piaget was the first to describe the infant as having intelligence. Piaget revealed that infants were, indeed, capable of thinking, analyzing & assimilating. He viewed development as stage-like cognitive changes. The child actively explores objects in an effort to understand his or her environment.

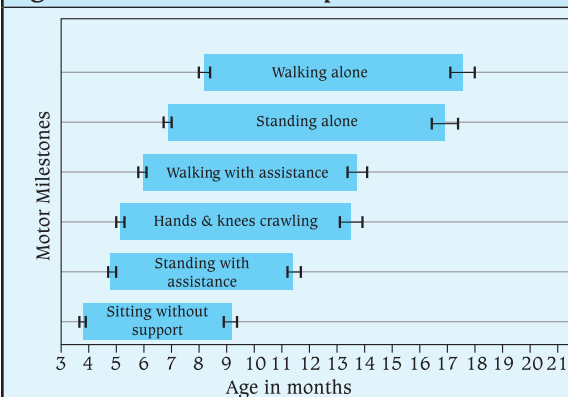
**Fields of Development** : Gross motor; Fine motor; Social; Cognitive; Psychological; Emotional; Problem solving; Adaptive; Language development.

**Developmental Quotient** : Developmental Quotient (DQ) is the developmental age divided by chronologic age times 100 (see Example in Box - 1). This provides a simple expression of deviation from the norm. A quotient above 85 in any domain is considered within normal limits; a quotient below 70 is considered abnormal. A quotient between 70 and 85 represents a gray area that warrants close follow-up. Values in the upper limit of normal do not particularly indicate supernormal abilities. The concept of windows of achieving milestones (Fig. - 1) becomes relevant as proposed by the WHO.

#### Box - 1 : Example - Motor Quotient

A 12-month-old boy is seen for health supervision. He is not walking alone, but he pulls up to stand (9 months), cruises around furniture (10 months), and walks fairly well when his mother holds both hands (10 months). This child has a gross motor age of 10 months at a chronologic age of 12 months. Should this 2-month discrepancy be a concern? To decide, one should calculate the DQ by using these gross motor milestones :  $DQ = \text{motor age} / \text{chronologic age} \times 100 = 10 \times 100 / 12 \text{ months} = 83$

Fig. - 1 : Windows of Development



Source : WHO Child Growth Standards

The motor age and the developmental quotient are good summary descriptors of the child and have more meaning than plotting each milestone. Because the lower limit is 70, this boy's DQ falls within the "suspect" or gray zone. In reality, infants falling into the gray zone of motor domains usually do quite well and rarely require referral to an early intervention program. This is in contrast to those falling in the gray zones of the cognitive domains.

**Factors in Development** : The factors that promote development include good nutrition, emotional support, play and language training.

**1. Good Nutrition** : Good nutrition is essential for normal growth and development. Unlike most other organs in the body, the brain is not fully developed at birth. Good nutrition in the first 6 months of life is extremely important. Malnutrition in this period may impair the growth of the brain. As a result of impaired brain growth, the child may suffer for the rest of life. A malnourished child is often tired, apathetic and not interested in learning new things that will promote normal development. Nutrition is discussed in detail elsewhere.

**2. Emotional Support** : The first 5 years of life are critical for the foundation of the skills. A newborn starts with no knowledge and learns a great deal during his/her first year of life. It is very important to realize that a child is a growing and developing human being right from birth. He ought to be treated very carefully, with love and affection, so that he can develop normally. He needs full emotional support.

**3. Play** : Play is a source of information, stimulation for the brain, stimulation for the muscles and a lot of fun. All these activities are necessary for physical, mental and social development. All normal children like to play.

**4. Language Training** : Another factor that promotes development is language training. Children should be offered opportunities to meet, use, and play with words in conversation and in reading books.

#### Growth Monitoring

Growth Monitoring was popularized by David Morley in 1960s' and 70s' (1-5). This strategy proved that growth monitoring could improve nutritional status. His "road to health" chart was a tool which possessed a number of precise functions-

- Provide a health record of the child which included weight but also relevant information on immunization, disease episodes, family planning, etc.
- Emphasize integration of curative and preventive care.
- Increase proportion of "care" as opposed to the prevailing "cure".
- Help the family to take care of its own health.
- Provide a support for the less qualified rural health worker.

In 1982, growth monitoring i.e. the regular weighing of children and charting their weight on a chart was taken up by UNICEF as part of the **GOBI** program. G= growth promotion, O= ORT (oral rehydration therapy), B = breast feeding, I= immunization. This programme was later extended with the three Fs of *Family Planning, Food and activities for Females to GOBIFFF*.

Growth monitoring is the process of maintaining regular

observation of a child's growth. It starts with measurements of weight daily, weekly, monthly, bimonthly etc. The successive weights are plotted on the growth chart of the child health card. A curve deviating downwards indicates a situation that the child is losing weight. The child needs extra care immediately. The baby may be suffering from malnutrition, tuberculosis, AIDS or other medical conditions. The mother is advised to take the baby to hospital for investigations and treatment. Any infant who does not gain weight for one month or a child who does not gain weight for two months should receive urgent attention. Such an infant or child is becoming malnourished.

**Importance of Growth Monitoring :** Health workers and parents should monitor the growth of children for the following reasons -

- (a) For early detection of abnormal growth and development.
- (b) To facilitate the early treatment or correction of any conditions that may be causing abnormal growth and development.
- (c) To provide an opportunity for giving health education and advice for the prevention of malnutrition.

Growth monitoring is one of the basic activities of the Under Five clinics where the child is weighed periodically at monthly intervals during the 1st year, every 2 months during the 2nd year and every 3 months thereafter up to the age of 5 to 6 years. The Anganwadi under ICDS is also based on Growth monitoring and supplementary feeding for children under six years of age.

**IAP Guidelines on Growth Monitoring :** Growth Monitoring Guidelines Consensus Meeting of the IAP recommended that-

**(i) Birth to 3 years :** Immunization contacts at birth, 6, 10 and 14 weeks, 9 months, 15-18 months may be conveniently used for growth monitoring. An additional monitoring visit at 6 months with opportunistic monitoring at other contacts (illness) is recommended. Normally growing babies should not be weighed more than once per fortnight under 6 months and no more than monthly thereafter, as this increases anxiety. After 18 months measurements are to be taken every 6 monthly. It is recommended that the height, weight and head circumference be measured up to 3 years of age.

**(ii) 4 to 8 years :** It is recommended that height and weight be measured 6 monthly during this period and BMI should be assessed yearly from 6 years of age.

**(iii) 9 to 18 years :** It is recommended that height, weight and BMI be assessed yearly during this period.

### Anthropometry

Anthropometry means "body measurements". Anthropometry is very useful for measuring overall health status, not just nutritional status.

#### The advantages of anthropometry

1. Simple, safe, non-invasive procedure
2. Applicable to large sample sizes
3. Requires inexpensive, portable and durable equipment, which can be made or purchased locally
4. Methods are precise and accurate if standardized techniques are used
5. Information on past long term nutritional history can be obtained

6. Helps in identification of mild, moderate or severe degree of malnutrition
7. Helps in evaluation of nutritional status over time and from one generation to the next (secular trend)
8. May be used in nutritional screening to identify individuals at high risk of malnutrition

#### Limitations of anthropometric assessment

1. Relatively insensitive method and can not detect change of nutritional status over short period of time.
2. Anthropometric information is non-specific and does not identify the cause of growth failure.
3. In poor communities, dietary inadequacies and infection are often major environmental determinants of growth failure. While anthropometry may index the problem, it does not, by itself, identify the specific cause or indicate the specific solution.
4. Certain non-nutritional factors, viz. disease, genetics, diurnal variation, reduced energy expenditure, etc. can reduce specificity and sensitivity of anthropometric methods.
5. Appropriate sampling or experimental design can largely exclude such limitations.

#### Uses of Anthropometry

1. Population assessment
2. Identification of target groups
3. Nutritional surveillance
4. Monitoring of nutritional status
5. Evaluation of program impact
6. Growth monitoring of individuals

**Reference Vs Standard :** Height and weight measurements mean little unless compared to a growth reference.

Instead of the term "*standard*", which originated from the "Harvard Standard" that was developed in 1955, the preferred term today is "growth reference", which is used to compare measurements. The characteristics of a reference population as defined by WHO, include measurements taken from a well-nourished population with at least 200 children/age and sex group, and from a cross-sectional sample. There have been several growth references developed. The first was the "Harvard Standard", also known as the "Boston Standard," the "Stuart-Meredith Standard" or the "Jelliffe Standard". A "*Reference*" is defined as a tool for grouping and analyzing data and provides a common basis for comparing populations; no inferences should be drawn about the meaning of observed differences.

**Deciding Cut-off Points :** Environment plays a more important role than genetics in determining preschool age child nutritional status using anthropometry, given an adequate environment, preschool-age children around the world should have similar growth curves. There are three different types of cut-off points that can be used to identify stunting, wasting, and underweight. Percentiles are useful but are problematic in classifying children who fall outside the extreme centiles of the growth reference (i.e. below the 3rd and above the 97th percentiles) since they cannot be accurately classified. The percent of median is very useful since it provides a more precise estimate of the HFA, WFH and WFA of a population, particularly where stunting, wasting, and underweight are expected, which is common in developing countries. The median of the NCHS



growth reference is used since it is the best comparison point in distributions of HFA, WFH and WFA. For example, with HFA, in any population there will be a few tall children, a few short children, and the rest in-between. Since the few very tall or few very short children do not adequately represent the group, the median is selected as the comparison point. The cut-off points of <90%, <80% and <70% of reference median for HFA, WFH and WFA to define stunting, wasting and underweight respectively, were selected because studies have shown that significant increases occur approximately at these three cut-off points for various functional parameters, such as mortality. Therefore, these cut-off points are really not as arbitrary as it may appear. The preferred method of cutoff points is Z-score, which is the number of standard deviation units (SD) from the reference median, which is "0" Z-score. The Z-score gives a much more precise measurement of stunting, wasting, and underweight than percentiles or percent of median.

### Measuring Growth

**Measurements :** There are various measurements that are used to measure growth.

1. Weight
2. Head circumference
3. Mid Upper Arm Circumference (MUAC)
4. Height / length
5. Chest circumference

**Indices :** Anthropometric indices are combinations of the measurements. They are important since mere measurements provide little useful information. For example, mere body weight has little utility unless it is related to age or height. An example of such combination of two measurements is BMI (weight in kg / height<sup>2</sup>). Ponderal index is weight/ height<sup>3</sup>. In children three common indices used are WFH (weight for height), HFA (height for age) and WFA (weight for age). These indices could be expressed in the form of Z-scores, percentiles and % of median which can then be used to compare a child to a reference population. To be useful, these measurements must be taken accurately using reliable equipment and correct measuring techniques.

**(a) Z score :** The deviation of the value for an individual from the median value of the reference population, divided by the standard deviation for the reference population.

$$Z \text{ score} = \frac{(\text{observed value}) - (\text{median reference value})}{\text{Standard deviation of the reference population}}$$

**(b) Percentile :** The rank position of an individual on a given reference distribution, stated in terms of what percentage of the group the individual equal or exceeds. For example, a child whose weight falls in the 10th percentile weighs the same or more than 10% of the reference population of children of the same age. Percentiles are easy to use and thus preferred in clinical settings. The percentile is interpreted by the percent of individuals above and below specified percentile value. For example 35th percentile is described by 35% of the individuals lying below the value and 65% above. However, the same interval of percentile values corresponds to different changes in absolute height or weight according to which part of the distribution is concerned. Another disadvantage being that

towards the extremes of the reference distribution there is little change in the percentile values for significant changes in height or weight.

For example : Consider a child of age 2 years having a weight of 10.5 kgs. When the child is tracked on the growth chart we first locate the age of 2 years i.e. 24 months on the Age axis and weight of 10.5 kgs on the weight axis. The intersection of these two is the point shown by coloured circle (Fig. - 2). We observe that the individual falls in between 50th percentile and 3rd percentile.

**(c) Percent of Median :** The ratio of a measured value in the individual, for example weight, to the median value of the reference data for the same age or height, expressed as percentage. The disadvantage is that this does not correspond to a fixed point of the distribution across age or height status.

For example consider a child who is 18 months of age and weighs around 7.5 kgs. Again while tracking the child on the growth chart we first locate the intersection point at the specified age and corresponding weight of the child. The coloured point denotes the intersection on the growth chart (Fig. - 3). We observe that the child falls in Grade II of malnutrition. Hence intervention is needed in this child.

**Why use 'Z score'?** : One of the problems with percent of median is that although 90% of reference median is the cut-off point for HFA where a child who has a HFA below the cut-off point is classified as stunted, each age group of children actually has a different cut-off point when using percent of median. For example, the cut-off point at -2 Z-score of boys 2 years 4 months is 92.2%; for boys 3 years 5 months, it is 91.1%; for boys 4 years 4 months, it is 91.7%. Therefore, using a cut-off point of 90% for all children may create problems in properly classifying children's nutritional status - using Z-score eliminates this problem.

### Advantages of using Z score over percentage of median

1. Z-score cut-off point always at -2 Z-score
2. Different cut-off points for % of median for different ages of children
3. Z-score and percentage of median can yield different results - can cause misclassification
4. Clearer interpretation of Z-score
5. Misleading interpretation of % of median

### Indicators

An indicator refers to the use or application of indices. Example, proportion of children below a certain level of weight for age (say -3SD) can be used as an indicator of undernourished children in a given community. These indicators could be used as indicators of body size, health or nutrition or a combination of these. The use of these indicators should be clearly defined as incorrect interpretation and its usage may lead to formation of unscientific interventions.

### Growth Charts

In Haiti, in the mid sixties, Beghin with Fougère and King designed a growth chart based on Gomez classification of degrees of malnutrition, to select children for referral to nutritional rehabilitation centers (1). In Colombia, Rueda Williamson adapted a chart developed earlier by Tony, which



combined weight and height. As the Director of National Institute of Nutrition, he actively promoted his “auxogramme” which, interestingly enough, was also used for counselling the child’s mother. While working on malnourished children, Dr David Morley introduced the concept of growth monitoring and developed the earliest growth charts. These have come to be known as ‘Road to Health’ charts. The growth chart shows progressive changes in the height and weight of a child in a graphic form. They depict average and permissible range of variation for the particular age and attribute.

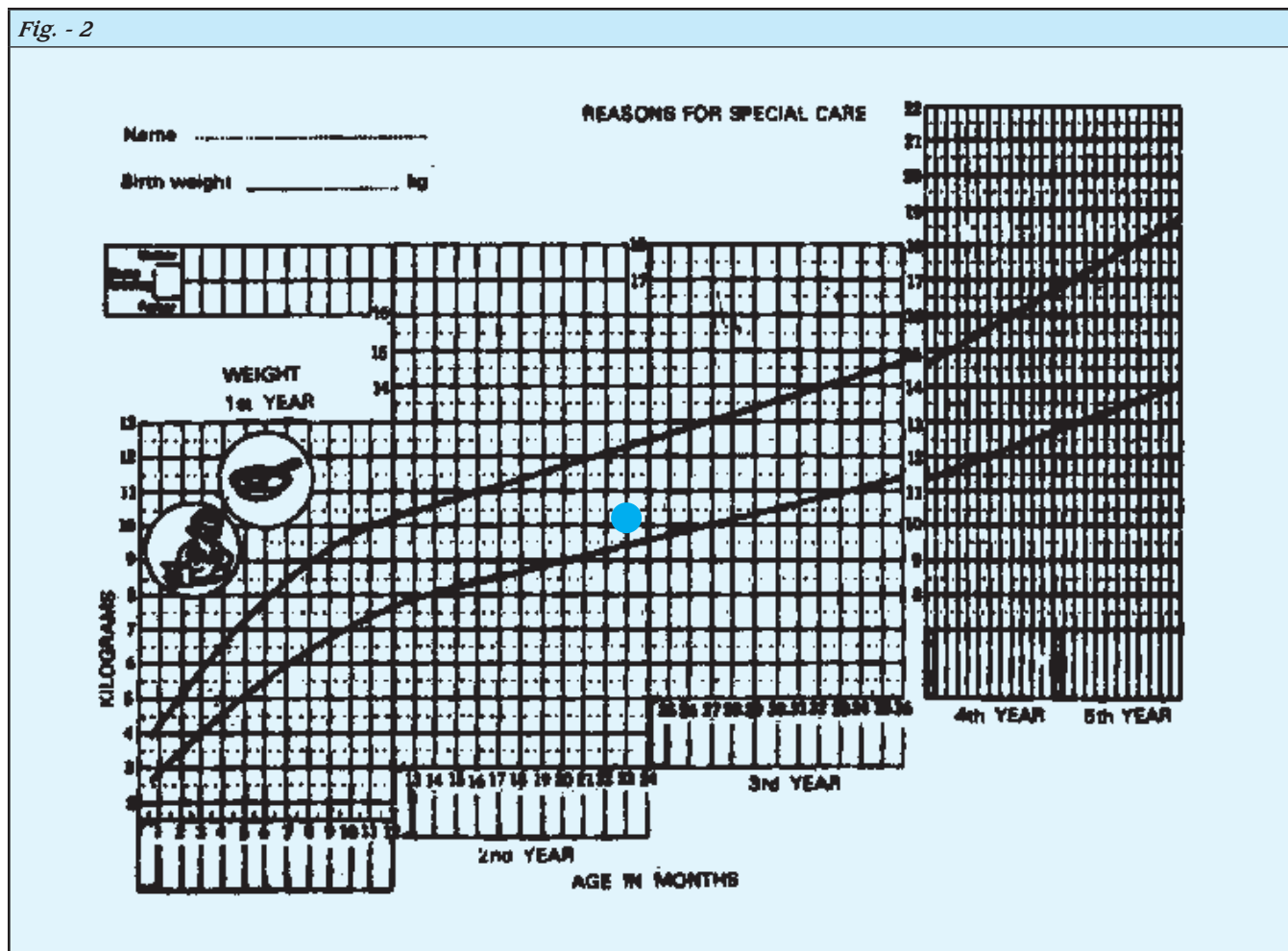
The Indian Council for Medical Research (ICMR) undertook a nationwide cross sectional study during 1956 and 1965 to establish Indian reference charts. The measurements were made on children of the lower socio-economic class and hence cannot be used as a reference standard. There are a number of different types of growth charts in use in India. The commonly used and approved by the Government had four reference curves depicting three different grades of malnutrition. The topmost curve represented 80 % of the median of WHO reference standards which is approximately equivalent to 2 SD below the median which is the conventional lower limit of normal range. The three lines below this curve represent 1st to 3rd degree of malnutrition. The prototype WHO chart (home based) had two reference curves. The upper curve represented the median for

boys (50th percentile) and the lower curve represented the 3rd percentile for girls. This chart had an advantage of application to both the sexes.

NCHS (National Center for Health Statistics) developed the growth charts in 1977 and were adopted by the WHO as a clinical tool to monitor growth of children. CDC (Center for Disease Control) in 2000 brought out growth charts and they represent the revised and improved version of NCHS charts. The CDC has introduced two BMI charts besides 16 (8 for boys and 8 for girls) charts. In 1993, the World Health Organization (WHO) undertook a comprehensive review of the uses and interpretation of anthropometric references. The review concluded that the NCHS/WHO growth reference, which had been recommended for international use since the late 1970s, did not adequately represent early childhood growth and that new growth curves were necessary. In response, WHO undertook the Multi-centre Growth Reference Study (MGRS) between 1997 and 2003 to generate new curves for assessing the growth and development of the children which could be applicable the world over.

**WHO Multi-centre Growth Reference Study (MGRS) Charts:** The MGRS combined a longitudinal follow-up from birth to 24 months and a cross-sectional survey of children aged 18 to 71 months. Primary growth data and related information were gathered from 8440 healthy breastfed infants and young

Fig. - 2



children from widely diverse ethnic backgrounds and cultural settings (Brazil, Ghana, India, Norway, Oman and USA). The MGRS is unique in that it was purposely designed to produce a standard by selecting

- (a) Healthy children living under conditions likely to favour the achievement of their full genetic growth potential.
- (b) The mothers of the children selected for the construction of the standards engaged in fundamental health-promoting practices, namely breast feeding and not smoking.

The growth standards provide a technically robust tool that represents the best description of physiological growth for children under five years of age. The standards depict normal early childhood growth under optimal environmental conditions and can be used to assess children everywhere, regardless of ethnicity, socioeconomic status and type of feeding. The new growth curves are expected to provide a single international standard that represents the best description of physiological growth for all children from birth to five years of age and to establish the breastfed infant as the normative model for growth and development.

**Epidemiological Aspects of the Standards :** As expected, there are notable differences with the NCHS/WHO reference that vary by age, sex, anthropometric measure and specific percentile or z-score curve.

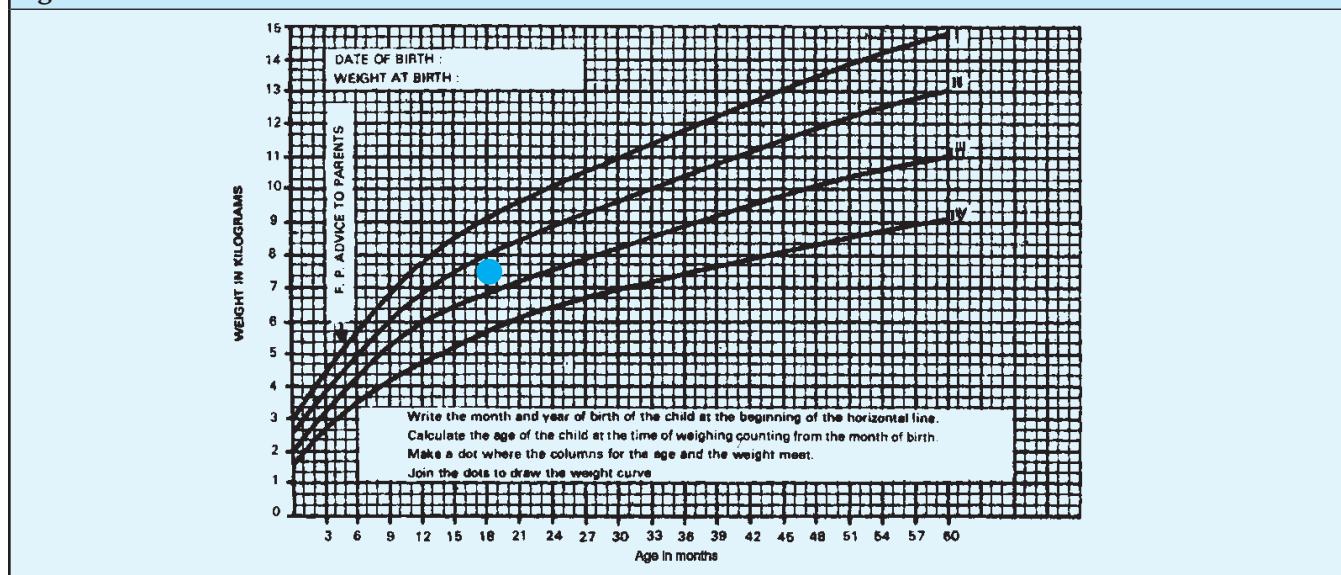
1. Differences are particularly important in infancy.
2. Stunting will be greater throughout childhood when assessed using the new WHO standards compared to the NCHS/WHO reference.
3. The growth pattern of breastfed infants will result in a substantial increase in rates of underweight during the first half of infancy and a decrease thereafter.
4. For wasting, the main difference is during infancy when wasting rates will be substantially higher using the new WHO standards.
5. With respect to overweight, use of the new WHO standards will result in a greater prevalence that will vary by age, sex

and nutritional status of the index population.

## Summary

Ensuring an optimal condition for a child's early years is one of the best investments that a country can make and it is a child's right to have every chance to survive and thrive. Environment plays a more important role than genetics in determining preschool age child nutritional status. Growth is the progressive increase in the size and development is progressive acquisition of various skills. Measurement of growth is an essential component of the physical examination in finding out the state of health and nutrition of a child. It follows a particular pattern over a period of time termed as *sigmoid curve* and the body, brain and gonads grow in a different manner in different phases of childhood. There are various measurements that are used to measure growth like Weight, Head circumference, Mid Upper Arm Circumference (MUAC), Height / length, Chest circumference. Weight for age in children from 6 months to 7 years of age is an index of acute malnutrition, and is widely used to assess protein energy malnutrition and over nutrition. HC is important because it is closely related to brain size. It can be used as an index of chronic protein energy nutritional status during the first two years of life. Arm contains subcutaneous fat and muscle. A decrease in MUAC may therefore reflect either a reduction in muscle mass, a reduction in subcutaneous issue, or both and it changes very little from 1-5 years of age and it can be used as an age-independent measurement. The length of a child is measured in the first 3 years and the height is measured after 3 years of age. On a height chart, you should determine whether the growth pattern is normal. A normal growth pattern is parallel to the printed percentile lines. The various skills the baby and a young child learn are called *milestones* and that's why we notice at what age the child achieves various milestones, such as smiling at the mother, sitting without support, grasping objects with his/her hands, standing, walking and talking. Infant development occurs in an orderly and predictable

Fig. - 3



manner that is determined intrinsically. Speech delays are the most common developmental concern. Piaget was the first to describe the infant as having intelligence. Developmental quotient (DQ) is the developmental age divided by chronologic age times 100. This provides a simple expression of deviation from the norm. A quotient above 85 in any domain is considered within normal limits. The factors that promote development include good nutrition, emotional support, play and language training. Growth Monitoring was popularized by David Morley in 1960s' and 70s' (1-5). This strategy proved that growth monitoring could improve nutritional status. In 1982 growth monitoring, i.e. the regular weighing of children and charting their weight on a chart was taken up by UNICEF as part of the *GOBI* program. Anthropometry is very useful for measuring overall health status, not just nutritional status. IAP has laid down various guidelines for growth monitoring according to different age groups. Height and weight measurements mean little unless compared to a growth reference. Anthropometric indices are combinations of the measurements. They are important since mere measurements provide little useful information; for example Ponderal index, WFH (weight for height), HFA (height for age) and WFA (weight for age). These indices could be expressed in the form of Z-scores, percentiles and % of median. The prototype WHO chart (home based) had two reference curves. The upper curve represented the median for boys (50th percentile) and the lower curve represented the 3rd percentile for girls. The growth standards provide a technically robust tool that represents the best description of physiological growth for children under five years of age.

## Study Exercises

**Long Question :** "Growth and development is very helpful in finding out the state of health and nutrition of a child". Explain in detail.

**Short Notes :** (1) Mid upper arm circumference (2) Development quotient (3) Growth monitoring (4) Anthropometry (5) Growth charts (6) IAP guidelines for growth monitoring

## MCQs and fill in the blanks

- 1) At birth head size is \_\_\_\_\_ % of the expected head size of the adult.
- 2) Weight for age in children from \_\_\_\_\_ years to \_\_\_\_\_ years of age is an index of acute malnutrition
- 3) Head circumference at birth is \_\_\_\_\_ cm
- 4) The length of a child is measured in the first \_\_\_\_\_ years.
- 5) By 2 - 2½ years of age the baby will have \_\_\_\_\_ primary teeth.
- 6) A developmental quotient below \_\_\_\_\_ is considered abnormal
- 7) Growth Monitoring was popularised by \_\_\_\_\_
- 8) Weight / height<sup>3</sup> represents a) Brocas index b) Ponderal index, c) Quetelet index, d) none
- 9) Z score = \_\_\_\_\_

**Answers:** (1) 65 to 70; (2) 0.5 yrs to 7 yrs; (3) 35; (4) 3; (5) 20; (6) 70; (7) David Morley; (8) b;

$$(9) Z \text{ score} = \frac{(\text{observed value}) - (\text{median reference value})}{\text{Standard deviation of the reference population}}$$

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Amitava Datta

### Historical Aspects

Homosapiens first appeared on this planet approximately 50,000 years ago. Early man seemed to be as curious as in the present day on matters of inheritance. Engravings in Chaldea in Babylonia (now Iraq) dating back at least 6000 years show pedigrees documenting the transmission of certain characteristics of the mane in horses. Early Greek philosophers and physicians such as Aristotle and Hippocrates concluded with typical masculine modesty that important human characteristics were determined by semen utilizing menstrual blood as a culture medium and the uterus as an incubator. Our present understanding of human genetics owes much to the work of the Austrian monk, Gregor Mendel, who in 1865 presented the results of his breeding experiments on garden peas. The importance of these findings were however only realized in 1900. It was a Danish botanist, Johannsen who coined the term “gene” for the hereditary factors postulated by Mendel. Credit for first recognition of a single gene trait is shared by William Bateson and Archibald Garrod who proposed that alkaptonuria was a rare recessive disorder. During the twentieth century, it gradually became clear that hereditary factors are implicated in many conditions and that different genetic mechanisms are involved. The study of genetics and its role in the causation of human disease has in modern times been at the forefront of medical research. Francis Crick, James Watson and Maurice Wilkins in 1962 gained acclaim for their elucidation of the structure of DNA. In the next 30 years or so the Nobel prize was awarded on twelve occasions to scientists working in the field of human and molecular genetics. Dramatic advances in technology lead to better and more complete understanding of the way we inherit different characteristics, why diseases occur and human biology. Increasing globalization and the internet enabled the gigantic “Human Genome Project” started in 1991, mainly with funding by United States Government, to map the complete human genome. Thus throwing up tremendous potential for diagnosis and management of human disease. Gene therapy, which till recently was considered in the realms of science fiction, suddenly became eminently possible although its routine use in the management of disease is still several years away.

Increasing control world wide on communicable diseases, ethical considerations of gene manipulation and better understanding of genetic basis of disease has pushed genetics into the realm of public health. A comprehensive knowledge of elementary genetics is now therefore inescapable for a potential public health specialist.

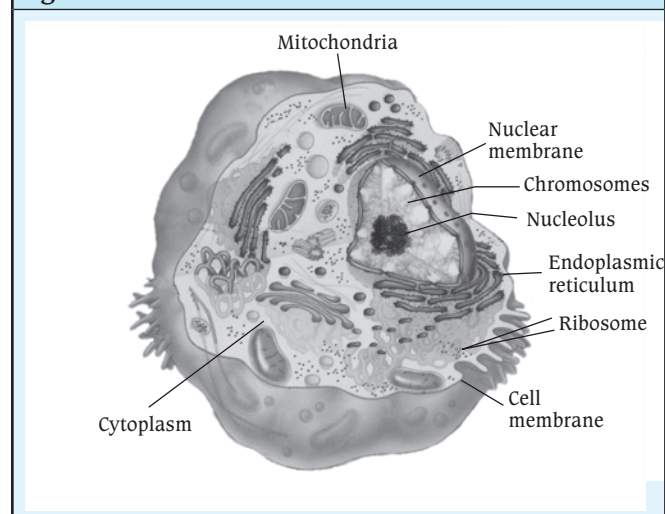
### Cellular basis of Inheritance

The structure of a cell as evident on light microscopy is shown in Fig 1.

The transmission of hereditary characteristics is controlled by chromosomes located inside the nucleus and containing genes which are made up of DNA. The double helical structure of DNA

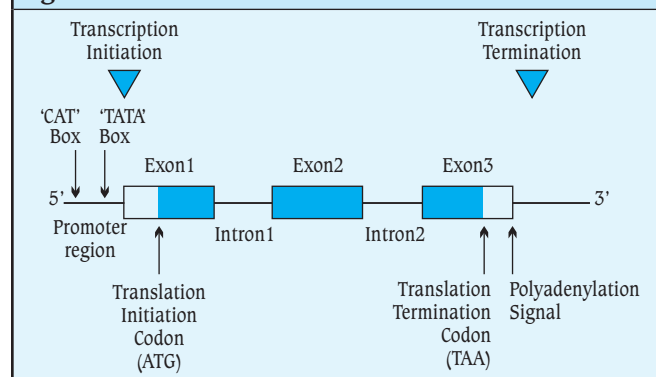
was proposed by Watson and Crick to explain the versatility of the transmission mechanism. The chromosome structure is however more complex. DNA sequences make up genes which code for different proteins necessary for life. It is estimated that there are upto 1,00,000 genes in the nuclear genome, which code for specific proteins in humans. Many human genes are single copy genes coding for polypeptides which carry out a variety of cellular functions. These include enzymes, hormones, receptors and structural and regulatory proteins.

**Fig - 1 : Structure of Cell**



The original concept of a gene as a contiguous sequence of DNA coding for a protein was turned on its head in the early 1970s by detailed analysis of the structure of the  $\beta$ -globin gene which revealed it to be much longer than the length necessary to code for the  $\beta$ -globin protein. The gene was found to be containing non-coding intervening sequences or “introns” separating the coding sequences or “exons”. The number and size of introns in various human genes is extremely variable although the general trend is that larger the gene, the greater the number of exons.

**Fig - 2 : Structure of Gene**

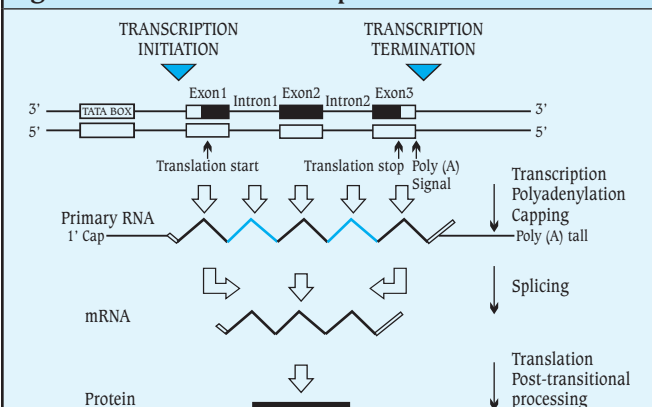


The process whereby genetic information is transmitted from DNA to RNA is called “transcription”. The information stored in the genetic code is transmitted from DNA to messenger RNA (mRNA) which is single stranded. The mRNA leaves the

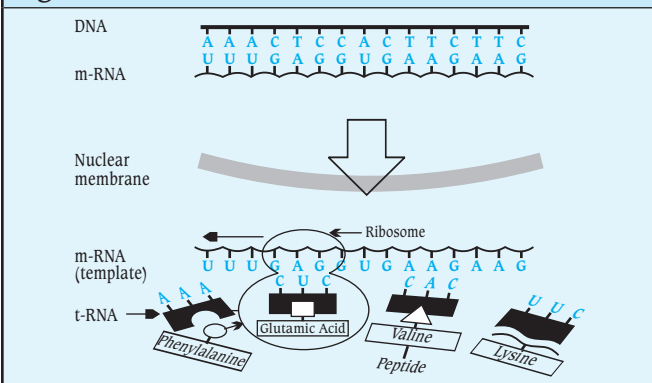


nucleus after undergoing “post-transcription processing”. The transmission of the genetic information from mRNA to protein is called “translation”. mRNA migrates out of the nucleus into the cytoplasm where it becomes associated with the ribosomes, which are the site of protein synthesis. In the ribosomes, the mRNA forms the template for producing a particular sequence of amino acids (See Fig. - 3a & b).

**Fig. - 3a : Process of Transcription**



**Fig. - 3b : Process of Translation**



Genetic information is stored with the DNA molecule in the form of a triplet code, that is a sequence of three bases determines one amino acid. Only 20 different amino acids are found in proteins. By experimentation with various refinements, triplet codes have been assigned to all 20 amino acids. The triplet of nucleotide bases in mRNA which codes for a particular amino acid is called “codon”. In addition to “Structural genes” ( which are concerned with the synthesis of specific proteins), there are “control genes” which regulate the activity of structural genes. It was initially believed that genetic information was transferred from DNA to RNA and thence translated into protein. However, at times genetic information can occasionally flow from RNA to DNA (as in the case of retro virus). This is referred to as “RNA directed DNA synthesis”.

### Mutations

A mutation is defined as an alteration or change in the genetic material. Mutations are usually harmful and can arise due to exposure to mutagenic agents but may occur in a vast number of cases spontaneously through errors in DNA replication and repair. Although mutations can occur in “coding” or “non-

coding” sequences, it is only in the former that some disease or condition arises. A mutation occurring in a somatic cell cannot be transmitted to future generations. It is estimated that each individual carries upto six lethal or semi-lethal recessive mutant alleles which in the homozygous state would have very serious effects. Occurrence of mutations in DNA, if left unrepaired, would have serious consequences both for the individual and subsequent generations. The stability of DNA is dependent on “DNA repair”. Defects in this mechanism can lead to chromosomal breakage syndromes.

### Chromosomes

Chromosomes are thread like structures and can be considered to be made up of genes. The centromere divides the chromosome into short and long arms designated ‘p’ = petit and ‘q’ = grand respectively. The tip of each end is referred as telomere, which plays an essential role in sealing the ends of the chromosome. In human cells, there are 22 pairs of autosomes and a pair of sex chromosomes - XX in female and XY in male. One member of each chromosome is derived from each parent. Somatic cells have a diploid component consisting of 46 chromosomes whereas gametes (ova or sperm) have haploid complement of 23 chromosomes. Recent developments have allowed the study of chromosomes to detect regions of allele loss and gene amplification. The process of cell division ensures that the human zygote which is a single cell at conception undergoes rapid division leading to approximately  $10^{14}$  cells in an adult. In some organs and tissues, the process of cell division continues throughout life. In mitosis (somatic cell division) the chromosome divides longitudinally and after separation forms two daughter cells. In meiosis (gamete formation) the chromosome number is halved during Meiosis I while Meiosis II is like ordinary mitotic division. Meiosis facilitates halving of the diploid number of chromosomes so that each child receives half of its chromosome complement from each parent. It also provides an extraordinary potential for generating genetic diversity as DNA derived from both parents are present in each chromatid. The process of gametogenesis is different in male and female.

In oogenesis, oogonia derived from primordial germ cells start undergoing meiosis by 3 months of intra uterine life. At birth all the primary oocytes enter a phase of maturation arrest known as dictyotene in which they remain suspended until meiosis I is completed at the time of ovulation when a single secondary oocyte is formed. The lengthy interval between onset of meiosis and its eventual completion upto 50 years later has been suggested as the reason for the well documented increase in chromosomal abnormalities in offspring of older mothers.

In spermatogenesis, spermatogonia mature into primary spermatocytes at puberty. Spermatogenesis is a continuous process involving many mitotic divisions so that spermatozoa produced by a man of 50 years or older could well have undergone several hundred mitotic divisions. DNA copy errors may lead to mutations in offspring of older parents.

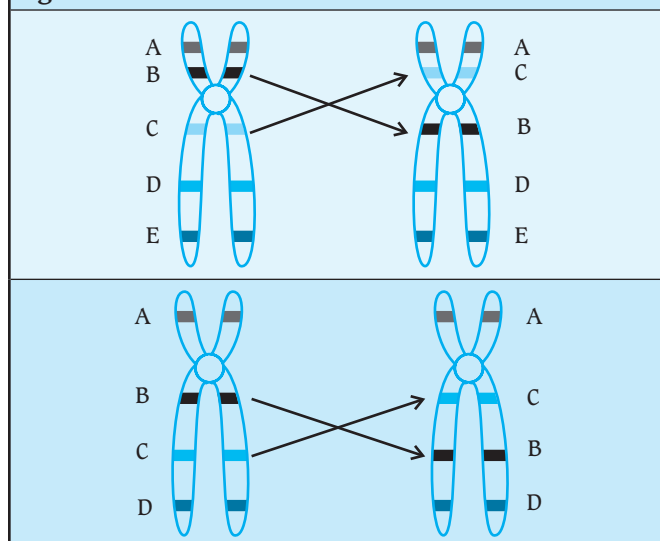
### Chromosomal Abnormalities

A large number of disorders are due to chromosomal abnormalities which can be due to either numerical or structural abnormality of chromosomes. Numerical abnormalities

involve the gain or loss of one or more chromosomes- aneuploidy or addition of one or more complete haploid complement of chromosomes - polyploidy. The common examples are Trisomy 21 (Down's syndrome), Trisomy 13 (Patau's syndrome), Trisomy 18 (Edward's syndrome), Monosomy X (Turner's syndrome), Super males (XYY) or Super females (XXX). The commonest cause is non-disjunction during meiosis (Fig.-4). Polyploidy is found relatively often in spontaneous miscarriage and is usually not commensurate with life. It is usually due to failure of a maturation meiotic division in ovum or sperm or fertilization of an ovum by two sperms.

Structural chromosomal abnormalities result from chromosome breakage with subsequent reunion in a different configuration (Fig. - 5). This may be due to translocation (transfer of genetic material from one chromosome to another), deletions (loss of part of a chromosome), insertions (segment of one chromosome becomes inserted into another chromosome), inversions (two break rearrangement involving a single chromosome in which a segment is reversed in position), ring chromosome (break on each arm of a chromosome leaving two "sticky" ends which reunite as a ring) and Isochromosomes (loss of one arm of a chromosome with duplication of the other arm). In all the structural abnormalities, when there is loss or gain of genetic material called balanced rearrangement, the effect is mild. When there is incorrect amount of genetic material due to loss or gain, it is called unbalanced arrangement and the clinical effects are usually very severe.

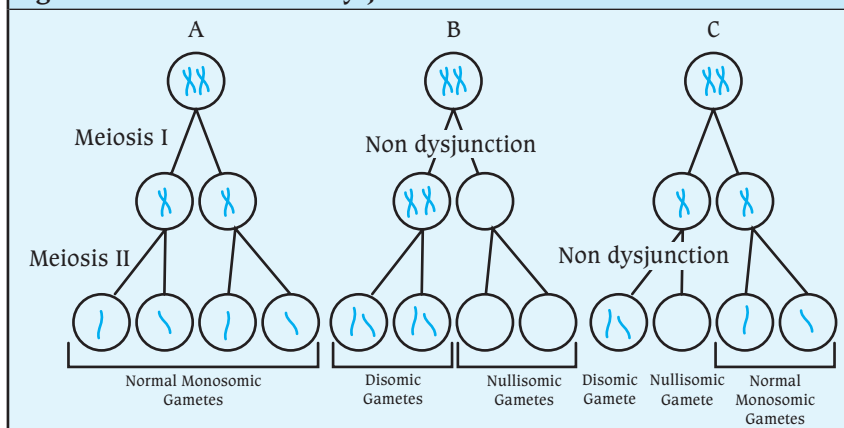
**Fig. - 5 : Chromosomal Abnormalities : Inversion**



### Incidence and Prevalence of Genetic disease

Genetic disease may manifest at birth or may remain without manifesting till several decades later. Besides the disorders which are clearly genetic in origin, several disorders like

**Fig. - 4 : Chromosomal Non-dysjunction**



Diabetes mellitus, cancers etc. are multi- factorial in origin. The genetic predisposition with suitable environmental conditions can lead to the occurrence of these diseases. The very process of aging is now considered to be genetically determined as are some of the diseases which have a rising incidence with age - "acquired somatic genetic disease".

Certain predictions have been made based on the assumption that heritability of disease declines with increasing age :

- Persons with early onset of symptoms are more likely to have severe disease and also to have affected first degree relatives.
- Age specific age at onset should reach a peak and then decline.
- Multi-genic diseases do not require a specific environment for their occurrence.
- Migration, socio-economic status and other environmental change may affect the age of onset and the likelihood of the clustering of the disease in families.
- If one sex is less often affected, early onset, severity and increased incidence in affected relatives should characterize it.
- Concordance in monozygotic twins should be greatest when disease onset is early.
- Patients with late onset of the disease have milder forms of the disease which are more amenable to prevention and treatment.

### Burden of Genetic Disease

The burden of diseases of genetic etiology in a community is determined by the "Gene pool", customs regarding marriage (breeding patterns) and migrations. The social and demographic structures of populations play a very significant role in the distribution patterns of specific inherited disorders. In countries with recent industrialization and urbanization, widespread population movement from the countryside (rural areas) to rapidly expanding towns and cities (urban areas) have resulted in dissolution of historical, local, regional and national boundaries. This has helped to exert a partial homogenizing effect on national gene pools. This is similar to the effect that large scale migration from Europe to Americas and Australia had in the previous centuries which resulted in significant mixing of previously distinct populations.

In most developing countries, local and regional clan, tribal and ethnic grouping have largely remained intact. In India, Pakistan and Bangladesh which collectively account for more than 20% of the world's population, marriage continues to be arranged within caste and *biraderi* boundaries that probably date back some 3000 years. In India, it is estimated that there are 50,000 to 60,000 separate endogamous communities. 25 percent of the population of more than 1 billion are members of the scheduled castes and scheduled tribes which number more than 1600. Muslims account for 130 million of India's population. Each of these groupings forms separate breeding pools - Hindus (divided into castes & regions), Muslims, Sikhs, Christians, Jains, Buddhists, Parsis etc.

Therefore diseases caused due to mutations of ancient origin are likely to be distributed throughout the population. However diseases due to mutation which have arisen more recently may be restricted or even unique to individual ethnic groups, sub-castes, tribes or clans.

Although adequate statistics are not available in India of the incidence and prevalence of genetic disorders, certain studies have attempted to estimate the burden due to genetic diseases in India. The large population, high birth rate and favouring of consanguineous marriage by significant numbers of communities, should lead to high prevalence of genetic disorders in the country. According to a study it is estimated that every year 4,95,000 infants with congenital malformations, 3,90,000 with G-6 PD deficiency, 21,400 with Down's Syndrome, 9,000 with thalassaemia, 5,200 with sickle cell disease and 9,760 with amino acid disorders are born each year. Studies on haemoglobinopathies indicate that they represent a significant national health burden in India. Distribution of specific disorders varies geographically and by community. Heterozygote frequencies of thalassaemia range from 1 to 15 percent resulting in an estimated 20 million carriers. Sickle cell anaemia is mainly present in tribal communities with carrier presence as high as 40 percent in some cases. It is estimated that there are 50,000 affected Hemophilia patients nation wide with an additional 1,500 new cases born each year. The prevalence of late onset multifactorial disorders including coronary artery disease, hypertension and psychiatric disorders is also large. Genetic eye disorders have been reported in large numbers. Shankar Nethralaya, the premier institute for ophthalmology in South India has reported 2,335 patients with genetic eye disorders over a five year period. 673 (28.8 percent) of these patients reported a family history of consanguinity. Retinitis pigmentosa was detected in a large proportion (63.9 percent) of those reporting family history of consanguinity.

The seriousness of the burden of genetic disorders in India is thus clearly appreciable inspite of lack of population based studies. Determining the role of genetics in disease will require better methods of classifying disease and processing health data. Computerized record keeping will become very important not only to build longitudinal health histories on individuals but also to link these into sibships and family groupings. Administrative and other health data sets that already exist can be combined to evaluate if familial clustering occurs. If familial clustering is detected, then various methodologies may be used to untangle whether this is due to genetic or shared

environmental factors or more likely to be an interaction between the two.

### Categories of Genetic Disease

The broad classification of various categories of genetic disease has evolved with the availability of sophisticated diagnostic tools which has enabled identification of genetic and molecular basis of these disorders.

### Chromosomal Disorders

Since the demonstration in 1959 that the presence of an additional number 21 chromosome (Trisomy 21) results in Down's syndrome, more than 1,000 chromosomal syndromes have been reported. They have a major contribution to morbidity and mortality in infants and account for a large proportion of spontaneous abortions. Chromosomal abnormalities have been detected in 10 percent of spermatozoa and 25 percent of mature oocytes. It is estimated that 15-20 percent of pregnancies do not survive beyond a few weeks due to presence of chromosomal abnormalities and also that more than 50 percent of all spontaneous abortions are having chromosomal abnormalities. The common abnormalities are :

- Trisomy (50 percent)
- Monosomy X (20 percent)
- Triploidy (15 percent)
- Tetraploidy (5 percent)
- Others (10 percent)

The presence of chromosomal abnormality in newborns ranges up to 90 per 10,000 births. The common abnormalities are Autosomal (20 per 10,000) & Sex chromosome (30 per 10,000). The presence of chromosomal abnormality reduces from conception to birth. The presence in still births is about 5 percent. It is known that spontaneous pregnancy loss occurs commonly in the presence of chromosomal abnormalities, with as high as 80%-98% pregnancies being lost among foetus having Monosomy or various forms of Trisomy. The common chromosomal disorders are :

#### Autosomal Disorders (Gain of entire chromosome)

- Down syndrome (Trisomy 21)
- Patau syndrome (Trisomy 13)
- Edward's syndrome (Trisomy 18)

#### Chromosomal Deletion Syndromes (Deletion of part of chromosome)

- Wolf Hirschhorn syndrome (Chromosome 4)
- Cri-du-chat syndrome (Chromosome 5)
- Retinoblastoma (Chromosome 13)
- Wilm's tumour (Chromosome 11)

#### Sex Chromosomal Disorders (Gain or loss of entire chromosome or part)

- Klinefelter's syndrome (47, XXY)
- Turner's syndrome (45, X)
- Super females (47, XXX)
- Super males (47, XYY)
- Fragile X Syndrome (46, XX\*)

The chromosomal disorders are all potentially detectable by pre natal diagnosis. Since only those subgroups of women identified as being at higher risk (due to family history or age) are screened pre-natally, there is an opportunity to avoid only a proportion of these conditions at present.



## Single Gene or Mendelian Disorders

Credit for the first recognition of a single gene trait is shared by William Bateson and Archibald Garrod who together proposed that alkaptonuria was a rare recessive disorder. Since then many more disorders have been identified - by 1966 almost 1500 single gene disorders or traits had been identified which follow the mendelian rules of inheritance. An American physician, Victor McKusick published a catalogue of all known single gene disorders. An online version of McKusick's catalogue has been created which is known as "Online Mendelian Inheritance in Man" (OMIM) which can be accessed on the World Wide Web. As on 07 July 2008, there were 18,811 single gene traits or disorders which were included in this catalogue. There are mainly four categories into which single gene disorders are grouped, based on patterns of inheritance as indicated below :

### Autosomal Dominant Disorders (AD)

An autosomal dominant trait is one which manifests in the heterozygous state i.e. in a person possessing both the abnormal or mutant allele and the normal allele. It is often possible to trace a dominantly inherited trait or disorder through many generations of a family. The disorder is transmitted to both sexes of the progeny. Any child born to a person affected with a dominant trait has a one in two (50%) chance of inheriting it and being similarly affected. Autosomal dominant traits can involve only one organ or part of the body e.g. Polydactyly. The clinical features can show striking variation from person to person and in some cases the findings can be undetected - "reduced penetrance" possibly due to the modifying influence of other genes. Examples of autosomal dominant traits or disorders are Huntington's chorea, Neurofibromatosis, Polyposis coli. There may be also some cases due to new mutations. In these cases it will not be possible to trace the trait in the family and hence pose problems in genetic counselling.

### Autosomal Recessive Disorders (AR)

Most recessive disorders are individually rare, each with a birth prevalence of 1 in 15,000 to 1 in 1,00,000. However, since there are so many, they have a considerable impact with 1 in 500 live born individuals being identified as having one of these disorders before age 25 yrs. The recessive traits and disorders are only manifest when the mutant allele is present in a double dose i.e. homozygosity. Individuals who are heterozygous for a recessive mutant allele show no features of the disorders and are perfectly healthy i.e. they are carriers. It is usually not possible to trace an autosomal trait or disorder through the family tree. However, consanguinity can be detected in the ancestors. Generally speaking, the rarer a recessive trait or disorder, the greater the frequency of consanguinity among the parents of the affected persons. Autosomal recessive traits are transmitted both to sons and daughters equally and both are capable of transmitting it to their sons and daughters. The progeny may however, not manifest unless they are in homozygous state. The chance of having an affected child inheriting the recessive trait is 1 in 4. Common examples of autosomal recessive traits or disorders are : cystic fibrosis, albinism, alkaptonuria, and haemoglobinopathies.

## Sex Linked Inheritance

It refers to the pattern of inheritance shown by genes which are located on either of the sex chromosomes. Genes carried on the X chromosome are referred to as X-linked, while genes carried on the Y chromosome are referred to as exhibiting Y-linked or "Holoandric inheritance".

**X-linked Recessive disorders (XR)** : An X linked recessive trait is one determined by a gene carried on the X chromosome and usually only manifests in males. These disorders are transmitted by healthy heterozygous female carriers to affected males, as well as by affected males to their obligate carrier daughters. The mode of inheritance whereby only males were affected by a disease which is transmitted by normal females was appreciated by the Jews nearly 2000 years ago. They were excused from circumcision, the son of all sisters of a mother who had sons with the "bleeding disease" i.e. Haemophilia. The sons of the father's sibs were not excused. A male transmits his X chromosome to each of his daughters and his Y chromosome to each of his sons. If a male affected with Haemophilia has children with a normal female, then all his daughters will be obligate "carriers", but none of his sons will be affected. A male can not transmit his X-linked disorder to his son except in very rare circumstances. For a carrier female having children with a normal male, each son has a 1 in 2 (50%) chance of being affected and each daughter has a 1 in 2 (50%) chance of being a carrier. Duchenne muscular dystrophy and Haemophilia are common examples of X-linked recessive disorders.

**X-linked Dominant Disorders (XD)** : There are few disorders in this category like familial Hypophosphataemia with rickets, Alport's syndrome etc. It superficially resembles autosomal dominant inheritance. Both sons and daughters of an affected female have a 1 in 2 (50%) chance of being affected. However, an affected male transmits only to his daughters and not to his sons. Affected females are more common than males but are less severely affected as compared to males.

**Y-linked Inheritance** : Y-linked or holandric inheritance implies that only males are affected. An affected male transmits Y-linked traits to all his sons but not his daughters. Hairy ears, H-Y histocompatibility antigens and genes involved in spermatogenesis are carried on Y chromosome and therefore transmitted accordingly.

### Mitochondrial Genetic Disorders

Genes coding for proteins involved in oxidative phosphorylation are located in mitochondria in human cells. These are always inherited from the mother. Disorders involving these genes therefore do not behave like other mendelian disorders. Some examples of mitochondrial genetic disorders are Leber's optic atrophy, infantile bilateral striatal neurosis and Kearns-Sayre syndrome.

## Multifactorial Disorders

Many disorders demonstrate familial clustering which does not conform to any recognized pattern of mendelian inheritance. Francis Galton, a cousin of Charles Darwin, had carried out research on human characteristics like stature, physique and intelligence based on studying identical twins. The differences among twins in these parameters could only be



due to environmental influences. He introduced to genetics the concept of “Regression co-efficient” as a means of estimating the degree of resemblance between various relatives. This model, polygenic inheritance, of quantitative inheritance in which many genes play a role in the phenotypic expression is now widely accepted to explain the pattern of inheritance of many relatively common conditions including cleft lip and palate, hypertension and diabetes mellitus. The underlying genetic mechanisms are however, still not well understood.

The liability / threshold model to explain multi-factorial inheritance of disorders proposes that a threshold exists above which the abnormal phenotype is expressed. This hypothesis (rather than proven fact) helps to explain the observed system of inheritance of certain multi-factorial diseases like cleft lip/palate, pyloric stenosis and spina bifida as follows :

- The incidence of the condition is greatest amongst relatives of the most severely affected patients.
- The risk is greatest amongst close relatives of the index case and decreases rapidly in more distant relatives.
- If there is more than one affected close relative then the risks for other relatives are increased.
- If the condition is more common in individuals of one particular sex, than relatives of an affected individual of the less frequently affected sex will be at higher risk than relatives of an affected individual of the more affected sex.
- The risk of recurrence for first degree relatives (siblings and offsprings) approximates to the square root of the general population incidence, for e.g. if the incidence in the general population of a disease is 1 : 1000, the risk for first degree relatives of an affected person will equal approximately 1 in 32 or 3%.

The inheritance patterns in insulin dependent diabetes mellitus or type - I diabetes mellitus lends a good example of the above elucidated multi-factorial inheritance. The concordance rate in monozygotic and dizygotic twins is 50% and 12% respectively. The sibling recurrence risk is 6%. These observations point to contributions both by environmental and genetic factors. Known environmental factors include diet, viral exposure in early childhood and certain drugs. The disease produces irreversible destruction of insulin producing beta cells in the pancreas by the body's own immune system probably as a result of an interaction between infection and an abnormal genetically programmed immune response. The polygenic susceptibility consists of one major locus (IDDM-1, which is in the HLA locus on chromosome 6p21), and up to 20 minor loci. The product of these gene loci are believed to interact in a complex and poorly understood manner to confer susceptibility to environmental triggers of auto immune pancreatic beta cell destruction.

### Acquired Somatic Genetic Disease

Not all genetic errors are present from conception. During the billions of cell division (mitosis), which occur during the life time, the opportunity for occurrence of mutations due to DNA copy errors and numerical chromosomal errors exist. Accumulating somatic mutations and chromosomal abnormalities are now known to account for a large proportion

of malignancies and possibly explain the rising incidence with increasing age of many serious illnesses including the ageing process itself.

### Public Health Issues in Genetic Diseases

Epidemiological studies have helped us understand how genetic diseases are distributed in a population. Genetic methods are increasingly allowing us to identify genetically susceptible individuals. New molecular genetic techniques now allow particular DNA sequences to be evaluated in patients and compare with control subjects and hold out the hope for future progress in early detection and even management (gene therapy). Various considerations in prevention of genetic diseases, thus needs detailed analysis.

#### Primary Prevention

**Eugenics** : It is science of improvement of genetic endowment through breeding. It has long attracted the attention of mankind. The term was first coined by Francis Galton. “Positive Eugenics” seeks to improve the genetic endowment in the population of “favourable traits” by encouraging persons with these traits to intermarry. However, as we now know, the inheritance of most of these traits like appearance, skin colour, height, intelligence etc. are inherited in a complicated manner and are difficult to control. “Negative Eugenics” in which people suffering from serious disorders which are genetic in origin are debarred from producing children is practiced in most communities. Many countries do not allow migration of people who are known to have serious genetic diseases. However, as new mutations continue to occur negative eugenics can not be an effective public health tool to reduce the burden of genetic diseases.

**Genetic Counselling** : More than 40 years ago genetic counselling services to cater for the needs of persons seeking information regarding genetic diseases were first introduced. Genetic counselling caters for the concerns of individuals / families who have a family history of serious diseases. Their concern may be whether they can develop the disease or whether they can transmit the disease.

Genetic counselling has been defined as a process of communication and education which addresses concerns relating to the development and / or transmission of a hereditary disorder. The person who seeks genetic counselling is known as “consultand”. During genetic counselling, the counsellor tries to provide the consultand with information which enables him/her to understand :

- The medical diagnosis and its implications in terms of prognosis and possible treatment
- Mode of inheritance of the disorder and the risk of developing and / or transmitting it
- Choices or options available for dealing with the risks

Genetic counselling is non directive, with no attempt to lead the consultand in any particular direction. The process presents medical scientific facts / risks so that the “consultand” can make their own decisions. Commonly, people seek counselling after the occurrence of a hereditary disorder in the family. Rarely, individuals / couples may seek pre-marital advice. Usually , for diseases like mental retardation, congenital abnormalities, etc., there is occasional seeking of such counselling which is thus

“retrospective” in nature. In certain occasions there may be an attempt to identify heterozygous individuals for a disease and explaining the risks of marrying another heterozygote for the same disease - “prospective” counselling. In both prospective as well as retrospective counselling, the outcomes sought would range from contraception, pregnancy termination or even adoption of a child.

### Steps in Genetic Counselling

**Establishment of diagnosis** : It is the most crucial step in any genetic counselling. Misleading advice may be given based on incorrect diagnosis which may lead to tragic consequences. A correct clinical diagnosis will require proper history taking, detailed clinical examination and appropriate investigations. The family history may need to be obtained by a properly trained genetics nurse or counsellor. Chromosomal and molecular studies will also be needed to establish the inheritability and genetic basis of the disease. At times, for example in hearing loss, etiological heterogeneity may affect the ability to correctly calculate the “recurrence risk”. Other disorders like congenital cataract (AD, AR, XR), ichthyosis (AD, AR, XR), retinitis pigmentosa (AD, AR, XR) and polycystic kidney disease (AD, AR) can also show “genetic heterogeneity”.

**Calculating and presenting the risk** : This is the next step based on the genetic diagnosis and calculation of risk based on well established norms like use of Bayes Theorem or use of “empirical risks”. The recurrence risks need to be quantified, qualified and placed in context. A risk statement “1 in 4” can be misunderstood that once it has occurred it will recur only after 3 normal children. Inheritance does not have any “memory” and applies for each offspring. For a risk of recurrence of “1 in 25”, it must also be explained that “24 out of 25” chance is for a normal baby. The risk needs to be qualified by aspects like long term burden rather than its precise numerical value. For a trivial disorder like polydactyly even a risk of “1 in 2” may not deter having more children. Whether a disease can be successfully treated, associated with pain and suffering and whether pre-natal advice is available can be relevant to the decision making process. Placing the risk in context is equally important. For a disease with a population risk of 1 in 40, an additional risk of 1 in 50 may in fact be considered low. As an arbitrary guide, risk of 1 in 10 or greater can be regarded as high while 1 in 20 or less can be regarded as low.

**Discussing the options** : It is a natural follow up after making the diagnosis and presenting the “risks”. All the choices should be provided with no attempt made to guide the consultand to select one of them. The issues need to be broached with care and sensitivity as the realization of the disease, its risks and the likely outcomes may be cause of great emotional shock to the consultand.

**Communication and support**: It is provided by most genetic counselling clinics. The setting of the counselling must be agreeable, private and quiet with ample time for discussion and questions. As far as possible, technical terms must be avoided but no attempt must be made to hide facts and questions answered honestly and openly. It is necessary to reiterate the aspects covered specially the aspects of risk in written communication as all aspects may not have been clearly

understood by the Consultand during the limited duration of the counselling session. A letter summarizing the topics discussed is then sent to the Consultand. Informal contact through a network of genetic associates or nurse specialist are also an added features of genetic counselling clinics.

**Other Health Promotional Measures** : Problems of increased genetic diseases in late marriages and advancing age of mother are now common knowledge. Appropriate counselling is required to restrict pregnancies arising from late marriages or in women past 35 years.

Consanguineous marriages are another cause for concern. Community involvement will be needed to overcome this social occurrence. A consanguineous marriage is defined as one in between blood relatives with at least one common relative no more remote than great-great-grand parents. Hearing loss, mental retardation, alkaptonuria are common among offsprings of consanguineous marriages.

**Specific Protection** : Radiation, chemicals and drugs are known to produce mutations and teratogenic effect. Adequate protection is needed to be ensured for persons in the reproductive age group. X-Ray and other ionizing radiations produce mutations which are proportional to the dose of radiation. There is no threshold. Genetic effects are known to be cumulative and protection is routinely provided to all those who are likely to be occupationally exposed to radiation.

Chemicals like mustard gas, benzene, formaldehyde, caffeine, etc. are known mutagens in animals. Caution is therefore required to prevent exposure to these and basic dyes by human specially those in the reproductive age groups. A large number of drugs have been known to be teratogenic and need to be avoided in pregnancy.

**Early Diagnosis** : Increasing awareness of the role of genetics in the etiology of disease and its overall impact on the burden imposed on individuals, families and society has lead to introduction of several population genetic screening programs. The primary objective is to enable individuals to be better informed about genetic risks and reproductive options. A secondary objective is the prevention of morbidity due to genetic diseases and alleviation of the suffering. The scope of early diagnosis thus covers apparently healthy persons who may wish to be made aware of genetic disease in themselves or their offspring, diagnosis of the presence of genetic abnormalities in utero as well as the new born and for diagnosis of genetic disease or carrier state in the siblings of a person (adult or child) diagnosed with a genetic disease.

A number of tests of different types are available to detect carriers for Autosomal and X-linked recessive disorders and for pre-symptomatic diagnosis of heterozygotes for Autosomal dominant disorders. Biochemical or hematological techniques can be used to detect carriers of Autosomal recessive disorders like Tay-sachs disease (reduced hexosaminidase A levels in serum), sickle cell disease / trait ( sickling of RBCs in deoxygenated condition), Duchenne muscular dystrophy (elevated serum creatinine kinase level) and G-6PD deficiency (reduced erythrocyte - G6PD activity). However these tests are reliable only in those cases where the gene involved is directly involved in the biochemical activity.

<b>Table - 1 : Pre-natal diagnostic techniques</b>			
<b>Technique</b>	<b>Test &amp; Result</b>	<b>Foetal age</b>	<b>Genetic conditions diagnosed</b>
Chorionic villus sampling (2-3% risk of miscarriage)	Chromosome analysis	10-11 wks	Chromosomal abnormalities
	Biochemical assay		Metabolic disorders, Molecular defects
Amniocentesis (0.5-1% risk of miscarriage)	$\alpha$ -fetoprotein raised	16 wks	Neural tube defects
	Chromosome analysis		Chromosomal abnormalities
	Biochemical assay		Metabolic disorders, Molecular defects
Ultrasound ( also indirect evidence of chromosomal disorders)		18 wks	Structural abnormalities (heart, kidney, limbs, CVS)
Fetoscopy (3-5% risk of miscarriage)		2nd trimester	Structural abnormalities & others
Radiography (now rarely used)		10 wks	Skeletal dysplasias
Maternal serum screening (usually standard screening for "at risk" mothers)	Fetoprotein raised	16 wks	Neural tube defects
	Quad test - $\alpha$ -fetoprotein reduced - Unconjugated oestriol reduced - HCG increased - Inhibin A increased		Down's syndrome

<b>Table - 2 : Treatment modalities in genetic diseases</b>	
<b>Treatment</b>	<b>Disorder</b>
<b>Enzyme induction by drugs :</b> Phenobarbitone	Congenital Non-haemolytic Jaundice
<b>Replacement of deficient enzyme / protein :</b> Blood transfusion $\alpha$ -glucosidase Factor VIII	SCID Gaucher's disease Haemophilia A
<b>Replacement of deficient vitamin / co-enzyme :</b> B <sub>6</sub> D	Homocystinuria Vit D resistant rickets
<b>Substrate reduction in diet :</b> Phenylalanine Leucine/isoleucine/valine Galactose Cholesterol	Phenylketonuria Maple syrup disease Galactosaemia Fam. hypercholesterolaemia
<b>Drug therapy :</b> Pancreatic enzymes Penicillamine	Cystic fibrosis Wilson's disease
<b>Replacement of diseased tissue :</b> Kidney transplant BM transplant	Polycystic kidney disease X-linked SCID
<b>Removal of diseased tissue:</b> Colectomy Splenectomy	Polyposis coli Hereditary spherocytosis

Until the recent past, couples at high risk of having a child with a genetic disorder had to choose between taking the risk or considering other reproductive options. In the recent past reliable pre-natal diagnosis of abnormalities in an unborn child have been widely used to assist decision making by such couples. The ethical issues are however very complex. The techniques used are amniocentesis, chorionic villus sampling, ultrasonography, fetoscopy, foetal blood sampling, radiography and maternal serum screening. A summary of the techniques is indicated in Table - 1.

**Treatment** : A large number of genetic diseases are “treatable” and the disablement reduced provided the defect has been diagnosed in time. Some of these treatable conditions are enumerated in Table - 2. Although still in the realm of research, gene therapy to correct the genetic abnormality is a distinct possibility and needs serious consideration.

### Strategy for public health action

The volume of new knowledge and technologies from genetic and genomic research is such that a concerted effort is needed to ensure the effective translation of these scientific advances into benefits for population health. International consensus has been achieved on a public health strategy for achieving this goal. This strategy recognizes the importance of knowledge integration. This integrated and interdisciplinary knowledge base is used for informing public policy, developing new health services (both preventive and clinical), communication and stakeholder engagement, and education and training of health professionals. A new initiative GRAPH *Int* (Genome-based Research And Population Health International) has been established to promote this strategy for public health action in the genomics era. It facilitates the responsible and effective integration of genome-based knowledge and technologies into public policies, programme and services for improving the health of populations. Practitioners of public health are expected to contribute to this endeavour by remaining aware of the growing importance of the understanding of genetic mechanisms in disease & of the potential to utilize the new genetic knowledge for the benefit of both individuals & society.

### Summary

Our present understanding of human genetics owes much to the work of Sir Gregor Mendel in 1865 on breeding experiments on garden peas. In 1962, James Watson and Maurice Wilkins discovered the structure of DNA. The gigantic “Human Genome Project” started in 1991 by US Govt to map the complete human genome to tap its tremendous potential for diagnosis and management of human disease through ‘gene therapy’. Genetic disease may manifest at birth or later or may remain without manifesting. Broadly genetic diseases are classified as Chromosomal disorders - numerical chromosomal abnormalities arising due to non-disjunction during meiosis while structural chromosomal abnormalities results from chromosomal breakage syndrome; Single gene / Mendelian disorders-includes autosomal dominant, autosomal recessive & sex linked disorders; Mitochondrial disorders; Multifactorial disorders-viz spina bifida, diabetes mellitus, cleft lip & cleft palate etc; and Acquired somatic genetic disease-due to accumulation of somatic mutations & aging process itself.

Newer molecular genetic techniques allows to detect particular DNA sequence responsible for causation of disease and therefore escalating importance of prevention of genetic diseases by ethically utilizing preventive approaches viz Eugenics, Genetic counselling, avoidance of consanguineous & late marriages and avoiding exposure to radiation, mutagenic/ teratogenic chemicals and drugs. Besides, myriad of population genetic screening tests and prenatal diagnostic tests are also available for early detection and timely intervention. A new initiative GRAPH *Int* - Genome based research and population health international has been established to promote the strategy for public health action in this genomic era.

### Study Exercises

1. The Austrian monk who presented the results of his breeding experiments on garden peas in 1865 was (a) James Watson (b) Gregor Mendel (c) William Bateson (d) Johannsen
2. The term ‘Gene’ was coined by (a) James Watson (b) Gregor Mendel (c) William Bateson (d) Johannsen
3. The double helical structure of DNA was proposed by (a) Watson & Crick (b) Mendel & Wilkins (c) Bateson & Garrod (d) Johannsen & Maurice
4. How many genes are estimated to be in the human genome (a) 50,000 (b) 1,00,000 (c) 1,50,000 (d) 2,00,000
5. The process where genetic information is transmitted from DNA to RNA is called (a) Processing (b) Transcription (c) Translation (d) Sequencing
6. The site for protein synthesis in the cell is the (a) Mitochondria (b) Nucleus (c) Cytoplasm (d) Ribosome
7. How many amino acids are involved in formation of proteins (a) 10 (b) 15 (c) 20 (d) 25
8. The triplet of nucleotide bases in mRNA which codes for a particular amino acid is called (a) Structural genes (b) Codon (c) Control genes (d) Genome
9. The stability of DNA is based on (a) Coding (b) Non-coding (c) Mutation (d) DNA repair
10. The process of cell division ensures that the human zygote which is a single cell at conception undergoes rapid division leading to cells in an adult (a)  $10^4$  (b)  $10^{10}$  (c)  $10^{14}$  (d)  $10^{20}$
11. Edward’s syndrome is (a) Trisomy 21 (b) Trisomy 13 (c) Trisomy 18 (d) Trisomy 22
12. Patau’s syndrome is (a) Trisomy 21 (b) Trisomy 13 (c) Trisomy 18 (d) Trisomy 22
13. Concordance in monozygotic twins should be greatest when disease onset is early: True/False
14. Multigenic diseases require a specific environment for their occurrence. True/False
15. The burden of diseases of genetic etiology in a community is determined by all except (a) Gene pool (b) Breeding pattern (c) Migration (d) None
16. Chromosomal deletion disorder associated with Chromosome 4 is called (a) Wolf Hirschhorn syndrome (b) Cri-du-chat syndrome (c) Retinoblastoma (d) Wilm’s tumour
17. Chromosomal deletion disorder associated with Chromosome 13 is called (a) Wolf Hirschhorn syndrome (b) Cri-du-chat syndrome (c) Retinoblastoma (d) Wilm’s tumour



18. As on 07 July 2008, there were \_\_\_\_\_ single gene disorders included in McKusick's catalogue (a) 16,811 (b) 17,811 (c) 18,811 (d) 19,811
19. The genes coding for proteins involved in oxidative phosphorylation are located in (a) Mitochondria (b) Nucleus (c) Cytoplasm (d) Ribosome
20. The concept of "regression coefficient" as a means of estimating the degree of resemblance between relatives was given by (a) James Watson (b) Gregor Mendel (c) William Bateson (d) Francis Galton
21. In multifactorial diseases, the incidence of a condition is greatest among relatives of the most severely affected patients : True/False
22. The science of improvement of genetic endowment through breeding is (a) Eugenics (b) Euthenics (c) Genetic counselling (d) None
23. The term 'Eugenics' was coined by (a) James Watson (b) Gregor Mendel (c) Francis Galton (d) Johannsen

24. The person who seeks Genetic counselling is called

25. GRAPH *Int* stands for \_\_\_\_\_

26. Chorionic Villous Sampling is ideally done at (a) 8 -10wks (b) 10 -12wks (c) 12 -14wks (d) 14 -16wks

**Answers :** (1) b; (2) d; (3) a; (4) b; (5) b; (6) d; (7) c; (8) b; (9) d; (10) c; (11) c; (12) b; (13) True; (14) False; (15) d; (16) a; (17) c; (18) c; (19) a; (20) d; (21) True; (22) a; (23) c; (24) Consultant; (25) Genome-based Research & Population Health International; (26) b.

### Further Suggested Reading

1. Genetics in disease prevention. Ron Zimmern and Alison Stewart in Oxford Handbook of Public Health Practice. 2nd ed, 2007. 276-281
2. Genetics and the Public Health. Patricia A. Baird and Charles R Scriver in Maxcy-Rosenau-Last. Public Health & Preventive Medicine. Appleton & Lange. 14th ed, 1998. 1069-1080
3. Human and medical genetics. Friedrich Vogel and Arno G. Motulsky in Oxford Textbook of Public Health. 4th ed, 2002. 131-148.

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## Preventive Health Care of the Elderly

*RajVir Bhalwar*

In general, "elderly" age group is defined as persons aged 65 years and above. With improvements in health care, there have been resultant increases in life expectancy and increase in the percentage of "elderly population". For instance, the current estimates are that in our country the percentage of population who are aged 65 years and above, which was 3% a few decades back, is now 5% and is likely to increase to 10% by 2025 AD and 18% by 2050 AD. These demographic changes will require shifting our focus to cater to geriatrics. i.e. special preventive health care needs as well as medical care needs of the elderly population.

### Peculiarities of elderly population in context of health needs

The peculiarities of health needs of elderly people are that their health problems cannot be seen in isolation. There is a wide gamut of social, psycho-emotional and physical correlates which determine the medical problems and this entire gamut of factors (and not simply the treatment of concerned condition) needs to be addressed. The important ones of these factors are as follows :

**Social Aspects :** As industrialization progresses, it will be difficult for the children to stay on with their parents and carry on with the conventional family occupations. As children move out and take up the vocation in other places, the problems

of isolation and lack of physical support of the old parents, left behind at ancestral places, will come up. Even day to day requirement of life like going out to pay the electricity / telephone bills, buying fresh fruits and vegetables and even cooking a proper nutritious meal would become difficult.

**Psycho-Emotional Aspects :** With loneliness at home, isolation will occur which would get aggravated if one of the spouses passes away. Friend circle will also get restricted because friends would also get old. The problem of isolation would get worse because of retirement when the old persons would find it difficult to keep them occupied. This complex interplay will not only increase the risk of mental stress and its consequences but also aggravate the impact of stress related diseases as IHD and hypertension.

**Financial Issues :** Unless backed up by adequate financial savings or pension plans, or else financially assisted by children, there will be definite reduction in income, to the extent that it may interfere with bare needs of life as adequate nutrition, clothing and shelter.

**Issues Related to Health care System :** At present we do not have a very effective health insurance system in our country, which coupled with the inadequacies of public / Govt. funded general health care system and inadequate training of medical, paramedical personnel in geriatric medicine would adversely affect the health care of the elderly.

### Medical Problems of the Elderly

A description of medical problems of the elderly is given in this chapter. However, as said earlier, these problems should not be seen as isolated medical issues but should be viewed in the larger context of socio-economic-emotive determinants as

an overall health issue. For example, organizing an eye camp for the elderly would have little benefit if the transportation system, traffic control and street / domestic lighting is not improved.

Medical officers and public health programme managers should make special efforts to understand both the preventive as well as curative aspects of health care of the elderly since a significant proportion of our clientele would belong to this age group, and the proportion is likely to further increase, given the steady increases in life expectancy that are occurring in our population.

The health problems of elderly can be divided into 3 groups :

- (a) Problems which are important for both genders.
- (b) Problems which mainly concern the elderly males.
- (c) Problems which mainly concern the elderly females.

#### **Problems which are Important for Both the Genders**

**Ocular Diseases** : Age related diminution of vision and cataracts are major issues among elderly and significantly compromise the quality of life as well as Activities of Daily Living (ADL). Glaucoma also is an important cause of suffering among elderly.

**Hearing Defects** : Reduction in acuity of hearing not only compromises the quality of life but even drives an old person into emotional isolation because they find it difficult to communicate.

**Reduced Muscular Strength and Coordination** : Reduction in muscular strength due to reduction in lean mass coupled with reduced flexibility and neuromuscular coordination occurs with age and results in increased proneness to accidents and injuries.

**Accidents and Injuries** : There is marked increase in risk of accidents and injuries among the aged. The major physiopathological factors which contribute to such increased proneness are diminution of vision and hearing, reduced muscular strength and neuro-muscular coordination, and various environmental factors, notably wet, slippery floors and poor lighting. The commonest areas of accidents are the toilet (due to wet floor, and a large number of fixtures in a small space), kitchen (mainly due to open flames), staircases and roads.

**Nutritional Deficiencies** : Both macro and micronutrient deficiencies are common among elderly. They result due to interplay of four major reasons, viz., lack of financial resources to buy nutritious food items; reduced ability to go out to the market and buy nutritious raw items; reduced physical abilities with resultant reduced ability to cook nutritious meals; and physical ailments especially oro-dental problems causing difficulty in mastication and reduced sense of taste.

**Dental Problems** : Reduction in number of teeth / edentulousness interferes with mastication, digestive process and also with the desire to eat. Ill-fitting dentures further aggravate the problem.

**Cardiovascular Diseases** : The end result of atherosclerotic process becomes most evident in the elderly age group. The incidence (as well as mortality due to) of IHD, Stroke and Hypertension is significantly increased in this age group.

**Increased Susceptibility to Adverse Effects of Physical Environment** : People aged >65 years are more susceptible to adverse effects of heat (heat stroke and heat exhaustion) as well as environmental cold (generalized hypothermia and local adverse effects of cold).

**Increased Susceptibility to Infections** : Age >65 years increases the susceptibility to nearly all infections due to decline in immunologic defenses. More particularly, lower respiratory tract infections (pneumonia) and urinary tract infections are an important cause of morbidity and mortality among elderly.

**Degenerative Neurological Diseases** : Alzheimer's disease and Parkinsonism are almost exclusively encountered among elderly. Besides morbidity, these diseases substantially reduce the quality of life.

**Complication of Diabetes** : The micro vascular as well as macro vascular complications are more prominent during advanced age.

**Cancers** : Oral, gastric, lung and colorectal cancers are more common in elderly age group.

#### **Problems which mainly affect the Elderly Male**

**Benign Prostatic Hypertrophy (BPH)** : This is one of the commonest diseases affecting males >50 years, particularly >60 years age.

**Prostatic Cancer** : The incidence shows a steep climb after 50 years age. Yearly Digital Rectal Examination (DRE) is a good screening tool for both BPH and prostate cancer. In addition, Prostate Specific Antigen (PSA) could be useful screening test for prostate cancer after 50 years of age. Levels of < 4 ng/ml can be considered as normal, 4 to 10 ng/ml as suspicious and >10 ng/ml as strongly suspicious and need to be followed up with a biopsy.

**Male Sexual Dysfunction** : Male sexual dysfunction among elderly may manifest as either libido, erectile or ejaculation problems.

#### **Problems which mainly concern with Elderly Females**

**Menopausal Problems** : There are five areas which are predominantly affected by menopause - increased risk of cardiovascular diseases; genitourinary atrophy; skeletal bone loss; skin and hair changes; and neuroendocrine and vasomotor changes. Skin changes include loss of elasticity (apparent as lagging and wrinkled skin), dryness of mucosal surface, minor facial hirsutism and voice changes. Uro-genital changes include atrophic vaginitis, dyspareunia, pruritis vulvae and irritable bladder. Neuroendocrine changes include hot flushes (which may sometimes interfere with quality of life) and psychological/ mood problems.

**Urinary Incontinence** : The impact is considerable both from medical as well as psychological point of view.

**Cancers and Other Disease of Female Genital Tract** : The 3 major cancers of genital tract affecting the elderly women are uterine (endometrial), ovarian and cervical cancers. Prolapse of uterus is another debilitating problem among elderly females.

**Osteoporosis** : Osteoporosis occurs in both sexes (Type-II Osteoporosis) but the incidence as well as the impact is much higher among females especially after menopause (Type-I

osteoporosis). Osteoporosis represents only a small proportion of the problem, in any community, for every case of osteoporosis there would be additional 3-4 cases of osteopenia. Osteoporosis results in a large number of low-trauma fractures. The major fracture sites are hip, spine, wrist and pelvis. Risk factors for primary osteoporosis include low body weight, history of prior fracture, family history of maternal hip fracture, lack of dietary calcium and vitamin D, menopause, lack of weight bearing exercise, smoking and excessive alcohol use, tall and thin stature and white-race. Weight of <58 kg may indicate risk. In fact, a rough guide is to calculate an index as  $\{0.2 \times (\text{Body weight in Kg} - \text{Age in years})\}$ ; if the result is less than 2, the same indicates increased risk.

### Prevention & Control

Prevention and control of health problems of elderly would need multifaceted approach. A well coordinated approach from health, social welfare, rural / urban development and legal sectors is desirable.

**Developing a Policy and Programme** : A community based geriatric health care programme should start with development of a policy, which should be comprehensive so as to include not only medical aspects but the large gamut of social, economic and emotive aspects of geriatric problems as well. Strong political commitment and social action is imperative for the enunciation and implementation of such a policy. There is also a need to translate such policy into a comprehensive geriatric health care programme, to be delivered at the grass root level by the general health services, but coordinated at the district / state level by specialized personnel.

**Social Measures** : Developing social ethos wherein children voluntarily take the responsibility of looking after their aged parents is important. In fact, young people need to be educated and motivated to utilize the experience and support of their parents / grandparents in day to day household matters to facilitate passing on the cultural heritage to the children. There is also a need to develop regulatory mechanisms which make it obligatory for the members of society to look after their aged parents.

**Developing a Health Insurance Scheme** : A large majority of the elderly are those who are not covered by any formal public sector health care support, unlike retired govt. servants. The need is to develop an affordable health insurance scheme in which people contribute, along with the employer and the government, to cater to subsequent expenses on medical care during old age.

**Pensionary Benefits** : Similar to the health insurance schemes suggested above, there is need to develop pension schemes based on contribution from employee, employer and government, so that old people can feed for themselves during old age, even if not supported by their children.

**Proper Construction of Roads, Walkways, Stair cases and Houses** : Accidents and injuries are an important cause of morbidity and mortality among the elderly. Proper designing of roads / walkways, and stair cases, along with adequate enforcement of traffic rules is a clear need. In addition, construction of "elderly friendly houses", giving particular attention to construction of toilets, kitchens, bedrooms and

common galleries is important. In general, the principles of construction and maintenance are that the floor should not be slippery / wet; that the fixtures and furniture should be adequately separated giving enough space for movement; lighting should be adequate; staircases should have side-supports, made of non-slippery material and be well lighted; open flames should be restricted to the minimum and, preferably, enclosed.

**Health Measures**: These include the following :

**Need to Initiate Primary Preventive Measures in Early Adulthood** : While a number of diseases finally manifest in elderly age (as cardiovascular disease, osteoporosis, cancers), the basic pathologic processes start during early adulthood, even during adolescence. Therefore, it would be wise for children / young people to start prevention at young age itself through healthy lifestyle (adequate and regular physical exercise, healthy diet, avoidance of tobacco and alcohol use). The details are discussed in the section on healthy lifestyle.

**Information, Education & Communication Strategies** : Health education should focus towards three broad groups - firstly, the elderly persons, secondly, the middle aged who would move into elderly age group in near future and thirdly the younger people who are the potential care providers for their elderly parents / relatives. The major areas of education should address the issues of hygiene, nutrition, physical exercise, avoidance of tobacco and alcohol, accident prevention measures, awareness about recognition of early signs / symptoms of common geriatric problems and motivation to seek treatment, and education regarding periodic health check-up.

**Training and Re-training of Medical and Paramedical Personnel** : This should be undertaken regarding the special health needs of the elderly and updating their knowledge regarding prevention and treatment of common geriatric diseases.

**Immunization** : Vaccines which have a potential for use among elderly include those against streptococcal pneumonia, influenza and tetanus.

**Periodic Health Assessment** : Ideally, all people, males & females, should undergo a detailed health assessment once they are 45-50 years of age. Subsequently, a thorough health evaluation should be done once in every 5 years till 65 years age and thereafter every year or at least once in 2 years. Assessment should include general clinical examination, assessment of hearing & vision, assessment of Dental and oral health, nutritional status including obesity, cardiovascular status, musculoskeletal system including spine, per-rectal examination for males and gynecological and breast examination for females. Depending on availability, important investigation would include Hb%, GB, urine routine and microscopic, stool routine and microscopy and test for occult blood, blood sugar estimation, lipid profile, renal function parameters and an ECG if required. Depending on the requirement, bone densitometry, PSA, Colonoscopy, USG studies and histo-pathological studies may be undertaken as indicated.

**Provision of Prostheses and Other Medical Aids** : Elderly persons will often need devices as spectacles, hearing aids, walking aids, dentures, cervical collars, wheel chairs and



so on. The preventive health care for elderly should cater to provide these implements to all those who are in need, ensuring availability, accessibility and affordability.

**Development of Gerontology Units :** There is a felt need to develop specialized units which would take care of the special and wide health related needs of the elderly as well as train health care workers in these issues. It would be worthwhile if a coordinated approach between departments of community medicine, internal medicine, general surgery, gynaecology, orthopaedics, ENT and ophthalmology be developed to initiate such comprehensive care through gerontology units, for the population of three PHCs which is to be providing health care by various medical colleges. Subsequently, such units may be developed at the level of district hospitals.

**Ensure Effective Communication :** Elderly people need special efforts for communication. Hence, medical personnel dealing with elderly should very effectively communicate their findings and advise to this group and ensure a system of feedback to verify that their communication has been correctly understood by the elderly subjects.

## Summary

Elderly age is defined as persons aged 65 years or more. In our country, proportion of elderly is consistently increasing and there is need to focus on their health needs. Health problems of elderly should not be seen as isolated medical issues but should be viewed in the larger context of socio-economic-emotive determinants as an overall health issue. Due to children moving out of home for employment, elderly face problems of isolation and lack of physical support. This isolation may be worsened by retirements or death of spouse, and predispose them to variety of lifestyle diseases. Financial crisis because of lack of income sources may compound the problem. Moreover the present health care system in our country is not very well geared up to cater to the health needs of elderly. The health problems of elderly can be divided into 3 groups, i.e. problems which are important for both genders, problems which mainly concern the elderly males and problems which mainly concern the elderly females.

Problems which are important for both the genders include-ocular diseases like age related diminution of vision, cataract and glaucoma; hearing defects; reduced muscular strength and coordination resulting in increased proneness to accidents and injuries; nutritional deficiencies; dental problems like reduction in number of teeth or edentulousness; cardiovascular diseases like IHD, stroke and hypertension; increased susceptibility to effects of heat and cold; increased susceptibility to infections, particularly lower respiratory tract infections (pneumonia) and urinary tract infections; degenerative neurological diseases like Alzheimer's disease and Parkinsonism; micro and macrovascular complications of diabetes and cancers like oral, gastric, lung, uterus, ovaries and colorectal cancers are more common in elderly age group. Problems which mainly affect the elderly males include benign prostatic hypertrophy (BPH); prostate cancer and male sexual dysfunction. Problems which mainly concern with elderly females include Menopausal Problems like increased risk of cardiovascular diseases, genitourinary atrophy; skeletal bone loss, skin and hair

changes, and neuroendocrine and vasomotor changes; Urinary incontinence; Osteoporosis; Cancers of female genital tract mainly uterine (endometrial), ovarian and cervical cancers.

Prevention and control of these problems need multifaceted approach. There is need to develop social ethos wherein children voluntarily take the responsibility of looking after their aged parents. The need is to develop an affordable health insurance scheme and pension schemes. There should be proper designing of roads / walkways, and stair cases, along with adequate enforcement of traffic rules. Houses should be constructed in such a manner that these are "elderly friendly houses". Primary preventive measures should start in early adulthood through life style modification. IEC about health problems of elderly should be targeted to elderly, adults who are likely to move in elderly group and also to younger people who are care provider to elderly. Training and retraining of health staff, so as to efficiently address health needs of elderly is required. Periodic health examination should be done at least every 5 years starting with age of 45 - 50 years till the age of 65, and thereafter it should be done at least once in every two years. All these measures should be communicated to elderly in an effective manner.

## Study Exercises

**Long Question :** Describe your plan of providing comprehensive health care to the elderly persons in your district, in your capacity as the district health officer.

**Short Notes :** (1) Osteoporosis (2) Benign Prostatic Hypertrophy (3) Health problems of the elderly

### MCQs

- 1) Elderly is defined as the person aged above: (a) 60 yrs (b) 65 yrs (c) 70 yrs (d) 75 yrs
- 2) The proportion of elderly in our country is: (a) 1% (b) 2% (c) 4% (d) 5%
- 3) Which of the following is not the primary disease of elderly age group: (a) Parkinsonism (b) Alzheimer's (c) Multiple sclerosis (d) Cerebrovascular disease
- 4) Which of the following malignancy is not commonly seen in elderly age group: (a) Stomach (b) Colorectal (c) Prostate (d) Testis
- 5) IEC strategies for prevention and control of health problems of elderly should be targeted to: (a) Elderly (b) People in late adulthood (c) Younger people (d) All of the above
- 6) Characteristics of "elderly friendly houses" does not include: (a) Furnitures should be adequately separated (b) Lighting should be adequate (c) Floor should not be slippery (d) Electrical appliances should not be used to avoid threat of electrocution
- 7) Periodic Health Assessment for elderly should ideally be done once in every: (a) 5 yrs (b) 4 yrs (c) 3 yrs (d) 1 yr
- 8) Routine Periodic Health Assessment for elderly should include all except: (a) Stool test for occult blood (b) blood sugar estimation (c) Renal function parameters (d) Pulmonary function tests
- 9) Risk factors for primary osteoporosis does not include: (a) High BMI (b) History of prior fracture (c) Family history of maternal hip fracture (d) Lack of weight bearing



exercise.

- 10) Which of the following is not a postmenopausal problem:  
(a) increased risk of cardiovascular diseases  
(b) Genitourinary atrophy (c) Skeletal bone loss  
(d) Atrophy of ovary
- 11) Major physio-pathological factors which contribute to increased proneness to accidents among elderly are all except: (a) Reduced muscular strength (b) Poor neuro-muscular coordination (c) Restlessness (d) Diminution of vision and hearing
- 12) Elderly are at risk of nutritional deficiencies because of:  
(a) Lack of financial resources to buy nutritious food items (b) Reduced physical abilities with resultant reduced ability to cook nutritious meals (c) Oro-dental problems  
(d) All of the above
- 13) Hot flushes occurring in postmenopausal women are mainly due to: (a) Psychological response  
(b) Neuroendocrine disturbance (c) Macrovascular changes  
(d) Microvascular changes
- 14) A rough guide to calculate an index of risk of osteoporosis based on body weight is {  $0.2 \times (\text{Body weight in Kg} - \text{Age in years})$  } the value of index which indicates increased risk if it is: (a)  $>1$  (b)  $<1$  (c)  $>2$  (d)  $<2$

- 15) Normal level of PSA (Prostate specific antigen) is (in ng/dl) : (a)  $<2$  (b)  $<6$  (c)  $<4$  (d)  $<8$
- 16) Presbyopia occurs in elderly because of: (a) Cataract change in ocular lens (b) Retinal degeneration (c) Insufficiency of power of accommodation (d) Corneal degeneration
- 17) Hearing loss among elderly is mainly because of:  
(a) Sensorineural deafness (b) Conductive deafness  
(c) Degenerative changes in temporal cortex (d) None of the above

#### Fill In the Blanks

1. The proportion of elderly in India is like to reach \_\_\_\_\_ by year 2050 AD.
2. Prostate Specific Antigen (PSA) of the level higher than \_\_\_\_\_ indicates strong suspicion of Ca prostate.
3. Females are at much higher risk of developing osteoporosis Type \_\_\_\_\_ especially after menopause.
4. Common fracture sites among elderly are \_\_\_\_\_
5. Hearing loss commonly occurring among elderly because of sensori-neural deafness is called as \_\_\_\_\_

**Answers : MCQs :** (1) b; (2) d; (3) c; (4) d; (5) d; (6) d; (7) d; (8) d; (9) a; (10) d; (11) c; (12) d; (13) b; (14) d; (15) c; (16) c; (17) a. **Fill In the Blanks :** (1) 18%; (2) 10 ng/ ml; (3) Type - I; (4) Hip, wrist, spine and pelvis; (5) Presbycusis

*Dashrath R. Basannar*

Demography is the scientific study of human populations. It is mainly concerned with

**Size :** It refers to the total number of persons in the given population.

**Distribution :** It refers to the arrangement of entire population with respect to the geographical areas at a given point of time.

**Structure :** It refers to the distribution of the given population with respect to age and sex.

**Change :** It refers to the increase or decrease in the size of the given population due to fertility, mortality and migration.

**Development :** It refers to the development of the given population with respect to socio economic aspects.

Other characteristic like genetic inheritance, intelligence and health.

**Role of Demography in Public Health Administration :** For effective planning, designing, evaluation and execution of health and health care needs for the entire population for the present as well as for the future, the knowledge about population with respect to its size, structure, change in its size

and their developments is essential. The following are number of the applications of demography in health related fields.

The knowledge in demography is helpful to public health administrators for various purposes :

- i) Mortality rates by age-sex and its geographical distribution with respect to various diseases are helpful in locating and identifying diseases of public health importance with respect to age-sex-location, for planning remedial measures to control these diseases, future planning for prevention of these diseases, for determining leading causes of mortality, for planning drugs/medicines/equipment/manpower/other medical facilities requirements etc.
- ii) Percentage distribution of population by age-sex-location are helpful in understanding health and health care needs of various age groups by sex by location, for planning, designing, evaluation and effective implementation of various public health programs. For example : Vaccination and immunization program for children under 5 years of age, Mother and Child Health program for mother and new born, Family planning program, old age program, nutritional program etc.
- iii) Determining the success or failure of health programs.
- iv) To describe the level of community health.
- v) To determine the leading causes of mortality and morbidity.
- vi) To determine the relative importance of different fatal

diseases with respective to age and sex.

vii) To discover solution to health problems and find clues for public health administration.

**Sources of Demographic Data :** The following are the sources of demographic data. The details of these sources have already been dealt with in detail in an exclusive chapter in the section on epidemiology :

1. Census
2. Vital Events Registers
3. Surveys
4. Sample Registration System

**Measures of Population Projection :** By "Population projections", we mean estimating and forecasting the population of a country or a region for a given time. There are mainly three types of population estimates namely inter-censal (during any two consecutive census period), post-censal (any period following latest census up to the present moment of time) and future (any period time after the present moment). Generally the data on population are available for census year only hence population estimates (inter-censal estimates) are required for calculating fertility rates, mortality rates etc. during the inter-censal period. Future population projections (future estimates) are very essential basically for understanding and planning future needs of the population for various purposes such as health, education, economic, social, employment, irrigation, food, housing, etc. The following measures of population estimates are commonly used.

**i) Mathematical Methods :** Some of the mathematical models which are commonly used for estimating inter-censal and post-censal population estimates are :

- Arithmetic Growth Method
- Geometric Growth Method
- Exponential Growth Method
- Component Projection Method

**a) Arithmetic Growth Method :** In this method it is assumed that there is an equal addition every year to the population during the inter censal period and this addition is taken to be average increase per year. Arithmetic Growth Method for estimating population is  $P_t = a + t \times b$  where  $P_0$  population at time t is,  $P_0$  and  $P_1$  are populations at two consecutive censuses.  $a = P_0$  and  $b = ((P_1 - P_0) \div 10)$  and inter census period = 10years. For example populations of a town A at censuses 1st Mar 1981 and 1st Mar 1991 were 50,000 and 90,000. Estimate population of the town on 1st Mar 1985. Here  $a = 50,000$ , inter-censal period = 10 years,  $b = 4,000$  per year and  $t = 4$ ,  $P_4 = 50,000 + 4 \times 4,000 = 66,000$

**b) Geometric Growth Method :** This method assumes the population begets population at a constant rate of increase on the compound interest law. Geometric Growth Method for estimating population is  $P_t = P_0 \times (1 + r)^t$  where r is growth rate

and  $r = \left[ \frac{P_1}{P_0} \right]^{1/10} - 1$ . In the above example,

$$r = \left[ \frac{90,000}{50,000} \right]^{1/10} - 1 = 0.0605.$$

$$P_4 = 50,000 \times (1 + 0.0605)^4 = 63,252.69$$

**c) Exponential Growth Method :** In this method it is assumed that there is an exponential growth. Exponential Growth

Method for estimating population is  $P_t = P_0 \times e^{r \times t}$

where r is exponential growth rate  $r = \frac{1}{10} \times \log_e \left[ \frac{P_1}{P_0} \right]$

In the above example  $r = \frac{1}{10} \times \log_e \left[ \frac{90,000}{50,000} \right] = 0.05878$  and

$$P_4 = 50,000 \times e^{0.05878 \times 4} = 63,252.69$$

**d) Component Projection Method :** This method is mainly used for future population projections (future estimates) using following model.

$$P_t = P_0 + B_{0-t} - D_{0-t} + I_{0-t} - E_{0-t}$$

Here 0 stands for base year from which population projected is made, t denotes the period of projection from the base year.  $B_{0-t}$ ,  $D_{0-t}$ ,  $I_{0-t}$ ,  $E_{0-t}$  represents number of births, number of deaths, number of immigration and number of emigration during the period 0-t respectively.  $P_0$  Represents population at the base year 0.

This method makes assumptions about fertility, mortality and migration for the projection period based. This method requires information regarding age-sex distribution, age-sex specific mortality, fertility and migration distribution by age-sex for the base year 0 and estimates for the period t.

**Demographic Transition :** In 1929 the American demographer Warren Thompson, observed changes in birth and death rates in industrialized societies over the past two hundred years or so and then formulated a model called "Demographic Transition" that describes population change over time in fully developed country today, such as The United States or Canada, the countries of Europe, or similar societies elsewhere (e.g. Japan, Australia etc.). The model is a generalization that applies to these countries as a group and may not accurately describe to less developed societies. As shown in the Fig. - 1, Demographic Transition model recognises five demographic stages namely high stationary, early expanding, late expanding, low stationary and declining.

- **High stationary (first stage) :** The first stage is associated with pre Modern times, and is characterized by very high birth rates and very high death rate (30-50 per 1000) balance between them results in only very slow population growth that is referred to as the "High Stationary Stage" of population growth. This situation was true of all human populations up until the late 18<sup>th</sup> century.
- **Early expanding (second stage) :** The second stage is characterized by a rise in population caused by a decline in the death rate while the birth rate remains unchanged, or perhaps even rises slightly. The decline in the death rate in Europe began in the late 18<sup>th</sup> century.
- **Late expanding (third stage) :** The third stage is characterized by further decline in the death rate while birth rate tends to fall that results in increase in the population

growth. In general the decline in birth rates in developed countries began towards the end of the 19<sup>th</sup> century.

- *Low stationary (fourth stage)* : The fourth stage is characterized by a low birth rate and low death rate; the balance between them results in no population growth that is referred to as the “low Stationary Stage” of population growth.
- *Declining (fifth stage)* : The fifth stage is characterized by a birth rate lower than death rate the balance between them results in decline in population growth that is referred to as the “Declining Stage” of population growth.

**Demographic transition in national Context** : As shown in the Table - 1 and Fig. - 1 & Fig. - 2, India's population growth during the twentieth century can be classified into four distinct phases as follows : 1901-1921, this period was characterised by a high birth rate and high death rate (46-49 per 1000) and growth rate was slow, close to zero and it was negative during 1911-21 and the year 1921 is called the year of great divide. There after growth rate steadily increased till 1991.

During 1921-1951, birth rate steadily declined from 48.1 in 1921 to 39.9 in 1951 and death rate also declined from 47.2 in 1921 to 39.9 in 1951 while growth rate steadily increased during this period which was more than 1 but less than 2. During this period India experienced rapid growth.

During 1951-1981, birth rate little further increased and then declined and death rate further declined and growth rate further increased and it crossed over 2 during this period. During this period India experienced explosive rapid growth.

During 1981-2001, birth rate further declined and came down to 26.1 and death rate further declined while growth rate started slowing down during this period. Growth rate during 1971 to 1991 was more than 2, first time after 40 years fall down below 2, still it characterises as very rapid growth.

From the Table - 1, it is evident that there is declining trend in CDR, it declined from 46.2 in 1911 to less than 10 i.e. 8.7 in 2001 and it was less than 7 in 2007 and it is close to some of

the developed countries like United States and Canada. During this period life expectancy at birth increased from 23.63 years for male and 23.96 years for female in 1901 to 62.30 years for male and 65.27 years for female in 2001. Similarly CBR declined from 49.2 in 1911 to almost half i.e. 26.1 in 2001.

India with 238.4 million population in 1901 almost doubled in 1961 in 60 years while it took just 30 years to double the population from 439.2 million in 1961 to 844.0 million in 1991. The population of India has increased nearly five times from 238 million to 1 billion during this century period.

In 2001 census India's population was 1,028,737, i.e. about 16 percent of the world's population on 2.4 percent of the globe's land area. It is the second largest populous country in the world. If current trends of fertility and mortality continue, India may overtake China in 2045, to become the most populous country in the world. As per census 2001 report, state with highest population was Uttar Pradesh (166,197,921) and state with lowest population was Sikkim (540,851); union territories with highest population was Delhi (13,850,507) and union territories with lowest population was Lakshadweep (60,650) ; district with highest population was Medinipur (West Bengal) (9,610,788) and district with lowest population was Yanam (Pondicherry) ( 31,394 ).

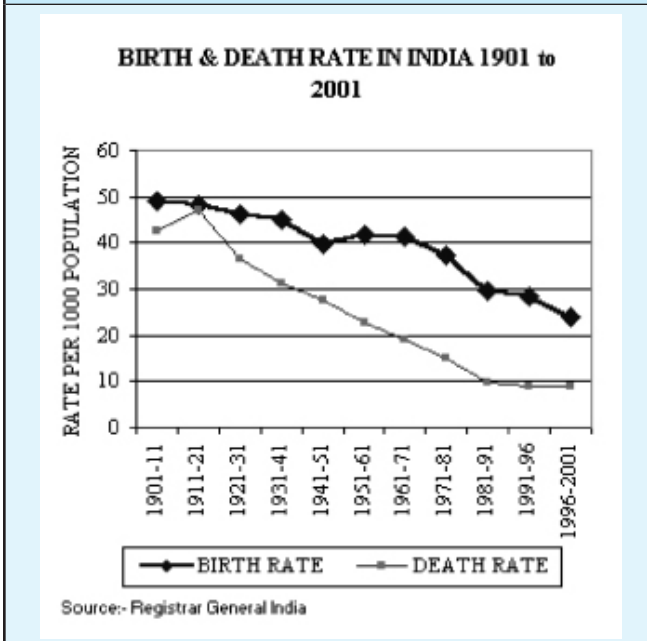
**National Policies to Control Population Growth** : India was the first country in the world to launch a national family planning to control birth rates to stabilize the population in 1952. The role of family planning programme was mainly to deliver contraceptive methods and creating facilities for abortion. After 1952, sharp declines in death rates were observed, however, not accompanied by a similar drop in birth rates. The Government has passed Child Marriage Act in 1978 and this Act specified the minimum age at marriage for females and males to be 18 and 21 years respectively. The National Health Policy, 1983 stated that replacement levels of Total Fertility Rate (TFR) should be achieved by the year 2000. Half a century after formulating the national family welfare programme, reduced Crude Birth

**Table - 1: Birth Rate, Death Rate and Growth Rate in India (1901-2001)**

Census year	Total population (million)	Decadal Growth (%)	Average annual exponential growth rate (%)	Growth rate over 1901 (percent)	Birth Rate/1000 live births	Death Rate/1000 population
1901	238.4					
1911	252.1	5.75	0.56	5.75	49.2	46.2
1921	251.3	-0.31	-0.03	5.42	48.1	47.2
1931	279	11	1.04	17.02	46.4	36.3
1941	318.7	14.22	1.33	33.67	45.2	31.2
1951	361.1	13.31	1.25	51.47	39.9	27.4
1961	439.2	21.64	1.96	84.25	41.7	22.8
1971	548.2	24.8	2.2	129.94	41.2	19
1981	683.3	24.66	2.22	186.64	37.2	15
1991	844	23.86	2.14	255.03	29.5	9.8
2001	1027	21.34	1.93	330.8	26.1	8.7

Source: SRS data 1999 and Census of India 2001

Fig. - 1



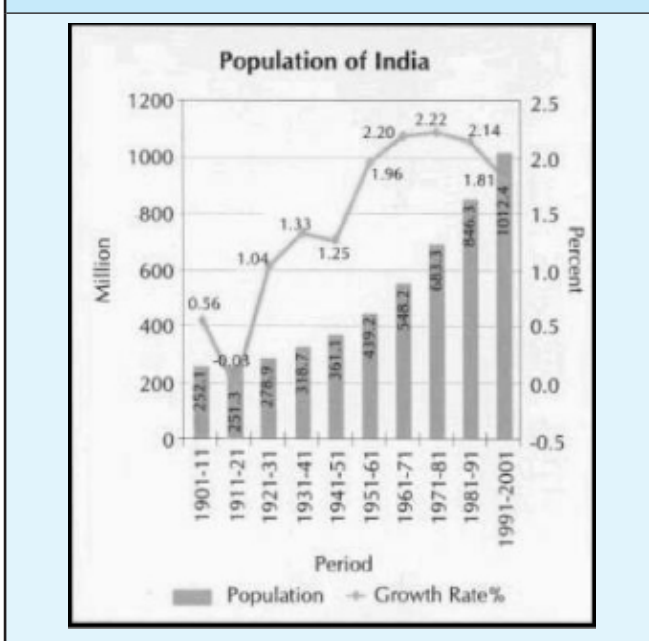
Rate (CBR) from 40.8 (1951) to 26.4 (1998, SRS) ; the Infant Mortality Rate (IMR) from 146 per 1000 live births (1951) to 72 per 1000 live births (1998, SRS) ; Crude Death Rate (CDR) from 25 (1951) to 9.0 (1998) ; Total Fertility Rate from 6.0 (1951) to 3.3 (1997). The National Population Policy (NPP), 2000, recently adopted by the Government of India states that 'the long-term objective is to achieve a stable population by 2045, at a level consistent with the requirements of sustainable economic growth, social development, and environment protection'. It has been assumed in the policy document that the medium-term objective of bringing down the Total Fertility Rate (TFR) to replacement level of 2.1 by 2010 will be achieved. It is envisaged that if the NPP is fully implemented, the population of India should be 1013 million by 2002 and 1107 million by 2010.

## Summary

Demography is the scientific study of human populations and it is mainly concerned with size, distribution, structure, change, development and other characteristics like genetic inheritance, intelligence and health. Demography plays an important role in public health administration for effective planning, designing, evaluation and execution of health and health care needs for the entire population for the present as well as for the future.

The important sources of demographic data are Census, Vital Events, Registers, Surveys, and Sample Registration System. There are mainly three types of population estimates namely inter-census (during any two consecutive census period), post census (any period following latest census up to the present moment of time) and future (any period time after the present moment). The measures of population estimates commonly used are Mathematical Methods - Arithmetic Growth Method, Geometric Growth Method, Exponential Growth Method, and Component Projection Method.

Fig. - 2



Demographic Transition model recognises five demographic stages namely high stationary, early expanding, late expanding, low stationary and declining. High stationary is characterized by very high birth rates and very high death rate. Early expanding is characterized by a rise in population caused by a decline in the death rate while the birth rate remains unchanged, or perhaps even rises slightly. Late expanding is characterized by further decline in the death rate while birth rate tends to fall that results in increase in the population growth. Low stationary is characterized by a low birth rate and low death rate the balance between them results in no population growth. Declining is characterized by a birth rate lower than death rate the balance between them results in decline in population growth.

In 2001 census India's population was 1,028,737, i.e. about 16 percent of the world's population on 2.4 percent of the globe's land area. It is the second largest populous country in the world. If current trends of fertility and mortality continue, India may overtake China in 2045, to become the most populous country in the world. As per census 2001 report, state with highest population was Uttar Pradesh (166,197,921) and state with lowest population was Sikkim (540,851).

National policies to control population growth : India was the first country in the world to launch a national family planning to control birth rates to stabilize the population in 1952. The Government has passed Child Marriage Act in 1978, the National Health Policy in 1983, and the National Population Policy (NPP) in 2000. It has been assumed in the policy document that the medium-term objective of bringing down the Total Fertility Rate (TFR) to replacement level of 2.1 by 2010 will be achieved. It is envisaged that if the NPP is fully implemented, the population of India should be 1013 million by 2002 and 1107 million by 2010.



## Study Exercises

**Short Notes :** (1) Important sources of Demographic Data (2) Demographic Transition (3) Role of Demography in Public Health

### MCQs

- According to the demographic cycle, India is in the following phase (a) High Stationary (b) Early Expanding (c) Late Expanding (d) Low Stationary
- According to Central Registration Act of 1969, birth is to be reported within : (a) 7 days (b) 14 days (c) 10 days (d) 21 days
- Annual growth rate is between (a) Crude birth rate - Crude death rate (b) Crude birth rate - IMR (c) Total Fertility rate - Death rate (d) Crude birth rate - Total Fertility rate
- Census in India is done every (a) 05years (b) 10years (c) 15 years (d) 20 years
- The most cost effective family planning method is (a) Vasectomy (b) Barrier method (c) IUCD (d) Oral pills
- The year of "Big Divide" is (a) 1900 (b) 1901 (c) 1920 (d) 1921
- As per Census 2001 Average annual growth rate of India is (in %) (a) 2.01 (b) 1.93 (c) 1.80 (d) 1.86
- As per Census 2001 Decadal growth rate of India is (in %) (a) 21.34 (b) 31.93 (c) 11.80 (d) 9.86
- As per Census 2001, the % of world's population from India is (a) 26 (b) 16 (c) 10 (d) 06
- As per Census 2001, lowest populated state of India is (a) Kerala (b) Sikkim (c) Goa (d) Nagaland
- The annual growth rate of India presently characterized as (a) slow (b) rapid (c) very rapid (d) explosive

**Answers :** (1) c; (2) b; (3) a; (4) b; (5) a; (6) d; (7) b; (8) a; (9) b; (10) b; (11) c.

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## Contraceptive Technology

*RajVir Bhalwar*

As per the National population policy - 2000 and the RCH program in our country, the couples should be given a choice out of various contraceptive methods. Promotion of contraception purely on a voluntary basis, without any coercion, and with provision of due information about the various contraceptive alternatives is the central ethos of our national family welfare programme. The strategies and operational details of the programme and the various contraception facilities being provided to the community are dealt with in the chapter on RCH program. The technical details of various methods of contraception are being dealt with in this chapter.

Broadly, methods of contraception would fall into two groups, viz. "Natural Methods" and "Artificial Methods". Artificial methods are further grouped into Temporary and Permanent methods.

**Efficacy of Contraceptive Methods :** Efficacy of a given contraceptive procedure is evaluated in terms of the "Pearl Index" which measures the number of failures (i.e. pregnancies occurring despite continuous usage of the particular method) per 100 woman years (HWY), or for every 1200 woman - months.

$$\text{Pearl Index} = \frac{\text{Total failures (pregnancies despite use of the contraceptive)}}{\text{Total months of continuous use of the contraceptive}} \times 1200$$

(Failure rate per HWY)

The numerator (total failures) should include all pregnancies which occur during the period of observation, irrespective of their outcome (i.e. whether the pregnancy terminated in live birth, still birth or abortion etc.). The denominator is taken in months and hence the numerator is multiplied by 1200, to make it equal to 100 years. In the denominator, for every pregnancy which is continued till full term, 10 months are deducted, while for every pregnancy that terminates in abortion, 4 months are deducted, from the total period of follow up for each woman. When studying the effectiveness of contraceptives, it is recommended that at least 600 woman-months (50 woman-years), preferably more, of follow up should be done. A failure rate of 3.33 per HWY means that, given the fertile period of a woman is 30 years (usually 15 to 44 years age) and if a woman uses that contraceptive continuously for her entire fertile period, she is likely to have one pregnancy due to failure of the contraceptive. (Calculated as 3.33 failures in 100 years for 1 woman, hence  $(30 \times 3.33) / 100 = 1$  failure in 30 years of usage. It also means that if 100 women use the contraceptive for 10 years continuously, thus giving 1000 woman years, then about 33 accidental pregnancies are likely to occur, in all, among these 100 women over the 10 years of use.

### Natural Methods of Contraception

These methods utilize either total avoidance of sexual intercourse (Abstinence) or by discharging the semen outside female genitalia (Coitus interruptus or withdrawal method) or else by utilizing methods which observe the naturally occurring signs / symptoms of fertile versus non-fertile periods of the menstrual cycle and avoiding sexual intercourse during the fertile period. These methods, which are also sometimes referred as the "Standard Day Methods" (SDM) work on the principle that during one menstrual cycle, one ovum is

discharged; very rarely, a second ovum can be discharged after 24 hours. Secondly, after intercourse, sperms stay alive upto 5 days (rarely 7 days) but can actually fertilize the ovum for at most 4 days. With this background the most fertile period of women is from 10th day to the 18th day, provided the cycle is of 28 days. Natural methods are based on detecting the fertile period and avoiding intercourse during the period. These are :

**(a) Rhythm Method** : For women who have a regular 28 days cycle, the fertile period would be generally from day 7 to day 21 (the day of onset of menstrual bleeding is taken as the first day). Sexual intercourse is avoided during this period.

**(b) Basal Body Temperature Method** : The woman should record her oral temperature first thing on getting up in the morning, daily, and plot it on a graph paper with the days of menstrual cycle along horizontal axis and temperature along vertical axis. Immediately following ovulation there is increase in oral temperature by 0.5 to 0.8°F (0.2 to 0.4°C). Couples should avoid intercourse for 3 days, once the rise in temperature is noted.

**(c) Cervical Mucous Method** : The woman notices daily, the quality of vaginal mucus discharge, by putting a finger into the vagina. Following cessation of menstrual flow, no mucus is felt in the vagina for couple of days. These are called the “dry days”. Following the dry days, cloudy, white or cream coloured mucus of sticky consistency with little moisture appears. This indicates that ovulation is approaching. Thereafter, just before and at time of ovulation the mucus becomes copious, clear and slippery, resembling the white of an egg and can be stretched into a thread if the thumb and finger on which the mucus is stuck, are gently moved apart. This persists for 3 days and is called the “wet days”. Following this wet period, the mucus again becomes scanty, sticky and cloudy indicating the post ovulation phase, which persists till onset of next menstrual flow. The couple should abstain as soon as the first sign of mucus appears in the pre-ovulatory phase, during the wet days in ovulatory phase and for 3 days after the completion of wet period.

**(d) Symptothermal Method** : This is based on combined observation of changes in BBT, mucus changes and also by palpating the cervix with a finger high up in the vagina. The cervix becomes softer and cervical os becomes more open during the fertile period.

Natural methods are reasonable efficacious; however, the problem is mainly the difficulty in maintaining compliance. If consistently and properly used, the failure rates per 100 women per year (HWY) (indicating the number of women who will become pregnant during one year out of 100 women who are using these method are :

- (i) Calendar Method - 9 / 100 HWY (9%)
- (ii) BBT Method - 1 - 2 / 100 HWY (1-2%)
- (iii) Cervical mucus Method - 3 / 100 HWY (3%)
- (iv) Symptothermal Method - 2 / 100 HWY (2%)

**(e) Lactational Amenorrhoea Method** : Full or nearly full breast feeding means that at least 85% of the baby's food requirement is being provided by breast milk. For women who are fully breast feeding their infants, chances of pregnancy are very less for 6 months or when menstrual flow returns,

whichever is earlier. If used correctly and consistently, the failure rate is 1 to 1.5%. Chances of pregnancy are, however, more if the woman is not having full lactation or if not fully breast feeding the infant.

## Artificial Methods

**Artificial, Temporary Methods** : The broad categories of contraceptives included in artificial (temporary) methods are Barrier methods, Spermicides, Intrauterine devices (IUDs), Oral contraceptives and Non-oral hormonal contraceptives.

### Barrier Contraceptives

**Condoms** : Condoms are made of latex and are available as nonlubricated (Nirodh, Kohinoor), lubricated (Nirodh - Lubricated, Kamasutra, Kohinoor - Pink and Sawan) and more lately, coated with spermicidal jelly which is usually nonoxynol-9 (Share, Rakshak). The average shelf life is 5 years from date of manufacture and they should be stored in cool and dry place. If further lubrication is required then glycerin, K-Y jelly or a spermicidal jelly can be applied, but not Vaseline, oils or butter. Some couples may complain of initial reduction in pleasure due to slight decrease in sensations and interruption in sexual play (since the man has to put on the condom just before insertion). However, it should be explained to them that this is only a transient phenomena, and most couples will adapt well with passage of time. Besides contraceptive effect, condoms are also very effective in preventing transmission of HIV, STDs, HPV infection (and amnionitic fluid infections while having sex during pregnancy).

The total “slippage” and “breakage” rate is 4% to 9%. The average failure rate is 12% to 14%, but if correctly used, it may be as low as 3%. Concurrent use of spermicidal jelly will further reduce the failure rate. Condoms are very good choice as temporary method, especially for couples in whom use of hormonal contraceptives and IUDs is not indicated among the female partner. The only contra-indication to condom use is allergy to latex rubber in which case condom made of polyurethane or silicon rubber may be used.

**Diaphragm, Cervical Cap (Check Pessary), Vault Cap and Vimule** : These are barrier methods to be used by the females but not much used now due to wide availability of other contraceptives.

**Female Condoms** : Available under trade name of “Femindon” and “Reality”. The device is inserted like a vaginal diaphragm. At present it is not much used as contraceptive but has potential in prevention of HIV transmission.

**Spermicides** : Most commonly used spermicide is nonoxynol-9. They are available as vaginal pessaries which are inserted high up in the vagina, 10 to 15mts before sex or as creams / jelly, as Delfen cream, Orthogynol jelly etc.

**Foam Tablets** : These are very commonly used. It is marketed in our country as “Today” as a vaginal foam suppository containing nonoxynol-9. The tablet is to be inserted high in the vagina (may be moistened slightly with water if vagina is dry), 10 minutes before sex act and the action lasts for 1 hour after sex. If properly used, failure rates are as low as only 0.5%.

**Intra Uterine Devices (IUDs)** : IUDs have been in use as contraceptives for many decades. However, their exact mode of

action is still not clear. In all probabilities, they act by inducing mild inflammatory changes and foreign body reaction in the endometrium, which combined with alterations in prostaglandin levels, incapacitate the sperms and ovum, prevent sperm from fertilizing the ovum, and even if fertilization occurs, makes the uterine environment inhospitable for the blastocyst to be implanted. The earliest IUDs, namely lippies loop, have now been almost phased out by copper-T and its subsequent variants. Copper - T 200 (Gynae-T) is made of propylene impregnated with BaSO<sub>4</sub> and carries 120mg of 0.25mm diameter copper wire wound around the vertical limb. The tail limb has a pair of threads (some variants have only one thread) which comes out of cervical os, into vaginal canal after the Copper-T has been inserted and can be felt with a finger to check that the Copper-T is in place. The copper has an exposed area of 200 sq. mm and hence the name Cu-T- 200. The US-FDA approved Cu-T-200 has an effective life of 4 years. Some additional variants available commercially in our country are Multiload ML Cu-T-250, ML Cu-T-375 and Nova Cu-T-200 (Nova T) which has a silver core added to the copper wire. The conventional Cu-T-200 has failure rate of 2%, while the newer variants have lower failure rate of 1-2%. In general Cu-T-200 is referred to a Group-I IUD; ML-250 and 375 as Group-II; while Nova-T and Cu-T-386A are referred to as Group-III IUDs. The advantages of IUDs is the ease of insertion (can be inserted at Sub centre level by paramedical workers), the semi-permanency (Cu-T-200 can be left in place and remains effective for 3 years) and the ease of removal. However, before advising IUD, proper history should be taken from the couple and correct advice given as per details given in succeeding paragraphs.

***Conditions which are absolute contra - indications to IUD insertion / continuation***

- (a) Pregnancy
- (b) Puerperal or Post abortal sepsis
- (c) Unexplained vaginal bleeding
- (d) Pelvic inflammatory disease within last 3 months
- (e) Known pelvic TB
- (f) STD during the past 3 months
- (g) Suspected neoplasia of genital tract
- (h) Uterine abnormalities

***Conditions which increase the risk due to IUD, and alternative contraceptive may be considered, if possible***

- (a) Post partum 48 hours to 4 weeks (more chances of perforation)
- (b) Women having increased chances of STD / HIV transmission (prefer condom)
- (c) Age <20 years
- (d) Nulliparity
- (e) Endometriosis
- (f) Menstrual irregularities with increased bleeding or dysmenorrhoea

Women who are best suited for IUD include those aged >20 years, who have given birth to at least one child, have diseases or conditions like Obesity, Tobacco use, Headache, IHD, RHD, Diabetes, Thyroid disease, Benign breast disease and Irregular menstruation but without heavy bleeding and those who are breast feeding.

***Timing of Insertion***

- (a) The best time to insert is during or soon after menstrual periods, post partum within 48 hours of delivery and after abortion.
- (b) However, after delivery or abortion it is preferable to insert IUD 6 weeks after the delivery / abortion and the couple may be advised to use another method, as condom, for that period.
- (c) It may be noted that as far as possible insertion should not be delayed just because of timing. In fact, the best timing is the one which is most convenient to the potential user, if it can be reasonably ascertained that she is not pregnant.
- (d) It can also be inserted post coitus, even up to 5 days after coitus to prevent pregnancy

***Instructions to be given to the lady, after insertion***

- (a) For the next few periods (at least for next 3 periods) she should watch her pads for any expelled IUD and, after the periods, should feel for the threads (tails) coming out of the cervical os, to ensure that the device is in place. She should report if she cannot feel the threads or sees the device on her pads, or feels the device to be in the vagina
- (b) She should come for a routine health check up after the next menstrual period
- (c) She should report in case of persistent, irregular or heavy bleeding, severe pain in lower abdomen or abnormal vaginal discharge, or amenorrhoea (in which case pregnancy should be excluded)
- (d) She should also report if she feels that she has been exposed to STD or HIV

***Indications for Removal***

- (a) Abnormal or excessive bleeding
- (b) Persistent pelvic pain or cramping
- (c) Expiry of effective life span (3 to 4 years from date of manufacture, for Cu-T-200)
- (d) Pregnancy
- (e) Acute pelvic infection or neoplasm of genital tract
- (f) Displacement of IUD either inside the uterus or outside it
- (g) Personal reasons
- (h) After menopause (within one year)

***Routine problems after insertion***

The lady should be advised that she may face certain routine problems following insertion as follows, and she should not unduly worry about them :

- (a) Some cramping abdominal pain for a few days
- (b) Some vaginal discharge for a few weeks
- (c) Heavier menstrual bleeding and possibly inter-menstrual bleeding for a few weeks

***Complications of IUD***

- (a) Increased menstrual bleeding and sometimes inter-menstrual spotting
- (b) Cramping lower abdominal pain
- (c) Expulsion : The overall expulsion rate is 2 - 8% in first year. It is commonest in first 3 months, especially after the 1st period following insertion
- (d) Leucorrhoeic vaginal discharge
- (e) Perforation of uterus (occurs in approximately 1 per 1000 insertion)



- (f) Infection, especially during first month
- (g) Pregnancy, due to failure (1 to 2%)
- (h) Ectopic pregnancy (Rare, approximately 1 per 1000 women years. However, if pregnancy occurs with IUD in situ, then chances of its being ectopic are very high, almost 30%)

### Oral Contraceptives

Hormonal Contraceptives have revolutionized the implementation of Planned Parenthood Programmes all over the world. Broadly, hormonal contraceptives could be either oral or parenterally administered. Oral contraceptives (OCs) can be further divided into two broad groups, viz. "Combined pills" (Containing both Estrogen & Progestogen) and "Progestogen only pills" (mini pills).

**(a) Combined Pills** : These can be of two types, viz. Monophasic pill in which every pill has same amount of Oestrogen as well as Progestogen, and the multiphasic pill in which, in a given pack for one menstrual cycle, the pills will have variable amount of Oestrogen & Progestogen. An example is "Triquila" available in our country. Monophasic pills can be, in turn, low dose pills which contain less than 0.05 mg of ethinyl estradiol (EE) in each pill along with progestogen. The other variety, i. e. high dose pills containing > 0.05mg EE per pill have been discontinued by now. Similarly, the earlier used sequential pills, which used only oestrogen in the tablets for first 14 days followed by combined Oestrogen & Progestogen for next 7 days have also been abandoned by now.

**(b) Progestogen only (Mini pill)** : These contain small amount of only a progestogen but no oestrogen. They are indicated for women >40 years age or who are lactating and have not completed 6 months from delivery. They are available under trade names of Microval or Femulen; they are generally not available in our country.

**Choice of pill** : Any of the low dose combined pill or else a triphasic pill (Triquilar) can be used. The choice will mainly depend on cost, since the triphasic pills are costly.

**Commonly Available Pills** : In our country, the following pills are commonly available :

#### Common low dose pills

- (a) Ovral-L or Mala-D - This contains L-norgesterol (LNGL) 0.15 mg and EE 0.03 mg per pill. Mala-D is available at subsidized rates in our country under the FW program.
- (b) Mala-N - This contains dl-NGL 0.30mg and EE 0.03mg per pill. This is available free of cost under the FW program in our country.

**Triphasic pills** : Triquilar contains L-NGL 0.05mg and EE 0.03mg for first 6 days, 0.75mg and 0.04 mg respectively for next 5 days and 0.125mg L-NGL with 0.03 mg EE for the next 10 days.

**Mechanism of Action** : Combined OCs produce contraceptive effect in different ways, viz. and inhibition of ovulation by bringing about changes in FSH & LH secretion, by altering the endometrium and by bringing about changes in cervical mucus.

**Mode of Administration** : The day on which menstrual flow starts is taken as day-1. The first pill is taken on Day-6, one pill every day for next 21 days. Thereafter the pill is stopped

and restarted after a gap of 7 days, irrespective of the onset or stoppage of menstruation during these pill free periods.

Very often the packet has 28 pills. In such cases, the last 7 tablets are actually iron tablets. In this scenario the next packet should be started on the very next day after the previous packet is finished, without any gap. Secondly, care should be taken to take the actual (hormonal) tablets on first 21 days and iron tablets on days 22 to 28.

**Action to be taken when a Pill is Missed** : If a pill is missed on a day, two pills should be taken on the next day, as soon as the woman remembers (preferably within 12 hours of last missed dose) and the other at bedtime; or else, if not remembered earlier, 2 tablets at bedtime on the next day. If 2 or 3 tablets are missed, the woman should take 2 tablets on each of the consecutive 2 or 3 nights and continue with rest of the packet as usual. In all such cases, when the pills have been missed the next packet should be started as usual after a gap of 7 days from the time last 21 days packet is finished. In such cases where this prompt initiation immediately after 7 days is delayed by 1 or 2 days, the women should use additional barrier method till the time of starting the next normal course of 1 pill a day (from the 7th or 8th day). These rules apply to all OC users, whether using combined or triphasic pills.

**Effectiveness** : Combined OC are very effective, with an overall failure rate of 0.1% (1 per 1000 women year). Failures are maximum during first year of use and are mainly due to missed pills, delay in starting the next course exactly after 7 days of finishing the last 21 days pack, and due to stopping the pill abruptly due to side effects without taking any other appropriate contraceptive measure.

**Side Effects** : These are of two categories, viz, minor side effects which are often temporary and the subject should therefore be properly counselled so that she does not unnecessarily discontinue the pills. The second category is the major side effects.

**Minor Side Effects** : These include nausea, vomiting and decrease in appetite for the initial 2 or 3 months; breakthrough bleeding usually during first few months; menorrhagia, irregular bleeding or oligomenorrhoea; breast heaviness and tenderness; headache; weight gain; acne and oily skin; and, rarely, depression and decline in libido.

**Major Side Effects** : These include increased risk of IHD, and stroke especially if the woman is also a smoker or hypertensive or diabetic or has history of venous thromboembolism. There is also risk of raised blood pressure especially if age is >35 years; slightly increased risk of breast cancer and possibly cervical cancer; interference with insulin action in diabetics; exacerbation of existing hepatic conditions and reduction in lactation.

**Who Should Avoid OCs** : The following women should avoid OCs and try to use some other contraceptive device :

- (a) Smokers, especially if age >35 years.
- (b) Women who are breast feeding their children, up to 6 months post partum.
- (c) Hypertensives.
- (d) Past H/o breast cancer.
- (e) Unexplained vaginal bleeding.



- (f) H/o stroke, thromboembolism or IHD
- (g) Cirrhosis of liver or active hepatitis or liver tumors
- (h) Using Rifampicin or anti-epileptics.
- (i) Undergoing major surgery or prolonged immobilization.
- (k) Diabetes with >20 years duration or with vascular complications.
- (l) Hyperlipidaemia.

**Warning Features** : Women should be educated to watch out for following features and seek medical attention should they occur :

- (a) Chest pain
- (b) Shortness of breath
- (c) Headaches which are severe or throbbing or occur on one side.
- (d) Blurred or diminished vision.
- (e) Swelling or severe pain in a leg
- (f) Missed periods, especially if 2 periods are missed.
- (g) Post coital or persistent irregular vaginal bleeding after 3 months of pill usage or excessive, white discharge especially if mixed with blood.
- (h) Yellowness of eyes or urine.

#### **Advantages of OC use**

- (a) Very effective, require minimal effort.
- (b) Return of fertility on stopping the pills is very prompt.
- (c) Can bring about relief in certain menstrual disorders as dysmenorrhoea.
- (d) May be protective against endometrial cancer and ovarian cancer.
- (e) May be protective against benign diseases of breast and ovaries.
- (f) Likely to be protective against ectopic pregnancy, PID, hirsutism, acne, osteoporosis and progression of rheumatoid arthritis.
- (g) At times, the increase in weight is quite welcome to women.

#### **Non-Oral Hormonal Contraceptives**

These are of 3 broad categories :

**(a) Injectable** : These include the progesterone only (Depot Medroxy Progesterone Acetate - DMPA and Norethesterone Enanthanate - NETEN) or the combined ones (DMPA 25mg Plus oestradiol 5mg or NETEN plus oestradiol 5mg)

**(b) Contraceptive Implants** : These include Norplant (6 capsules of levo-norgesterol) and Implanon (single rod of 3-keto desogesterol).

**(c) Contraceptive Impregnated Devices** : as progesterone releasing IUD (progestinsert, LNG-20, Levonova); or contraceptive vaginal rings.

Of the above, DMPA (Depot provera) and NET-EN are often used and available in India. DMPA is given 150mg i. m. inj and remains effective for 3 months; NETEN is given 200mg as an oil based i. m. inj and remains effective for 2 months. These are most effective when given within first 1-5 days of menstrual cycle. The failure rate is only 0.1 to 0.4%.

Absolute contra-indications for their use are pregnancy, unexplained vaginal bleeding and current breast cancer. Relative contraindications include less than 6 weeks postpartum among breast feeding women, history of breast cancer, jaundice,

cirrhosis, liver tumor, severe headache, undiagnosed breast disease, previous OC related liver diseases, and H/o IHD, hypertension or stroke. Fertility may take 6 to 12 months to return after discontinuation of this injection.

#### **Emergency (post-coital; morning-after) contraception**

Emergency contraception pills (ECPs) are a very good method of preventing pregnancy likely to occur due to unprotected sex or else due to suspected failure, as rupture of a condom. The following are the salient features of ECPs :

- (a) ECPs are hormonal oral contraceptives having the same hormones as used in OCs but in a higher concentration.
- (b) ECPs come in a pack of two pills. The first should be taken as soon as possible, but certainly within 72 hours of an unprotected sex. The second should be taken 12 hours after the first pill.
- (c) One ECP packet can protect only against one episode of unprotected sex.
- (d) ECPs are available free of cost at PHCs and with ANMs at subcentres, under the name of "E-Pill". They are also commercially available under brand names like Ecee-2, Norlevo, E-P-72 and Pill72.
- (e) ECPs are safe for all women including those who are breast feeding.
- (f) If the lady vomits within 1 hours of taking the pill, the dose should be repeated after taking an antiemetic as Meclizine HCL (Pregnidoxin)
- (g) Some women may have minor side effects as breast tenderness, headache, nausea, vomiting, spotting, fatigue, and dizziness which may last for maximum of 24 hours.
- (h) It should be clearly conveyed to the clientele that ECP is not an abortion pill since it cannot dislodge an implanted ovum.
- (i) ECP is quite effective in that they may prevent up to 75% pregnancy which would have otherwise occurred following unprotected sex.
- (k) After taking ECP, if onset of next menstrual cycle is delayed by more than 1 week of expected date, a pregnancy test should be done. She should also report if the period starts on time but the flow is scanty or is unusually foul smelling.
- (l) ECP should not be used as a regular contraceptive method.
- (m) In case E-pill or such ECP preparation is not available, the women can take 4 tabs of Mala-D at the earliest but within 72 hours of unprotected sex, followed by 4 Tablets of Mala-D after 12 hours of first dose.
- (n) Reassure the women that her next period will start on the expected date or sometime 2-3 days earlier or later than expected date.

#### **Non-Hormonal Oral Contraceptives : Centchroman**

This is a new form of oral contraceptive pill that does not contain any steroidal hormones, developed by the Central Drug Research Laboratory, Lucknow. It appears to be safe and economical and is sold under the brand names "Saheli" and "Centron". It is taken once a week and is very convenient. It is very effective and can increase client privacy. There are no known side effects, except that in about 8% of users there is a delay in menses.

## Permanent Methods

Permanent methods include male sterilization (Vasectomy) and female sterilization (Tubectomy). Any couple who has at least one child and is voluntarily motivated can be offered sterilization procedure. Medical officers should emphasize on the clientele that these procedures are perfectly safe and do not carry adverse effects like decline in libido, low backache, obesity and so on, as are commonly thought of. In fact the sexual performance and pleasure may improve since the fear of unwanted pregnancy is removed.

**Vasectomy** : In the conventional procedure, an incision is given on the scrotal skin and a piece of vas deferens 1 to 1.5 cm long is removed. In the more recent technique of "No Scalpel Vasectomy" a puncture is made in scrotal skin using a reverse scissor and a hole of approx half a cm is created through which vas is ligated after removing a piece 1 cm long. The advantage of this method is that no stitches need to be given on the scrotal skin. It must be emphasized on the acceptor that it will take 3 months for him to become completely sterile. For this duration, he or his wife should use an alternative temporary method. After 3 months, seminal analysis should be done to confirm azoospermia. The following advice should be given for implementation during post operative period :

- He or his partner should use some other contraceptive procedure till such time the semen exam indicates definite azoospermia, which is generally after 3 months.
- To keep the local area clean and dry.
- To wear a T-bandage for 2 weeks
- To avoid cycling or lifting heavy weights for 2 weeks
- To get the stitches removed as advised by the surgeon.

There are very few complications of vasectomy and even these are minor. Some persons may get pain, local infection and haematoma which last for a few days and respond well to antibiotics and analgesics. Local granuloma formation may occur in a very few patients and subsides over time. The most important complications are, in fact, psychological, as feeling of low backache, development of abdominal obesity and reduced sexual drive. Subjects should be adequately educated and counselled about these psychological problems.

Overall failure rate of vasectomy is between 1 to 2 per 1000 person years (0.1 to 0.2 per 100 person years). The two important causes of its occurrence are firstly, mistakenly removing some other anatomical structure (as a local vein or spermatic chord) instead of vas. This problem is negligible in expert hands. The second reason is spontaneous recanalisation of the vas, the potential of which always exists to the tune of 0 to as high as 6%. Therefore, all persons undergoing vasectomy should be explained of this unforeseen complication and advised regular follow up for at least 3 years. In addition, another cause of pregnancy could be unprotected intercourse before complete azoospermia, which usually takes 3 months, but may be more in some subjects. It is therefore important to advise the subjects on these various aspects, since misconceptions and lack of knowledge may lead to serious domestic conflicts.

**Tubectomy** : In the conventional method (Pomeroy's method), a piece of the loop of Fallopian tubes about 1 cm long on both sides is removed. The same is done in minilaparotomy.

In Laparoscopic tubectomy the tubes are either blocked by electrocoagulation or sealed with a silastic band. The ideal time for tubectomy is soon after menstrual flow is over or in the post partum period. However, it can be done anytime in between the menstrual period but the woman should continue to use alternative contraceptive till her next menstrual flow.

**Recanalisation** : For couples who have undergone sterilization operation but now need children, recanalisation operations are available. The success of recanalisation depends on many factors, the most important being the fertility state of both the partners. In case of tubal recanalisation it also depends on the original method by which tubectomy was done - if the original method was spring loaded clip, the pregnancy rate following recanalisation may be as high as 88%, while for Pomeroy method it is about 60%. As regards recanalisation of vas, in expert hands, the patency rate may be as high as 80% but actual pregnancy rate may be lower due to various other factors as fertility status of the husband and wife.

## Summary

As per present policy in the country, people are given choice to adopt contraceptive methods voluntarily out of various choices available. The various methods of contraception are divided broadly into artificial and natural methods. The natural methods include Rhythm method, Basal body temperature method, cervical mucous method, Symptothermal method and Lactational amenorrhoea method.

Artificial methods are further subdivided into temporary and permanent methods. Temporary methods include barrier contraceptives, spermicides, IUDs, oral & non-oral hormonal contraceptives. Most commonly used barrier contraceptive is condom which has the additional advantage of providing protection against STDs and HIV. It has average failure rate of 12-14 HWY, mainly because of incorrect technique of use.

IUDs act mainly by inducing inflammatory changes in endometrium, incapacitating the sperm & ovum and preventing implantation. IUDs are divided into Gp I, II & III. Before its insertion, various contraindications should be ruled out. It should be inserted soon after menstruation upto 10th day of cycle. It can also be inserted in immediate postpartum or ideally 6 weeks after delivery/abortion. It can be used as a postcoital contraceptive. After its insertion woman should be instructed regarding regular checking of IUD in place, and regular health checkups. Important complications include menorrhagia, dysmenorrhoea, expulsion, perforation, Infection & ectopic pregnancy. Average failure rate is 1-2 HWY.

OCPs are divided into combined pills and progesterone only pills. Progesterone only pills can be used in women >40 yrs. or lactating period upto 6 months of postpartum. Combined pills act by inhibiting ovulation, altering endothelium and changing cervical mucus. Combined pills can be monophasic or triphasic. Commonly used monophasic pills now come with low amount of estrogen i.e. < 0.05mg ethinyl estradiol. The first pill is taken on 6th day of period and is continued for 21 days, and after stopping for 7 days it is restarted. Failure rate is as low as 0.1 HWY. Major side effects are increased risk of IHD, CVA and venous thromboembolism.

Non-oral hormonal contraceptives include Injectable (DMPA, NETEN), Contraceptive Implants (Norplant, Implanon), Contraceptive Impregnated Devices (Progestinert, LNG-20). Emergency contraception pills (ECPs) have the same hormones as combined pills but in higher dose, the 1st dose should be taken as soon as possible after unprotected sex (max 72 hr) and 2nd dose 12hr after the 1st dose.

Permanent methods include vasectomy and tubectomy. Vasectomy can be conventional or No scalpel vasectomy. An alternative temporary method should be used till azoospermia is achieved after vasectomy (usually 3 months). Tubectomy can be done by Pomeroy's method using conventional, laparoscopic or minilap procedure. In laparoscopic tubectomy, electrocoagulation or sialistic rings are used. Recanalisation after permanent methods is possible with varying degree of success results.

## Study Exercises

**Long Question :** How will you educate a group of approximately 150 adult, married men and women aged 20 to 50 years, belonging to a rural background and most of them educated between 4th to 8th class, as regards the various available contraceptive procedures.

**Short Notes :** (1) Pearl Index (2) Compare and contrast OCs and IUDs (3) Emergency contraception.

### MCQs & Exercises

- In Rhythm method for contraception, intercourse is avoided during : (a) 3-14 days (b) 5-25 days (c) 10-28 days (d) 7-21 days
- In Basal Body Temperature Method for contraception, increase in body temperature occurs : (a) Just before the ovulation (b) Ovulation period itself (c) Immediately after ovulation (d) Menstruation
- The failure rate of cervical mucus method if used correctly is : (a) 1 per HWY (b) 2 per HWY (c) 3 per HWY (d) 4 per HWY
- The failure rate of Condom is : (a) 12-14 HWY (b) 14-17 HWY (c) 17-20 HWY (d) 20-25 HWY
- The active agent in spermicidal jelly is : (a) 9-Xylenolol (b) 9- Xylene (c) 9- Nonoxynol (d) 9- Nonxynol
- In Cu T-200, 200 signifies : (a) Weight of Cu in mg (b) Surface area of Cu in sqmm (c) Length of Cu wire in mm (d) Diameter of Cu wire in  $\mu\text{m}$
- The mechanism of action of IUD does not include (a) Inducing mild inflammatory changes and foreign body reaction in the endometrium (b) Incapacitate the sperms and ovum, prevent sperm from fertilizing the ovum (c) Makes the uterine environment inhospitable for the blastocyst to be implanted (d) Increases the reverse peristalsis of uterus
- Which of the following IUDs belong to Gp II IUDs : (a) Cu T- 200 (b) Lippe's loop (c) Cu T-380A (d) ML-250
- The presence of Cu-T in place is checked routinely by (a) Feeling the thread coming out of cervical os (b) Absence of menstruation (c) Feeling the metal tip in upper part of vagina (d) None of the above only X-ray can check it
- Which one is not an absolute contraindication for IUD insertion : (a) Pregnancy (b) Puerperal sepsis (c) Anaemia

- (d) Bleeding P/V of unknown etiology
- Which of the following is not the likely adverse effect of IUD : (a) Menorrhagia (b) Metrorrhagia (Intermenstrual bleeding) (c) Polymenorrhoea (d) Anaemia
- Single pill of MALA-D contains : (a) L-norgesterol (LNGL) 0.15mg and EE 0.03mg (b) L-norgesterol (LNGL) 0.03mg and EE 0.15mg (c) D-norgesterol (LNGL) 0.15mg and EE 0.03mg (d) D-norgesterol (LNGL) 0.03mg and EE 0.15 mg
- Which of the following is not the likely mechanism of action of OCPs : (a) Inhibition of ovulation by bringing about changes in FSH & LH secretion (b) By altering the endometrium (c) By bringing about changes in cervical mucus (d) Incapacitates sperm
- Which of the following is not the likely adverse effect of OCP : (a) Menorrhagia (b) Breast Heaviness (c) Oligomenorrhoea (d) Dysmenorrhoea
- The failure rate of OCP is : (a) 1 HWY (b) 2-3 HWY (c) 0.1 HWY (d) 10 HWY
- Which is not the contraindication for OCP use (a) Hyperlipidaemia (b) Cirrhosis of liver (c) Unexplained vaginal bleeding (d) Anaemia
- Which of the following is most cost effective method for permanent sterilization : (a) Vasectomy (b) Pomeroy's tubectomy (c) Laparoscopic tubectomy (d) No scalpel vasectomy
- After vasectomy/ no scalpel vasectomy, for at least how many months should the couple use alternative temporary method of contraception : (a) 3 weeks (b) 3 months (c) 2 weeks (d) 2 months
- Emergency contraceptive pill should be used within a max period of : (a) 24 hr (b) 48 hr (c) 72 hr (d) 96 hr
- What is a mini pill : (a) Pill containing lesser amount of estrogen and progesterone (b) Once a month pill (c) Progesterone only pill (d) Emergency pill

### Match the Following :

1. Cervical mucus Method	a. 12 to 14 / HWY
2. Condoms	b. 3 / HWY
3. IUDs	c. 1 per 1000 women year
4. Combined OC	d. 1 to 2/ HWY

### Fill in the Blanks

- Emergency Contraceptive Pills (Hormonal) come in a pack of \_\_\_\_ Pills, The first should be taken as soon as possible, but certainly within \_\_\_\_ hours of an unprotected sex. The second should be taken \_\_\_\_ hours after the first pill.
- The first pill is taken on Day \_\_\_\_, one pill every day for next \_\_\_\_ days. Thereafter the pill is stopped & restarted after a gap of \_\_\_\_ days, irrespective of the onset or stoppage of menstruation during these pill free periods.
- \_\_\_\_ Oral contraceptive pill is available free of cost under the FW program in our country. This contains \_\_\_\_ dl-NGL and \_\_\_\_ Ethinyl estradiol (EE) per pill.
- Oral Contraceptives produce contraceptive effect by \_\_\_\_ and \_\_\_\_ and \_\_\_\_
- The best time to insert Copper-T is \_\_\_\_

**Answers : MCQs :** (1) d; (2) c; (3) c; (4) a; (5) c; (6) b; (7) d; (8) d; (9) a; (10) c; (11) c; (12) a; (13) d; (14) d; (15) c; (16) d; (17) d; (18) b; (19) c; (20) c; **Match the Following :** (1) b; (2) a; (3) d; (4) c; **Fill in the Blanks :** (1) 2, 72, 12 (2) 1, 21, 7; (3) Mala-N, 0.30mg, 0.03mg (4) Inhibition of ovulation by bringing about changes in FSH & LH secretion, by altering the endometrium and by bringing about changes in cervical

mucus (5) During or soon after menstrual period.

### Further Suggested Reading

1. Hatcher RA, Rinechant W, Blackburn R, Galler JS. The essentials of contraceptive technology. John Hopkins School of Public Health, Baltimore, USA. First edition 1997.
2. Chaudhari SK. Practice of fertility control : A comprehensive text book. BI Chuchil Livingstone, New Delhi, 5th Edition 2001.



# 8

## Entomology in Public Health Practice



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Rina Tilak

The word 'Entomology' is derived from the Greek words 'ENTOMON' meaning an insect and 'LOGOS' meaning science, thus ideally making Entomology 'the branch of science which deals with the study of insects'; however, the scope of the subject has been broadened to include study of all Arthropods. Phylum Arthropoda constitutes all invertebrates with jointed appendages and presence of chitinous exoskeleton besides other features. The word Arthropoda is derived from two words 'ARTHRON' meaning jointed and 'PODA', which means legs or appendages. The Phylum has many important classes of which Class Insecta is the largest, constituting more than four million insect species. The other important classes are Arachnida, Crustacea and Myriapoda.

Vector borne diseases are one of the leading causes of morbidity and mortality the world over and pose a major public health challenge especially to the third world or developing countries. One of the important measures to combat these diseases is through control of vectors. To ensure effective vector control, the knowledge about their lifecycle, habits, habitat and diseases transmitted is essential. The chapters in this section will guide the reader on these aspects so that sound vector control strategies can be formulated, wherever and whenever, vector control is desired.

### Classification of Arthropods

Diversity of structures amongst arthropods necessitates the sub-division of the phylum Arthropoda into a number of classes, orders, families, genera and species. The following classes include species of medical importance.

**(a) Class Insecta** : It comprises about 70% of all the known species in the animal kingdom. The insects are characterized by the presence of six legs, body divided into head, thorax and abdomen and presence of antennae besides other features. The head bears the mouthparts, eyes in the form of compound or simple eyes or at times may have no eyes and a pair of antennae. The thorax is subdivided into three segments with a pair of legs in each called the pro, meso and metathoracic legs. The class is further subdivided into 29 orders of which only 4 contain species of medical importance.

**(i) Order Diptera** : It possesses one pair of wings and a pair of 'halteres', which are vestigial wings. This is the largest order comprising about seventy thousand described species with world wide distribution. It contains such insects of medical importance as mosquitoes, sandflies, simuliid flies and house-flies.

**(ii) Order Anoplura** : It comprises true or sucking lice, which are parasitic on mammals and the chewing lice, which infest birds as well as mammals. Lice of medical importance to man are human lice.

**(iii) Order Siphonaptera** : It contains many species of fleas including the rat flea, which is a vector of plague and endemic typhus.

**(iv) Order Hemiptera** : It contains the bedbugs and some other species like kissing or 'assassin' bugs, which act as vectors of 'Chagas' disease.

**(b) Class Arachnida** : It includes arthropods like ticks, mites, spiders and scorpions. The class is characterized by the presence of eight legs, body divided into two parts viz. cephalothorax (head and thorax are fused together) and abdomen and absence of antennae and wings. The cephalothorax bears six pairs of appendages, the first two pairs function as mouthparts (chelicerae and pedipalps) and last four pairs as walking legs.

**(c) Class Crustacea** : It includes lobsters, crabs, water fleas and cyclops; some species of these are intermediate hosts of certain human helminths, e.g. Cyclops as intermediate host of guinea worm infestation.

**(d) Class Myriapoda** : It includes centipedes and millipedes.

### Modes of Disease Transmission

Arthropods transmit diseases to man through specialized modes of disease transmission. The modes of disease transmission by arthropods can be classified as under :

**Direct Contact** : When two hosts are in direct contact with other, the arthropod vector itself gets transferred from one host to the other, e.g. pediculosis and scabies.

**Mechanical transmission** : In this mode of transmission, the disease causing organism is transmitted on the outside or inside the bodies of arthropods without undergoing any development, propagation or any changes in the pathogenicity e.g. diseases transmitted by houseflies - diarrhoea, dysentery, cholera, hepatitis A & E etc.

**Biological Transmission** : The disease causing organism undergoes certain biological changes inside the body of the vector. Depending on the type of biological changes, biological transmission has been further classified as :

**Cyclo-developmental** : In this mode of transmission, the disease causing organism undergoes a part of its cycle in the vector and simply develops or grows inside the body of the vector, e.g. *Wuchereria bancrofti* (Filariasis) transmitted by Culex female.

**Cyclo-developmental-propagative or Cyclo-propagative** : In this mode of transmission, the disease causing organism undergoes a part of its life cycle in the vector and also grows/develops and multiplies inside the body of the vector. Example is *Plasmodium* sp (Malaria) transmitted by Anopheles female.

**Propagative** : In this transmission mode, the disease organism simply grows and multiplies in the body of the vector, e.g. *Yersinia pestis* (Plague) transmitted by rat flea and all bacterial, viral, spirochaetal or rickettsial diseases transmitted by arthropods.

**Other Specialized Modes of Disease Transmission** : These specialized modes of disease transmission are generally encountered in ticks and mites.

**Trans-ovarian** : The disease organism is transmitted to eggs through ovary of infected female, e.g. *Orientia tsutsugamushi*, the agent for Scrub typhus transmitted by trombiculid mite-*Leptotrombidium deliense*.

Table - 1 : Important arthropod borne diseases			
Disease	Vector	Causal organism	Reservoir
<b>I Mosquito borne diseases</b>			
Malaria	<i>Anopheles species</i>	<i>Plasmodium species</i>	Man
Filariasis	<i>Culex quinquefasciatus</i> <i>Aedes niveus group</i> <i>Mansonioides species</i>	<i>W bancrofti</i> (nocturnal, periodic) <i>W. bancrofti</i> (diurnal sub-periodic) <i>Brugia malayi</i>	Man Man Man, Primate
Chikungunya	<i>Aedes species</i>	Arbovirus group A	Man
Dengue fever & DHF	<i>Aedes species</i>	Arbovirus group B	Man
Yellow fever	<i>Aedes species</i>	Arbovirus group B	Man/ Monkeys
Japanese Encephalitis	<i>Culex vishnui group</i> ( <i>C tritaeniorhynchus</i> )	Arbovirus group B	Mammals/ Birds
<b>II Sandfly borne diseases</b>			
Leishmaniasis			
Visceral (Kala azar)	<i>Phlebotomus argentipes</i>	<i>Leishmania donovani</i>	Man/Mammals
Cutaneous (Oriental sore)	<i>P. papatasi</i> <i>P. sergenti</i>	<i>L. tropica</i> <i>L. braziliensis</i>	Man/Mammals Man
Espundia			
Sandfly fever	<i>P. sergenti, P. papatasi</i>	Virus	Man
<b>III Fly borne diseases</b>			
Bacillary dysentery	<i>M domestica</i>	<i>Shigella</i>	Man
Amoebic dysentery	<i>M domestica</i>	<i>E. histolytica</i>	Man
Gastroenteritis	<i>M domestica</i>	Specific/Non specific organisms	Man/animals
Typhoid	<i>M domestica</i>	<i>Salmonella typhi</i>	Man
Paratyphoid	<i>M domestica</i>	<i>Paratyphoid A&amp;B</i>	Man
Cholera	<i>M domestica</i>	<i>Vibrio cholera</i>	Man
Poliomyelitis	<i>M domestica</i>	Virus	Man
Viral hepatitis (Type A)	<i>M domestica</i>	HAV	Man
Trachoma	<i>M domestica</i>	<i>C trachomatis</i>	Man
Yaws	<i>M domestica</i>	<i>T pertenue</i>	Man
<b>IV Flea borne diseases</b>			
Plague (Bubonic)	<i>Xenopsylla species</i>	<i>Yersinia pestis</i>	Rodents
Endemic/Murine Typhus	<i>Xenopsylla species</i>	<i>R. typhi</i>	Rodents/ Domestic animal
Chiggerosis (Jigger)	<i>Tunga penetrans (chigoe)</i>	-	-
Dipylidium caninum	<i>Ctenocephalides felis/canis</i>	<i>Dipylidium caninum</i>	Dogs, cats, wild
Hymenolepis diminuta	<i>X cheopis / N.fasciatus</i>	<i>Hymenolepis diminuta</i>	Carnivores
H nana	<i>X cheopis / C canis/ Pulex irritans</i>	<i>H nana</i>	Rats, mice
<b>V Louse borne diseases</b>			
Epidemic typhus	<i>Pediculus humanus</i>	<i>R. prowazeki</i>	Man
Epidemic relapsing fever	<i>Pediculus humanus</i>	<i>Borrelia recurrentis</i>	Man
Trench fever	<i>Pediculus humanus</i>	<i>Bartonella quintana</i>	Man/animals
Dermatitis	<i>Pediculus humanus/capitis</i>	Secondary organisms	Man
<b>VI Tick borne diseases</b>			
Kyasanur Forest Disease (KFD)	Hard ticks species	Arbovirus group B	Monkeys/Birds
Tick typhus	Hard ticks species	<i>R conorii</i>	Dogs
Tularaemia	Hard ticks species	<i>P tularensis</i>	Rabbits/ Rodents/ cattle
Relapsing fever	Soft Tick	<i>B duttoni</i>	Rats
<b>VII Mite borne diseases</b>			
Scrub typhus	<i>L. deliense</i>	<i>Orientia tsutsugamushi</i>	Rodents
Rickettsial pox	<i>Allothrombomys sanguineus'</i>	<i>R akari</i>	Rodents
Scabies	<i>S scabiei</i>	-	Man
<b>VIII Cyclops transmitted diseases</b>			
Dracontiasis	Cyclops species	<i>D medinensis</i>	Man
Fish tape worm	Cyclops species	<i>D. latum</i>	Fish
<b>IX Reduviid bugs</b>			
Chagas disease	Reduviid/Cone-nosed	<i>T cruzi</i>	Domestic animals/ man
<b>X Tsetse flies</b>			
Trypanosomiasis	<i>Glossina species</i>	<i>T gambiense and T rhodesiense</i>	Wild animals/ cattle/ man



**Trans-stadial** : The disease causing organism is transmitted from one stage to another e.g. Tick typhus organism - *Rickettsia conorii* transmitted from infected larva to nymph to adult.

### Arthropod Borne Diseases

Arthropods are responsible for transmission of innumerable diseases. Some of the important arthropod borne diseases is listed in Table - 1 along with their vectors, causative organisms and reservoir hosts.

### Summary

Entomology is the branch of science which deals with the study of insects, however, the scope of the subject has been broadened to include the study of all Arthropods. Amongst the many important classes of the phylum, Insecta is the largest constituting more than 4 million species. Vector borne diseases are one of the leading causes of morbidity & mortality especially in the developing countries. These diseases can be largely combated by effective vector control for which a sound knowledge of the bionomics of the vector is needed. The important classes of Phylum Arthropoda are Insecta, Arachnida, Crustacea, Myriapoda. The class Insecta is characterized by presence of six legs, body divided into head, thorax & abdomen. The class has 4 orders of medical importance, Diptera, Anoplura, Siphonaptera & Hemiptera. The order Diptera has 1 pair of wings and contains insects such as mosquitoes, sandflies, simuliid flies and houseflies. The order Anoplura comprises true or sucking lice. Order siphonoptera includes the rat flea; the order hemiptera contains bed bugs. The class Arachnida includes ticks, mites, spiders and scorpions; body is divided into cephalothorax and abdomen and presence of eight legs. The class crustacea includes lobsters, crabs, water fleas and Cyclops. Myriapoda includes millipedes and centipedes.

Arthropods transmit diseases to man by different modes of transmission, mainly direct, mechanical & biological. In direct transmission, two hosts come in direct contact with each other e.g. pediculosis & scabies, mechanical transmission where disease causing organism is transmitted without undergoing any change in pathogenecity or development e.g. diseases transmitted by houseflies. Biological transmission is further divided into *cyclodevelopmental* - the disease causing organism undergoes part of its life cycle in the vector e.g. *Wuchereria bancrofti*; *cyclopropogative* - the disease causing agent undergoes part of the lifecycle in the vector & also multiplies inside the vector e.g. malaria transmitted by Anopheles female. The other mode is *propogative* where disease causing organism simply grows & multiplies in the body of vector e.g. *Yersinia pestis* (plague) transmitted by rat flea, other specialized modes are transstadial & transovarian.

### Study Exercises

**Short Notes** : Modes of disease transmission.

#### MCQs & Exercises

- 1) Class Insecta is characterised by presence of how many legs? : (a) 4 (b) 5 (c) 6 (d) 8
- 2) Mosquito belongs to the order a) Diptera (b) Anoplura (c) Siphonoptera (d) Hemiptera.
- 3) Mode of transmission of malaria by Anopheles is : (a) Cyclo - developmental (b) Cyclo - propogative (c) Propagative (d) Cyclo - developmental propagative
- 4) *Orientia tsutsugamushi* is the causal organism for the diseases (a) Scrub typhus (b) Epidemic typhus (c) Endemic typhus (d) Tick typhus.
- 5) Which of the following is not a mosquito borne disease : (a) Dengue (b) Filariasis (c) Leishmaniasis (d) Yellow fever
- 6) Aedes species cannot transmit : (a) Chickungunya (b) Dengue haemorrhagic fever (c) Japanese Encephalitis (d) Yellow fever
- 7) Causal organism for bubonic plague : (a) *R. typhi* (b) *Y. pestis* (c) *H. nana* (d) *H. diminuta*
- 8) Murine Typhus is transmitted by : (a) Hard tick species (b) Soft tick species (c) Xenopsylla species (d) Trombiculid Mite species
- 9) Causal organism for epidemic Typhus : (a) *B. quintana* (b) *R. prowazeki* (c) *Borrelia recurrentis* (d) *R. typhi*
- 10) KFD is transmitted by : (a) Soft Tick (b) Mite (c) Hard Tick (d) Lice
- 11) \_\_\_\_\_ is the largest class of Phylum Arthropoda constituting more than \_\_\_\_\_ insect species
- 12) Direct mode of transmission is seen in \_\_\_\_\_ & \_\_\_\_\_
- 13) Entomology is derived from the Greek word ENTOMON meaning \_\_\_\_\_ & LOGOS meaning \_\_\_\_\_
- 14) Arthropoda is derived from two words ARTHRON meaning \_\_\_\_\_ & PODA meaning \_\_\_\_\_
- 15) *Leptotrombidium deliense* is vector for \_\_\_\_\_

**Answers** : (1) c; (2) a; (3) b; (4) a; (5) c; (6) c; (7) b; (8) c; (9) b; (10) c; (11) Insecta ; 4 Million; (12) Pediculosis; Scabies; (13) Insect, Science; (14) Jointed, Appendages; (15) Scrub Typhus.

### Further Suggested Reading

1. Gordon C cook, Alimuddin Zumla, Manson's Tropical diseases, 21st Ed, 2003, Chapter 50, Rickettsial infections, p 900.
2. Service Mike. Medical Entomology for students. 3rd ed. Cambridge : Cambridge University Press, 2004.
3. Kettle DS. Medical and Veterinary Entomology. 2nd ed. CAB International, 1995.
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Control of arthropods is one of the key strategies in the management of vector borne diseases. A strategist should have sound knowledge of the bionomics, distribution, seasonal prevalence, vectorial capacity, insecticide susceptibility status and role of arthropods in diseases transmission coupled with the knowledge of identification features of the incriminated vectors for formulating effective control strategies. Once armed with this knowledge, the choice of effective vector management tools may be exercised; the range and sophistication of control methods is impressive. The various control options available are as follows :

- Environmental Control
- Chemical Control
- Biological Control
- Personal Protective measures
- Mechanical control
- Physical control
- Genetic control
- Legislative control

### Environmental Control

The important environmental control measures which are increasingly being used are described below :

#### Environmental Management

This has been defined as “The planning, organization, carrying out and monitoring of activities for the modification and/or manipulation of environmental factors or their interaction with man with a view to prevent or minimize vector propagation and reducing man-vector-pathogen contact.” This is a naturalistic approach which attempts to extend and intensify natural factors which limit vector breeding, survival and contact with man.

**(a) Environmental Modification** : It is defined as “A form of environmental management consisting of any physical transformation that is permanent or long-lasting of land, water and vegetation aimed at preventing, eliminating or reducing the habitats of vectors without causing unduly adverse effects on the quality of the human environment”. Environmental modification includes drainage, filling, velocity alteration, land levelling and transformation of impoundment margins.

**(b) Environmental Manipulation** : It is defined as “A form of environmental management consisting of any planned recurrent activity aimed at producing temporary conditions unfavourable to the breeding of vectors in their habitats”. Examples of environmental manipulation activities are water salinity changes,

stream flushing and regulation of the water level in reservoirs, vegetation removal, shading and exposure to sunlight.

**(c) Modification or Manipulation of Human Habitation or Behaviour** : This means “A form of environmental management that reduces man-vector - pathogen contact”. Examples of this approach are siting of settlements away from vector sources, mosquito/rodent proofing, personal protection and hygienic measures against vectors and provision of mechanical barriers, providing facilities for water supply, disposal of waste water and excreta, laundry, bathing and recreation to prevent or discourage human contact with infested water.

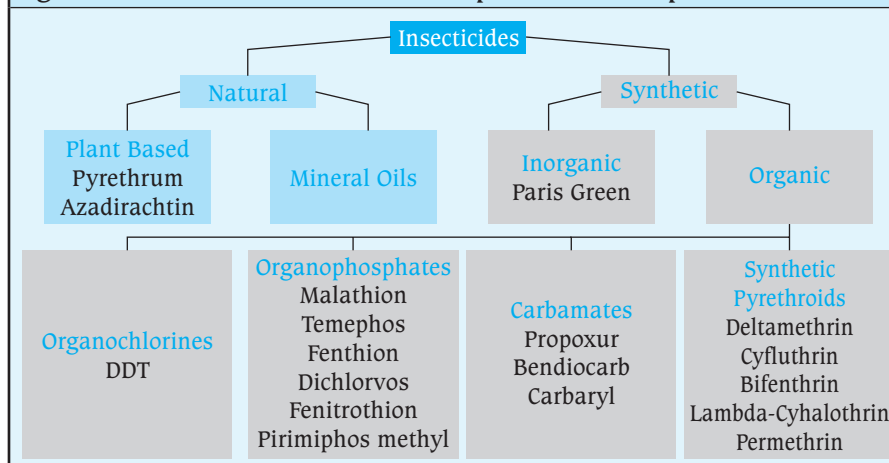
### Chemical Control

The new era of control of vector borne disease began with the discovery of the insecticidal value of Dichloro Diphenyl Trichloro ethane (DDT). DDT was first synthesized by Othmar Zeidler in 1874 at Strasbourg, Germany. In 1939, Paul Muller of the Geigy Company in Basle, Switzerland, discovered its remarkably long residual insecticidal property, earning him the Nobel Prize in Medicine. The availability of several effective, safe and low cost pesticides, coupled with improvements in the techniques of their application, made it possible for many governments in the developed as well as developing countries to embark upon extensive countrywide programmes for the control or eradication of vector borne diseases. However, development of resistance amongst vectors to insecticides has necessitated reassessment of the place of pesticides in vector control programmes. Besides the technical and financial difficulties, there is a growing concern about the environmental contamination resulting from the persistent use of insecticides.

#### Classification of Insecticides

Pesticides may be classified in many ways based on mode of entry, target stage, chemical composition and mode of action. However, the most common classification used is based on chemical composition. According to this classification, the insecticides are classified in the following categories as presented in Fig. - 1.

Fig. - 1 : Classification of insecticides as per chemical composition



## Natural Insecticides

### Plant based

**Pyrethrum** : Pyrethrum extract is obtained from the dried heads of the flower *Chrysanthemum cinerariaefolium* and contains the active ingredients pyrethrins I and II, constituting 1 to 2% of the total weight of the raw pyrethrum. Pyrethrum is characterized by rapid knockdown action on arthropods even when used in very low dilution. It is very unstable in light and air and has practically no residual effect. This makes repeated applications necessary. Pyrethrum is available as 2% extract, which needs 20 times dilution to make it 0.1% solution, which is actually used for spraying. Using a 0.4 mm or lower calibre nozzle, 50 to 100 ml of pyrethrum solution in kerosene oil is sprayed per 100 m<sup>3</sup> of space. Addition of an Organophosphorus insecticide to pyrethrum formulation is a common commercial practice for obtaining a better effect. It is one of the main insecticidal constituents in aerosol dispensers and also an insecticide of choice for ULV sprays. Pyrethrum is perhaps the most acceptable insecticide for use in cook houses, dining halls and other food preparation areas.

**Azadirachtin** : The active ingredient Azadirachtin is obtained from the seed kernels of neem plant *Azadirachta indica*. Azadirachtin has insecticidal, fungicidal, bactericidal, viricidal properties including insect growth regulating qualities besides deterrent, anti-ovipositional, anti-feedant, fecundity and fitness-reducing properties on insects. It has been variously formulated for mosquito larval and adult control in the form of liquid and cream formulations. Neem products contain up to 3% Azadirachtin.

**Mineral Oils** : Kerosene oil, diesel oil, petrol and crude engine oil have been successfully used as mosquito larvicides. The oil film cuts off the air supply, enters and blocks the trachea, may act as a stomach poison, and also lowers surface tension which prevents larvae from floating. Malariol is the best and easiest larvicidal oil to use for Anopheline and Culicine larvae. Malariol is used as it is @ 10 litres per 500 linear meters.

**Synthetic Insecticides** : These can be organic or inorganic. The only inorganic compound used in vector control (mosquito larvicide) was Paris green (Copper-aceto-arsenite). It acted as stomach poison when ingested by mosquito larvae. However, it is not used any more for mosquito control.

The Organic Insecticides fall into four major groups viz. Organochlorines, Organophosphates, Carbamates and Synthetic pyrethroids.

**Organochlorine Compounds** : These compounds are contact poisons and act on the nervous system. These or their degradation products are more or less stored in body fat and may be demonstrated in milk, urine or sweat. They all have variable residual action for variable periods and are toxic to man and animals. The most important and the only member of this group used in Public Health is DDT.

**Dichloro-diphenyl-trichloroethane (DDT)** : Currently DDT is being used for indoor residual spray in the North Eastern states of India. A deposit of 1 g of DDT/m<sup>2</sup> of surface area of walls and ceiling upto a height of 3.5 m in all dwellings applied at 8 weeks' interval, effectively controls majority of the mosquitoes and also other arthropods resting on the treated wall (Refer to

Chapter on Mosquitoes for further details on use). As per Govt. of India Gazette notification number S.O. 378(E) dt 26<sup>th</sup> May 1989, the use of DDT in Agriculture has been withdrawn and restricted to 10000 MT/ annum for Public Health programme except in case of North East as Insecticidal Residual Spray (IRS).

**Organophosphorus Compounds** : These insecticides are derivatives of phosphoric acid and act by inhibiting the activity of cholinesterase. Many of the insects, which have become resistant to Organochlorines are still susceptible to the members of this group. However, due to their extensive use in agricultural as well as public health field, more and more insects are developing resistance to Organophosphorus compounds. Some of the common compounds are Malathion, Temephos, Fenthion, Dichlorvos (DDVP) and Fenitrothion.

**Malathion** : It is one of the least toxic Organophosphorus compounds. Malathion is a broad spectrum insecticide, with efficacy against a large number of pests ranging from mosquitoes, houseflies, cockroaches, bedbugs, lice etc. It is available as Malathion Technical (95%) for use as space spray, 50% Water Dispersible Powder (WDP) and Emulsifiable Concentrate (EC) for residual control and 90% dust for use against fleas and lice. Malathion under the National Vector Borne Diseases Control Programme of India is being used as Indoor Residual Spray against mosquitoes in areas where the vectors have become resistant to DDT. The dosage of its application is 2 g/m<sup>2</sup> (Refer to Chapter on Mosquitoes for further details). As ULV spray it has been very widely used during outbreaks of Dengue and JE as an anti adult mosquito measure. However, development of resistance has been reported in a large number of vectors to Malathion.

**Temephos** : It is available as 50% EC. It is the only insecticide approved for use in potable water. Because of its low toxicity, it has been successfully used for the control of *Anopheles stephensi* breeding in wells and domestic containers at a dosage of 1ppm (Refer to Chapter on Mosquitoes for details). Sand impregnated with Temephos in 1% concentration has been used in some countries against *Aedes aegypti* which breeds in containers of clean and potable water. It has proved to be very successful in Guinea worm eradication programme in India.

**Fenthion** : It is formulated as 82.5% EC and as granules containing 2% toxicant. It is a good mosquito larvicide but can not be used in potable water bodies. It is highly effective as a larvicide against *Culex quinquefasciatus* or any other vector found breeding in non potable water bodies at a dosage of 1 ppm (Refer to Chapter on Mosquitoes for further details). It can also be used for housefly control as a larvicide (Refer to Chapter on Houseflies for details).

**Pirimiphos methyl** : This insecticide is being considered as an alternative insecticide for Indoor residual spray. It is available as 25% WP; 2 kg is mixed in 10 litres of water and sprayed @ 10 litres/ 250 sq m area to give a deposit of 2g/sqm. Three rounds of spray are recommended as is followed in case of Malathion.

**Dichloro-dimethyl-dichlorvinyl-phosphate (DDVP or Dichlorvos)** : It differs from other organophosphorus compounds in that it possesses a much greater vapour pressure at ordinary temperature which produces fatal insecticidal



vapour. It is available as 72.6% EC. It can be combined with solid substances like wax and used as tablets or bricks thus allowing it to evaporate slowly. It is one of the common insecticides used for disinsecting aircraft. It is an effective housefly larvicide.

**Fenitrothion** : It is available as Fenitrothion 40% water dispersible powder (WDP). The insecticide has shown promise as an effective insecticide for control of bedbugs; however toxicity constraints have limited its widespread use.

**Carbamates** : These compounds are derivatives of carbamic acid and resemble Organophosphorus compounds in their mode of action. Some of the preparations produce a rapid knockdown effect like that of pyrethrum. The inhibition of Acetylcholine esterase is reversible with Carbamates and hence these compounds are less toxic. Some of the compounds in common use are Propoxur, Carbaryl and Bendiocarb.

**Propoxur** : It is formulated as WDP as well as EC. It is considered as the least toxic Carbamate compound for man and domestic animals. It has a flushing out effect and therefore is commonly used for cockroach and bedbug control. It is also used in bait formulations against houseflies and cockroaches.

**Bendiocarb** : Bendiocarb is an alternative insecticide for Indoor residual Spraying. It is available as 80% WP. For indoor residual spraying, it is recommended @ 200 mg/sqm. Two rounds of spray are recommended for effective control against malaria.

**Synthetic Pyrethroids** : These are synthetic derivatives or analogues of natural Pyrethrum. These are broad spectrum, highly potent with quick knock down action and long residual life. Synthetic pyrethroids are many times more effective than the previously available insecticides. Their relative safety to man and higher animals, their efficient biodegradability together with their higher target specific toxicity makes them very attractive materials for integrated vector control. The commonly available products are Permethrin, Allethrin, Phenothrin, Cypermethrin, Cyfluthrin, Deltamethrin and Bifenthrin. The Synthetic pyrethroids are formulated as WDP, EC, SC, Flow, EW and ULV formulations. Being broad spectrum, these insecticides are being used for vector control as residual spray, space spray and topical application as well as for treatment of clothing.

**Deltamethrin** : It is one of the most widely used Synthetic pyrethroid molecule in the field of vector control. It is available in many formulations for various vector control strategies viz. SC 2.5% (Flow) formulation for treatment of bednet and routine household pest control activity; 2.5% WP formulation for Indoor Residual spray in Malathion resistant areas and 1.25 ULV for space spraying. The target dose (for Indoor Residual Spray) is generally 20 mg of a.i. (active ingredient) per sq m of surface area.

**Cyfluthrin** : Besides Deltamethrin, this is the next most widely used molecule. It is available as 0.5% EW formulation for treatment of bednets; 5% EC for household use and 10% WP for use as indoor residual spray in Malathion resistant areas.

**Permethrin** : Widely used for control of lice, scabies and for treatment of clothing and bednets. The product is formulated in varying concentration as Shampoo formulation for use as anti-lice treatment and 5% cream for use in scabies treatment. Bed nets treated with Permethrin at the manufacturing stage itself

are available as Pretreated or Long Lasting Nets (LLNs).

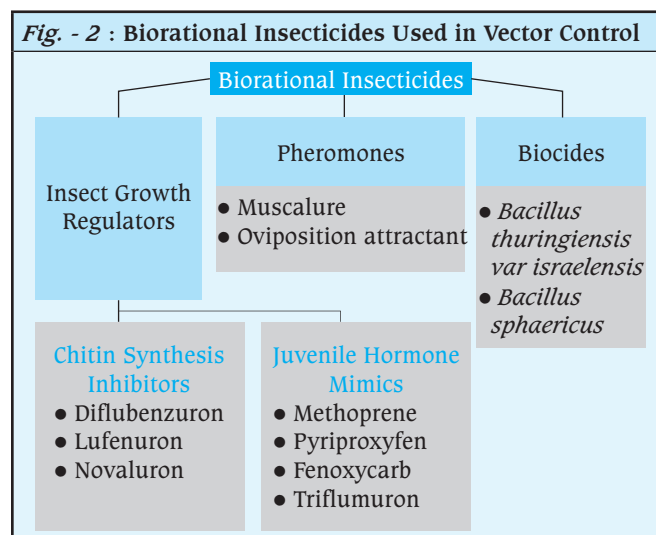
**Other Synthetic pyrethroids used in Public health** : There is a large range of molecules used in the field of Public health besides the ones listed above. These molecules are Allethrin, Resmethrin, Phenothrin, Cypermethrin, Imiprothrin, Bifenthrin, Cyhalothrin, Cyphenothrin etc. These are all available as WP, EC or Aerosol formulations for use against pests like cockroaches, houseflies and mosquitoes.

#### Newer Group of Insecticides

**Phenyl pyrazoles** : Fipronil is the only member of this class of insecticide. Fipronil acts by antagonizing the effect of GABA. It is available as 0.3% Gel for use against cockroach as a crack and crevice treatment. It is a systemic material with contact and stomach activity. It has a unique action called 'cascade effect' which is evident due to necrophagy seen in cockroaches. When cockroaches consume the insecticide bait, they are killed; these dead cockroaches when consumed by other cockroaches bring about the death of these cockroaches and this goes on for about two months or so, thus obviating the need to retreat the area at lesser intervals.

**Neo Nicotinoids** : Imidacloprid is the sole member from this class. It acts by causing irreversible blockage of postsynaptic acetylcholine receptors. Imidacloprid is a systemic insecticide, having notable contact and stomach action. Imidacloprid is available as 2.15% Gel for use against cockroaches and as Bait for use against houseflies, where it is formulated with housefly pheromone - Muscalure.

**Biorational Insecticides** : 'Biorational' means any substance of natural origin that has a detrimental or lethal effect on specific target pest, e.g. insects. These insecticides are non-toxic to man, plants and animals and have little or no adverse effects on the environment. An overview of the biorational insecticides is presented in Fig. - 2.



**Insect Growth Regulators** : A new approach to vector control is the use of substances that adversely affect insect growth and development. The enzymes and hormones that regulate developmental processes within an insect's body can sometimes be exploited as chemical control weapons. These compounds,



often known as Insect Growth Regulators (IGRs) can be used to stimulate development at inappropriate times or inhibit it at other times. They are quite selective in their mode of action and potentially act only on target species. Most of the IGRs that have shown effectiveness against insect pests, cause the rapid death of the insect through failure of a key regulatory process to operate or function. IGRs generally control insects either through inhibition of chitin synthesis or interference with metamorphosis by mimicking the action of juvenile hormone. The major groups of IGR compounds include :

**Chitin Synthesis Inhibitors** : These chemicals inhibit the moulting process by blocking the activity of chitin synthetase, an enzyme needed by epidermal cells when constructing a new exoskeleton. Because of this mode of action, Chitin Synthesis Inhibitors (CSIs) are highly specific to arthropods. They act rather slowly (2-5 days), but eventually disrupt any process that involves construction of new cuticle (e.g., molting, hatching, pupation). They are most effective when used against the immature stages of a vector. Diflubenzuron, is used for controlling mosquitoes, houseflies etc. It is available as 25% EC, WP & 0.5% Granules and is used @ 1.0 g/ acre of surface water as mosquito larvicide. Lufenuron, is a systemic CSI and is especially effective for flea and tick infestation control on animals. Novaluron is a recent addition to the list, which has been found effective against the mosquitoes. It is a contact larvicide and is available as 10% EC. It is used @ 20 µg a.i./ l and the efficacy lasts up to 3 months.

**Juvenile Hormone Analogues or Mimics** : Juvenile hormone analogues or Juvenile Hormone Mimics (JHM's) act by inhibiting the developmental changes associated with embryogenesis, morphogenesis, and reproduction. During normal development, JH levels are elevated in larvae (or nymphs) and decrease prior to pupation (or adult eclosion). Contact exposure to JH analogues during the egg stage or after the last larval molt can inhibit development, delay maturation, and eventually result in death. Since the onset of mortality is usually quite slow (days to weeks), these chemicals are not used during epidemics; however, these chemicals are much in demand for routine vector control due to their specificity and safety to non-target organisms. Several compounds (e.g., Methoprene, Pyriproxyfen, Fenoxycarb, Triflumuron) have been successfully incorporated into vector management programmes especially Dengue and Malaria and in products used for controlling ants, fleas, and other household pests. Pyriproxyfen can cause sterilization and inhibition of growth of adult insects; it has a residual effect up to 3 to 6 month indoors and 30 days outdoors. It is widely used against mosquitoes @ 2gm a.i./ sq m.

**Pheromones** : Pheromones are semiochemicals (chemicals which mediate interactions between organisms) secreted by an organism which provokes specific reaction in receiving organisms of the same species. These chemicals may further be classified based on the type of interaction mediated e.g. sex pheromone (muscalure secreted by houseflies), oviposition attractant (mosquito larvae), aggregation pheromone (cockroach, bedbugs), alarm pheromones, trail pheromones etc. The scope of pheromones in vector control is promising, however so far only two pheromones viz. Muscalure (in combination with Imidacloprid insecticide as baits against

houseflies) and oviposition attractant (Aedes control) have been exploited in the field of vector management.

**Biocides** : The development of insecticide resistance amongst the major pests and vectors coupled with the non target toxicity, necessitated development of safer alternatives to insecticides. This led to the screening, promotion and use of a large number of biorational products of which biocides are one of the most important control options. The two biocides used in the field of vector control are *Bacillus thuringiensis var israelensis* and *Bacillus sphaericus*. Both these products are widely used as larvicides in Mosquito control programmes and act as stomach poison.

***Bacillus thuringiensis var israelensis (Bti)*** : It was discovered in 1976 and has been found to be effective as mosquito larvicide. It is a gram positive spore forming bacteria. Bti produces toxins which are present in parasporal body called the 'protein crystal'. It primarily kills by the action of delta-endotoxin. When the mosquito larva ingests the protein crystal (inactive protoxin), it is activated inside its midgut by the action of proteases into active protoxin; these bind to the cell receptors present on midgut epithelium and cause disturbance in osmoregulatory mechanism which leads to swelling and eventual bursting of the epithelium and finally death of the larvae. The product is available as WP, Granules, AS & Briquette. Bti 12 AS is used @ 20ml/m<sup>2</sup> and has been found to be effective up to 15 days (for details refer chapter on mosquito). Bti however, suffers from the disadvantage that it can not be used in polluted waters or where particulate matter is more; it also cannot recycle in nature. It is used in non potable water bodies.

***Bacillus sphaericus*** : A naturally occurring bacterium used against mosquito larvae. It is more effective in polluted water and can recycle and persist in nature. It is available in various formulations like Bti viz. pellets, briquettes, granules & WP. It is used @ 20ml/m<sup>2</sup> and has been found to be effective up to three weeks.

**Fumigants** : Some of the fumigants used as pesticides are carbon tetrachloride, methyl bromide, ethylene dibromide, chloropicrin, carbon disulphide and dichlorvos (DDVP).

## Application Techniques

Control of arthropods in different habitats necessitates the use of different types of spraying equipment as well as a variety of formulations such as liquids, granules and dusts. For example control may involve treatment of small domestic or peridomestic water collections which are ideal breeding places for Aedes mosquitoes; applications to stagnant waters in cesspools, ditches and drains where Culex mosquitoes breed, large bodies of standing water where certain Anopheles mosquito species may be breeding; or aerosol spraying of extensive areas to halt epidemics. To meet with diverse situations, significant progress has been made in improving the spraying equipment. The Ultra Low Volume (ULV) equipment for ground and aerial spray to control mosquitoes and other haematophagous arthropods has resulted in not only the elimination of several impediments like frequent mixing and reloading but helped in increasing the speed of application and reducing the dosages and costs. It is specially recommended for control of an outbreak of vector borne disease.

## Formulations

Manufacturers combine pesticides with other materials to make usable concentrations called formulations. These formulations are designed to kill insects readily without causing undue hazards to non-target organisms when diluted and applied correctly. Factors influencing application and efficacy of an insecticide are its toxicity, size and shape of its particles, concentration in formulation; type of solvent used, type of surface to be sprayed, atmospheric temperature and humidity, type of sprayer and its nozzle, training of the spraying personnel, the bionomics, morphology and physiology of the particular arthropod. No single preparation can meet the requirement of vector control in all spheres of human ecology. Solutions, emulsions, suspensions, water dispersible powders, dusts and granules to suit different conditions and problems are therefore, prepared and used.

### Technical Grade Pesticide

This is the basic toxic agent in its purest commercial form. Some technical grade pesticides are liquids; others occur in solid form. Technical grade Malathion is used in ultra low volume space applications.

### Types of Formulations

Formulations essentially are of three types : Solid or dry, liquid and gaseous formulations.

#### Solid or Dry formulations

**Dusts** : Dusts are normally ready-to-use formulations with a low percentage of active ingredient (usually 1 - 10%) plus a very fine inert carrier such as talc, chalk, diatomaceous earth, clay or volcanic ash. These materials are usually low in cost, easy to apply, non-staining and non-toxic to vegetation. Dusts are always used dry and can easily drift into non-target areas if they are not applied carefully. For this reason, outdoor applications should be made only when the wind is calm. A common use for dusts is in crack and crevice or spot treatments indoors in out-of-sight areas (behind equipment, in wall voids and so on) which remain dry. The residual pesticidal activity of dust is normally fairly long, provided the dust stays dry, but quickly loses its toxicity in the presence of moisture. They don't adhere well to vertical surfaces.

Dusts are used on people during mass delousing operations to control outbreaks of lice borne diseases. Dusts are also used for flea control during plague outbreak. Dusts aren't generally absorbed through the skin, but may be dangerous if inhaled into the respiratory tract.

**Granules** : These are basically the same as dust formulation, except the carrier particles are larger and thus don't stick to leaves allowing penetration in dense foliage. This is a real advantage when the pesticide must reach the water surface for mosquito control in vegetated swamps, or if it must get to the ground surface through trees and shrubs for chigger control. Granules are also available in timed-release formulations that release a dosage of the pesticide over an extended period of time. Other advantages of using granules are that they provide longer lasting effects and their use results in less drift than generally occurs with liquids or dusts.

The percentage of insecticide in granules and pellets varies

from 1 to 5%. These can be used in irrigation channels, irrigated or flooded lands, paddy fields and particularly where there is vegetation on the water surface. After sinking, these formulations disintegrate slowly releasing small particles of insecticides. These can be effectively used also in small water collections such as ornamental tanks and earthen pots, tree holes and other domestic or peridomestic breeding places of *Aedes* mosquitoes.

**Wettable Powder** : This formulation consists of the technical grade pesticide, an inert carrier and a wetting agent (usually a synthetic detergent) that helps it mix with water. These usually contain 50 to 75% of the toxicant. Most of these can be put directly into water and require only slight agitation to make suspension; others may require mixing with a small amount of water to form a paste or slurry. The required volume of water is then added to paste or slurry followed by thorough agitation of the mixture.

When water is added to a wettable powder it makes a suspension; this enables the pesticide to stay on porous surfaces like concrete, plaster or unpainted wood. Water penetrates these surfaces, leaving the carrier and the maximum amount of the pesticide on the surface available to kill pests. Suspensions have other advantages, too. They have no solvent odour, and they don't tend to irritate or penetrate skin. However, they generally need agitation to keep pesticidal particles from settling out. Also, they tend to clog sprayer nozzles and strainers, especially when the wettable powder is stored for long periods in humid areas or when a high concentration is used.

#### Liquid formulations

**Emulsifiable Concentrates** : Emulsifiable concentrates consist of the technical grade pesticide (typically 45% to 75%), a solvent, and an emulsifying agent, usually a synthetic detergent. This agent is used to allow the concentrate to be diluted in water, resulting in an emulsion.

Emulsifiable concentrates are usually clear but emulsions look similar to milk. Finished sprays are emulsions or solutions diluted to field strength. Unlike solutions, most emulsions need a little periodic agitation to keep the concentrate from separating out of the water. Emulsions are used for residual treatments. Pests that contact these surfaces are killed by the pesticidal residue. Emulsions may damage aluminium, varnish, and painted surfaces due to the action of solvents such as Xylene. Emulsions may also be corrosive to metal sprayers and their fittings and hence sprayers made of stainless steel, aluminium or other non-corrosive materials should be used.

**Oil Solutions** : These formulations consist of a technical grade pesticide dissolved in a solvent such as kerosene or diesel oil. Solutions are available as ready-to-use formulations (for example ordinary household fly and mosquito sprays with a low percentage of pesticide) and as solution concentrates. These concentrates contain a high percentage of insecticide and must ordinarily be diluted in oil or another suitable solvent. Some concentrates are used without dilution in Ultra Low Volume (ULV) applications. Oil solutions applied as finished sprays often kill insects on contact, since the oil helps the pesticide penetrate the insect's waxy body wall.

**Ultra-Low Volume (ULV)** : While most items of ULV pesticide

dispersal equipment use the readily available solutions or technical grade formulations, there are special ULV formulations available for e.g. Deltamethrin 1.25 ULV etc.

**Gaseous formulations** : Gases are primarily used in fumigation operations. They may be prepared as liquefied gases and packaged in pressure containers or in a material form that reacts with the moisture in the air to form a gas. The gas molecules can penetrate cracks, crevices and tightly packed material. Gases are the most dangerous pesticides used and hence special safety equipment and training are necessary when using gases and must never be attempted except by trained pest management personnel operating in pairs. One of the common gaseous formulations viz. Calcium cyanide (powder) and Aluminium phosphide (tablet) are used for rodent control.

#### Special formulations

**Resin Strips** : Pesticide-impregnated resin strips release vapours as they are heated or exposed to normal room temperatures. The use of resin strips in rooms occupied by the young, the elderly or in food preparation and food serving areas is strictly prohibited.

**Baits** : Baits are commonly used to manage scavenging pests such as rodents, ants, flies, and cockroaches, which are particularly difficult to manage with standard techniques. Baits consist of the toxicant mixed with a food attractive to the target pest or with water. For this reason, baits made with local foods are normally more effective than premixed formulations. Recent development is the use of pheromone Muscalure with Imidacloprid as bait for houseflies.

**Gel** : One of the special formulations developed for use against cockroaches is Gel formulation. Gels comprise some food attractant mixed with the toxicant and some stabilizing agents. Examples are Fipronil and Imidacloprid Gels marketed against cockroaches.

**Shampoo** : This formulation has been specially developed for use against head lice infestation. Permethrin is the most common ingredient of the commercially available anti-lice Shampoo formulations worldwide.

**Beads / Pellets / Briquettes** : Small floating beads, pellets or briquettes incorporating biocides - *Bti* and *B sphaericus* have been developed against Anopheline larvae. These formulations can be made as controlled release formulations as well.

**Paints and Lacquers** : These can be used for incorporation of insecticides especially for control of pests on ships. These preparations remain effective for long periods. The new insecticide, Imidacloprid is also available as a paint formulation against houseflies.

**Mats / Coils** : These are special formulations which have been developed as controlled release formulation for indoor use against mosquitoes. These have synthetic pyrethroids such as Allethrin, which acts as toxicant to knock down the mosquitoes when used indoors.

**Aerosols** : Aerosols are pressurized cans containing a small amount of pesticide driven through a small nozzle. They're commonly used as space sprays for flying insects viz. mosquitoes and houseflies and as residual sprays for Mites/

Ticks depending on the formulation. Care should be taken while handling aerosol cans since they can explode if punctured or overheated, even after the pesticide has been dispensed. Common insecticides used as aerosols are Pyrethroids, Malathion, DDVP and repellents like DEET and DEPA. These are used for disinfecting aircrafts, tents, rooms, other small enclosures, uniforms and for topical application. An emission of nearly 15 seconds is enough for a 100 m<sup>3</sup> space.

## Equipment

Equipment used for vector control can be broadly classified as ground equipment and equipment used for aerial applications.

### (a) Ground Equipment

- (i) Sprays for production of fine or coarse spray which may be either manually operated or power operated.
- (ii) Sprayers for the production of mist which may be either with gaseous energy nozzles (manual operated or power operated) or with centrifugal nozzles.
- (iii) Devices for the production of aerosols which may be mechanical, thermal or gaseous energy aerosol generators.
- (iv) Dusting equipment which may be manually operated or power operated.
- (v) Applicators for granules and pellets, manually or power operated.

### (b) Aerial Equipment

Equipment for aerial sprays is essentially the same but with certain modifications. The equipment in common use is the boom and nozzle system.

## Sprayers

The equipment commonly used for spraying various insecticidal formulations are the hand operated sprayers, power operated sprayers, aerosol dispensers, fog generators and dusters.

### (a) Hand Operated

These are hand sprayers, knapsack sprayer and compression sprayer.

**(i) Hand Sprayer** : The hand sprayer is used for space spraying of small apartments. It is provided with a small can for holding ½ to 1½ litres of spray fluid and a cylindrical plunger type air pump. The nozzle size is less than 0.4 mm in order to produce a fine spray. The simplest form is the familiar 'flit gun' producing intermittent spray. A number of other light hand sprayers have been designed, which can be pressurized in the manner of compression sprayers and are used to produce a mist or fine droplet spray.

**(ii) Knapsack Sprayer** : This is designed to fit on to the back of the operator and usually has a capacity of 15 to 20 litres. It incorporates a light but powerful diaphragm pump actuated by a lever carried forward to the operator's hand where it is worked by an up-and-down movement. These sprayers are used both for larviciding and residual spraying. The nozzle size used for residual spraying varies between 0.78 to 1.0 mm so as to produce a coarse spray.

**(iii) Compression Pneumatic Sprayer** : This is the commonest type of equipment used in National Vector Borne Diseases Control Programme for the application of insecticides. It has



a hand operated pump incorporated to build up adequate pressure. When the pressure is released by a trigger on the lance, the liquid is forced out from the tank to the nozzle by the compressed air and a continuous spray of the insecticide formulation is produced. It is slung over the shoulder with one strap or may be carried on the back with two straps. It is operated by one person.

### (b) Power Operated Sprayers

These are useful for application of insecticides over large areas. These are hydraulic sprayers in which the spray liquid is expelled to the nozzle by positive displacement by the plunger pump. Insecticide tanks built into a truck or mounted over a hand trolley are connected directly to a power operated compressor. By means of a long hose the spraying fluid is conveyed under pressure through the lance to the nozzle.

### (c) Insecticidal Fog Generators

Several types of fog generators are now available for the production of insecticidal fogs in the open on a large scale. In these fogging machines the oily solution of the insecticide is finely atomized by the powerful blast of hot exhaust gases from a petrol engine.

### (d) Aerosol Dispensers

These are used for disinfestations of aircrafts, tents, rooms and similar small enclosures. It contains insecticide and a propellant. Common aerosols contain Synthetic pyrethroids or their combination, which are routinely used for mosquito, cockroaches and fly control.

### (e) Dust Gun

Insecticidal dusts are applied against lice and fleas in rat burrows or on water surfaces as dry powders diluted with inert dusts. Small light weight guns are used for mass delousing of infested people.

## Residual Spraying

This is the application of insecticides to surfaces so that the insecticide particles remain on the surface in the form, size and quantity suitable for insects to pick up on contact and sufficient to exert a lethal effect over a long period. Organochlorine, Organophosphorus, Synthetic pyrethroids and Carbamate compounds can thus be applied on the inside walls of houses and also on thick bushes in forests. The type of surface to which an insecticide is applied influences its toxicity against insects and its persistence. Solutions and emulsions quickly get soaked in the absorbent surfaces of soft bricks and mud walls which take in a large portion of insecticidal material deposited on them; but when suspended in water it remains over the surface after the water evaporates or gets absorbed. The nozzles of sprayers used for residual spraying must conform to the need of having a droplet size which is neither too large nor too small. Similarly, safety precautions should be observed, as follows, while spraying as per standard WHO guidelines :

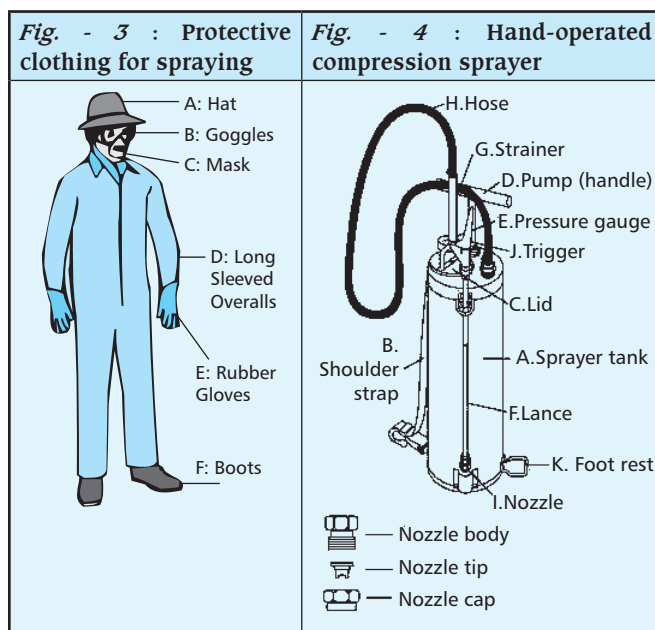
- Do not eat, drink or smoke while working.
- Wash your hands and face with soap and water after spraying and before eating, smoking or drinking.
- Shower or bathe at the end of every day's work and change into clean clothes.

- Wash your overalls and other protective clothing at the end of each working day in soap and water and keep them separate from the rest of the family's clothes.
- If the insecticide gets on your skin, wash off immediately with soap and water.
- Change your clothes immediately if they become contaminated with insecticides.
- Inform your supervisor immediately, if you do not feel well.
- Wear protective clothing (Fig. - 3) :
  - Broad rim hat (protects head, face and neck from spray droplets).
  - Goggles or face shield (protects face and eyes against spray fall-out).
  - Face mask (protects nose and mouth from airborne particles of the spray fall-out).
  - Long sleeved overalls (Keep overalls outside of boots).
  - Rubber gloves.
  - Boots.

## Preparations

**The Household :** Inform the householder of the spraying schedule and the purpose of spraying, giving them time to prepare and vacate the house. Occupants MUST leave houses before spraying. Rooms occupied by sick people who cannot be moved must NOT be sprayed. Remove all household items, including water, food, cooking utensils and toys from the house. Move and cover, or take out the furniture to allow easy access for spraying walls. Items that can not be removed should be well covered.

**Equipment :** Indoor residual spraying of insecticides is normally done using hand-operated compression sprayers. Before starting a spray operation, the equipment must be checked. Faulty sprayers may result in poor control or over-treatment. Examine the sprayer visually to ensure that all parts are present, assembled correctly and are in good condition (Fig. - 4).



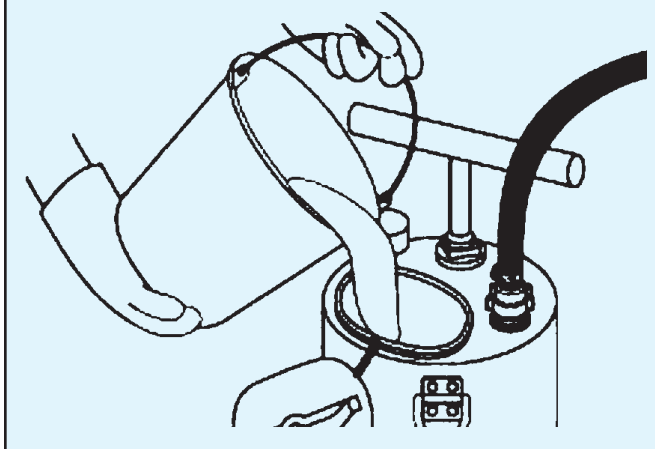


- A. Sprayer tank
- B. Shoulder strap
- C. Lid
- D. Pump (handle)
- E. Pressure gauge
- F. Lance
- G. Strainer
- H. Hose
- I. Nozzle - check correct type of nozzle is fitted and is not damaged or worn (flat fan nozzle with 55° to 60° swath and 0.75 l/min flow rate at 700 g/ sq cm).
- J. Trigger on/off valve. Is the strainer inside valve handle clean?
- K. Footrest

Before using an insecticide, use clean water to ensure that the equipment operates properly and does not leak. Wear protective clothing. To check, follow the steps below :

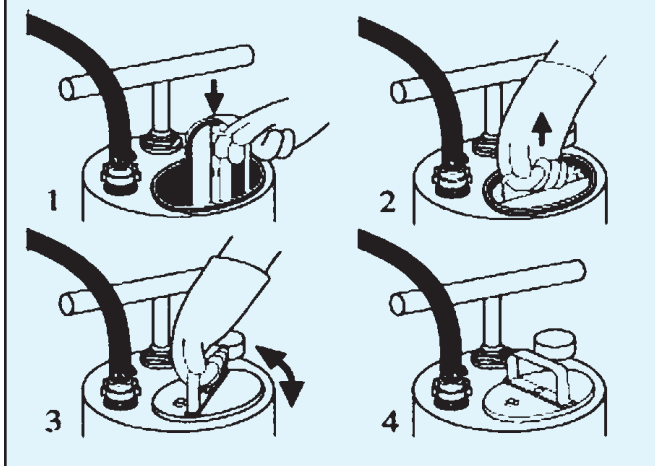
- (a) Pour clean water into the tank (never fill tank more than 3/4 full) (Fig. - 5).

Fig. - 5



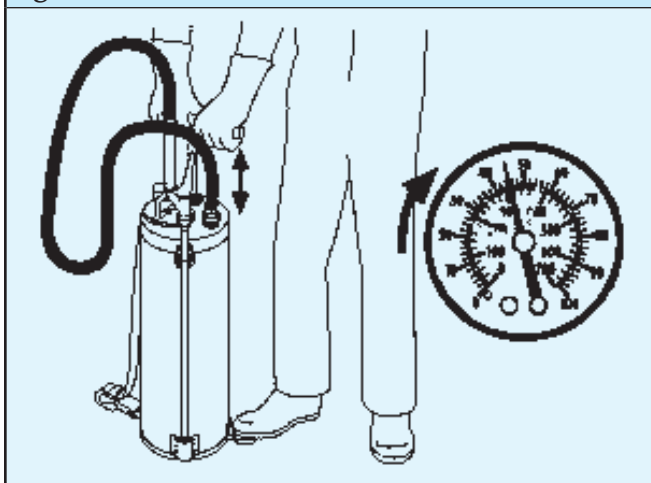
- (b) Fit the lid. Turn the handle to lock the lid in position (Fig. - 6).

Fig. - 6



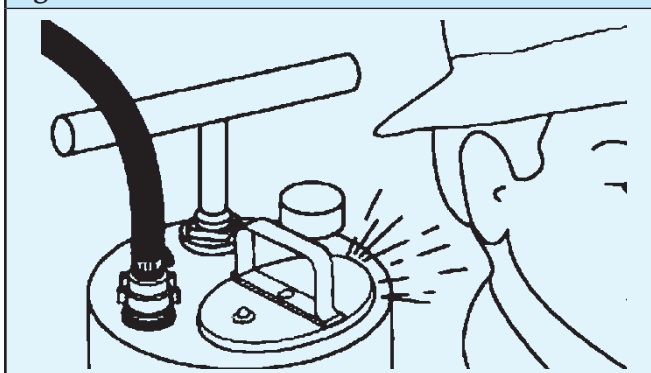
- (c) Operate the pump using both hands and with foot on the footrest. Pump to the working pressure of 55 psi (Fig. - 7).

Fig. - 7



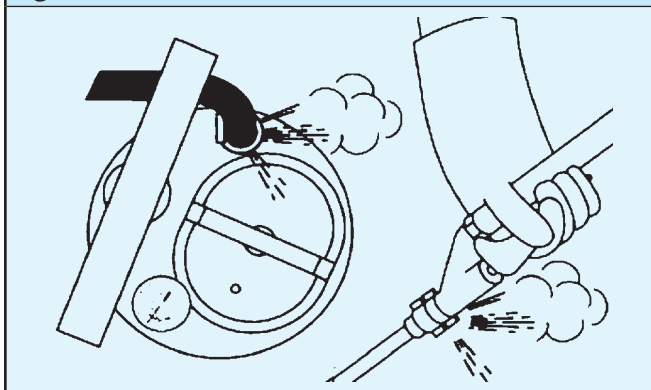
- (d) Check tank is holding pressure. Listen for hissing sound of escaping air (Fig. - 8).

Fig. - 8



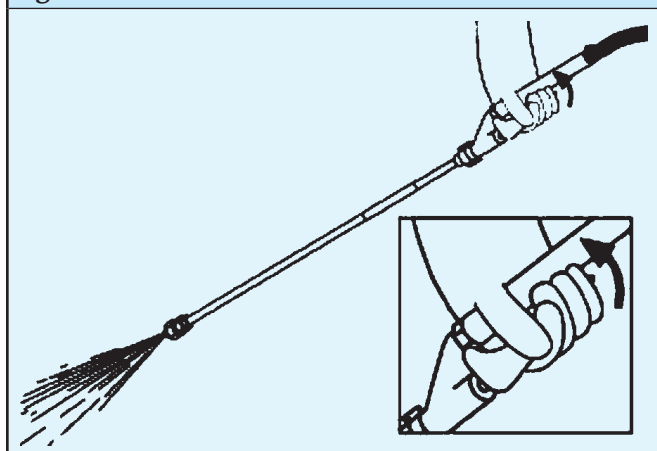
- (e) Check to make sure there are no leaks along lance and hose, especially where hose joins tank and trigger on/off valve (Fig. - 9).

Fig. - 9



- (f) Operate trigger on/off valve to make sure that spray is emitted from the nozzle (Fig. - 10).

Fig. - 10



- (g) Check the spray pattern from the nozzle by spraying a dry wall surface. Look to see that the pattern is even and without streaks. Ensure nozzle does not drip when trigger on-off valve is released (Fig. - 11).

Fig. - 11



- (h) Calibrate the nozzle with water in the tank. Pump to 55 psi (700 g/ sq cm). Open the trigger on-off valve for one minute, collect the discharge and measure the amount in a measuring jug. Empty the jug. Discharge for a further one minute and measure the amount. Repeat again and calculate the average of the three, one-minute measurements.

With the above procedure, the average discharge of an 8002 nozzle is about 750 ml per minute. If the discharge is incorrect, check the nozzle and the screen filters to ensure they are not clogged. If necessary replace nozzle. Repeat the calibration.

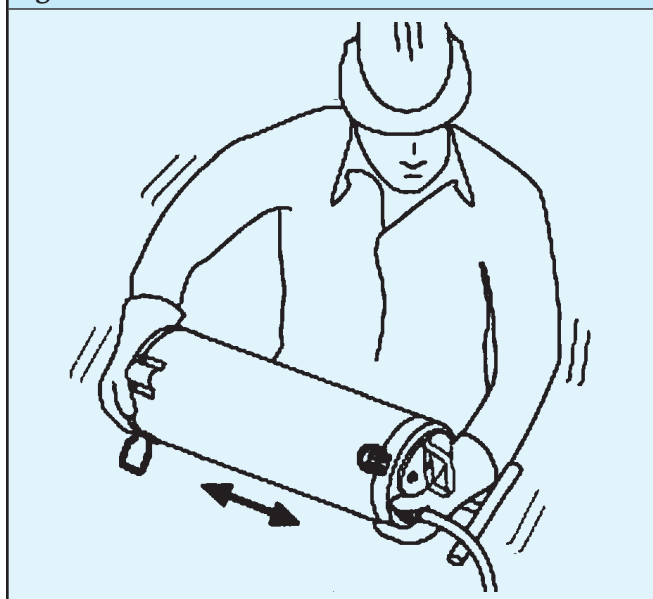
**If the nozzle is clogged :** The opening in a nozzle is very small and must not be damaged. Clogged nozzles should be put in a

container with water for several hours before the blockage is removed by a very soft toothbrush. NEVER clean nozzle with a hard pin or piece of wire and NEVER put a nozzle to your mouth to blow through it.

### Mixing, Handling and Spray Techniques

Prepare the insecticide spray according to the manufacturer's instructions. The insecticide may be mixed separately in a bucket and poured into the sprayer. Water soluble sachets, tablets and insecticides granules are added directly to the water filled tank. These formulations mix readily with water and reduce the hazards associated with handling and mixing in a separate container. When the sprayer has been filled with water to the maximum level indicated on the tank, the lid of the tank is fitted and the sprayer pumped to a pressure of 55 psi by pumping 55 times (700 g/sq cm). The contents of the tank should be thoroughly mixed by shaking the tank before starting to spray (Fig. - 12).

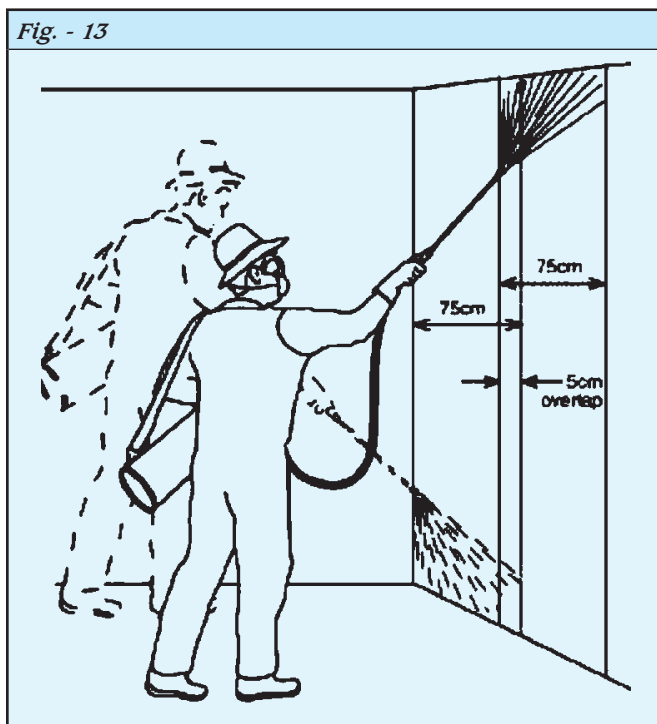
Fig. - 12



Spraying in a room should commence from the backside of a door clockwise completing the plain surfaces of walls. Then the crevices on the walls and inside portion of windows etc. should be sprayed. Thereafter the pillars, under surfaces of furniture and lastly the ceilings should be taken for spray.

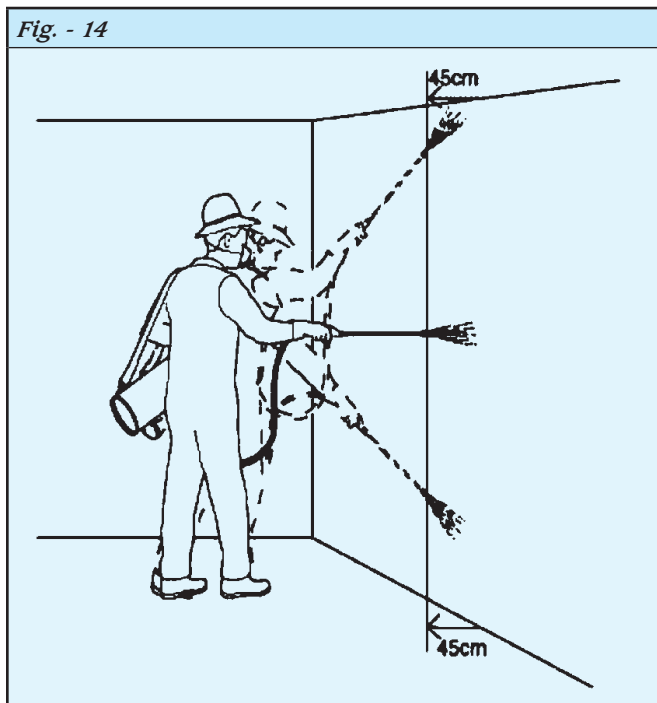
Spray is done from roof to floor, using downward motion, to complete one swath; then stepping sideways and spraying upwards from floor to roof. Spray is applied in vertical swaths 52-56 cm wide. Swaths should overlap by 5 cm and spraying should be undertaken as shown in Fig. - 13. Normal swath coverage will take 2.7 sec if height of wall is assumed to be 3 meters and hence in one minute 22-23 swaths will cover a wall of 10-11 metres length and 3 metres height i.e. 30 - 33 sq m. It takes about 5 minutes to spray a house with an average surface area of 150 sq m.

Fig. - 13



To ensure the correct swath width, keep the spray tip about 45 cm from the wall. Lean forwards as you spray from top of the wall and move back as you bring the nozzle downwards (Fig. - 14).

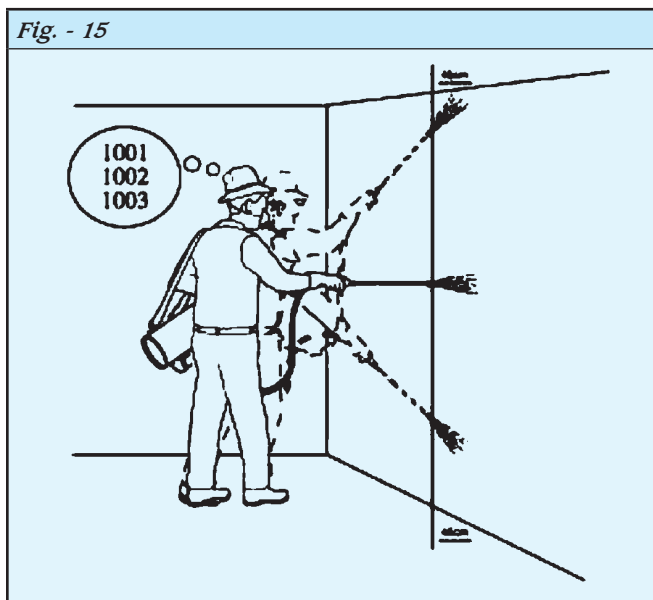
Fig. - 14



The flow of liquid from the nozzle tip at 700 g/sq cm pressure is 750 ml/minute. Hence 30 sq m surface will be covered with 750 ml of the insecticide solution.

Time your spray speed to cover one meter every 2.2 seconds, i.e. 4.5 seconds for a 2 m high wall. Timing may be aided by mentally counting "one thousand and one - one thousand and two - one thousand and three ...". Adjust the mental counting procedure according to the local language (Fig. - 15). If spray stops due to a blockage in nozzle, unscrew the nozzle cap, remove blocked nozzle and replace with a new one. The blocked nozzle should be cleaned as explained above. Do not let spray drip on the floor. Re-pressurize the tank when the pressure falls.

Fig. - 15



#### Procedures after Spraying

- Advise the occupants to stay outside until the spray is dry.
- Instruct the householder to sweep or mop the floor before children or pets are allowed to re-enter.
- Instruct the householder not to clean the sprayed surfaces.

#### Disposal of Remains of Insecticides and Empty Packaging:

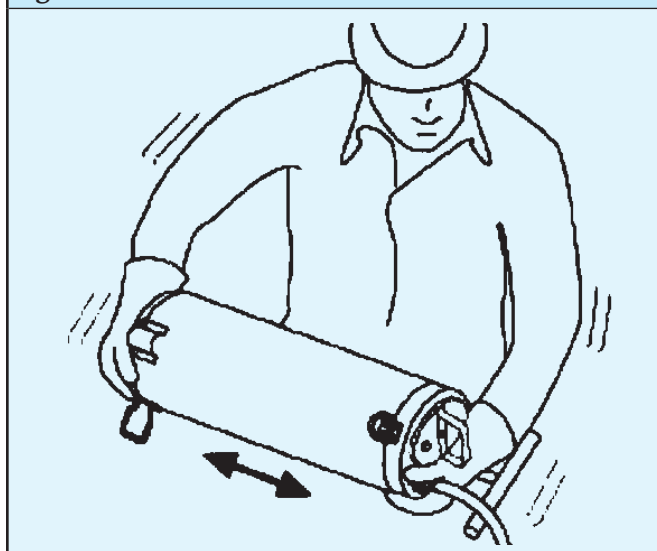
At the end of the day's work, put the washings from the sprayer into pit latrines, if available, or into pits dug especially for this purpose and away from sources of drinking water. Dilute any insecticide with more water before putting into pits. It is advisable to prepare only sufficient insecticidal solution to avoid disposal of remaining insecticidal solution. Never pour the remaining insecticide into rivers, pools or drinking water sources. All empty packaging should be returned to the supervisor for SAFE disposal. Never re-use empty insecticide containers. Empty insecticide containers should NOT be burned or buried.

**Maintenance of Equipment :** After completing the day's work, de-pressurize the tank and empty any remaining insecticide, following the instructions given in the previous section. Clean the tank as explained below :

- De-pressurize the tank.
- Fill the tank half-full with clean water.
- Replace the lid.

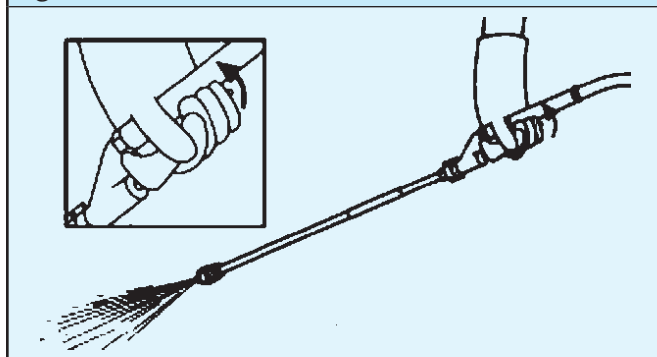
- Shake the tank so all inside surfaces are washed (Fig. - 16).

Fig. - 16



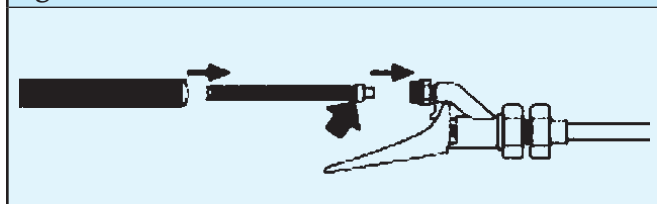
- Pump up to 700 g/ sq cm pressure. Spray water through nozzle (Fig. - 17).

Fig. - 17



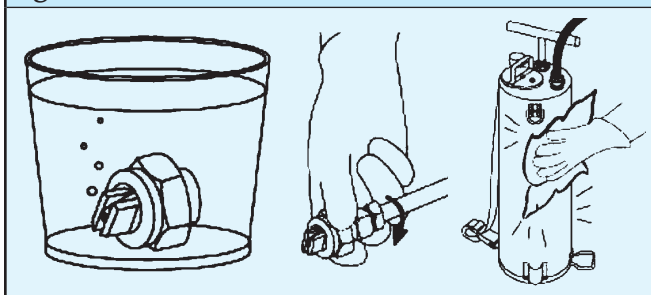
- De-pressurize the tank and pour out any remaining water into pit latrines or into a pit away from sources of water.
- Unscrew trigger on/off valve handle and check and clean the strainer.
- Reassemble the trigger on/off valve (Fig. - 18).

Fig. - 18



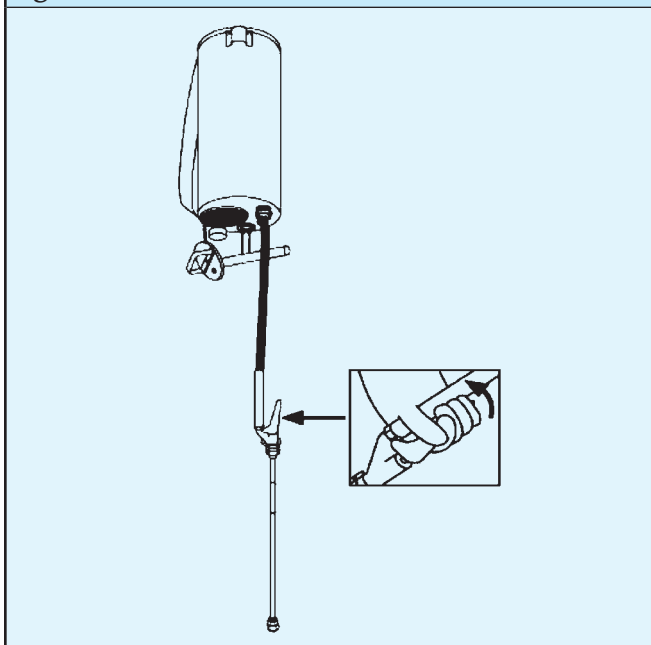
- Remove the nozzle tip and wash
- Refit the nozzle
- Clean the outside of tank.

Fig. - 19



- With lid open, turn tank upside down, open the on/off valve and let all the water drain out of the hose and lance.
- Ensure the lance is parked to protect nozzle when not in use.
- When storing the sprayer for a long period, hang it upside down with lid open to allow air circulation. Allow lance to hang from D-ring on the tank with the trigger valve kept open (Fig. - 20).

Fig. - 20



## Space Spraying

It is an ideal method for bringing about rapid control of vectors in emergency or epidemic situations and may also be used for seasonal control of flying insect pests or vectors. An additional objective may be to reduce or interrupt the transmission cycle of insect-borne diseases. However, it may not be ideal for all vectors or situations and as such may not be an economical method of control. Among the disease vectors affecting public health, the most important and widespread are mosquitoes, houseflies, sandflies and other biting flies; some of these may be targeted for space treatment.

Immediate killing of actively flying insects requires a cloud of insecticide droplets that they will encounter in flight. To



be cost-effective and obtain good biological efficacy, space spraying requires :

- (a) Knowledge of the behaviour and biology of the target species - to understand where and when space treatments will be effective;
- (b) Knowledge of insecticides and formulations most suitable for space spraying;
- (c) Knowledge of pesticide application technology - to know which equipment is needed and how to use it; and
- (d) Monitoring and surveillance of the target species and vector-borne disease problem to evaluate the efficacy of the programme.

A space spray - technically a fog (sometimes referred to as an aerosol) is a liquid insecticide dispersed into the air in the form of hundreds of millions of tiny droplets less than 50  $\mu\text{m}$  in diameter with a view to cause by contact, immediate knock down of the flying or resting insects in confined spaces. Space sprays, even when they settle on surfaces do not have much residual action. It is only effective while the droplets remain airborne. Therefore, they have to be repeated at frequent intervals. Space sprays are applied mainly as thermal fogs or cold fogs.

### Thermal Fog

Thermal fog is produced by special devices known as thermal foggers that use heat to break up the chemical into very small droplets (usually in 5-30  $\mu\text{m}$  diameter range) which then disperse in the air. When the chemical (usually diluted with oil-based carrier) is heated, it is vaporized in a combustion chamber and then expelled via an outlet tube to form a dense fog cloud when it condenses on contact with cool ambient air.

The insecticide used in thermal fogs is diluted in a carrier liquid, which is usually oil-based. Hot gas is used to heat the pesticide spray, decreasing the viscosity of the oil carrier and vaporizing it. When it leaves the nozzle, the vapour hits colder air and condenses to form a dense white cloud of fog. Most of the droplets are smaller than 20  $\mu\text{m}$ . The droplet size is affected by the interaction between the formulation, the flow rate and the temperature at the nozzle (usually > 500°C). The volume of spray mixture applied in vector control is usually 5-10 litres per hectare, with an absolute maximum of 50 litres per hectare. The hot emission gas is obtained from engine exhaust, friction plate/engine exhaust or from a pulse jet engine.

#### Advantages

- Easily visible fog, so dispersal and penetration can be readily observed and monitored;
- Good public relations in some circumstances as people can see something being done about the problem; and
- Low concentration of active ingredient in the spray mixture and reduced operator exposure.

#### Disadvantages

- Large volumes of organic solvents are used as diluents, which may have bad odour and result in staining;
- High cost of diluents and spray application;
- Householders may object and obstruct penetration of fog into houses by closing windows and doors;
- Fire risk from machinery operating at very high temperatures with flammable solvents; and
- Can cause traffic hazards in urban areas.

### Cold Fog

The cold fog is produced by a special device (cold fogger) that breaks up the chemical into microscopic droplets by mechanical means, basically with a high-pressure pump and an extremely fine nozzle. The spray droplets are generated without any external heat. With cold fogs, the volume of spray is kept to a minimum. Ultra-low-volume insecticide formulations are commonly used for such applications. The cold fogger may dispense formulations in a very concentrated form and generate the droplets (usually in the 5-30 micron diameter range) in a precise manner. However, its ability to penetrate dense foliage or obstacles is not as good as that of the thermal fogging. Cold fogging is sometimes called Ultra Low Volume (ULV) treatment as it allows the utilization of only a very small amount of chemical for coverage of a large area.

Like thermal fogging, cold fogging also does not have lasting residual effects. It is, therefore, essential to carry out fogging at the time when the vectors are most active to hit them directly.

#### Advantages

- The amount of diluents is kept to a minimum, resulting in lower application cost and increased acceptability. Some formulations are ready to use, thereby reducing operator exposure
- Mostly water-based and water-diluted formulations are used which pose a low fire hazard and are more environmental friendly
- Application is more efficient because a lower volume of liquid is applied
- No traffic hazard as the spray cloud is nearly invisible

#### Disadvantages

- Dispersal of the spray cloud is difficult to observe
- Higher technical skills and regular calibration are required for efficient operation of equipment.

### Space Spray Equipment

Selection of appropriate equipment for space spraying depends on the size and accessibility of the target area as well as the human resources and operational capacity of the programme. Sometimes smaller machines may be needed in conjunction with vehicle-mounted equipment to treat narrow pathways and other areas inaccessible to vehicles or sheltered from prevailing air movements. Cold fog equipment is recommended where thermal fogs may cause a traffic hazard. Aerial application of space sprays may be justified where access with ground equipment is difficult and/or extensive areas need to be treated very quickly.

### Equipment for Thermal Fogging

**Hand-carried Thermal Foggers** : These are used for treating houses and certain outdoor areas of limited size or accessibility, e.g. markets, hotel grounds and parks. There are two types of hand-carried thermal foggers; pulse jet and friction plate.

**Vehicle-mounted Thermal Foggers** : Large thermal fog generators use an air-cooled motor to run an air blower, fuel pump and insecticide pump. Air from the "roots type air blower" is delivered into the combustion chamber. There it is mixed with gasoline vapour and ignited so that temperatures reach 426-648°C. The diluted insecticide liquid is pumped via a simple flow delivery valve and injected into a cup in the fog head or directly

into the nozzle. The insecticide liquid is vaporized by the blast of hot gases. Despite this high temperature, insecticides show very little degradation of active ingredient. This is because the time spent at that temperature is only a fraction of a second, which is not long enough to cause serious degradation. The hot gases then pass out of the machine. As the hot oil vapour is discharged through a relatively large nozzle into the cooler outside air, it condenses to form very small droplets of thick white fog. Delivery rates of up to 10 litres per minute can be achieved with larger machines.

**Aircraft Application of Thermal Fogs** : For aircraft application of thermal fogs, the diluted insecticide formulation is fed into the aircraft exhaust. The exhaust is adapted with vanes to swirl the fog droplets as they are formed. The application of thermal fogs by aircraft is very limited.

### Equipment for Cold Fog Application

**Hand-carried Cold Foggers** : Most of these machines have gasoline engine or electric operated which drives a blower unit to discharge air through the nozzle. Air may also slightly pressurize the insecticide formulation tank so that the liquid is fed via a restrictor to the nozzle. However, negative pressure generated by the air flow passing through the nozzle allows liquid to flow from the tank. In addition to hand-carried units, knapsack cold fogging units are also available as are several electrically driven models.

**Vehicle-mounted Cold Foggers** : A high volume air blower forces air at a rate of approximately 6 m<sup>3</sup> per minute at low pressure to nozzle. The pesticide container may be pressurized to force the formulation to the nozzle, or positive-displacement pumps may be used.

Alternatively a high-pressure, low-volume air source is used with an air compressor, rather than a blower. On these machines, nozzles ranging from the standard industry "paint gun nozzle" to proprietary nozzles that atomize well up to a flow rate of 0.5 litres per minute are available. Another design uses a rotary nozzle coupled with an electric motor which operates at a very high speed.

**Aircraft Application of Cold Fogs** : Both fixed-wing aircraft and helicopters have been used to apply cold fogs. Conventional low-volume nozzles (e.g. flat fan) have been used on fixed wing aircraft to create fine sprays, using moderate or high pressures. However, the droplet spectrum is generally poor so preference is given to the use of rotary atomizers or very-high-pressure

systems.

### Insecticide Products for Space Spraying

Space-spraying formulations are generally oil-based. The oil carrier inhibits evaporation of small fog droplets. Only insecticide products with high flash points are used for thermal fogging. Diesel is used as a carrier for thermal fogging, but creates a thick smoke and oily deposits, which may lead to public rejection. For environmental reasons, water-based formulations have been made available in recent years. These formulations may also contain substances that prevent rapid evaporation. Table - 3 lists selected insecticides suitable for space spraying against mosquitoes. These insecticides may also be used against other insect pests and vectors, but different dosages may be required.

### Space Spray Treatments - General Considerations

**Optimum Droplet Size** : Space treatments are only effective while the droplets remain airborne. Droplets fall by gravity and some are deposited on horizontal surfaces while the majority is lost to the atmosphere especially in outdoor spraying. Droplets bigger than 30 µm in diameter are less effective as they do not remain airborne for sufficient time. Droplets smaller than 5 µm in diameter do not readily come in contact with flying insects, as the movement of the smallest droplets is affected by the air turbulence created by the insect's flight. It is generally accepted that droplets should be generated in the range of 10-30 µm so that even with some evaporation and after some time, they remain in the correct range for optimal airborne suspension and insect impact. The optimum droplet size for space spraying against mosquitoes is 10-20 µm.

**Spray Concentration** : For a flying insect to be killed, it must acquire a lethal dose of insecticide in the droplets that impact on it. The lower the concentration of active ingredient, the larger the number of droplets of a given size required to achieve a lethal dose. Ultra-low-volume spraying aims, largely for operational reasons, to minimize the total volume of diluted insecticide applied (usually < 2 litres per hectare).

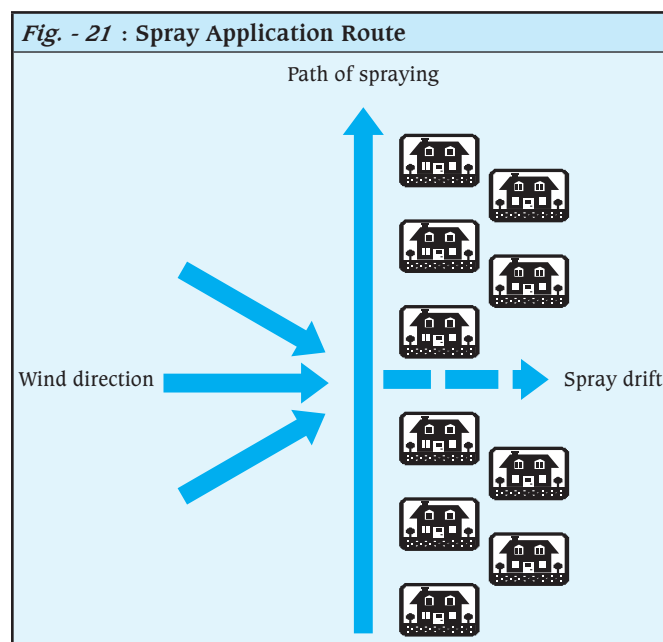
**Wind Speed** : Wind speed has a profound effect on droplet distribution and impingement on insects. Spraying should not take place when wind speed exceeds 15 km/hour. The type of terrain and vegetation affects air movement and hence the distribution of the droplets. In open terrain with relatively sparse vegetation, wider effective swaths can be obtained than in urban areas where the obstruction of buildings alters the

**Table - 3 : Insecticides Used for Space Spraying**

S No.	Insecticide	Dilution	Equipment required	Remarks
1	Pyrethrum 2% Extract	1 litre in 19 litre Diesel (0.1%)	Flit gun/ Thermal Fogging machine	For space spray indoors (Keep rooms closed for 30 min) or outdoors
2	Pyrethrum 2% EC	1 litre in 19 litre Water	ULV Fogging machine	For space spray indoors
3	Malathion Tech	5 litres in 95 litre Diesel (5%)	Thermal Fogging machine	For space spray outdoors
4	Deltamethrin 1.25 ULV	1 litre in 199 litre Diesel	Thermal Fogging machine	For space spray outdoors
5	Deltamethrin 1.25 ULV	1 litre in 19 litre Diesel	ULV Fogging machine	For space spray outdoors
6	Deltamethrin 1.25 ULV	1 litre in 19 litre Water	ULV Fogging machine	For space spray indoors

flow of air.

**Wind direction** : With vehicle-mounted and aerial spraying the spray route must take account of the wind direction to maximize the distribution of the spray throughout the target area. Fig. - 21 illustrates the spray application route relative to wind direction.



**Temperature Effects** : In direct sunlight the ground is heated. This causes air to rise. In the middle of the day, outdoor space spraying will largely be wasted as the spray droplets will tend to rise upwards rather than drift horizontally. Ideally an inversion is needed, i.e. colder air closer to the ground. This generally occurs early in the morning after the ground temperature has fallen during the night, but can also occur in the evening when the sun has set and ground temperatures begin to fall.

**Time of Treatment** : Knowledge of the time of peak flight activity of the target species is crucial to ensure that space treatments are planned to coincide, as far as possible, with these times. Fortunately, peak flight activity of many vectors is around dusk and/or dawn, when weather conditions are often favourable for space treatment. *Aedes aegypti* and *Aedes albopictus*, mosquito vectors of Dengue fever and Chikungunya are active during daytime with peak flight activity in the morning and afternoon. With these species, a compromise is usually made outdoors by spraying in the early morning or late afternoon. The timing is less important if indoor spraying is conducted.

### Indoor Fogging

Personnel conducting this work require training on the safety measures to be followed. Several rules apply :

- Protect all water containers and foodstuffs.
- Remove fish or cover fish tanks.
- Ensure all occupants and animals remain outside the house during spraying and stay outside for 30 minutes after spraying. Ensure that the building is ventilated before

reoccupation.

- Close all doors and windows before spraying and keep them closed for 30 minutes after spraying to ensure maximum efficacy.
- Spray operators should work backwards and away from the fog to minimize exposure.
- For small single-storey houses, the spray can be delivered from the front door or through an open window without having to enter every room of the house, provided that adequate dispersal of the insecticide droplets can be achieved.
- For large single-storey buildings, it may be necessary to apply the spray room by room, beginning at the back of the building and working towards the front.
- For multi-storey buildings, spraying is carried out from top floor to the ground floor and from the back of the building to the front. This ensures that the operator has good visibility at all times.

### Outdoor Ground Fogging

Advanced route planning should precede outdoor ground fogging operations and may require a combination of vehicle-mounted and hand carried or knapsack equipment in areas with difficult or limited vehicle access. Consideration must also be given to the following :

- Spraying should not be undertaken when it is raining, when winds exceed 15 km/hour, or in the heat of the day.
- Doors and windows of houses and other buildings should be open to allow penetration of the spray cloud for improved efficacy.
- For vehicle-mounted equipment, in areas where the roads are narrow and the houses are close to the roadside, the spray should be directed backwards from the vehicle. In areas where the roads are wide, with buildings far from the roadside, the vehicle should be driven close to the roadside and the spray should be directed at an angle (downwind) to the road rather than directly behind the vehicle.
- The nozzle of vehicle-mounted cold fog machines may be directed upwards at an angle when there are barriers that impede airflow, e.g. boundary walls and fences; for vehicle-mounted thermal foggers, the nozzle should be directed horizontally.
- A track spacing of 50 metres is generally recommended, with the vehicle moving upwind so that the fog drifts downwind away from it and the operators.

**Aerial Application of Fogs** : Suppression of vector populations over large areas can be carried out using space sprays released from aircraft, especially over areas where access with ground equipment is difficult and extensive areas need to be treated very rapidly.

### Evaluation

Evaluation of the efficacy of spray operations is carried out using techniques that are largely specific to the target insect. Space sprays are transient and only insects flying at the time of the application are affected.

### Area Spraying

This is carried out for treatment of land against mites and ticks and also as an anti-larval measure over vast water surfaces.

Against mites and ticks, suspensions are used on land and vegetation; WDP is used for anti-larval treatment of lakes and swamps. Aerial spraying is resorted to for agricultural purposes and sometimes for veterinary and rarely medical purposes. Dusts are applied to manure yards and dry refuse yards to control flies and other pests. For all such uses, power driven sprayers and dust guns are used. The larvicidal oils are applied by spraying it on the surface of water by means of a knap-sack sprayer or hand pumps or by a mop stick.

### Resistance of Vectors to Insecticides

**History** : Ever since the introduction of the potent synthetic insecticides into public health programmes at the close of the Second World War, the main problem has been the development of resistance to them by the arthropods they formerly controlled. In 1947, DDT resistance was discovered in the housefly and *Culex molestus* in Italy. In 1951, DDT resistance was noticed in body louse in Korea and in *Anopheles sacharovi* in Greece. In 1955, Dieldrin resistance was discovered in *Anopheles gambiae* in Northern Nigeria. In 1959, in Western India the oriental rat flea was found to have developed resistance to DDT. The number of arthropods showing resistance is on the increase.

**Definition** : Resistance is defined as “the development of an ability in a strain of insects to tolerate doses of toxicants which would prove lethal to the majority of individuals in a normal population of the same species”. A more pertinent definition of resistance promoted by the Insecticide Resistance Action Committee (IRAC) is “the selection of a heritable characteristic in an insect population that results in the repeated failure of an insecticide product to provide the intended level of control when used as recommended”. It is important to remember that resistance does not mean that it is impossible to control the population.

The word *tolerance* is normally used when the increase in  $LC_{50}$  is less than the indicated minimum for the tests, but is nevertheless statistically significant. It is generally due to sub-lethal exposure to insecticide and is not passed on to offspring. *Vigour tolerance* is a term, which has been applied to enhanced insecticidal tolerance resulting from extra vigour of the strain rather than from any specific defence mechanism.

**Types** : Resistance is of two types i.e. physiological and behavioural. Physiological resistance is the one described above. Behaviouristic resistance means the development of ability to avoid a lethal dose. This term is applied most often to mosquitoes in relation to DDT.

### Resistance Mechanisms

**Metabolic Resistance** : This is the most common resistance mechanism encountered amongst insects, based on detoxification enzymes. In resistant strains, these enzymes are generally more enhanced thus enabling the insects to metabolize or degrade the insecticide before their lethal effect is exerted. The enzyme systems involved in these processes are Esterases, Monooxygenases and Glutathione-S-transferases (Table - 4).

- Esterases - Dominant mechanism of resistance conferring resistance to OP compounds. It also affects Pyrethroids and Carbamates.
- Monooxygenases are importantly involved in the resistance mechanism in insects to Pyrethroid class of insecticides. It also affects DDT and OPs.
- Glutathione S transferase - It has been implicated in DDT resistance.

**Target - Site Resistance** : This is the second most common resistance mechanism encountered in insects. The site of action of the insecticide is modified so that the insecticide no longer binds effectively at that site. Resistance to DDT and pyrethroids is due to the modified gene *Kdr*, which leads to reduction in the sensitivity of the site to the binding of DDT and Pyrethroids. On the other hand, an altered site of action as a cause of resistance to Organophosphates (OPs) and Carbamates has been definitely established with cholinesterase inhibitors. In these cases, mutated forms of AChE (MACE - modified acetylcholinesterase) are produced that is inhibited more slowly than the normal enzyme in susceptible strains. This produces resistance against a large number of compounds of the OPs and Carbamates and the resultant extensive cross-resistance which makes it a serious type of resistance.

**Reduced Penetration** : Not a major resistance mechanism, may contribute to the overall development of resistance to an insecticide. Modification in cuticle (applicable for contact poison) or digestive tract linings (in case of stomach poisons)

**Table - 4 : Biochemical resistance mechanisms conferring resistance to important classes of insecticides in mosquitoes (dot size gives the relative impact of the mechanism on resistance)**

Biochemical Mechanism of Resistance					
	Metabolic			Target-site	
	Esterases	Monooxygenases	GSH-S transferases	kdr	MACE
Pyrethroids	•	●		•	
DDT		•	●	•	
Carbamates	•				●
Organo-phosphates	●	•			●

Source : Prevention & management of insecticide resistance in vectors and pests of public health importance. Manual by Insecticide Resistance Action Committee (IRAC).



leads to prevention or reduced penetration of insecticides in the body of the insects has been reported in a number of resistant insects e.g. houseflies.

**Behavioural Resistance** : It is a modification in the behaviour of insects to avoid toxic doses of the insecticide. It is also a contributory factor in development of resistance and not an important resistance mechanism. It may be stimulus dependent (when insects avoid insecticide treated surface) or independent (selective and sustained occupation of an untreated area).

**Cross Resistance** : Cross resistance occurs when a resistance mechanism that allows insects to resist one insecticide also confers resistance to insecticides of the same chemical class or different chemical class which act on the same target site in the insect. e.g. kdr resistance to DDT and to Pyrethroids, OPs and Carbamates due to altered AChE.

**Multiple Resistance** : It is a common type of resistance when different resistance mechanisms are present simultaneously in resistant insects. It may combine to produce resistance to multiple classes of insecticides.

**Genetic Basis of Resistance** : Resistance develops in arthropods after a long period of insecticidal pressure. It is brought about by the accumulation of the contributing genes through successive selection with a number of insecticides, each of which confers some cross-resistance. This is called polygenic or multiplicate resistance. In contrast, the resistance may be due to a single gene and bear no similarity to the complexities involved in the multiplicate resistance. Monogenic resistant strains are more vulnerable to counter measures such as addition of synergists; hence the importance of distinction between the two types.

Resistance genes may be dominant, semi-dominant or recessive; most of the resistance reported so far are either semi-dominant or recessive and therefore may be managed effectively as compared to situations when resistance is genetically dominant.

**Resistance Management** : The factors that favour development of resistance are frequency of application, dosage and persistence of insecticide, rate of reproduction (short lifecycle and high rate of reproduction) and population isolation.

Resistance management can be attained by rotation of insecticides, using mixture of insecticides at their optimum dosage (efficacy & persistence of the two insecticides being mixed should be broadly similar) and fine scale mosaic (using two insecticides in different houses in the same village).

## Biological Control

Intentional manipulation of populations of living beneficial organisms, called natural enemies, in order to reduce the numbers of pests or amount of damage is called Biological Control.

Natural control strategies that employ biological agents for pest suppression are classified as biological control tactics. In conventional usage, this term usually refers to the practice of rearing and releasing natural enemies like parasites, predators, or pathogens. Biological control is a particularly appealing pest control alternative because, unlike most other tactics, it does not always have to be reapplied each time a pest outbreak occurs. However, Biological control is not a “quick fix” for

most pest problems. Natural enemies usually take longer to suppress a pest population than other forms of pest control and therefore often regarded as a disadvantage or limitation of biological control. It also may be difficult to “integrate” natural enemies when pesticides are still in use. Beneficial insects are often highly sensitive to pesticides and their resurgence (recovery to pre-spray densities) is usually much slower than that of pest populations. Rapid pest resurgence often leads to a vicious cycle of continued chemical usage that prevents natural enemies from ever becoming re-established.

The biological agents are broadly classified as Predators, Parasites and Pathogens.

### Predators

Predators are insects or other insectivorous animals, each of which consumes much insect prey during its lifetime. Predators are often large, active, and/or conspicuous in their behaviour, and are therefore more readily recognized than are parasites and pathogens. Most commonly used predators are the larvivorous fishes for the control of mosquitoes.

**Larvivorous Fish** : There are areas and habitats where larvivorous fish, such as *Gambusia affinis* (Fig. - 22) and *Poecilia reticulata* (Fig. - 23), can make considerable contribution to vector control. The larvivorous efficiency of *Gambusia* is due to the fact that a single full grown fish eats about 100 to 300 mosquito larvae per day, is a surface feeder, hence it is suitable for feeding on both Anophelines and Culicines, is small and inedible and can tolerate salinity. *Poecilia*'s larvivorous efficiency is due to its capability to negotiate margins of ponds more easily, tolerate handling and transportation very well, survives and reproduces when introduced into new water bodies, survives in new places (water bodies) and multiplies easily and can survive in good numbers for years and does not require constant care.

Fig. - 22 : *Gambusia affinis*



Fig. - 23 : *Poecilia reticulata*



Release of fishes is done at the rate of 5-10 fish per linear meter. If the larval density is high up to 20 fishes can be released. Fishes should be released in the morning hours or in the evening.

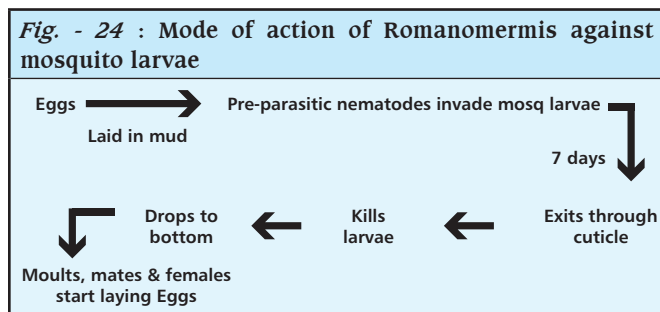
**Criteria for selecting a water body for a fish hatchery are :**

- It should be a permanent water body.
- Depth of water should be at least 1.5 metre or more.
- Water should be confined and without big natural outlet.
- The minimum size of water body should be at least 5m X 4m. The water body of 10 m X 5 m can support 50,000 fish.
- It should be free from other carnivorous fish.
- Water should not be contaminated by chemical or other harmful substances.
- Easily accessible for daily or periodic inspection and for collection of fish.
- De-weeding in ponds and shallow water bodies and cleaning of margins should be carried out periodically.

### Parasites

Parasites are those organisms which depend on their host for shelter or food. Many parasites are very specific to the type of host insect they can attack, and they are not harmful to humans. Although insect parasites are very common, they are not well known because of their small size. Some of the categories of Parasites are as follows :

**Nematodes** : Nematode *Romanermis culicivorax* and *R iyengari* have been evaluated and have been found to give variable control of mosquitoes. The mode of action of the nematodes is presented in Fig. - 24.



**Fungi** : Fungal agents *Lagenidium* and *Culicinomyces* have shown immense potential as mosquito larval control agents and can be exploited for use against mosquitoes.

### Pathogens

The pathogens which have been found promising are the Bacterial agents' *Bacillus thuringiensis var israelensis* and *Bacillus sphaericus* in mosquito larval control. However, these have been classified as Biocides or Microbial insecticides (discussed earlier). Viruses like Nuclear Polyhedrosis virus and Irido virus have also shown promise against mosquito larvae.

### Genetic Control

This is defined as "the use of any condition or treatment that can reduce the reproductive potential of noxious forms by altering or replacing the hereditary material". The various methods of genetic control fall into two general groups : those

leading to population control, reduction or elimination through the release of partially or completely sterile insects in sufficient numbers to overcome the reproductive capability of the natural population; and those leading to population control or population replacement through the release of partially sterile or fully fertile genetically altered insects.

New genetic control methods, such as those involving sex distortion mechanisms or the selection and release of strains refractory to pathogens, sensitive to selected ecological factors, or susceptible to insecticides, are being tested under field conditions. However, unless some new and revolutionary ideas emerge, the genetic control measures so far known are capable of achieving only "management" or "manipulation" of insect population rather than complete suppression or reduction in densities.

### Personal Protective Measures

The role of personal protective measures in arthropod-borne disease control is to prevent the arthropod vector from biting and feeding on its host, whether susceptible or already infected, thereby blocking the chain of transmission of disease from one host to another. Biting can be prevented either by protective clothing or chemically by using appropriate repellents.

#### Protective Clothing

Individual personal protection against bites of arthropods can be achieved by wearing long trousers, rolled down sleeves of shirts, socks, shoes and anklets, particularly when going out on patrols and exercises in areas heavily infested with arthropods. These measures will vary according to the nature of problem faced in a particular locality. Personal protective measures have already been described as part of control measures against different arthropods elsewhere in this chapter.

#### Repellents

Insect repellents are chemicals which repel insects when applied to body surfaces or clothing. The suitability of substances for use as repellents is dependent primarily on their inherent repellency and duration of effectiveness. The important factors are the ease of application on the skin; odour, appearance or feel on the skin e.g. oily or greasy; the likelihood of being rubbed off, or absorbed by the skin; irritant effect or toxicity if absorbed; and its stability under high humidity, high temperature, rain and perspiration. The efficacy may also be influenced by the amount of sweating, rubbing and the avidity of the insect itself. Moreover as is the case with insecticides, repellents exhibit specificity of action so that some species of insects are more sensitive to one and some to other repellents.

**Common Repellents** : The following compounds are among the most effective when used alone as repellents against one or more groups of arthropods : benzyl benzoate, DEET (N, N-diethyl-m-toluidide), dibutyl phthalate, DEPA (di ethyl phenyl acetamide), and Neem oil. Repellents are formulated as liquids, gels, creams and in pressurized containers. Some of the common compounds are discussed below :

**(a) N, N-diethyl m-toluamide (DEET)** : DEET has been reported to be an outstanding all-purpose repellent. It provides 6-8 h of protection against mosquitoes, 2-3 hour against Chrysops, 9 hour against Culicoids. It feels less oily on the skin than the

other repellents. DEET can also be used very effectively for impregnation of clothing. In experiments conducted at AFMC it has been shown to provide repellence up to two launderings of the clothing. As a skin application DEET may be used for protection against mosquitoes, sand flies, fleas and other biting Diptera. It is a good repellent against all haematophagous arthropods and also against leeches.

**(b) Dibutyl Phthalate (DBP)** : It is more persistent but somewhat less rapid repellent. When smeared on clothing, its effect lasts up to 2-4 washes, ironing destroys it. It is specifically useful against ticks and mites as it is an acaricidal, as well as a repellent. DBP is a good repellent against leeches and Dimdam flies.

**(c) Benzyl Benzoate** : The oily liquid has a faintly pleasant aromatic odour and sharp bitter taste. It has been applied in 5% emulsion to skin as repellent for many arthropods. Clothing impregnated with benzyl benzoate show repellence to fleas, chiggers and other arthropods. A mixture of equal parts of diethyltoluamide and benzyl benzoate with the addition of an emulsifier acts as a good impregnant for clothing against trombiculid mites.

**(d) Diethyl phenyl acetamide (DEPA)** : It is available as cream and sprays. It is a broad spectrum repellent and can be used for topical application against mosquitoes, ticks & mites or any other haematophagous arthropod and leeches. It can also be applied on clothing/uniform as repellent. It can withstand 2-3 launderings and ironing. It matches DEET in its spectrum and efficacy.

#### Application Procedures

**Skin Application** : Repellents like DEET and DEPA are applied to the skin as cream formulation. These are generally effective against such pests as midges, mosquitoes, sandflies and so on. A good repellent applied in this way gives protection from insect bites for about five to seven hours.

**Impregnation of Clothing** : Application to clothing is carried out when longer protection against insects is required. Application of DBP, DEET or DEPA to clothing to protect one self from mites and ticks is much more persistent than skin treatment and remains effective for a period up to a month.

**(i) Hand Application (Repellent Drill)** : Hand Application of repellent is the simplest way to treat the clothing. The fingers of one hand are dipped into the chemical in an open container or a few drops of the chemical are poured into one hand, both the hands are rubbed together and then they are wiped lightly on the inside and also on the outside of all the openings of all garments to produce a thin layer of the chemical on them. The chemical should be applied more particularly to the opening such as inside the neckband of shirts, turn ups of trousers and tops of socks turned inside out. 60 ml per man per fortnight of DBP is enough to impregnate two shirts, two pairs of trousers, 2 pairs of socks, anklets and two sets of underclothing. The application should be started a fortnight before the mite borne disease (like scrub typhus) season in any area begins, and repeated every fortnight thereafter until the season lasts. This should be done on a parade as a drill supervised by a person who has had training and experience of the procedure. The repellents DEET, DEPA require lesser quantities for impregnation.

**(ii) Spraying / Impregnation** : The chemical can be applied to the entire clothing by spraying or the clothing can be impregnated with a solution or emulsion of the repellent when large quantities of clothing are required to be treated. Clothing should be soaked in the solution, then wrung out lightly and dried. DEPA is available as spray formulation for treatment of clothing.

**Barrier Application** : Considerable protection may also be obtained by treating only the openings of the clothes inside the neckband and cuffs of shirts, inside the waistband, fly and turn ups of trousers and on the socks above and inside the shoes and below its tongue. These methods, called the barrier application, are particularly useful when people go for amateur camping or trekking or when sufficient supplies of repellents are not available.

#### Household Products

Use of mosquito coils, vapourising mats, liquid vapourisers consisting of pyrethroids is an important measure in reducing man-vector contact. These products basically aim at deterring the insects from entering the rooms and with continued contact bring about death of the exposed insects. The allergic risks which these products pose on continued exposure especially to children necessitates adoption of safer preventive measures for personal protection.

#### Mosquito Nets

Mosquito nets are very effective means of protection against the bites of haematophagous arthropods. Untreated or insecticide treated nets may be used as per the availability. The bednets may be treated manually or may be purchased as pre-treated nets.

**Manually Treated Bednets** : Insecticide treated bednets may be manually treated with Synthetic pyrethroids like Deltamethrin 2.5% SC or Cyfluthrin 05 EW. These nets have to be treated every six months as per the procedure described in Box - 1.

**Long Lasting Insecticide Nets (LLINs)** : The advancement in the insecticide treated net technology has seen the development of pretreated or Long Lasting Insecticide Nets (LLIN's). These nets may also be treated manually or may be pretreated with insecticide Permethrin or Deltamethrin (Box 2). The shelf life of these nets is 5 years.

#### Mechanical Control & Physical Control

Use of flyswatters, fly traps for housefly control, use of lice combs, glue traps for various pests like cockroaches and rodents, other mechanical trapping devices used for other vectors are few examples of the use of this control option in vector control.

Physical control measures exploit devices which aim to control vectors by affecting them physically or their environment. Sometimes they may be indistinguishable from environmental or cultural methods. Fly electrocutors and use of temperature extremes (hot water for bedbug control, sun exposure and boiling in hot water of infested material for lice control) are some physical control measures used in public health for vector/ pest control.

<b>Box - 1 : Steps for treatment of bednets</b>
(a) <i>Measure the total area of the net in m<sup>2</sup>.</i> (2 x length x height + 2 breadth x height + length x breadth) in metres. Average area of a single net is 10 sq m.
(b) <i>Measure the absorption capacity</i> <ul style="list-style-type: none"> <li>• Measure 1 litre of water and take it in a tub.</li> <li>• Immerse the dry net, when completely wet, take it out by gently wringing the net to prevent dripping of water.</li> <li>• Measure the remaining water in the tub. 1 litre - the remaining water gives us the absorption capacity of the net.</li> </ul>
(c) <i>Wash the net to be treated and dry it.</i>
(d) <i>Calculate the dosage of the insecticide required</i> <ul style="list-style-type: none"> <li>• Deltamethrin 2.5% SC- dosage required 25 mg a.i. per m<sup>2</sup>. 1 ml of the 2.5% insecticide contains 25 mg; therefore the dosage will be 1ml per m<sup>2</sup> to give the dosage of 25 mg a.i./m<sup>2</sup>. So if the net is of 10 m<sup>2</sup> and the absorption capacity is say 500 ml then we need to add 10 ml of insecticide in 500 ml of water to give the reqd. dosage.</li> <li>• Cyfluthrin 05% EW- dosages required 50 mg a.i. / m<sup>2</sup>. 1 ml of the 05% insecticide contains 50 mg; therefore the dosage will be 1ml per m<sup>2</sup> to give the dosage of 50 mg a.i. /m<sup>2</sup>. So if the net is of 10 m<sup>2</sup> and the absorption capacity is say 500 ml then we need to add 10 ml of insecticide in 500 ml of water to give the reqd. dosage.</li> </ul>
(e) <i>Put the net in the insecticide solution prepared as per the procedure given above and knead it well to ensure the net is completely soaked in soln.</i>
(f) <i>Take out the net and spread it in shade, once semi dry it can be hung for drying.</i>

<b>Box - 2 : Long Lasting Insecticide Nets (LLIN's)</b>
A Long lasting insecticide net is a treated net which can withstand insecticidal efficacy up to at least 20 washes with more than 80% mortality after 24 hrs (95% Knockdown after 60 min).
The treatment is done by either incorporating Insecticide <ul style="list-style-type: none"> <li>• In the yarn itself which is made into textile and then used for making nets e.g. <b>Olyset Net</b>. <ul style="list-style-type: none"> <li>- It is Permethrin impregnated (500 mg a.i./m<sup>2</sup> net) Polyethylene net.</li> <li>- Washing cleans the surface and hence it is recommended to be heated up (i.e. sun dried) after washing for the active ingredient to "migrate" to the surface.</li> </ul> </li> </ul> <p style="text-align: center;"><b>OR</b></p> <ul style="list-style-type: none"> <li>• By coating around fibres, e.g. <b>Perma Net</b>. <ul style="list-style-type: none"> <li>- It is a regular polyester net treated with 55 mg a.i./ m<sup>2</sup> Deltamethrin.</li> <li>- Resists multiple washes.</li> <li>- Biological activity lasts as long as the net itself (3 to 4 years for polyester nets, 4 to 5 years for polyethylene ones).</li> </ul> </li> </ul>
<b>Manually treated LLIN</b> <ul style="list-style-type: none"> <li>• Any untreated net can be treated with long lasting formulation of Deltamethrin using K-O Tab.</li> <li>• Low cost as compared to pretreated nets.</li> </ul>

## Legislative Control

Use of laws and bye-laws to prevent / reduce propagation and spread of vectors is an effective means of vector management, although stringent in approach.

## Integrated Vector Management

Development of resistance, effects on non-target organisms and damage to the environment can all be minimized with selective and judicious use of multi-faceted control tactics (Fig. - 25). This approach, commonly known as integrated control, requires an understanding of ecological principles as well as a thorough knowledge of the pest's life history and population dynamics. Today, integrated pest control forms the foundation of Integrated Vector Management programs (IVM) that take a comprehensive and multi-disciplinary approach to

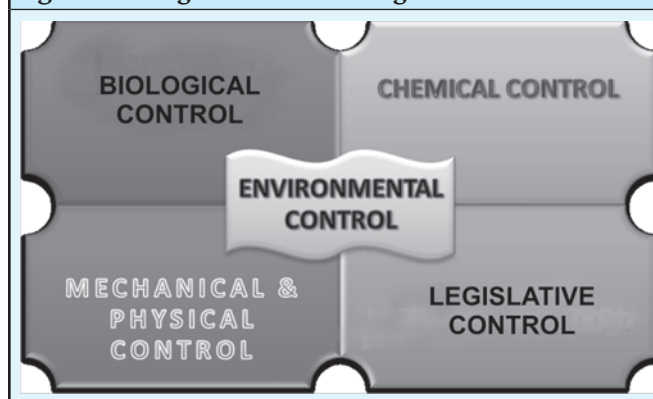
solving pest problems. These programs emphasize management rather than eradication. They take a broad ecological approach to pest problems, focusing on all members of a pest complex in an effort to identify the optimum combination of control tactics that will reduce vector populations below economic thresholds and maintain these levels with the least possible impact on the rest of the environment.

IVM is a dynamic approach which requires a broad knowledge of vector biology, ecology and behaviour on the one hand and that of system analysis approach on the other so that a variety of control measures, such as environmental, chemical, biological, genetic and personal protective measures, can be integrated with a view to achieve the ultimate aim of combating human disease. Chemical and biological methods may provide temporary control of vectors but implementation



of environmental control measures leads to permanent control. In this approach, initial costs may be high and programmes may require years for implementation, but authorities at all levels should be advised to include environmental changes and improvements relating to vector control in all long term planning. However, these methods require elaborate organization, longer time and liberal finances. Species control and vector control are the two modifications circumscribing the wider concept of vector control.

**Fig. - 25 : Integrated Vector Management**



### Future Policy

The aim of future vector control by use of insecticides should be to reduce the intensity of chemical selection by reducing the frequency and coverage of insecticide sprays in public health programmes, minimizing the agricultural use of persistent chemicals as far as possible and by supplementing the chemical control methods by other methods whenever feasible. There is a need to strengthen existing surveillance methods and incorporating the benefits of the newer methods like Remote sensing, Geographical Information System, Global Positioning System etc. whenever and wherever, feasible. There is a continued effort to evolve safer alternatives for vector control coupled with intensive research using molecular biology tools for production of Genetically Modified Vectors (GMV) to address the problems of vector control.

### Summary

Arthropod control is one of the key strategies in the management of vector borne diseases. This requires a sound knowledge of bionomics, insecticide susceptibility & role in arthropod borne disease transmission. The various control options available are environmental, biological, chemical, personal protective measures, mechanical, physical, genetic & legislative control. Environmental control consists of a naturalistic approach with the aim of minimizing vector propagation & reducing man-vector-pathogen contact. Environmental modification consists of transformation that is permanent like drainage, filling and velocity alteration. Environmental manipulation aims at producing temporary conditions unfavourable to the breeding of vectors in their habitats like water salinity changes, stream flushing etc.

Chemical control began with the discovery of the insecticidal value of Dichloro Diphenyl Trichloro ethane (DDT). Insecticides

form a part of extensive countrywide programmes for control & eradication of diseases and are broadly divided into natural & synthetic. Natural insecticides can be plant & mineral based whereas Synthetic insecticides can be organic or inorganic. The organic Insecticides fall into four major groups viz. Organochlorines, Organophosphates, Carbamates and Synthetic pyrethroids. Organochlorine Compounds are contact poisons and act on the nervous system, the only member of this group used in Public Health is DDT.

Currently DDT is being used only in North Eastern states of India for Indoor Residual Spray. A deposit of 1 g a.i of DDT/m<sup>2</sup> of surface area of walls and ceilings up to a height of 3.5 m in all dwellings applied at 8 weeks' interval effectively controls majority of the mosquitoes and also other arthropods resting on the treated wall. Organophosphorus Compounds - insects which have become resistant to Organochlorines are still susceptible to the members of this group. Some of the common compounds are Malathion, Temephos, Fenthion, Dichlorovos (DDVP) and Fenitrothion. Malathion is one of the least toxic Organophosphorus compounds. Malathion is a broad spectrum insecticide with efficacy against a large number of pests ranging from mosquitoes, houseflies, cockroaches, bedbugs, lice etc. Malathion (25% WP), under the National Vector Borne Diseases Control Programme is being used as Indoor Residual Spray against mosquitoes in areas where the vectors have become resistant to DDT. As ULV spray, Malathion has been very widely used during outbreaks of Dengue and JE as an anti adult mosquito measure. Temephos (Abate) is the only insecticide approved for use in potable water (20ml a.i/sqm). Fenthion (Baytex) 82.5% EC is a good mosquito larvicide but cannot be used in potable water bodies. It is highly effective as a larvicide against *Culex quinquefasciatus*. Dichloro-dimethyl-dichlorovinyl-phosphate (DDVP or Dichlorvos) produces fatal insecticidal vapour and can be combined with solid substances like wax and used as tablets or bricks. It is one of the common insecticides used for disinfecting aircraft and is also an effective housefly larvicide. Carbamates are derivatives of carbamic acid; some of the compounds in common use are Propoxur, Carbaryl and Bendiocarb. Synthetic Pyrethroids are broad spectrum, highly potent, have quick knock down action and long residual life. Synthetic pyrethroids are many times more effective & safer than the previously available insecticides and include insecticides like Permethrin, Allethrin, Phenothrin, Cypermethrin, Cyfluthrin, Deltamethrin, Bifenthrin etc. Deltamethrin, Cyfluthrin are used for bednet treatment & routine household pest control activity.

Equipment for vector control can be broadly classified as ground equipment and equipment used for aerial applications. Commonly used for spraying various insecticidal formulations are the hand operated sprayers, power operated sprayers, aerosol dispensers, fog generators and dusters. Residual Spraying is the application of insecticides to surfaces so that the insecticide particles remain on the surface in the form, size and quantity suitable for insects to pick up on contact and sufficient to exert a lethal effect over a long period. Organochlorine, Organophosphorus, Synthetic pyrethroids and Carbamate compounds can thus be applied on the inside walls of houses and also on thick bushes. Before starting a spray operation, the

equipment must be checked; the average discharge of an 8002 nozzle is about 750 ml per minute. Spraying in a room should commence from the backside of a door clockwise completing the plain surfaces of walls to the crevices on the walls and inside portion of windows etc. The pillars, under surfaces of furniture and lastly the ceilings should be taken for spray. Spray is done from roof to floor, using downward motion, to complete one swath; then stepping sideways and spraying upwards from floor to roof. Spray is applied in vertical swaths 52-56 cm wide. Swaths should overlap by 5 cm.

Space Spraying is an ideal method for bringing about rapid control of vectors in emergency or epidemic situations and may also be used for seasonal control of flying insects, pests or vectors. Space sprays are applied mainly as thermal fogs or cold fogs. Thermal fog is produced by special devices known as thermal foggers that use heat to break up the chemical into very small droplets (usually in 5-30 micron diameter range) which then disperse in the air. The insecticide used in thermal fogs is diluted in a carrier liquid, which is usually oil-based. Cold fog is produced by a special device which breaks up the chemical into microscopic droplets by mechanical means basically with a high-pressure pump and an extremely fine nozzle. The spray droplets are generated without any external heat. With cold fogs, the volume of spray is kept to a minimum. Ultra-low-volume insecticide formulations are commonly used for such applications. The cold fogger may dispense formulations in a very concentrated form and generate the droplets (usually in the 5-30 micron diameter range) in a precise manner. However, its ability to penetrate dense foliage or obstacles is not as good as that of thermal fogging. Cold fogging is sometimes called Ultra Low Volume (ULV) treatment as it allows the utilization of only a very small amount of chemical for coverage of a large area. Space-spraying formulations are generally oil-based. Diesel is used as a carrier for thermal fogging, but creates a thick smoke and oily deposits, which may lead to public rejection. Insecticides used for fogging are Pyrethrum 2% Extract, EC, Malathion Tech, Deltamethrin 1.25 ULV. The lower the concentration of active ingredient, the larger the number of droplets of a given size required to achieve a lethal dose. Suppression of vector populations over large areas can be carried out using space sprays released from aircraft, especially over areas where access with ground equipment is difficult and extensive areas need to be treated very rapidly. Area Spraying is carried out for treatment of land against mites and ticks and also as an anti-larval measure over vast water surfaces.

Biological Control is the manipulation of populations of living beneficial organisms in order to reduce the numbers of pests or amount of damage. The biological agents are broadly classified as Predators, Parasites and Pathogens. Predators are often large, active, and/or conspicuous in their behaviour e.g. larvivorous fishes for the control of mosquitoes like *Gambusia affinis*. Parasites like Nematodes - *Romanomermis culicivorax* and *R. iyengari* have been evaluated and have been found to give variable control of mosquitoes. Fungi *Lagenidium* and *Culicinyomys* have shown immense potential as mosquito larval control agents and can be exploited for use against mosquitoes. Pathogens - *Bacillus sphaericus* and *Bacillus thuringiensis var israelensis* which acts via delta endotoxin are

promising control options. Bti 12 AS is used @ 20ml/m<sup>2</sup>.

Genetic Control is the "use of any condition or treatment that can reduce the reproductive potential of noxious forms by altering or replacing the hereditary material".

Personal protective measures to prevent the arthropod vectors from biting and feeding on their host can be achieved by use of mosquito nets, wearing of long trousers, rolled down sleeves of shirts, socks, shoes and anklets (particularly when going out and in areas heavily infested with arthropods) and use of repellents by application on body surfaces or clothing (are effective in reducing man-vector contact). The commonly used repellents are benzyl benzoate, N, N-diethyl-m-toluidide (DEET), Dibutyl phthalate (DBP), Diethyl phenyl acetamide (DEPA) and Neem oil.

The development of resistance, effects on non-target organisms and damage to the environment can all be minimized with selective and judicious use of multi-faceted control tactics. Integrated Vector Management is a dynamic approach which requires a broad knowledge of vector biology, ecology and behaviour on one hand and that of system analysis approach on the other so that a variety of control measures such as environmental, chemical, biological, genetic and personal protective measures can be integrated with a view to achieve the ultimate aim of combating human disease.

## Study Exercises

**Short Notes :** (1) Environmental Management (2) Biological control (3) Biorational insecticides (4) IRS

### MCQs & Exercises

- Organophosphorus insecticides include all except (a) Temephos (b) Malathion (c) Propoxur (d) Dichlorvos
- Deltamethrin belongs to which group of insecticides (a) Carbamates (b) Synthetic Pyrethroids (c) Organophosphates (d) Organochlorides.
- Which of the following is a chitin synthesis inhibitor : (a) Imidacloprid (b) Novaluron (c) Fenoxycarb (d) Cyfluthrin.
- Maximum amount of pesticide on surface is available for killing pests in this formulation (a) Dusts (b) Granules (c) Wettable powder (d) Liquid formulation.
- Hand operated equipment for vector control does not include : (a) ULV fogging machine (b) Hand sprayer (c) Knapsack sprayer (d) Compression pneumatic sprayer
- Commonest type of equipment used in National Vector Borne Disease Control Programme (a) Power operated sprayer (b) Hand sprayer (c) Knapsack sprayer (d) Compression pneumatic sprayer
- Insecticide not used for bed net treatment : (a) Deltamethrin (b) Permethrin (c) Cyfluthrin (d) Allethrin
- Space spraying is used as method of bringing down rapid control of vector in (a) Emergency (b) Epidemic (c) Seasonal control of flying insects (d) All.
- Which of these is not true for thermal fogging (a) easily visible fog (b) Low conc. of active ingredient (c) Pyrethrum 2% & Malathion tech used (d) Mostly water diluted formulations used.

10. Predators used in biological control are all except  
(a) *Poecelia reticulata* (b) *Gambusia affinis* (c) *Bacillus sphaericus* (d) *Gaurami*

11. Match the Following :

1. Pyrethrum	(a) Malathion
2. DDT	(b) Temephos
3. Broad spectrum insecticide used in IRS where resistance to DDT has occurred	(c) Available as 2% Extract. Require 20 times dilution to get 0.1% solution. Has rapid knockdown action.
4. Available as 50% EC. Used in potable water	(d) Used as IRS in the dose of 1g/m <sup>2</sup> of surface area of walls & ceilings up to a height of 3.5m.
5. Mosquito larvicide, cannot be used in potable water bodies, highly effective against <i>Culex quinquefasciatus</i>	(e) Fenthion
6. Effective housefly larvicide, available as 76% EC & in aerosol formulations.	(f) Propoxur
7. Flushing out effect makes it useful for cockroach & bed bug control	(g) Available as 2.5% SC, 2.5% WP & 1.25 ULV in space sprays
8. Deltamethrin	(h) DDVP
9. Cannot be used in potable water, available as 12AS	(i) Available as 2.15% gel for use against cockroaches & bait against houseflies
10. Imidacloprid	(j) Bti

Fill in the Blanks :

- 12) Residual insecticidal property of DDT was discovered by \_\_\_\_\_  
13) Mechanism of action of Pyrethrum \_\_\_\_\_

- 14) \_\_\_\_\_ effect is unique action of Fipronil.  
15) \_\_\_\_\_ powder & \_\_\_\_\_ tablet is used for rodent control.  
16) Average discharge of an 8002 nozzle is \_\_\_\_\_  
17) Mechanism of action of Bti is by the action of \_\_\_\_\_

**Answers :** (1) c; (2) b; (3) b; (4) c; (5) a; (6) d; (7) d; (8) d; (9) d; (10) c; (11) 1-c; 2-d; 3-a; 4-b; 5-e; 6-h; 7-f; 8-g; 9-j; 10-i; (12) Paul Muller; (13) Rapid knockdown; (14) Cascade (15) Calcium cyanide & Aluminium phosphide (16) 750ml/ min (17) Delta-endotoxin

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## 156 Housefly

Rina Tilak

Houseflies live in close association with man. Despite the best and most extensive efforts taken to control it, housefly control has remained a challenge. The important genera include *Musca*, *Fannia* and the biting flies, *Stomoxys*, *Sarcophaga* and the various blowflies viz. *Chrysomya*, *Calliphora* and *Lucilia*.

However, the most abundant and widely distributed is the Housefly.

### Classification and Distribution

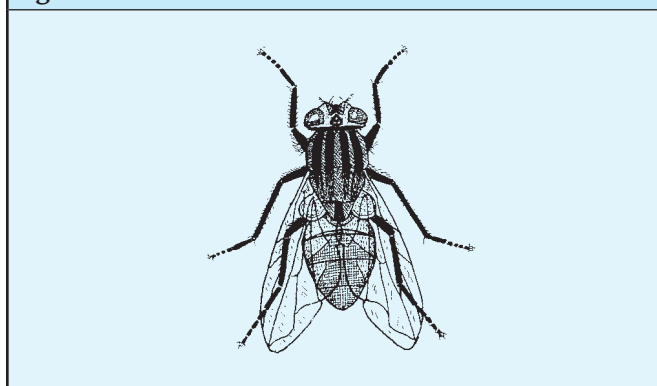
The houseflies have a world wide distribution with about 1700 genera under family Muscidae, order Diptera to which the medically important flies - houseflies and stable flies belong. There are 70 species of flies in genus *Musca*, of which *Musca domestica* (common housefly) and *Musca sorbens* (bazaar fly) are abundantly encountered in tropical and subtropical countries.



## Morphology

Adult houseflies are 6-9 mm in length, greyish in colour with 4 distinct longitudinal black stripes on the thorax. The head bears a pair of compound eyes which are close together in males but are widely separated in females. The mouth parts, collectively known as the proboscis are capable of considerable extension and retraction and are adapted for lapping-sponging. The antennae generally remain hidden in the antennal groove on the head. The thorax bears four narrow black stripes, a pair of clear transparent wings and a pair of halteres (knob like structure behind the wing), three pairs of legs - each terminating in five segments of tarsus; the last segment bears a pair of claws and pair of pad-like 'pulvilli' provided with a large number of glandular hairs. These glandular hairs secrete a substance which keeps the pads wet and sticky and enables the flies to cling to vertical and smooth surfaces. The abdomen is short, broadly oval with five visible segments (Fig. - 1).

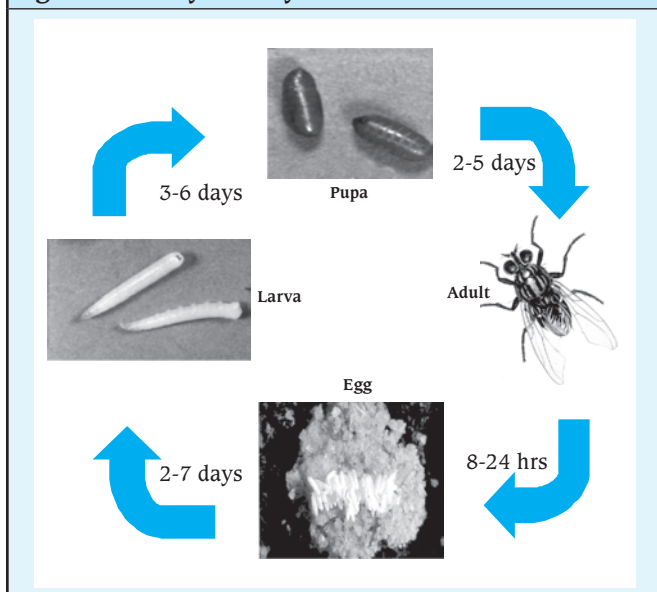
Fig. - 1 : *Musca domestica*



## Life History

The life cycle of housefly undergoes complete metamorphosis with egg, larva (maggot), pupa and adult stages (Fig 2).

Fig 2 : House fly - Life cycle



Houseflies breed in decaying organic matter of animal or plant origin. The eggs are pearly white, oval in shape and measure about 1 mm in length. They are laid in cracks & crevices in moist manure heaps or any decaying animal or vegetable matter. A female fly may lay 300 to 900 or more eggs in 5 to 6 batches during her lifetime. In summer, the eggs hatch after 8-12 h, whereas in winter it may take 2 to 3 days. There are three larval stages or instars in the life of a fly. The larvae are photophobic and thus are found in the deeper layers of the manure. After 3-5 days, the third stage larva moves from deep moist burrows to the neighbouring dry soil and contracts to form a dark brown barrel shaped pupa about 6 mm in length. The pupa neither feeds nor grows. Within 2-5 days, the adult fly emerges out of the pupal case. Under favourable conditions of temperature and food supply, the whole life cycle from egg to adult may be completed in about less than a week's time. During winter it may take as many as 20 to 22 days. The length of life is usually 2-3 weeks but in cooler conditions it may be as long as three months.

## Bionomics

The housefly has a remarkable capacity to reproduce. It is estimated that at an average of 7 day's developmental cycle for each generation, one female housefly, laying about 120 eggs, could produce a progeny of 5,598,72000,000 adult flies by the end of 5 months in summer. However, nature does not allow this as a large number of eggs, larvae and pupae are lost due to desiccation, starvation, predators and adverse climatic conditions. A high percentage of flies remain near the breeding places. Depending on the prevailing wind and availability of food, some of them may migrate up to 20 km from breeding places (however most stay within 1-2 km of the larval habitat if sufficient food is available). High temperature is lethal to larvae and so the heat generated in tightly packed manure heap quickly kills them. The adult houseflies are attracted to light. The housefly is omnivorous and a voracious feeder; it is particularly partial to faecal matter, sputum, discharges from wounds and open sores. It is also easily attracted to sugars, milk and other articles of food meant for human consumption. The solid or semi-solid foods are softened by extrusion of a vomit drop and then sucked up. Well fed fly defecates every 5 min, particularly while feeding, and vomits every 2-3 minutes. Water is an essential part of a fly's diet and flies do not ordinarily live more than 48 hours without access to it.

## Ecology of Adult Flies

An understanding of the ecology of flies is essential for effective management of houseflies. Flies are mainly active during daytime when they feed and mate. They are generally found resting indoors on floors, on the ground and walls at less than 5 feet from the ground; whereas outdoors they rest on fences, walls, steps, pit latrines, clothes lines, grasses, weeds and garbage cans. At night, flies rest above 5 feet height on walls, on hanging wires and vertically suspended articles and ceilings, usually close to their daytime food sources.

## Vector Potential

Immediately after visiting a dirty place, the fly may rest on any foodstuff or drink meant for human consumption or an exposed part of body e.g. mouth, eyes or a wound, and deposit the



disease producing organisms. The housefly is thus a mechanical carrier of the causative organisms of diarrhoeas, dysenteries, gastroenteritis, cholera, enteric group of fevers, intestinal worms, poliomyelitis, viral hepatitis A, other entero- viruses, trachoma, conjunctivitis, anthrax, yaws and tuberculosis. At times, the housefly may cause conditions known as internal and external myiasis, in which the flies breed in sloughing wound, intestinal contents and suppurating cavities.

## Fly Control

**(a) Environmental Control** : The best method of control of houseflies is to eliminate their breeding places and to maintain a high standard of environmental sanitation, especially by proper disposal of human and animal excreta, swill, garbage and all other decaying organic rubbish, offal and carcasses. Access of flies to faeces should be prevented by fly proofing the latrines and latrine pans and prompt removal of faeces. Their access to food is prevented by fly-proofing cook houses and messing blocks and by use of fly-proof cupboards and containers. The doors of all entrances and windows should open outwards and preferably should have vacuum levers especially in cookhouses. Constant vigilance is necessary to destroy all flies that gain entrance, otherwise the fly-proofed rooms become large fly-traps. In pantries and mess rooms, fly-proof cupboards for food storage and wire gauze, weighted with beads afford protection to food in jugs or bowls but their repair and cleanliness requires constant supervision. When the table is being laid, cups should be inverted in saucers and bowls should be kept either upside down or under cover when not in use.

### **(b) Insecticidal Control (Box - 1)**

**(i) Space Spray** : For immediate destruction of flies and especially for prevention of fly borne diseases, pyrethrum (0.1%) spray is useful, mainly in cook houses and dining rooms before meal times and in canteens. Certain combinations of space sprays containing Pyrethrum or Synthetic pyrethroids and/or Organophosphorus/Carbamate compounds are available commercially. ULV spray in large areas may also prove effective in controlling houseflies.

**(ii) Baits** : Propoxur baits have been in use since long for fly control. Recent introduction in this concept is Imidacloprid baits containing Imidacloprid as the toxicant with Pheromone - Muscalure, which helps in attracting the flies to the bait. This bait has been found to be effective for use in areas with low to moderate fly infestation. However, while using these baits in cookhouses/ dining areas, care should be taken that they are not placed close to cooking or serving place.

**(iii) Cord and Ribbons** : During the night, houseflies prefer to rest on strings and hanging wires or any object; this fact is utilized for killing them by use of insecticide treated cords and strips which are hung from ceilings in kitchens, dining halls, store rooms, dairy farms and poultry houses to provide effective control during the fly season. Dark coloured material is preferred for treatment @ 1m cord or strip for each square metre of floor space. The period of effectiveness ranges from 1 to 6 months. For this any insecticide with high vapour pressure and quick knock down effect should be used. These treated materials should not be hung over food containers,

water containers/ troughs or within reach of animals or pets. Curtains treated with Synthetic pyrethroids will be of additional benefit.

**(iv) Larvicides** : Insecticides such as DDVP (2%), Fenthion (4%) have been used as larvicides to control fly breeding but the use of larvicides may favour the development of resistance, the choice should therefore be made carefully. Insecticides like Dimilin (IGR) may be used to retard development of resistance. Larvicides should be applied at a rate sufficient to wet the upper 10-15 cm of the breeding medium thoroughly i.e. 0.5 - 5 l/m<sup>2</sup>.

<b>Box - 1 : Newer Insecticides Against Houseflies</b>			
<b>Insecticide</b>	<b>Formulation</b>	<b>Dilution</b>	<b>Area to be sprayed</b>
Cyphenothrin	5%EC	10 ml + 990 ml of water	500 ml/sq m
Diiflubenzuron	2.5% WP	8 g in 1 litre water	500 ml/sq m
Diiflubenzuron	5% G	As it is	50 g/sq m
Imidacloprid bait	0.5%	As it is	5 g / bait station
Propoxur bait	2%	As it is	Moisten and keep in bait stations

**(v) Paints** : The concept of using insecticidal paint for housefly is catching up. Imidacloprid baits wetted with water may be used as paint on housefly resting places.

**(vi) Residual Spray** : The housefly has developed resistance to most of the Organochlorine as well as Organophosphorus and Carbamate group of insecticides routinely used in public health. Residual sprays are ideally not recommended for fly control.

### **(c) Mechanical Control**

**(i) Fly Traps** : Various types of fly traps such as the cage trap and the kerosene tin trap were used in the past with fairly good results. These are no longer in use because of the availability of more potent and convenient methods. Newer mechanical fly catching devices have been developed which have bags with attractants inside, which attract the houseflies and on entry inside the bag, they get trapped and eventually are killed.

**(ii) Swatting** : It is used in situations where infestation is so low that routine fly control measures are either not indicated or feasible. However, it is important to remember that fly population of a cook house or dining room cannot be greatly reduced by persistent swatting. A good swat is the one, which is resistant enough to affect a rapid hit. The flaps should be perforated and washable.

**(iii) Fly Paper** : Commercially available fly papers may be used or alternately sticky fly papers (Fig. - 3) can be prepared by mixing 8 parts of powdered resin and 5 parts by weight of crude castor oil and heating the same in a water bath while stirring constantly. The paste mixture is spread on glazed paper. The latter can be prepared by coating an ordinary paper with a hot

solution of 1 g of glue in 3ml of water and allowing it to dry. The fly papers do not give lasting results and hence are not much in use for control purpose. They are however considered an effective method for monitoring fly density.

**Fig. - 3 : Fly paper**



**(d) Physical Control** : Use of light traps (electrocutors) is very useful in the dining areas & other public eating places. The light traps should be placed away from dining tables & food.

## Summary

Houseflies live in close association with man. The most abundant and widely distributed is the Housefly - *Musca domestica*. Adult houseflies are 6-9 mm in length, greyish in colour with 4 distinct longitudinal black stripes on the thorax. The head bears a pair of compound eyes. The thorax bears a pair of clear transparent wings, three pairs of legs - the last segment of the tarsus bears a pair of claws and a pair of pad-like 'pulvilli' provided with a large number of glandular hairs. These secrete a substance which keeps the pads wet and sticky for clinging to vertical and smooth surfaces. The life cycle of housefly undergoes complete metamorphosis with egg, larva, pupa and adult stages. Houseflies breed in decaying organic matter of animal or plant origin, eggs are laid in cracks & crevices in moist manure heaps or any decaying animal or vegetable matter. The larvae are photophobic and thus, are found in the deeper layers of the manure. After 3-5 days, the third stage larva moves from deep moist burrows to the neighbouring dry soil and contracts to form a dark brown barrel shaped pupa. Within 2-5 days, the adult fly emerges out of the pupal case. Under favourable conditions of temperature and food supply, the whole life cycle from egg to adult may be completed in about less than a week's time. During winter it may take as many as 20 to 22 days.

The housefly has a remarkable capacity to reproduce. High temperature is lethal to larvae and so the heat generated in tightly packed manure heap quickly kills them. The adult houseflies are attracted to light. The housefly is omnivorous and a voracious feeder. It is particularly partial to faecal matter, sputum, discharges from wounds and open sores. The housefly is a mechanical carrier of the causative organisms of diarrhoeas, dysenteries, gastroenteritis, cholera, enteric group

of fevers, intestinal worms, poliomyelitis, viral hepatitis A, other entero- viruses, trachoma, conjunctivitis, anthrax, yaws and tuberculosis.

The best control of houseflies is to eliminate their breeding places and to maintain a high standard of environmental sanitation, especially by proper disposal of human and animal excreta. Access of flies to faeces should be prevented by fly proofing the latrines and latrine pans and prompt removal of faeces. Their access to food is prevented by fly-proofing cook houses and messing blocks and by use of fly-proof cupboards and containers. The doors of all entrances and windows should open outwards and preferably should have vacuum levers. Insecticidal Control : Space Spray of pyrethrum (0.1%) useful for immediate destruction of flies & for prevention of fly borne diseases. Propoxur baits have been in use since long for fly control. Recent introduction is Imidacloprid baits. Use of insecticide treated cords and strips provide effective control during the fly season. Other useful insecticides are DDVP (2%), Fenthion (4%), Dimilin etc. Mechanical fly catching devices have been developed which have bags with attractants inside, which attract the houseflies and on entry inside the bag, they get trapped and eventually are killed. Swatting is used in situations where infestation is so low that routine fly control measures are either not indicated or feasible. Commercially available fly papers may be used or alternately sticky fly papers can be prepared. Use of light traps (electrocutors) is very useful in the dining areas & other public eating places, however, they should be placed away from dining tables & food.

## Study Exercises

### MCQs

- 1) Housefly transmits all except (a) Poliomyelitis (b) Hepatitis B (c) Tuberculosis (d) Intestinal worms.
- 2) Environmental control measures for housefly control do not include (a) Fly proofing (b) Pyrethrum spray (c) Proper garbage disposal (d) Vacuum levers in doors.
- 3) Anti adult control measure is (a) Fenthion (b) DDVP (c) Dimilin (d) Imidacloprid bait.

### Fill in the Blanks

- 4) Size of a housefly is \_\_\_\_\_
- 5) \_\_\_\_\_ secrete a substance which keeps pads wet & sticky for clinging to vertical & smooth surfaces.
- 6) Larvae of housefly are \_\_\_\_\_

**Answers** : (1) b; (2) b; (3) d; (4) 6-9mm; (5) Pulvilli; (6) Photophobic.

## Further Suggested Reading

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Rina Tilak

Mosquitoes qualify to be rated as one of the most important vectors, the world over, from amongst the numerous species of blood sucking arthropods, due to the sheer magnitude of morbidity and mortality caused by them. The mosquitoes belong to phylum Arthropoda, class Insecta, order Diptera and family Culicidae. The family Culicidae is divided into sub-families Culicinae, the Chaoborinae and the Dixinae. Of these, only the sub-family Culicinae, which comprises all the true mosquitoes, is of medical importance. Amongst the mosquito genera, only *Anopheles*, *Culex*, *Aedes* and *Mansonia* are of importance in India. The mosquitoes are further classified as 'Anophelines', which comprises only one important genera - *Anopheles* and 'Culicines' comprising three important genera viz. *Culex*, *Aedes* and *Mansonia*.

### Distribution

Mosquitoes have a worldwide distribution, being found in the tropics, temperate zones and also in the arctic circles. They have even been found breeding in underground tunnels, deep mines and at altitudes as high as 4000 m above sea level.

### Morphology

Mosquitoes are about a centimetre long and greyish black in colour. The division of the body into the head, thorax and abdomen is sharply defined. The head bears two large compound eyes, a pair of antennae and the mouthparts which are collectively called 'proboscis'. The mandibles and maxillae of only the female are developed for cutting the human skin and therefore only the female mosquitoes can suck blood and transmit diseases.

Sexual dimorphism is clearly seen in mosquitoes; males can be identified by their antennae, which are densely haired and look like moustache, whereas, in females the antennae is sparsely haired.

The palps are also helpful in identification of males and females of Anophelines and Culicines; In *Anopheles* male, the palpi are long and club shaped at the termination; in the females, they are as long as proboscis and are straight. In Culicines, the male palpi are long and tapering and deflected out, whereas in females, the palpi are much shorter than proboscis and budlike.

The thorax bears a pair of wings and three pairs of legs. The thorax of Culicines is humped in all the three genera, giving them a hunchback appearance while resting; whereas, Anophelines rest with their head, thorax and abdomen in the same line and forming an angle of 45° with the surface, with the exception of *Anopheles culicifacies* which rests like the Culicines i.e. with the body parallel to the surface. The abdomen of mosquitoes consists of 10 segments of which 7 or 8 are clearly marked out and the terminal ones form the male and female external genitalia.

### Life History

Mosquitoes undergo complete metamorphosis through the

stages of egg, larva, pupa and adult. Water is required for egg laying with variations existing among genera and species for the type of water desired by them. The number of eggs laid at each oviposition varies between 50 and 150. Anophelines prefer to lay their eggs singly in clean water collections and have lateral floats; *Culex* sp prefers dirty/ polluted water and the eggs are deposited as raft; *Aedes* sp prefers to lay eggs singly on some substratum/ debris in containers (natural or artificial), whereas *Mansonia* sp breeds in water bodies with aquatic vegetation namely *Pistia* and lay their eggs on the under surface of the leaves in star shaped clusters. The eggs hatch into larvae in one to two days, but in cold weather, the hatching may be delayed. Mosquito larvae feed voraciously on micro-organisms, water algae or other organic matter and breathe through spiracles. Larvae pass through four stages or 'instars' in five days depending on the species, the temperature of the water and availability of food supply. In Anophelines, the larvae rests parallel to the surface and have palmate hair on the dorsal surface of the abdomen and do not possess siphon tube, whereas in case of Culicines, the larvae rest at an angle with the head downwards and possess a single siphon tube. At the end of the fourth instar, the fully grown larva casts its skin and becomes a comma shaped 'pupa', which is a motile but non-feeding stage and has two respiratory trumpets originating from the cephalothoracic area. During this stage, it undergoes transformation to the adult usually within 1-2 days. The adult mosquito wriggles out of the pupal skin through a 'T' shaped slit and balances itself on the water surface or some near by floating object until its wings are dry and then flies off. The total duration of the life cycle varies between seven days to one month. The life span of adult mosquitoes is up to a maximum of 6 months in the temperate zones, but in the tropics they seldom survive for more than a month.

### Bionomics

The females of all the medically important mosquitoes are normally bloodsuckers, as they require a blood meal for maturation of eggs. Females are fertilized during swarming (nuptial dance) at dusk. The source of the blood meal varies with the species. Those feeding on human blood are called anthropophilic and those feeding on animals are called zoophilic. They are attracted by the body odours, carbon dioxide and heat emitted from animals or humans. Majority of species are nocturnal in their feeding habits, while others feed indiscriminately by day or night. Some are outdoor biters (exophagous) and some are indoor biters (endophagous). After blood meal, female goes in search of a quiet place indoors (endophilic) or outdoors (exophilic) to rest for a variable period, usually 2 days and matures her eggs. When the eggs are fully matured, she goes in search of water collection for oviposition (act of laying eggs). Male mosquitoes feed on flower-nectar and plant-juices and do not survive long after fertilizing the female mosquito.

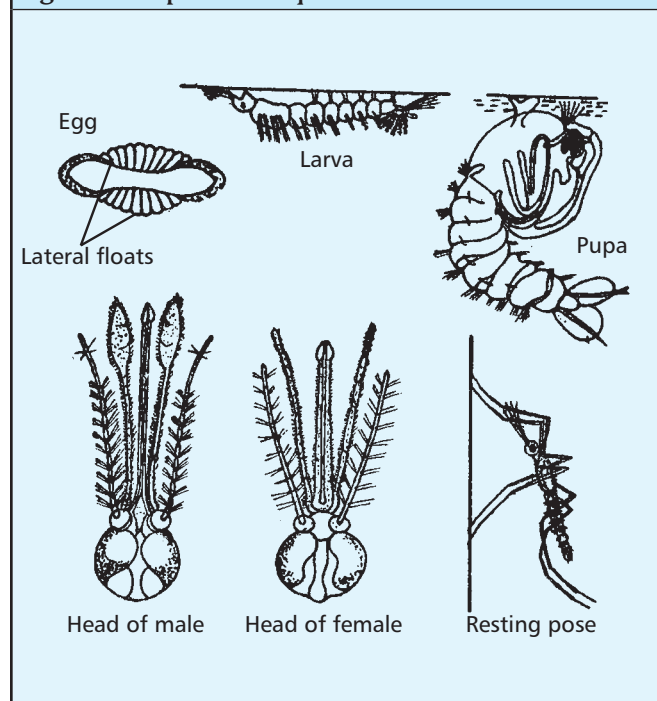
### Genus Anopheles

Members of this genus have 58 species in India. Females of only 9 species of Anopheline mosquitoes are the vectors of human Plasmodia in India (Fig. - 1). In certain parts of the world, some species of Anopheline mosquitoes transmit *Wuchereria bancrofti* and *Brugia malayi* infections as well.



All important vector species are preferentially anthropophilic. The time of feeding is also variable; some species prefer dusk for their blood meals, others late night while still others select early morning. Knowledge of the habits is useful in designing control measures. *An identification key for common Anophelines of India is presented at the end of the section.* Detailed entomological techniques are given in the WHO manual and a pictorial identification key has also been published by Das et al.

**Fig. - 1 : Anopheles Mosquito**



### Genus Culex

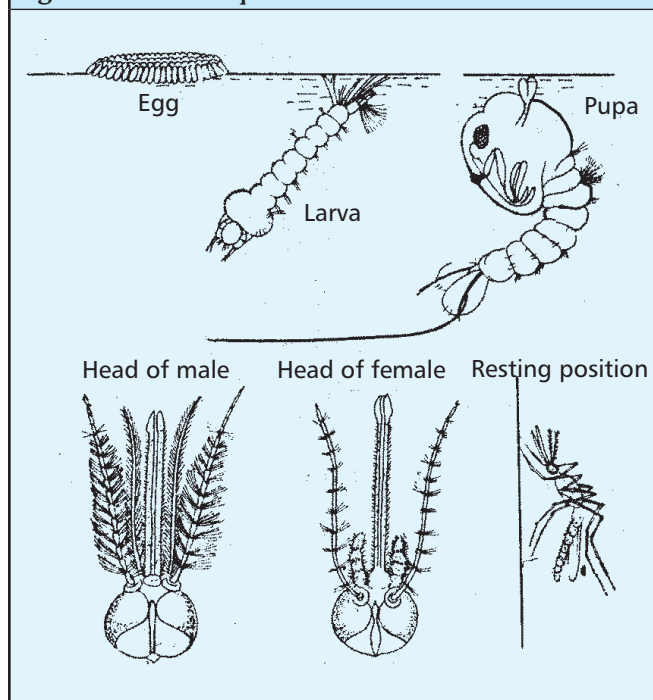
Members of this genus are found in temperate and tropical zones throughout the world. There are 240 Indian species in this Genus. Adult mosquitoes of this genus are generally dull in colour and inconspicuous due to unspotted wings (Fig. - 2). Their breeding sites vary from clear water, such as wells and springs, to collections of muddy, brackish or polluted water; but unlike Anopheline mosquitoes, these mosquitoes generally prefer stagnant and muddy pools. *C quinquefasciatus* is the common house mosquito and is prevalent universally; it bites at night and is the most important vector of Filariasis caused by *Wuchereria bancrofti*.

### Genus Aedes

Some members of the genus *Aedes* have almost worldwide distribution while others have restricted habitats. The chief species in India are *Aedes aegypti*, *Ae albopictus* and *Ae vittatus*. They are black or dense brown and medium sized mosquitoes with silvery white scales forming patterns on the thorax, bands on the legs and rings around each abdominal segment.

These mosquitoes are mostly anthropophilic and are adapted to domestic or semi-domestic environments. These are container breeders. The cigar shaped eggs are laid singly on

**Fig. - 2 : Culex Mosquito**



damp surfaces on stagnant water. During the pre-monsoon period, the breeding is restricted to water collections meant for domestic use. Communities or sections of the cities with water scarcity, which leads to water storage practices, are mostly harassed by *Ae aegypti*. In the shore areas, barges and country crafts provide ample place for *Aedes* breeding and constitute a permanent source of *Aedes* infiltration in the shore establishments and cities. They are well adapted for breeding in small collections of water in a wide variety of natural and artificial containers such as masonry tanks, earthenware pots, small and large tins, barrel drums, coconut shells, stored or discarded motor car tyres, junk and hardware, flower pots, fire buckets, depressions in tree trunks, leaf axils etc. They may breed in tree holes if these are situated within about 20 metres of human habitat.

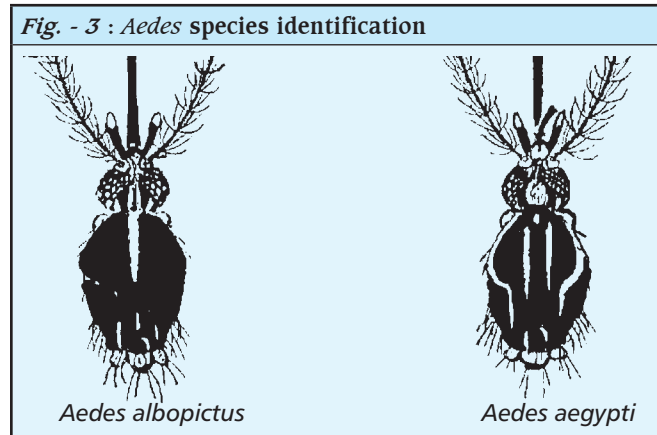
The eggs after maturing may remain viable for considerable periods even after drying-up of the breeding sites, and hatch out during rains. Such surviving eggs rapidly build up the adult mosquito population, once it starts raining. Their capacity to complete life cycle indoors enables them to breed in urban areas throughout the year, irrespective of the prevailing external climate.

*Aedes* mosquitoes are day biters with dawn and dusk as peak biting time. They may feed indoors or outdoors and rest near the breeding places in dark, shady corners outdoors, whereas indoors they rest behind cupboards, hanging clothes, inside shoes, umbrellas, below the furniture and in containers providing breeding sites. *Aedes aegypti* prefers to breed in artificial containers, whereas *Aedes albopictus* prefers natural containers.

*Aedes* mosquitoes are the vectors of urban and rural yellow fever (not in India), dengue, dengue haemorrhagic fever



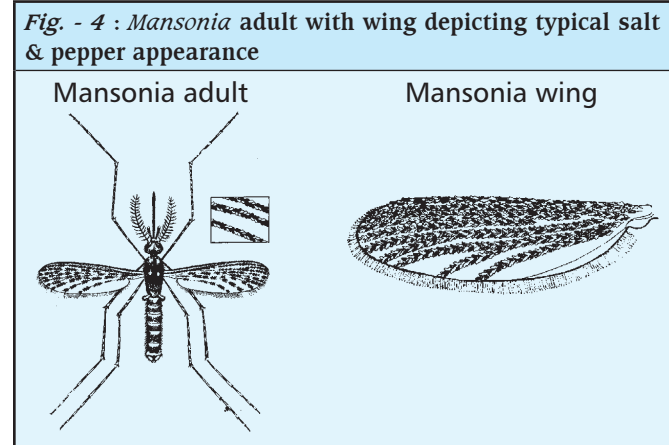
and chikungunya. *Ae niveus* has been reported as vector of *W bancrofti* (diurnally sub periodic) infection in Nicobar Islands. *Ae aegypti* and *Ae albopictus*, the two important vector species can be easily distinguished by their thoracic pattern. *Ae aegypti* has sickle or lyre shaped pattern on the thorax, whereas *Ae albopictus* has a single central mark present on the thorax (Fig 3).



#### Genus *Mansonia* (Fig 4)

This has wide distribution in tropical countries. In India, *Mansonia annulifera*, *M uniformis* and *M indiana* are the prevalent species in Kerala. The adult mosquitoes are robust and yellowish brown. The wings are covered with flat, broad scales, which give the wings a speckled appearance as if sprinkled with mixed salt and pepper. The female lays eggs in cluster

anchored to the under surface of the leaves of aquatic plants such as *Pistia*, *Lemna*, *Eichhornia* and *Salvinia*. On hatching out, the larvae obtain oxygen from the plant cells through their modified siphon tubes by attaching themselves to the rootlets of these plants. The pupae are similarly attached to the plant stems by the modified breathing trumpets. When matured they detach themselves and come to the water surface. They are persistent biters, particularly during darkness. *Mansonia* mosquitoes are the vectors of *B malayi* infection of filariasis in several pockets in rural areas of Kerala, Tamil Nadu, Andhra Pradesh, Madhya Pradesh, Assam and West Bengal.



Some of the important differences between Anopheline and Culicine mosquitoes are shown in Table - 1.

Table - 1 : Important differences in Anopheline and Culicine mosquitoes		
Stage	Anopheline	Culicine
Egg	<ul style="list-style-type: none"> <li>Boat shaped</li> <li>Laid singly</li> <li>Possess lateral floats</li> </ul>	<ul style="list-style-type: none"> <li>Elongated</li> <li>Aggregation occurs into rafts of hundreds of eggs in <i>Culex</i></li> <li><i>Aedes</i> eggs are laid singly</li> <li><i>Mansonia</i> eggs are laid on under surface of leaves of aquatic plants in star shaped clusters</li> </ul>
Larva	<ul style="list-style-type: none"> <li>No siphon tube but only apertures on 8<sup>th</sup> abdominal segment</li> <li>Larvae rest parallel to the surface of water</li> <li>Swim with swift wriggling movements</li> <li>Palmate hairs for floatation arranged in pairs on all abdominal segments</li> </ul>	<ul style="list-style-type: none"> <li>Single siphon tube on 8<sup>th</sup> abdominal segment <ul style="list-style-type: none"> <li>In <i>Culex</i>, siphon tube is long and narrow</li> <li>In <i>Aedes</i>, it is short and broad</li> <li>In <i>Mansonia</i>, larvae are attached through siphon tube to roots of aquatic plants</li> </ul> </li> <li>Larvae rest at an angle to surface</li> <li>Swim with slow snail or worm like movements</li> <li>No palmate hairs for floatation</li> </ul>
Pupa	<ul style="list-style-type: none"> <li>Pupa is comma shaped</li> <li>In Anophelines, respiratory trumpets are short stumpy and funnel shaped</li> </ul>	<ul style="list-style-type: none"> <li>Pupa is comma shaped</li> <li>In Culicines, respiratory trumpets are longer, slender and trumpet shaped</li> </ul>
Adult	<ul style="list-style-type: none"> <li>Wings usually spotted</li> <li>Rests at an angle to surface, with the exception of <i>A culicifacies</i></li> <li>In the males, palpi are long and club shaped at the termination; in females, they are as long as proboscis and are straight</li> </ul>	<ul style="list-style-type: none"> <li>Wings usually not spotted</li> <li>Rests parallel to the surface</li> <li>Thorax is humped</li> <li>In the males, palpi long and tapering and deflected out; in females, palpi are much shorter than proboscis and budlike</li> </ul>

## Vectors of Malaria

There are 58 species of Anopheline mosquitoes in India but only 9 are incriminated as vectors and another 5 species have been found to be of local importance in transmission of malaria. In Northern and Peninsular India, the main vectors are *A. culicifacies*, *A. stephensi* and *A. fluviatilis*, while the local vectors are *A. sundaicus*, *A. annularis* and *A. varuna*. In Eastern India, the main vectors are *A. dirus*, *A. sundaicus*, *A. philippinensis*, *A. minimus*, and *A. maculatus*. In Andaman and Nicobar Islands, the main vector is *A. sundaicus* while the new vectors are *A. dirus*, *A. maculatus* and *A. tessellatus*. A detailed list of these vectors is presented in Table - 2.

The following characteristics of vector mosquitoes play an important role in the epidemiology of malaria.

(a) **Breeding Habits** : The breeding habits of mosquitoes show a lot of variation and hence vector mosquitoes tend to be confined to certain geographical areas only. A few examples are as shown in Box - 1.

Box - 1 : Breeding Habits of Vectors	
Slow moving water, seepages, terraced rice fields	<i>A. fluviatilis</i>
Brackish waters	<i>A. sundaicus</i>
Wells, cisterns and over head tanks	<i>A. stephensi</i>
Tanks, pools, burrow pits and ditches	<i>A. philippinensis</i> , <i>A. annularis</i>
Forest pools, streams and slit trenches	<i>A. dirus</i>

(b) **Vectorial Capacity** : Only certain species act as vectors; moreover, within the known vector species, some are more efficient while some are less. The exact reasons for this are

not known. Certain new species are emerging as secondary vectors in different parts of the country. The Vectorial capacity (C) can be expressed as a mathematical expression to measure vector efficiency and assess risk and impact of interventions as follows :

$$C = \frac{ma^2p^n}{(-\log_e p)}$$

where :

m = density of vectors in relation to man

a = number of blood meals taken on man per vector per day

p = proportion of vectors surviving per day

n = incubation period in the vector (days) - 8 days

when they survive (1/-log<sub>e</sub> p) days.

Theoretically, incidence of infection rises when C > 1, incidence falls when C < 1.

(c) **Density** : For effective transmission of malaria in a locality, the mosquito vector must attain and maintain a certain density. This is called *critical density* and it varies from one mosquito to another and also under different environmental conditions. *A. culicifacies* needs a very high density for transmission of malaria, while *philippinensis*, *dirus* and *fluviatilis* need much lower critical density.

(d) **Longevity** : A mosquito, after an infective blood meal, must live for at least 10 days to complete the development of malaria parasites. Therefore aim in malaria control programme is to reduce the life span of mosquitoes to less than 10 days.

(e) **Tropism** : Some mosquitoes like *A. fluviatilis* prefer human blood and are called anthropophilic. Others like *A. culicifacies* preferably feed on animal blood and are called zoophilic. This preferential feeding habit is called tropism.

Table - 2 : Malaria Vectors of India and Vectors of local importance

S No.	Name of Species	Role in transmission
1	<i>A. stephensi</i>	Primary urban vector in most of India except North-East and Rajasthan
2	<i>A. culicifacies</i>	Primary rural vector all over India except North-East
3	<i>A. fluviatilis</i>	Primary rural vector in foothill areas of the country
4	<i>A. minimus</i>	Primary vector in North Eastern regions, West Bengal
5	<i>A. philippinensis</i>	Primary vector in rice field ecosystem of North Eastern regions
6	<i>A. dirus</i>	Primary vector in regions of evergreen forests in the North East
7	<i>A. sundaicus</i>	Primary vector in Andaman & Nicobar Islands
8	<i>A. varuna</i>	Eastern ghats (Andhra Pradesh), Singbhum hills (Bihar) & Kerala
9	<i>A. annularis</i>	Secondary vector in rice field ecosystem in Uttar Pradesh and coastal areas of Orissa
<b>Vectors of local importance</b>		
1	<i>A. aconitus</i>	Orissa, Assam
2	<i>A. jeyporiensis</i> (var <i>candidiensis</i> )	In certain localities in Kerala, Karnataka and Assam
3	<i>A. maculatus</i>	In certain localities in Assam & Meghalaya
4	<i>A. tessellatus</i>	Lakshadweep Islands (on epidemiological grounds)
5	<i>A. subpictus</i>	In Madhya Pradesh

(f) **Biting Behaviour** : Some vector mosquitoes bite at or soon after dusk, others either during late night or early hours of the morning. However, some species may be active at two different periods during the same night.

(g) **Resting Habits** : A female mosquito after a blood meal rests either indoors (endophilic) or outdoors (exophilic) for maturation of its eggs. The common resting places are either human dwellings, cattle sheds or mixed dwellings.

(h) **Flight Range** : The range of flight and dispersion varies from one vector to another. Some have a short flight range e.g. flight range for *A. dirus*, *A. annularis* and *A. fluviatilis* is upto 1 km distance; whereas *A. culicifacies* and *A. stephensi* fly up to 2 km and *A. sudaicus* may fly even up to 8 or 10 km.

(j) **Resistance to Insecticides** : When a vector mosquito in a locality becomes resistant to a particular insecticide, use of an alternative insecticide is recommended.

### Vectors of Filariasis

(a) **Culex quinquefasciatus** : This species is the main vector of bancroftian filariasis in India. It preferentially breeds in dirty water collections such as in drains, cesspools, soakwells and septic tanks. When denied such opportunities, it can also breed in clean water.

(b) **Mansonioides** : *Mansonioides* species are the vectors of *B. malayi* infection in India. In Kerala, *M. annulifera* and *M. uniformis* are the major vector species. These mosquitoes are associated with aquatic plants like *Pistia stratiotes*, *Eichhornia speciosa* and *Salvinia auriculata*.

(c) **Aedes niveus** : This species has been incriminated as a vector of diurnally subperiodic form of Bancroftian filariasis in Nicobar group of islands.

(d) **Other Species** : In India, Anopheline mosquitoes have not been found to play any significant role in the transmission of any type of filarial infection unlike in some other parts of the world.

### Mosquito Surveillance

In places which are endemic for mosquito borne diseases or outbreak prone, it is deemed mandatory that mosquito surveillance system be established. The aim of the surveillance should be to inform about changes in density and major characteristics of vectors, to forecast an impending outbreak and to recommend appropriate strategies for mosquito control which would prevent outbreak.

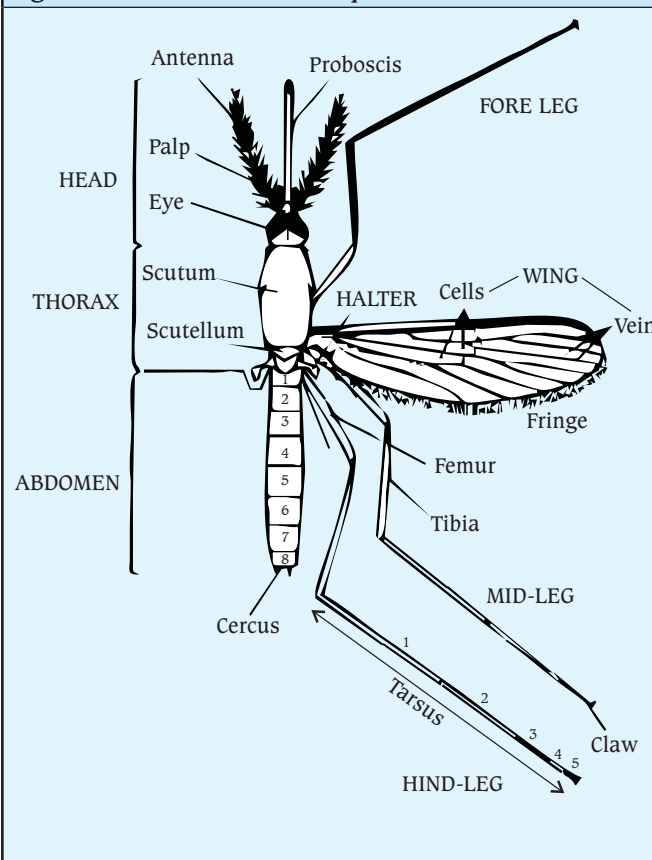
#### Steps for Establishing Mosquito Surveillance System

**Step 1** : Acquaint yourself with basics of mosquito identification both larval and adult mosquitoes up to genera level (*Culex*, *Anopheles* and *Aedes*) and mosquito bionomics.

#### Adult

**Identification of mosquito** : Mosquitoes are identified from other such flies by the presence of forward projecting mouthparts or proboscis, wing veins (veins 2, 4 and 5 are branched) and a fringe of scales along the posterior margin of wings (Fig. - 5).

**Fig. - 5 : Identification of mosquito**



**Identification of Male & Female Mosquito** : The mosquito sexes can be identified by their antennae. It's bushy in males and not so bushy in females (Fig. - 6).

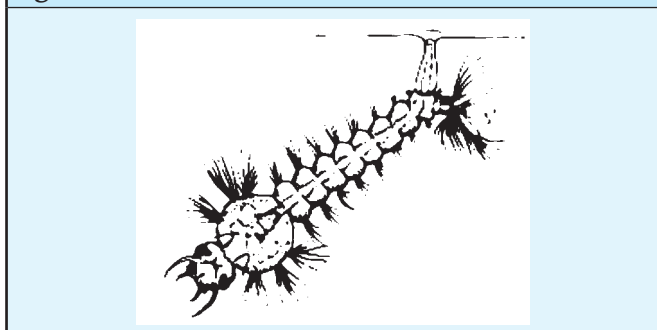
**Fig. - 6 : Identification of Male & Female Mosquito**



**Identification of Anopheles, Culex and Aedes** : If the wings are spotted, it is anopheline vector species; whereas, if the legs are having silvery stripes against dark black legs it is *Aedes* and if there are no spots on the wings or stripes or legs, it is *Culex* adult. The length and shape of terminal area of palpi can also be used for discriminating, as explained in Table - 1 earlier.

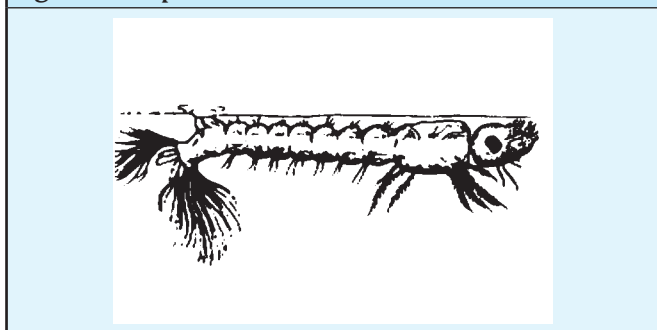
**Larvae** : If the larvae have siphon tube at its tail end, it belongs to Culicine group and could be *Culex* or *Aedes*. For this reason, the larvae of Culicines are suspended upwards down, at an angle with the water surface. If the siphon tube is long and narrow, it is *Culex* species, whereas short and broad siphon tube indicates it is *Aedes*. It is also important to remember that *Aedes* is essentially a container breeder and will be found only in artificial or natural containers. The Culicine larvae float at an angle to the water surface as shown in Fig. - 7.

**Fig. - 7 : Culicine Larva**



*Anopheles* in contrast does not have siphon tube and floats parallel to the water surface of water as shown in Fig. - 8.

**Fig. - 8 : Anopheline Larva**



**Step 2 - Sector Allocation and Mapping** : Once armed with the basic information, start by dividing the entire area of your responsibility into four or five sectors and make a map of the sector. Each sector should be covered every fortnight or at least once a month for surveillance.

**Step 3 - Conduct a Preliminary Survey** : First a baseline survey (larval and adult) is conducted to determine the prevalence, abundance and distribution of the vector species.

**Step 4 - Data Compilation and Preparation of Spot Map** : The data collected in preliminary survey is compiled and analyzed to determine the above mentioned variables and a spot map is prepared with clearly marked out areas where density is high, medium or low or where potential of breeding exists.

**Step 5 - Establish Monitoring / Catching Stations** : In each of the four or five sectors, establish four fixed stations (minimum two if manpower is less), with preferably two from the high density and two from the medium density spots and an equal number of random stations (2 each from the high density and the medium density areas). Poor or worst ventilated houses

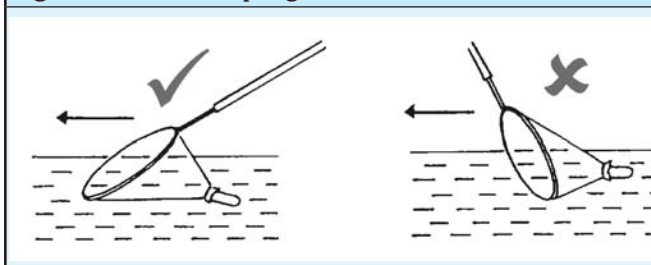
located close to the breeding places, discarded bathrooms, abandoned buildings are considered ideal; for room selection, the room which has fewer openings is selected.

**Step 6 - Conduct Fortnightly Surveys** : Conduct surveys in the fixed and random stations and record your data in the format given in Appendix 'A' and 'B' at the end of this chapter.

**Larval Sampling Procedure** : The mosquito larval sampling should be done by standard larval ladles. The method is as follows :

**Dip the ladle sideways** : A minimum of five dips may be taken for calculation of larval density (Fig. - 9).

**Fig. - 9 : Larval Sampling**



**Transfer the larvae in enamel bowl** : count the total number of larvae in the bowl after five dips.

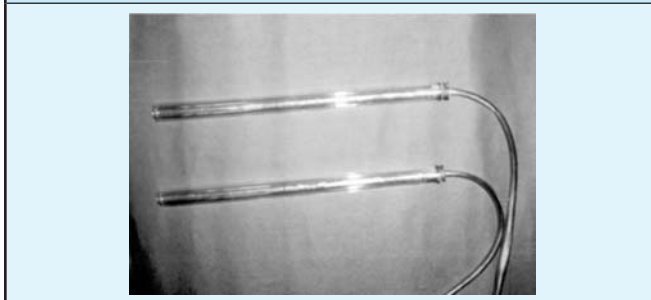
**Calculate larval density** : For example :

- Total no. of dips taken-5
  - Total number of larvae counted -50
  - Larval density (Total no. of larvae/ no. of dips)-50/5 = 10
- Other larval sampling procedures like larval nets (when the water body has vegetation) or well nets (when mosquito breeding is noticed in wells) may be used in specific situations. The density is calculated in the same way and given as larvae/ larval net or well net.

#### Adult Sampling Procedure

**Aspirators / Suction tube** : This is the most common method of sampling adult mosquitoes (Fig. - 10). It is normally undertaken in the mornings. Before using suction tube ensure that muslin cloth or gauge piece is placed between the glass tube and the rubber tubing to prevent mosquitoes being sucked inside your mouth.

**Fig. - 10 : Aspirator / Suction Tube**



- With the aid of a torch look for resting mosquitoes on the walls, ceilings (when it's low), behind and under furniture/ wall hangings etc.



- For practical purposes, while undertaking mosquito surveillance, one insect collector should spend at least 15 minutes in each of the 4 fixed and each of the 4 random stations. Thus, 2 insect catchers should be deputed; one for the 4 random stations and one for the fixed stations (15 minutes at each station) on the day surveillance is being conducted in that sector.
- While using suction tube, keep the end of rubber tubing in your mouth and place the opening of the glass tube 1-2 cm from the resting mosquito. Move the end closer to the mosquito by applying gentle suction to draw the mosquito inside the tube, now place your finger over the tube to keep the mosquito from flying away.
- Do not collect more than five mosquitoes in one tube. After collection, transfer the mosquitoes in transport cages by gentle blowing.
- Density of mosquitoes is calculated by the following formula :

$$\text{Density (Per Man Hour)} = \frac{\text{Total No. of mosquitoes collected}}{\text{Man Hour spent in collection}}$$

If 2 persons have collected 18 mosquitoes and each man has spent 1 hr each (15 minutes per station), the density is calculated by the following method :

2 Persons X 1 hr = 2 Man Hour

Total mosquitoes collected in 2 Man Hour = 18

∴ Mosquitoes collected Per Man Hour (PMH) = 18/2 = 9

Density = 9 PMH

**Total Catch or spray sheet collection** : Involves the use of Pyrethrum for collection of mosquitoes resting indoors (Box - 2). This is a more efficient method of sampling as it can also collect those mosquitoes which are hiding under furniture or resting on high ceilings or where the density of mosquitoes resting is low.

**Other types of mosquito sampling devices** : The other sampling tools are the window traps, magoon traps, direct bait collection and light traps.

### Surveillance of *Aedes* mosquitoes

**(i) Larval survey** : Three indices are commonly used to record *Ae aegypti* and *Ae albopictus* density levels :

**House Index (HI)** : Percentage of houses or premises positive for *Aedes* larvae.

$$HI = \frac{\text{No. of houses positive for Aedes larvae}}{\text{No. of houses inspected}} \times 100$$

**Container Index (CI)** : Percentage of water-holding containers positive for *Aedes* larvae.

$$CI = \frac{\text{No. of positive containers}}{\text{No. of containers inspected}} \times 100$$

**Breteau Index (BI)** : Number of positive containers per 100 houses in a specific location.

$$BI = \frac{\text{No. of positive containers}}{\text{No. of houses inspected}} \times 100$$

(An HI >5% &/or a BI >20 for any locality is an indication that the locality is dengue sensitive and therefore adequate preventive measures should be taken).

**(ii) Oviposition Traps** : "Ovitrap" provide a sensitive and economical method for detecting the presence of *Ae aegypti* and *Ae albopictus* in situations where *Aedes* density is low and general larval surveys produce unsatisfactory results (e.g. when the Breteau Index is < 5). The standard ovitrap is a wide-mouthed glass jar of approximately 250 ml which is painted black on the outside to attract the *Aedes* females to oviposit. A piece of hardboard/ wooden paddle or filter paper is placed diagonally inside the glass as an oviposition substrate. In addition, the jar is partially filled with clean water and placed in a shaded and protected place (rain, people/ animal) for oviposition.

**(iii) Adult Survey** : Human bare-leg catches (landing / biting catches) of *Aedes* adults (both male & female) or indoor resting collections of adults are normally used to assess adult *Aedes* populations. The data collected are calculated to reflect the number of female *Aedes* mosquitoes landing/biting on single human bait per hour (e.g. number per man hour). The collectors should move from house to house and not collect in one place for more than 15 or 20 minutes. In a similar manner, indoor resting collections can be made and the data expressed as numbers collected per man-hour or per house. Adult indices can also be elicited just like the larval indices i.e. 'Adult House Index', 'Adult Room Index' and 'Adult Breteau Index'.

#### Box - 2 : Total Catch or Spray sheet collection

- Remove all animals, small items of furniture, food items. Close all windows and doors and close / cover all openings with cloth.
- Spread white cotton bed sheets to cover the entire surface area (no. of sheets will depend on the size of the room). Ensure that sheets have been placed under furniture also. Sheets placed on furniture should not touch the floor as it will prevent the insecticide from reaching underneath.
- Prepare the Pyrethrum solution from 2% Pyrethrum extract available to a workable strength of 0.2% by mixing 100 ml of Pyrethrum with 900 ml of Kerosene to make a total volume of 1 litre of prepared soln. of 0.2%.
- Use a hand sprayer (Flit gun) for spraying. After entering the room first close the door of the room and then start spraying in open spaces and holes in the wall and thereafter proceed to apply spray towards the ceiling until the room is filled with fine mist; always taking care to move in a clockwise direction. After spraying, close the door and keep the room closed for at least 10 min.
- After 10 min, open the door, move gradually from the doorway picking up the mosquitoes by forceps in a container. A torch may be needed for collection of mosquitoes in rooms.

## Mosquito Control

Anti-adult measures and anti-larval measures are the two most important mosquito control measures. Personal protection against their bites aids these measures in control of disease. Methods related to environmental management by way of minor manipulations or major engineering steps should always be an important consideration in overall anti-malaria plan. The details of these various mosquito control methods have already been presented in detail in an earlier chapter on principles of vector control and the readers are suggested to go through the details.

### Anti-adult Measures

**(a) Residual Insecticides** : Indoor residual spray is considered to be the most important tool for controlling mosquito borne diseases. This is a more practicable and simpler method of interruption of transmission of disease. However, there are certain conditions under which the absolute efficacy of this procedure may be doubted, for instance, where vector is exophilic though biting indoors or where the surfaces sprayed are subject to frequent mud plastering or white washing. Even when local conditions do not appear to be absolutely favourable, the application of residual insecticide gives relative success in disease control. DDT, Malathion and the members of synthetic pyrethroids like Cyfluthrin, Deltamethrin etc. are the residual insecticides of choice depending upon the susceptibility of the vectors. The dosages and formulations of common adulticides used in mosquito control are given in Appendix 'C'.

**(b) Space Sprays** : Space treatments are usually designed to provide rapid knock-down and mortality with little or no residual effect. Such treatments must be considered in conjunction with other control methods as part of an integrated vector management programme. The details of space spraying and other adult measures are given in the Chapter on "Principles of Vector Control".

### Anti-larval Measures

Larval control is the only effective method of radical mosquito control. In urban areas, this method complements the adult mosquito control. Anti-larval work is carried out by preventing breeding and destruction of larvae and pupae. For long term and permanent mosquito control, greater emphasis should be placed on the prevention of breeding during non-transmission season than on larvicidal measures during breeding season.

**(a) Vector Engineering** : Avoidance of man-made mosquitogenic conditions is of primary importance. The details are presented in the Chapter on "Principles of Vector Control".

**(b) Dry Day** : Intermittent drying once a week is an effective method of prevention of breeding especially for container breeders like *Aedes* by observance of a weekly 'dry day'. All fire fighting tanks, ornamental ponds or water storage tanks, fire buckets, and all domestic water containers should be emptied, scrubbed and allowed to remain dry for a few hours on the weekly 'dry day'.

**(c) Larvicidal Measures** : Destruction of larvae is achieved by application of larvicidal oils, Organophosphorus insecticides, use of IGR's, biocides and use of larvivorous fish. The details are presented in the Chapter on "Principles of Vector Control".

The list of anti-larval chemicals along with their dosages is presented in Appendix 'D'.

### Personal Protection

Individual personal protection against mosquito bites is achieved by use of mosquito nets, repellents and protective clothing. The details are presented in the Chapter on "Principles of Vector Control".

### Summary

The mosquitoes are rated as the most important vectors amongst the blood sucking arthropods. They belong to phylum Arthropoda, class Insecta, order Diptera & family Culicidae. Amongst the mosquito genera, only *Anopheles*, *Culex*, *Aedes* and *Mansonia* are of importance in India. The mosquitoes are further classified as Anophelines which comprises only genus *Anopheles* & Culicine comprising three important genera viz. *Culex*, *Aedes* & *Mansonia*.

The length of the mosquito is about 1 cm and the body is divided into head, thorax & abdomen. Head has two compound eyes, antennae & mouth parts collectively called proboscis. Males can be identified by their densely haired antennae which look like moustache. Thorax in all the three genera of Culicines is humped. Mosquito undergoes complete metamorphosis through stages of egg larva, pupa & adult. Numbers of eggs laid vary between 50 & 150. Larvae pass through 4 instars in 5 days and become a pupa. Duration of lifecycle varies between 7 days to 1 month. Female mosquitoes are blood suckers (anthropophilic - prefer to feed on humans & zoophilic- prefer to feed on animals). Mosquitoes as per their biting habits may either be exophagus or endophagus and depending on their resting preference may be endophilic or exophilic. Males feed on plant juices & flower nectar.

The genus *Anopheles* comprises 58 species in India, of which 9 are vector species with most of them being anthropophilic. *Culex* adults are dull in colour & have unspotted wings and prefer stagnant water. *Culex quinquefasciatus* is the main vector of bancroftian filariasis in India. Chief species of *Aedes* in India are *aegypti*, *albopictus* & *vittatus*. They are well adapted for breeding in small containers of water such as masonry tanks, earthenware pots, small and large tins, barrel drums, coconut shells, stored or discarded motor car tyres, junk and hardware, flower pots, fire buckets, depressions in tree trunks, axils of leaves & tree holes. *Aedes* mosquitoes are the vectors of urban and rural yellow fever (not found in India), dengue, dengue haemorrhagic fever and chikungunya. *Mansonia* species lay eggs in cluster anchored to the under surface of the leaves of aquatic plants.

Mosquito surveillance is done to elicit information on vector density and major characteristics of vectors, to forecast an impending outbreak and to recommend appropriate strategies for mosquito control which would prevent outbreak. It is thus important to identify mosquitoes from other such flies; they are identified by the presence of forward projecting mouthparts or proboscis and wing venation (veins 2, 4 and 5 are branched) besides other characteristics. If the wings are spotted, it is generally anopheline mosquitoes; whereas, if the legs are having silvery stripes against dark black legs, it is *Aedes*.

and if there are no spots on the wings or stripes on legs, it is *Culex* adult. If larvae have siphon tube at its abdominal end, it belongs to Culicine group. Larvae are sampled using standard larval laddles & larval density is calculated by dividing the total no. of larvae by the no. of dips. Adult sampling is generally done using aspirators & suction tube. The mosquito density is calculated by Total no. of mosquitoes collected divided by the man hours spent in collection. Other methods are spray sheet collection & use of window trap, magoon trap or direct bait collection. *Aedes* larval surveys include computing indices viz. Container, House & Breteau index. The adult sampling procedures are the landing catch and resting catch, whereas breeding can be detected by oviposition traps.

## Study Exercises

### MCQs & Exercises

- Wings in mosquito are attached to (a) Thorax (b) Abdomen (c) Both (d) None
- Branched veins in a mosquito wing are (a) 1,3,6 (b) 2,4,5 (c) 2,4 (d) 1,6.
- Eggs are laid in rafts in (a) *Aedes* (b) *Culex* (c) *Anopheles* (d) *Mansonia*.
- Boat shaped eggs with lateral floats and larva without siphon tubes are features of (a) *Anopheles* (b) *Aedes* (c) *Culex* (d) *Mansonia*.

### Fill in the Blanks :

- \_\_\_\_\_ is the main rural vector of Malaria.
- Respiratory apparatus in larvae of Culicine is \_\_\_\_\_

- Most important vector of *Wuchereria bancrofti* is \_\_\_\_\_
- Vector species can be distinguished by their thoracic pattern in \_\_\_\_\_

### True or false

- Mosquitoes can be found in altitudes as high as 4000mts.
- The palpi & proboscis in *Culex* female are equal.

**Answers :** (1) a; (2) b; (3) b; (4) a; (5) *Anopheles culicifacies*; (6) Siphon tube; (7) *Culex quinquefasciatus*; (8) *Aedes*; (9) True; (10) False.

## Further Suggested Reading

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### Appendix 'A' : Mosquito Larval Surveillance Register

Sector No.	Date	Anopheles			Culex			Aedes		
		No. of dips	Total larvae & pupae	Larvae/dip and Pupae/dip	No. of dips	Total larvae & pupae	Larvae/dip and Pupae/dip	Type of container	No. of container Positive for breeding	Remarks (**)

(\*\*) Remarks to include details of House index, Container and Breteau index for Aedes if situation warrants.

### Appendix 'B' : Adult Mosquito Surveillance Register

Date	Sector No.	Species	Fixed catching station			Random catching station			Total				Density Per Man Hour
			Time spent	No. collected		Time spent	No. collected		Time spent	No. collected			
				M	F		M	F		M	F	Total	
		<i>Anopheles</i>											
		<i>Culex</i>											
		<i>Aedes</i>											
		<i>Anopheles</i>											
		<i>Culex</i>											
		<i>Aedes</i>											

**Appendix 'C': Insecticides Used for Indoor Residual Spray with Dosage and Residual Efficacy**

Insecticide	Preparation of suspension in water	Dosage of a.i. / sq m	Residual effect in weeks	No. of spray rounds/ annum	Area to be sprayed by 10 lit of suspension	Remarks
DDT 50% WP	1 kg/ 10 lit	1 g	10 - 12	2	500 sq m	In North East only
Malathion 25% WP	2 kg/ 10 lit	2 g	6 - 8	3	250 sq m	In DDT resistant areas
Deltamethrin 2.5% WP	400 g/ 10 lit	20 mg	10 - 12	2	500 sq m	In Malathion resistant areas
Cyfluthrin 10% WP	125 g/ 10 lit	25 mg	10 - 12	2	500 sq m	In Malathion resistant areas

**Appendix 'D' : Insecticides Used for Mosquito Larval Control**

Insecticide	Dilution rate	Dosage /sq m	Area in linear metre to be sprayed by 10 lit of solution/ suspension	Frequency of application	Remarks
MLO	As it is	20 ml	500	Weekly	Applied along shore of water body
Temephos 50% EC	2.5 ml in 10 lit for water depth up to 50 cm. 5 ml in 10 lit for >50 cm depth	20 ml	500	Weekly	Applied in all water bodies
Fenthion 82.5% EC	5 ml in 10 lit for water depth up to 50 cm. 25 ml in 10 lit for >50 cm depth	20 ml	500	Weekly	Not used in potable water
Fenthion 2G	-				Not used in potable water
<i>Bacillus thuringiensis</i> H -14 (12 AS)	250 g in 10 lit	20 ml	500	Fortnightly	Not used in potable water
<i>Bacillus sphaericus</i>	500 g in 10 lit	20 ml	500	Once in three weeks	Not used in potable water

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## Fleas

*Rina Tilak*

Fleas are one of the few important vectors which have been historically linked with mankind the world over, since time immemorial. Plague, transmitted by rat flea, was one of the vector borne diseases which played an important role in redefining geographical boundaries for many centuries.

### Distribution

Fleas are distributed all over the world and belong to the order Siphonaptera comprising about twenty five hundred species

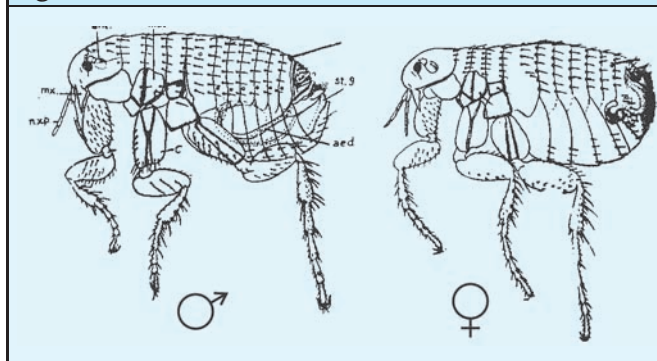
and sub-species. Fleas can be classified into two main groups viz. the 'combless' fleas and the 'combed' fleas, depending on whether they have chitinsed teeth like structure called 'genal comb' around the mouth, or not.

The Combless fleas contain the important genus *Xenopsylla* which has about sixty species and sub-species including the well known vectors of plague viz, *X cheopis*, *X astia* and *X braziliensis*. The oriental rat flea (Fig. - 1), *X cheopis*, is widely distributed in the tropics and is the principal vector of plague in India. *X astia* is also found in India, Burma, Sri Lanka, Hongkong and Iran. *X braziliensis* is found in Africa, especially in Nigeria, Congo, Kenya and in South America but in India its distribution is very restricted. The other important combless flea is *Pulex irritans* (Human flea), which occurs only in the



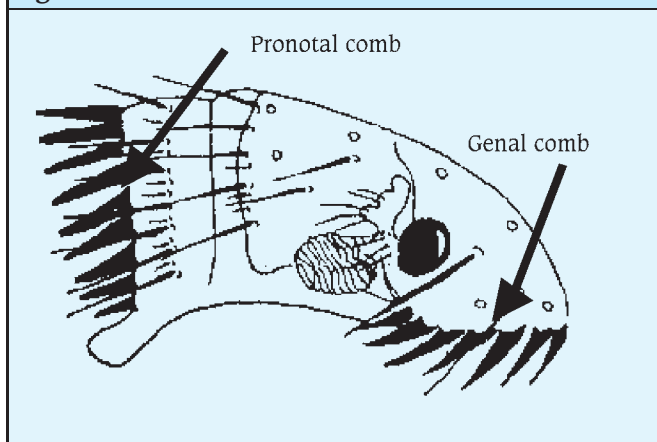
hills of the tropical countries of the Eastern Hemisphere. It breeds in and around dwellings and principally attacks man besides animals and rats.

**Fig. - 1 : Adult Rat Flea**



The Combed fleas are the cat fleas - *Ctenocephalides felis* (Fig. - 2), the dog flea - *C. canis* and the rat fleas of temperate zones, *Nosopsyllus fasciatus*. In addition to the genal comb, they also possess 'pronotal comb' on the thorax (Fig. - 2). These fleas serve as intermediate host of certain veterinary cestodes (dog-tapeworm) but are more of a biting nuisance to man. *Tunga penetrans*, a sandflea is found in tropical and sub-tropical regions of North and South Americas, Africa and occasionally in Western India.

**Fig. - 2 : Adult Cat Flea**



### Morphology

Adult fleas are small, bilaterally compressed, highly chitinated, wingless, 6 legged, blood sucking ectoparasites of many warm blooded vertebrates. The size varies from 1.5 to 6 mm in length and the colour from light amber to dark brown.

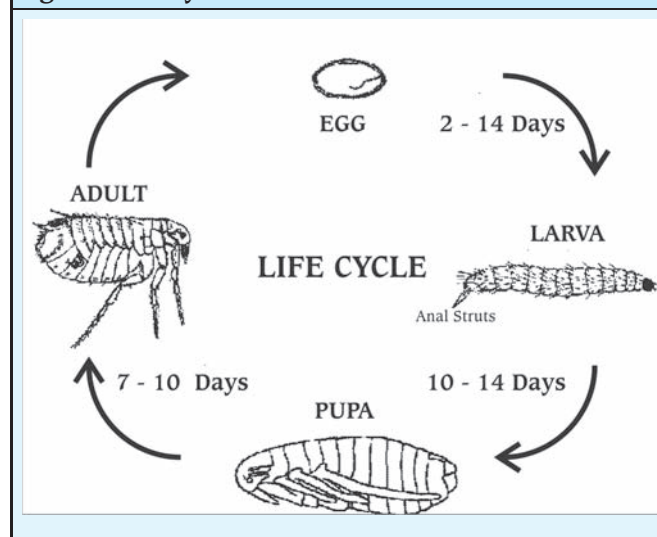
They have a compact appearance without a sharp division between the head, thorax and abdomen. The head is roughly triangular and bears a pair of three segmented antennae, the mouth parts and in certain flea species, a row of powerful teeth like spines collectively known as the 'genal comb', arranged on the lower border of the head, and a set of 'pronotal combs' on the thorax. However, the rat fleas are devoid of both these combs. The mouth parts are adapted for biting, piercing and

sucking blood, which forms the only food for both sexes. The thorax of the flea is compact without any wings. The legs are long and powerful and are adapted for the purpose of hopping and jumping. The abdomen consists of 10 segments, the 9<sup>th</sup> and 10<sup>th</sup> being modified for sexual functions. In the female, the abdomen has a rounded terminal outline whereas in the male it has a rather cocked up appearance. The body and the legs are provided with stiff setae, which give the insect a bristly appearance. The tapering pharynx continues into the oesophagus leading into the conical proventriculus. This is an important structure involved in the transmission of bubonic plague.

### Life History

The flea undergoes a complete metamorphosis through the successive stages of egg, larva, pupa and adult (Fig. - 3). When the female is ready to lay eggs, it leaves the body of the vertebrate host and lays eggs in dark place in the host's nest, debris, accumulation of dust, in cracks or crevices in the floor of granaries etc. or under carpets in houses. During her lifetime of 6 months or a year, the female lays 300 to 500 eggs in small batches of about a dozen at a time. A temperature between 18°C and 27°C and humidity about 70% favour egg laying. However, most fleas complete their life cycle in one to two months. The eggs are just visible to the naked eye and hatch in 2-10 days depending on temperature and humidity. The larvae are very active, slender, 13 segmented and yellowish white with a number of bristles. They feed on the excreta of rodents and on partially digested blood discharged from the faeces of adult fleas. Larvae complete their development in a week or two and enter quiescent stage, spin cocoons which are whitish, translucent and so loosely spun that the pupae can be seen within them. Hence the pupa closely resembles the adult which usually emerges within a week. It is important to note that presence of ground vibration (caused by movement of hosts i.e. rodents, animals, humans or earthquakes) is essential for the emergence of adult from the pupa. The whole metamorphosis takes two to four weeks, but may need several months under less favourable conditions.

**Fig. - 3 : Life Cycle of Flea**



## Bionomics

The adult fleas are temporarily parasitic on their host while their immature forms are free living. Both, males and females are haematophagous and frequently leave the host between blood feeds. After the death of the host, its body becomes cold and the flea seeks a new host. Fleas feed frequently and much more than their actual requirements, and as a result much of the ingested blood is passed out in a semi-digested state. Fleas are not strictly host specific and may attack unusual hosts when hungry or with rise of ambient temperature, when they feed more frequently. They are very sensitive to light and air currents. They always hide under dark objects and when blown up, they at once get agitated. Adult fleas can survive several months without food. They are able to jump up to 16 cm and hop 30 cm.

## Vector Potential

Flea transmits mainly the zoonoses to man, chiefly from rodents and also from dogs and cat. The most important microorganism that is conveyed to man from rat is *Yersinia pestis* causing bubonic plague. The most important vector species is *X cheopis*, however, *X astia* and *X braziliensis* are also effective vectors. *Rickettsia typhi*, causative organism of endemic (murine) typhus, is also transmitted from its rodent reservoir to man by the same rat fleas. Cat and dog tapeworms use fleas as their intermediate hosts for the development of cysticercoid stages. Cats and dogs become infested by the ingestion of infested fleas. Children also get infected similarly due to accidental ingestion of the infected fleas. The South American and African flea *Tunga penetrans* burrows under the soft skin in between toes and under the nail bed and causes a disease called 'chigger', 'jigger' or 'chigoe' in endemic areas.

## Modes of Transmission of Diseases

Bubonic plague is transmitted by infected fleas called 'Blocked flea'. When a flea (*Xenopsylla* species) feeds on a host suffering from plague, it ingests plague bacilli (*Y pestis*) along with the blood meal. The blood is digested in the stomach, however, the bacilli rapidly multiply and block the proventriculus thereby rendering the proventriculus partially blocked and incapable of preventing regurgitation of stomach contents (the normal role or functioning of the proventriculus) while feeding. Since the stomach is filled with plague bacilli, the amount of blood digested is minimal and hence this flea feels hungrier and bites repeatedly and in the process, regurgitates plague bacilli in the wound thus causing plague in the host. After a few days, the multiplying plague bacilli completely block the proventriculus thus rendering it totally ineffective in preventing regurgitation. Since no amount of blood gets digested, this flea though bites repeatedly and inoculates the bite wound with bacilli, lives

for a very short duration. A partially blocked flea is thus more efficient in transmitting plague as compared to a completely blocked flea.

Endemic typhus is transmitted through the faeces of the rat flea which contains the semi digested blood along with the causative organism *R typhi*. The flea has a habit of defaecating while feeding and hence while scratching the bitten area; the organism finds its way in to the host's body. The organism can also find an entry into the body through conjunctiva, inhalation and skin abrasions and also by accidental ingestion of infected flea.

## Flea Control

Chemical control of fleas is one of the best methods of flea control. These are effective against both adult as well as larval fleas. The areas or places generally frequented by fleas like rodent burrows and rat runs are treated. The insecticidal treatment is either done in the form of residual sprays, dusting or treatment of rodent burrows. Dusting is done by applying a patch of insecticide dust of about 20-25cm wide and 0.5cm thick in all infested areas. For rodent burrows, 30 g of insecticidal dust is used.

In plague susceptible areas, treatment is undertaken when flea index i.e. *X cheopis* index exceeds 1 (the other flea indices are presented in Box - 1). However, during an outbreak, no rodent control activity is undertaken. In the event of a plague case occurring, immediate treatment of the patients dwelling and of other dwellings within 200 m is undertaken.

**(a) Vector Control** : DDT has become non-effective against fleas in many parts of the world. Malathion resistance has also appeared in certain parts of India. Prior susceptibility tests should be carried out to find out the most effective insecticide. Indoor residual spraying at the lower one metre of the wall surface and adjacent floor area is effective. Patch dusting also brings about marked reduction in flea density. For this, dusts of Propoxur (1%), Malathion (5%) or Carbaryl (5%) may be applied at a dosage of 2 to 3 g per m<sup>2</sup> of surface area under grain bins, on rat runs, furniture, upholstery, rugs and bedding. The dust of Deltamethrin (0.05%) may also be used for dusting in rodent infested area.

**(b) Disinfestation** : Disinfestations of pet animals like dogs and cats along with good environmental sanitation of the household and public places (by keeping houses well swept and floors washed) help in flea control. Pet animals may be treated with dusts, sprays or dips of Malathion, Propoxur, Permethrin or Pyriproxyfen. Animal premises may be sprayed with insecticides (Malathion, Deltamethrin, Pyrethrum etc.) @ 4 - 8 l/100 m<sup>2</sup>. Insecticidal treatment of animals and their premises should be carried out simultaneously. Lufenuron

### Box - 1 : Flea Indices

- **General flea index** - Average number of fleas (all species included) per rodent. e.g. if, in all, 20 fleas were recovered from a total of 4 rodents examined, the index would be  $20/4 = 5$ .
- **Specific flea index** - (important is *X cheopis* index). This is same as general flea index but calculated exclusively for *X cheopis*. e.g. in above example, if a total of 2 of the 20 fleas were *X cheopis*, this index would be  $2 / 4 = 0.5$
- **Percentage incidence of flea species** - This is the percentage of each species of fleas, out of the total fleas sampled per rodent.
- **Rodent infestation rate** - If 10 rodents were caught and 6 were infested with fleas, this index would be  $6/10=60\%$

tablets are recent introduction in the armoury of flea control measures against cats and dogs; it is taken up by the female flea during feeding and acts by inhibiting egg development. A dose of 30 mg Lufenuron per Kg of body weight for cats & 10 mg/Kg of body weight for dogs is ideal for flea control. Details of insecticides used in flea control are shown in Table - 1.

Table - 1 : Flea control measures		
Insecticide	Concentration	Dilution
<b>a) For Fleas :</b>		
Propoxur 20%	1%	Mix 50 ml + 950 ml water
Malathion 50%	5%	Mix 100 ml + 900 ml water
Deltamethrin 2.5%	0.05%	Mix 20 ml + 980 ml water
<b>b) For Animal treatment:</b>		
Propoxur 1%	1% spray/dust	As it is
Malathion 50%	0.25% Dip	Mix 5ml in 1 l of water
Deltamethrin 0.0025%	0.0025% shampoo	As it is
Permethrin 1%	1% shampoo	As it is
<b>c) For Premises :</b>		
Pyrethrum 2% Extract	0.2%	Mix 100 ml + 900 ml water
Malathion 50%	2%	Mix 40 ml + 960 ml water
Chlorpyrifos 20%	0.5%	Mix 25 ml + 975 ml water

**(c) Rodent Control** : It is an indirect method of flea control. Though a radically effective method during non-epidemic period, it is dangerous during epidemics, because the fleas leave dead rats quickly and starts attacking human beings. However, a constantly sustained campaign keeps the rodent population down and aids significantly in keeping the flea index constantly low. In general, during control of urban plague, insecticides to kill rat fleas should be applied a few days earlier or at least at same time (and not after) when rat poison baits are being applied. The detail on rat poisons is presented in the chapter on rodents.

**(d) Personal Protection** : This is achieved by the use of protective clothing such as wearing long trousers, socks and shoes. Use of a high charpoy with the net, and application of repellents viz. DEET are necessary precautions while in endemic or epidemic areas of flea borne disease. Using flea collars for pets are effective means of keeping them free from infestation (for 3-4 months).

## Summary

Fleas are important vectors, linked with mankind since long. Fleas can be classified into two main groups, 'combless' fleas and the 'combed' fleas. The combs can be genal comb arranged on the lower border of the head or pronotal combs on the thorax. *Xenopsylla* species are combless fleas and include the well

known vectors of plague viz, *X cheopis* (Rat flea), *X astia* and *X braziliensis*. The combed fleas are the cat fleas - *Ctenocephalides felis*, the dog flea, *C canis* and the rat fleas of temperate zones, *Nosopsyllus fasciatus*. Adult fleas are small, bilaterally compressed, highly chitinised, wingless, 6 legged, blood sucking ectoparasites of many warm blooded vertebrates. The mouth parts are adapted for biting, piercing and sucking blood, which forms the only food for both sexes. The flea undergoes a complete metamorphosis through the successive stages of egg, larva, pupa and adult. Eggs are laid in dark place in the host's nest, debris, accumulation of dust, in cracks or crevices in the floor of granaries etc. or under carpets in dwelling houses. A temperature of 18° and 27°C and humidity about 70% favour egg laying. The adult fleas are temporarily parasitic on their host while their immature forms are free living. Both males and females are haematophagous.

Flea transmits mainly the zoonoses to man, chiefly from rodents and also from dogs and cat. The most important microorganism that is conveyed to man from rat is *Yersinia pestis* causing bubonic plague. *Rickettsia typhi*, causative organism of endemic typhus, is also transmitted from its rodent reservoir to man by the same rat fleas. Bubonic plague is transmitted by infected fleas called 'Blocked flea'; Endemic typhus is transmitted through the faeces of the rat flea.

Chemical control of fleas is one of the best methods of flea control effective against both adults & larvae. The insecticidal treatment is either done in the form of residual sprays, dusting or treatment of rodent burrows. In Plague susceptible areas, control is undertaken when flea index i.e. *X cheopis* index (the average number of fleas per rodent) exceeds 1. However, during an outbreak, no rodent control activity is undertaken. Flea control can be achieved by Indoor Residual Spraying using Propoxur (1%), Malathion (5%) or Carbaryl (5%). Disinfestation of pet animals like dogs and cats and use of flea collar, along with good environmental sanitation of the household and public places helps in flea control. Use of a high charpoy, insecticide treated nets and application of repellents viz. DEET are necessary precautions while in endemic or epidemic areas of flea borne disease.

## Study Exercises

**Short Notes** : (1) Blocked Flea (2) Flea Index.

### MCQs

- Combed flea is (a) *Xenopsylla cheopis* (b) *Xenopsylla astia* (c) *Pulex irritans* (d) *Ctenocephalides felis*.
- Flea transmits all except (a) Bubonic Plague (b) Endemic typhus (c) Epidemic typhus (d) Chiggerosis.
- The insecticides that can be used for flea control are (a) Propoxur (b) Malathion (c) Deltamethrin (d) All.

### Fill in the Blanks

- The Rat flea lives for a duration of \_\_\_\_\_
- Average no. of fleas per rodent gives the \_\_\_\_\_

### True or false

- Presence of ground vibration (caused by movement of hosts i.e. rodents, animals, humans or earthquakes) is essential for the emergence of adult from the pupa.
- A partially blocked flea is more efficient in transmitting plague as compared to a completely blocked flea.



**Answers :** (1) d; (2) c; (3) d (4) 06 months to 01 year; (5) Flea Index; (6) True; (7) True.

### Further Suggested Reading

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## Human Lice

Rina Tilak

Human lice are true ecto-parasites of man. There are three species of human lice viz. *Pediculus capitis* (head louse), *Pediculus humanus* (body louse) and *Phthirus pubis* (crab or pubic louse). Adults (both female & male) as well as nymphs are haematophagous, however, only body louse has been incriminated as vector.

The head louse infests the hair on the head and may be found in the neck region and behind the ears. The body louse infests the hairs of chest and axilla, seams of clothing in contact with the body and sometimes linen. The crab louse infests the hair of the pubic region and occasionally invades eyelashes and eyebrows.

### Morphology

Lice are small (4.5mm), dorso-ventrally flattened, wingless insects with simple metamorphosis. They are permanent obligatory ecto-parasites living entirely on mammals. The mouthparts are of a sucking and piercing type. They have no eyes. The legs are short, stout, and thick with claws for grasping hairs and fibres. The abdomen is oval or somewhat circular in shape. In the females, the last abdominal segment

is bilobed while in the male, it is pointed from which the aedeagus (penis) projects. *Phthirus* resembles *Pediculus* in its general morphology, but its body is almost circular, all the three pairs of legs of *Pediculus* are equal whereas in *Phthirus*, the first pair is less developed. *P. capitis* has a smaller and deeply pigmented body, while that of *P. humanus* is larger and non-pigmented. Abdominal segments of *P. humanus* are rounded with shallower inter segmental indentations while those of *P. capitis* are clearly marked and deeper. Antennae and legs of *P. humanus* are longer and thinner than those of *P. capitis* (Fig. - 1 & 2).

### Life History

The life histories of all the three varieties are similar (Fig. - 3). After fertilization, the female lays eggs either on the hairs or under clothing chiefly along the seams of the vests, pants and shirts etc. Freshly laid eggs are white and proportionally large for the size of the insect. They are firmly cemented to the hair or seams of the clothing, singly or in groups. As the embryos develop they become yellowish. The number of eggs laid depends upon the food supply and the temperature. Under optimum favourable conditions, the louse lays 4 to 9 eggs in each batch. Total number of eggs laid during the life span of 4 to 5 weeks may be 300 in a body louse, 150 in a head louse and 50 in a crab louse. Within a weeks time, the immature stages called nymph emerge and begin sucking blood at once and throughout their development feed frequently during the

Fig. - 1 : Head Louse

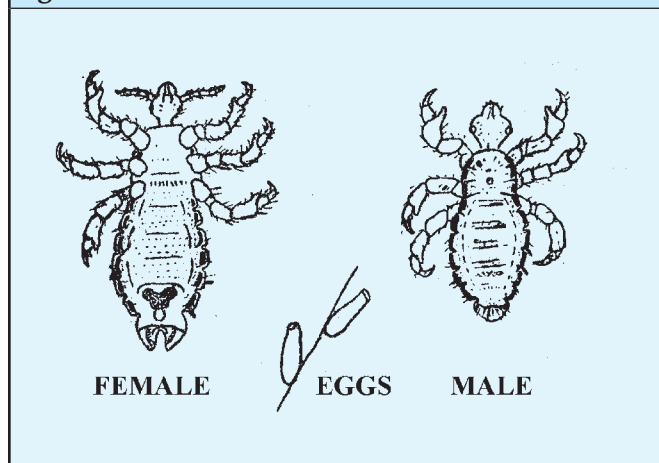
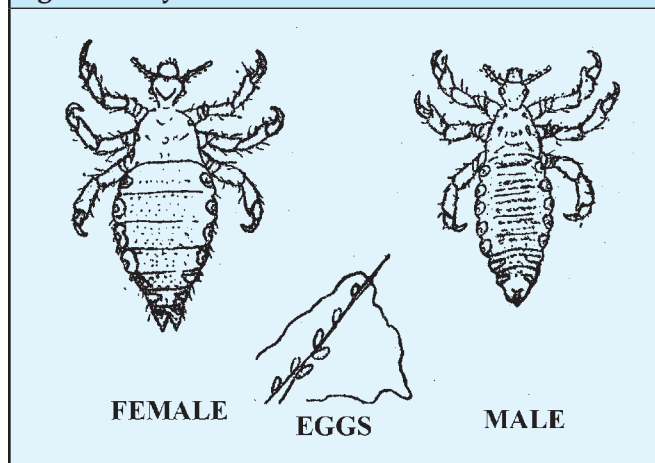


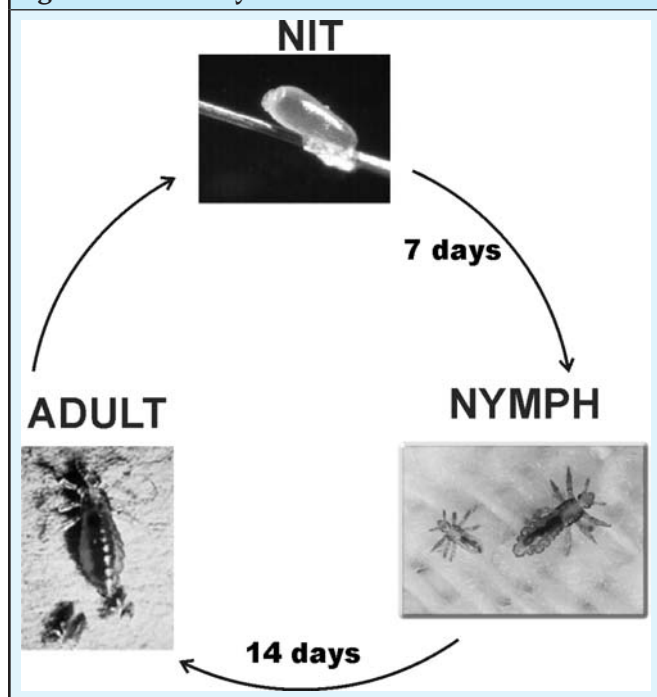
Fig. - 2 : Body Louse





day and night, mostly when the host is quiet. There are three nymphal stages and the young ones resemble the adults except in size. It takes about 21 days between hatching of the eggs and appearance of the adults.

**Fig. - 3 : Life history of Lice**



### Bionomics

Lice prefer warm and moist environments; 38°C is the optimum temperature. Higher temperature and death of the host are detrimental and make lice leave the body of the host. The average life of a louse is 30 to 50 days. Females live longer than the males.

Once lice are acquired by a human host, their multiplication depends on the neglect of personal hygiene. Following factors are responsible for the dissemination of lice.

- Close contact with lousy persons; sharing the same bed and clothing etc. In fact any prolonged crowding of human beings in unsanitary surroundings will spread lousiness. Hence lice and louse borne diseases are closely associated with wars and disasters among prisoners and refugees.
- Indirect contact - for example exchange of beddings, clothing, blankets, towels, hats, combs and brushes.
- Hair bearing eggs from lousy persons scattered in public conveyance are picked up from the seats and cushions of railway carriages and buses etc.
- Head lice easily pass from one child to another in school by close contact while playing and also by sharing of combs.
- The pubic or crab lice spread through sexual contact and sometimes from toilet seats, beds and by close personal contact. Small children may become infested with crab lice on their eyebrows and eyelashes from their mothers or other close contact.

### Vector Potential

Body lice are responsible for the transmission of *Rickettsia prowazekii*, causing Epidemic typhus, *Bartonella quintana* causing Trench fever, and *Borrelia recurrentis* causing Relapsing fever. The presence of lice on any part of the body is termed 'pediculosis' which causes irritation with loss of sleep and scratching which may lead to secondary infections. Toxic reactions to the saliva injected into the skin may lead to weariness and a general feeling of illness. The skin of a heavily louse infested person becomes hardened and deeply pigmented and results in a condition known as 'Vagabonds' disease or melanoderma.

### Prevention and Control

Regular washing of hair with soap and warm water and combing with lice comb may prevent/reduce head lice infestation. Similarly, regular washing of clothes with hot water (more than 60°C) and ironing and changing of clothes prevents body louse infestations.

In the past, use of anti louse powder (10% DDT) was used for reduction of infestation in a controlled community by dusting the lousy individuals and garments. Currently, the insecticides of choice are Permethrin dust (0.5%), Propoxur dust (1.0%); for mass treatments against body louse, dusts should be applied through neck openings, up sleeves and from all sides of the loosened waist of trousers. Socks, head coverings, the inner surfaces of extra garments and bedding should also be treated. Treatment of clothing with synthetic pyrethroid or use of pretreated uniforms may prove an effective means of prevention of body lice infestation amongst Armed Forces personnel during war.

Shampoo formulations like Phenothrin (0.2-0.4%), Permethrin (1%) and Malathion (5%) lotion are ideally used for head lice infestation. For application on hair, the hair of the infested persons should be wetted thoroughly before application. The insecticidal shampoo is thoroughly massaged on the head and left for minimum 10 min. Thereafter, the shampoo is rinsed off from the hair, hair is towel dried and combed with lice comb to remove dead/ stunned lice.

### Summary

Human lice are true ecto-parasites of man. There are three species of human lice viz. *Pediculus capitis* (head lice), *Pediculus humanus* (body louse) and *Phthirus pubis* (crab or pubic). They are obligatory ecto-parasites living entirely on mammals. After fertilization, the female lays eggs either on the hairs or under clothing chiefly along the seams of the vests, pants and shirts etc. The number of eggs laid depends upon the food supply and the temperature (38°C). It takes about 18 days between hatching of the eggs and appearance of the adults. Dissemination of lice occurs with close contact, in unsanitary surroundings, exchange of beddings, hats, comb & brushes. Transmission occurs through public conveyance, in school & through sexual contact.

Body lice are responsible for the transmission of *Rickettsia prowazekii*, causing Epidemic typhus, *Bartonella quintana* causing Trench fever, and *Borrelia recurrentis* causing Relapsing fever. Insecticides of choice are Permethrin dust (0.5%), Propoxur

dust (1.0%) and insecticide treated uniforms for body louse and shampoo formulations like Phenothrin (0.2-0.4%), Permethrin (1%) and Malathion (5%) for head lice infestation.

## Study Exercises

### MCQs & Exercises

- 1) Lice cause all of the following except (a) Epidemic Typhus (b) Trench fever (c) Relapsing fever (d) Endemic Typhus
- 2) Body louse infests (a) Hair on chest & axilla (b) Seams of clothing (c) Linen (d) All

### Fill in the Blanks :

- 3) Presence of lice on any part of the body is called as \_\_\_\_\_
- 4) Dust application through neck openings, up sleeves & trousers is used for \_\_\_\_\_ against \_\_\_\_\_ louse.

**Answers :** (1) d; (2) d; (3) Pediculosis; (4) Mass treatment, body.

## Further Suggested Reading

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## Sand Flies

Rina Tilak

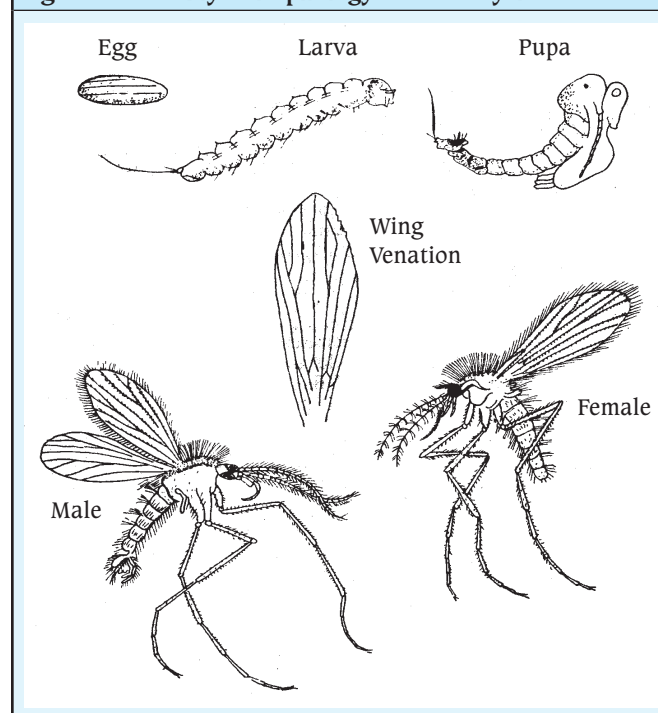
Sand-flies bite humans and transmit diseases to them. There are about 700 species of sand-flies of which only 70 species have been incriminated as vectors so far. The sand-flies belong to the subfamily Phlebotominae of the family Psychodidae. The haematophagous species belong to the three genera of *Phlebotomus*, *Lutzomyia* and *Sergentomyia*, the former two being more important as vectors of diseases. The medically important Phlebotomus vector species in India include *P argentipes*, *P papatasi*, *P sergenti* and *P braziliensis*.

### Morphology

The adult sand-fly is a small, greyish yellow to brown insect and about 1.5 to 4.0 mm in size. The insect is typically characterized by large conspicuous eyes and stilt like legs. The entire body is densely covered with hair. The antennae are long filamentous and give a beaded appearance. The mouth parts are very short and are adapted for biting and piercing in the females. The thorax is markedly humped and bears a pair of lanceolate wings which are held erect over the body when the fly is at rest. The wings are densely hairy and the second vein branches twice, the first branching in the centre of the wing and second at the margin. Legs are long, slender and used for hopping as sand-flies are poor fliers. The abdomen consists of 10 segments; the last two are modified for sexual functions. The abdomen of a female is rounded posteriorly; in the males, it is modified and bears claspers (Fig. - 1).

### Life History

Fig. - 1 : Sand Fly - Morphology and Life Cycle



The sand-flies prefer to breed in dark places rich in organic matter and moisture. Sand-flies lay torpedo shaped eggs in small batches which hatch out in one or two weeks under optimum

favourable conditions. The larvae are legless and whitish with a dark head capsule and pass through four instars. The larvae feed on organic excrement of lizards and mammals and other decaying material. Its life span is from 2 to 6 weeks, depending on the temperature and humidity. The larva bears two anal spines. The pupa is golden brown in colour and naked and requires about 10 days for development after which the adult emerges. Male sand flies emerge about 24 h before females, for their external genitalia to rotate 180° for achieving the correct position for mating before the females have emerged. The total period required from egg to the adult stage is about 4 weeks under favourable conditions. In the tropics, the breeding goes on throughout the year. In north India, they appear about the middle of March and persist until November, with their maximum density in March and April.

### Bionomics

The sandflies live entirely on plant juices or similar fluids from other available sources but the females need a blood meal in order to develop eggs. Phlebotomines are crepuscular or nocturnal biters and most of the biting occurs outdoors with only a few species feeding indoors. The adults are weak fliers and generally confine themselves up to 50 yd from their breeding place and are not found resting beyond 3 ft on the wall. After fertilization and a blood meal, the female lays eggs in shady, damp and warm places with sufficient supply of organic matter such as insect remnants and faeces and excrements of tiny animals which form the future larval food. Such conditions are found under stones, in stables and poultry houses, around soakage pits, grease traps and water sinks, in hollowed trees and rodent burrows, bases of walls and embankments. Large population of sandflies can build up in dwellings where cattle are kept at night; the cattle provide an abundant source of blood, while the stables and houses provide suitable resting place.

### Vector Potential

Sand-flies are responsible for the transmission of various species of *Leishmania* causing Kala-azar or Visceral leishmaniasis, Oriental sore or Cutaneous leishmaniasis, and Espundia or Mucocutaneous leishmaniasis (naso-oral). Sand-flies also transmit the virus of sand-fly fever, also known as papatasi or Phlebotomus fever or 3 day fever and the re-emerging viral disease - Chandipura disease. It also transmits *Bartonella bacilliformis* or Oraya fever also known as Bartonellosis or Carrion's disease. In addition, the sand-flies have biting nuisance causing skin reactions (Herara) in sensitized persons.

### Phlebotomus Control

**(a) Prevention of Breeding :** This is primarily achieved by good environmental tidiness. Places providing humidity, darkness and organic matter should be dealt with by removing all collections of rubble and heaps of rubbish; obliterating all cracks and fissures in the floors of the buildings and indoor constructions, sides of culverts, gutters, *nullahs*, cattle sheds and poultry houses which are common breeding places for sand-flies. Cracks and holes in the walls up to a metre from the ground should be sealed by plastering and the earthen floor of cattle sheds should be rammed down and made hard to make

it difficult for the larvae to burrow. Empty buildings should be kept in good repairs; soak pits and grease traps should be well maintained.

**(b) Anti-larval Measures :** Anti larval measures are generally difficult to undertake as identification of larval breeding sites is difficult. Even if insecticidal control is planned, it has been found to be of little importance in the control of sand-flies.

**(c) Anti-adult Measures :** Anti adult measures are based on the principle that sand-flies make short flights with relatively long pauses on entering or leaving any place or shelter. Therefore, any surface treated with residual insecticide on which the flies rest will have a lethal impact. The anti adult measures are the same as followed under the National Programme for Indoor residual spraying against mosquitoes; this strategy has proved to have a dramatic impact on the density of sand-flies in the area. If outdoor resting sites have been identified, they can also be sprayed with residual insecticides. Outdoor fogging may provide additional benefit in reduction of Sand-fly density.

**(d) Personal Protection :** Use of repellents viz. DEET is one of the most efficient methods of preventing bites from sand-flies; the repellents may be applied topically or sprayed on clothes. A sand-fly net is useful, but it reduces air movements and causes great discomfort. Use of insecticide treated mosquito nets has been found very effective in protecting against bites of sand-flies. Personal protection may also be achieved by barrier clothing.

**(e) Other Measures:** These include encouragement of gardening (cultivation of ground) and planning of embankments with native aromatic plants. Free cross ventilation and ingress of sunlight keeps the sand-fly out of habitations or animal sheds. Electric fans are useful as the air current drives them away. Electric light shades smeared with Vaseline, traps a large number of sand-flies. Siting of human habitation beyond 50 yards of the breeding place is an effective method of preventing transmission of sand-fly borne diseases as also sleeping on cots.

**(f) Treatment of Animals:** Earlier practice of culling of dogs or killing of rodents is no more undertaken. Dogs are treated by dipping in insecticide solution (Deltamethrin 50 ppm) or applying insecticide solution (1-2 ml of 65% Permethrin or Imidacloprid 10%). Even insecticide treated dog collars and treatment of non-reservoir animals reduces transmission of Leishmaniasis.

## Summary

Sand-flies belong to the subfamily Phlebotominae, bite humans and transmit diseases to them. The medically important vector species in India include *P argentipes*, *P papatasi*, *P sergenti* and *P braziliensis*. The adult sand-fly is a small, greyish yellow to brown insect about 1.5 to 4.0 mm in size; body is densely covered with hair. Sandflies possess a pair of lanceolate wings. The wings are densely hairy and the second vein branches twice. Sand-flies prefer to breed in dark places rich in organic matter and moisture. Females have piercing mouth parts and are blood suckers. The males live entirely on plant juices or similar fluids from other available sources. After fertilization

and a blood meal, the female lays eggs in shady, damp and warm places with sufficient supply of organic matter such as insect remnants and faeces.

Prevention of breeding is achieved by good environmental tidiness. All collections of rubbish should be removed from places providing humidity, darkness and organic matter. Cracks and holes should be sealed. Earthen floor of cattle sheds should be rammed down and made hard to make it difficult for the larvae to burrow. The anti adult measures are the same as followed under the National Programme for Indoor residual spraying against mosquitoes. Use of repellents like DEET is one of the most efficient methods of preventing bites from sandflies. Other methods like treated nets or barrier clothing may be used. Free cross ventilation and ingress of sunlight keeps the sandflies out of habitations or animal sheds.

## Study Exercises

### MCQs & Exercises

- 1) The vein which branches twice in a sandfly wing is (a) 4 (b) 5 (c) 6 (d) 2
- 2) Sandfly eggs can be laid in (a) Stables (b) Hollow trees (c) Rodent burrows (d) All of these
- 3) Sandfly does not transmit (a) Kala-azar (b) Oriental sore (c) Chikungunya (d) Sandfly fever
- 4) Which of these preventive measures is difficult to undertake (a) Prevention of breeding (b) Antilarval measures (c) Anti adult measures (d) Personal protection

### Fill in the Blanks

- 5) The sand-flies belong to the subfamily \_\_\_\_\_
- 6) The males of sandfly live entirely on \_\_\_\_\_

**Answers :** (1) d; (2) d; (3) c; (4) b; (5) Phlebotominae (6) Plant juices.

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## Some Annoying Pests

Rina Tilak

### Simulium Flies

Simulium flies are commonly known as Black flies. They have a world wide distribution. They belong to the family Simuliidae, which contains over 1800 species; however, the important genera are only four which bite humans and out of these four genera, Simulium is the most important. The members of this family are found from sea level to a height of 2000 m. In India, these have been reported from Kumaon Hills, Himachal Pradesh, Kashmir, Assam, Arunachal Pradesh, Manipur, Nagaland, Bengal, Bihar, Maharashtra, Tamil Nadu and Nilgiri Hills. In Arunachal Pradesh, they are known as Dimdam flies.

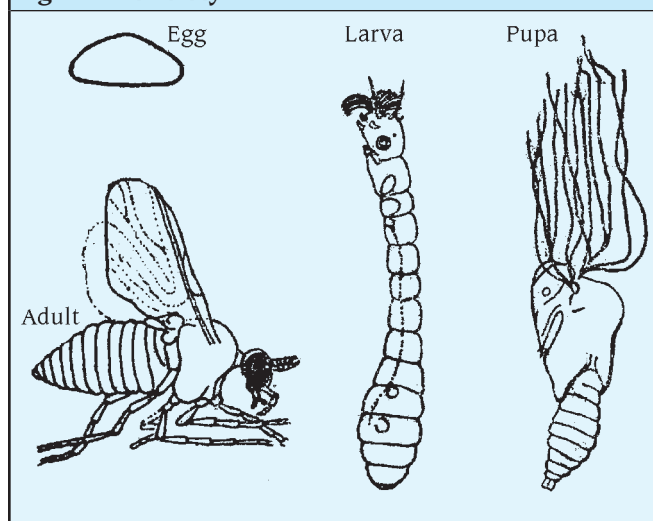
#### Life History

The adults are small; stout bodied with a humped thorax and blood sucking flies varying in length from 1 to 5 mm. The colour varies from dark amber to bright yellow to orange. The name "black fly" is therefore, a misnomer.

Simulium flies breed in fast flowing turbulent mountain streams and torrents because they require well aerated water. A female lives for 2 to 3 months and lays several batches of eggs under the rocks, stones, vegetation or debris submerged just below the water surface (Fig. - 1). Eggs hatch in one to two days; in temperate zones the hatching period may be one week. The larvae are attached to submerged objects with their heads downstream. They feed on microscopic animals and plants and do not swim. The larva undergoes six moults in about 10 to 14 days in the tropics and 3 to 4 weeks in temperate regions.

The silken pupa is also firmly anchored to the substratum. The pupal stage may extend from 4 to 5 days to 2 to 3 weeks. The imago emerges from the submerged pupal case and comes on to the water surface where it rests for a while and after sometime starts flying. In the tropics and subtropics breeding is continuous throughout the year. The life span of the adult is about three months.

Fig. - 1 : Black Fly



#### Bionomics

Simulids are strong fliers. Their normal flight range is about 4 to 5 km. Flights up to 20 to 40 km with favourable wind are not unusual. Both male and female Simulids feed on plant juices, nectar and pollens of flowers; the females however,



require blood meal for development of eggs and are voracious and persistent biters. They may enter through any opening in the clothing such as sleeves or through the lower opening of trousers for biting. They bite only by day in the open and are especially active on bright sunny days and retire at night to the neighbouring vegetation where the females mature their eggs.

### Vector Potential

Several species of simuliids are known vectors of Onchocerciasis, a filarial disease due to *Onchocerca volvulus* occurring in tropical Africa, Central America and Venezuela, where *S. damnosum*, *S. mettalicum* and *S. neavei* are the vectors. In India, Simuliids however, are not vectors of any known human disease. But the very annoying and persistent attacks in large numbers make working in the open virtually impossible. The immediate trauma caused by its bite produces a red haemorrhagic spot leading to papule formation. In certain cases, it may lead to secondary infections and ulcers like 'ulcus tropicum.' In sensitized persons, allergic reactions like lymphangitis, lymphadenitis, rhinitis and fever may occur. Their bites are responsible for loss of livestock.

### Control Measures

Control of the biting flies has been achieved by use of larvicides and aerosol treatment. In the Onchocerciasis control programme in Africa, Temephos 200 g/l emulsion has been used as a larvicide with good results. BTI has also been used @ 0.54 - 0.72 l/m<sup>2</sup> with great success. Aerosols and fogs produced by fogging machines are useful in killing adult flies. Clearing of vegetation around the perimeter also reduces Dimdam fly nuisance. Other compounds like Permethrin and Etofenprox have also been evaluated and found effective. Use of protective clothing will prevent the flies from ascending up the sleeves and trousers or entering into the shirt front. Socks should be pulled over the bottom of trousers. Additional protection may be obtained by treating the clothing and the exposed parts of the body with any of the repellents such as Dibutyl phthalate (DBP), Diethyl toluamide (DEET) or Diethyl phenyl acetamide (DEPA).

## Bugs

Bugs (Order Hemiptera) have been associated with man since antiquity. They have a world wide distribution and consist of two important families viz. Cimicidae and Reduviidae. Family Cimicidae includes the 'bed bugs', *Cimex lectularius* of temperate regions and *C. rotundatus* or *C. hemipterus* of the tropics. Family Reduviidae includes the cone nose *Triatomine* bugs, also known as 'kissing' or Assassin bugs. In India, bedbugs have a great nuisance value.

### Morphology

Bed bugs are small, 5 to 6 mm long, dorso-ventrally flattened, wingless, dark brown insects with a mahogany tint (Fig. - 2). They have a very short and broad head attached to the thorax. The head bears antennae and a pair of well developed eyes. On either side of the thorax, the stink-glands are situated which give off the nasty, pungent or offensive odour associated with this group.

Fig. - 2 : Bed Bug - Adult



### Life History

A bed bug passes through egg stage and 4 nymphal stages. The fertilized females lay flask shaped, operculated eggs singly in hidden sites, such as cracks and crevices in the walls and floorings, spaces in the wood work of furniture, behind pictures, mattresses, pillows etc. A female lays 2 to 10 eggs a day with a total up to 200 to 300 in her life time of 6 to 8 months. The eggs usually take 5 to 10 days to hatch. The nymph starts feeding within an hour or two after emergence and continues to feed intermittently in all the further stages of development. There are four nymphal stages, each lasting 6 to 7 days; at the end of each, a skin is cast off. It takes 4 to 6 weeks for the development from egg stage to adult.

### Bionomics

Adults can subsist without food for months under favourable conditions. Bugs are disseminated through travelling bags, laundry, furniture, bedding, old charpoys, soiled clothing, infested household goods, public conveyance and public places. Bed bugs like lice have been companions of man for centuries. Hiding in cracks and crevices during the day, they become active during the night and come out of their hiding places to feed on hosts and engorge completely in 3-6 min. They may travel long distances for sucking blood. They are gregarious, occurring in great assemblages. All stages are parasitic and thrive on human blood.

### Medical Importance

Bedbugs have all along been suspected for the transmission of various diseases but so far have not been incriminated for any human disease. They are of public health importance primarily for their biting nuisance and demoralizing effect as their infestation may cause insomnia and pruritis / dermatitis.

## Prevention and Control

The first and foremost principle for the prevention of bedbug infestation is to maintain a very high standard of hygiene. All furnitures and belongings of new occupants should be thoroughly checked for the presence of bed bugs and immediate measures taken to prevent their multiplication by one of the appropriate insecticides. Residual insecticides applied directly into the hiding places control the bedbugs. Solution of Malathion @2% or Chlorpyrifos @0.5% may be used. Disinfestations of blankets, beddings, mattresses and mosquito nets may be carried out by subjecting them to heat at or above 70°C. Synthetic pyrethroids like Bifenthrin (0.096%), Permethrin (0.125%), Cyfluthrin (0.04%) and Deltamethrin (0.03%) can also be used to achieve optimum results. Residual insecticidal spraying for malaria control undertaken systematically and methodically will also help in reducing the density of bed bugs as a collateral benefit. Insecticide treated bed-nets will also help in reducing the menace of bed bugs.

**Debugging** : The bed (Bed stand) need not be inclined against the wall nor the coir netting loosened. The cots should be thoroughly treated on all sides with insecticidal spray. All cracks and crevices should be fully flooded. The chairs, tables and other items of furniture may be similarly treated. The insecticide formulation may also be directly applied to the hiding places such as joints, cracks and crevices in the cots/chairs/tables and folds or creases in the mattresses and other items of beddings.

Slow drip technique involving the use of the common two inches thick paint brush for treatment of the infested cots and other items of furniture is reportedly superior as compared to the routine method of spraying with compression sprayer. In this technique, the ready to use solution of insecticide in water is taken in a plastic mug of one litre capacity, a paint brush is dipped in the solution, and the solution so lifted is slowly drained into the cracks and crevices as well as the joint spaces from different directions. The process is repeated by turning the cot upside down so that all such hiding places are thoroughly flooded with insecticide.

## Cockroaches

One of the most annoying pests encountered in an urban area are the Cockroaches. The common domestic species which infest buildings are *Blatella germanica*, the German roach; *Periplaneta americana*, the American roach and *Blatta orientalis*, the Oriental roach (Fig. - 3). The German cockroach, although a native of Europe, is the most widely distributed species.

### Morphology

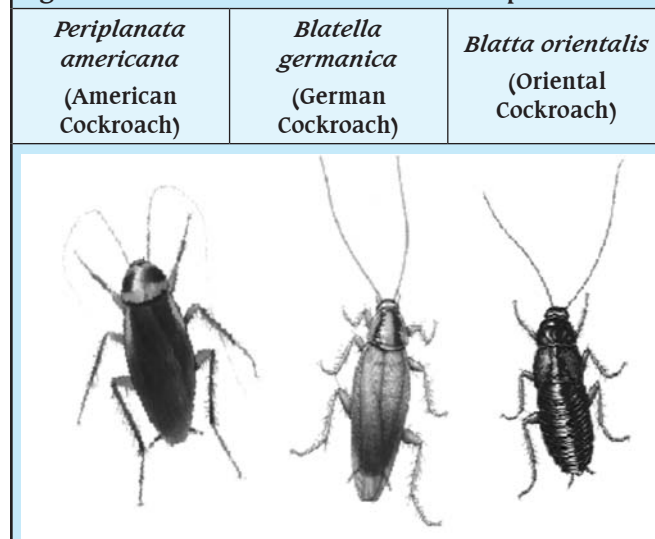
Cockroaches are dorso-ventrally flattened creatures with colour varying from dark brown to black. The head is flexed backward and the antennae are filiform. Most of the species have two pairs of wings. In some of them the wings are vestigial. In the oriental cockroach, the wings are short in the females but much developed in the males which possess the power of flight.

### Life History

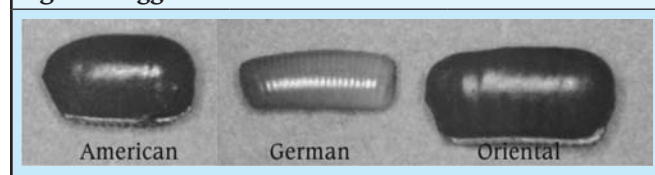
They have simple metamorphosis and lay 16 to 48 capsulated eggs depending on the cockroach species (Fig. - 4). The eggs

hatch out in 2-6 months in most of the species, depending on temperature and humidity. The young ones are almost white and wingless. They moult a number of times and the total developmental period may be 6 months to 1 year. They may produce three generations in a year and usually have a long life span.

**Fig. - 3 : Cockroaches - Common Domestic Species**



**Fig. - 4 : Egg cases of the domestic cockroaches**



## Bionomics

They breed in warm moist places in the humid microclimate of the kitchen and pantry, laying eggs in cracks, crevices and sinks. They can run swiftly by means of long well developed legs. They are highly gregarious and primarily nocturnal in habit, but may be seen during the day as well. The mouth parts are adapted for biting and chewing and they are omnivorous, feeding on any material meant for human consumption like meat, milk, grains and sugar.

### Disease Potential

They are filthy, annoying pests imparting a nauseating 'cockroach' odour to the food articles and utensils they come in contact with and the places they infest. They destroy food, damage fabrics, books and other household articles. They may enter houses and other buildings from outdoors through infested containers or from adjoining rooms and apartments or through drains. On account of their indiscriminate roaming and feeding habits, they mechanically spread diseases like cholera, typhoid, dysentery, protozoal cysts, intestinal worms etc. by polluting food with infective material carried on their legs and bodies.

## Control Measures

(a) **Prevention** : This includes :

- (i) Good house-keeping is the key to cockroach control, whether in the home, restaurant, hotel or grocery stores.
- (ii) All cracks and crevices should be properly filled up.
- (iii) All areas should be kept thoroughly clean so that no food particles, debris, dust and rubbish remain to support and nourish cockroaches.
- (iv) Keeping surveillance on the occurrence or increase in the density of cockroaches in a house by use of sticky traps or else by use of visual assessment method, whereby light is switched on late in night and the cockroaches counted for a stipulated time period, say five minutes. This method also indicates the hiding places in a room of the cockroaches besides indicating the level of infestation.

(b) **Control** : Cockroach infestation can be controlled with insecticidal sprays, dusts or baits. The insecticide should be applied thoroughly to runways, cracks, crevices, undersides of tables and even under the table spreads, rear of sinks, meat safes and other harbourage areas. Use of 2-5% dust or 1-3% solution or emulsion of Organophosphorous compounds like Malathion or Carbamate insecticide such as Propoxur gives excellent results. To obtain a quick effect in heavy infestations or to drive them out from the hiding places, a direct spray containing 0.3% Pyrethrum or 0.5 to 1.0% DDVP or Fenitrothion may be used. Small pills of flour containing boric powder left on dining table, food safes and pantry boards or under table cloth also kill cockroaches. Abamectin and Synthetic pyrethroids (Table - 1) are currently being used for control. Newer insecticides, Fipronil and Imidacloprid Gel have been found to be very effective in controlling cockroaches. Fipronil has been demonstrated to have "cascade effect" (secondary killing of cockroaches due to necrophagy amongst them, whereby they consume Fipronil killed cockroaches and get killed in turn). It is important to remember that chemical control gives only temporary results and maximum efforts should be made to improve the environmental sanitation and housing conditions. Moreover, there are reports that the German cockroach has become resistant to several Organo-chlorine, Organo-phosphate, Carbamate & Pyrethroid insecticides. The insecticides used for cockroach control are summarised in Table -1.

Table - 1 : Insecticides for Cockroach control		
Insecticide	Concentration	Use
Boric acid	100%	Baits/ sprinkle along corners
Imidacloprid Gel	1.85 - 2.15%	Cracks and crevices
Fipronil Gel	0.01 - 0.03%	Cracks and crevices Has a cascade effect
Fenitrothion	1 - 2%	Spray
Malathion	3%	Spray
Cyphenothrin	0.5%	Spray
Deltamethrin	0.03%	Spray

## Summary

Simulium flies have worldwide distribution & are commonly known as Blackflies; in Arunachal Pradesh, they are known as Dimdam flies. As they require well aerated water, they breed in fast flowing turbulent mountain streams. The life span of the adult is about three months. The colour varies from dark amber to bright yellow to orange. Male and female Simulids feed on plant juices; the females require blood meal for development of eggs. They can enter through any opening in the clothing and bite during the day. Simulids are vectors for Onchocerciasis in some parts of the world; however, they do not cause any disease in India. Control can be achieved by the use of larvicides like temephos & BTI. Use of aerosols & fog with clearing of vegetation is other means of achieving control, besides protective clothing & use of repellants.

Bugs have a world wide distribution and consist of two important families viz. Cimicidae (bed bugs) and Reduviidae (kissing bugs). Bed bugs are small, 5-6 mm long, dorso-ventrally flattened, wingless, dark brown insects. The nasty pungent odour which this group emanates is because of the presence of stink glands. Metamorphosis is incomplete with presence of egg stage & 4 nymphal stages. Females lay flask shaped, operculated eggs singly in hidden sites. It takes 4 to 6 weeks for the development from egg stage to adult. Bugs can stay without food for months & can travel long distances through traveling bags, laundry, furniture, bedding, old charpoys, soiled clothing etc. Bugs so far have not been incriminated for any human disease; though have been suspected for transmitting diseases. Infestation though can cause insomnia, pruritis, dermatitis etc. Prevention includes maintenance of hygiene, thorough check of furniture & belongings. Insecticides viz. Malathion @2% or Chlorpyrifos @0.5% etc. may be used. Disinfestations of blankets, beddings, mattresses and mosquito nets may be carried out. Debugging can be used for treatment of the cots (charpoy).

Cockroaches are one of the most annoying pests encountered in an urban area. The common domestic species are *Blattella germanica* (infest buildings), *Periplaneta americana* & *Blatta orientalis*. Cockroaches are dorso-ventrally flattened with colour varying from dark brown to black. They breed in warm moist places (humid microclimate of the kitchen), laying eggs in cracks, crevices and sinks. Feed on any material meant for human consumption, their mouth parts are adapted for biting & chewing. They destroy food, damage fabrics, books and other household articles. Cockroaches spread diseases like cholera, typhoid, dysentery, protozoal cysts, intestinal worms etc. by polluting food with infective material carried on their legs and bodies. Prevention comprises of good housekeeping, filling up of all cracks & crevices. Infestation can be controlled with insecticidal sprays (Malathion or Propoxur), dusts or baits. Spray containing 0.3% Pyrethrum or 0.5 to 1.0% DDVP brings about quick effect. Newer insecticides, Fipronil and Imidacloprid have been found to be very effective in controlling cockroaches.



## Study Exercises

### MCQs & Exercises

- 1) *Cimex lectularius* & *C rotundatus* consist of two important families of (a) Simulium flies (b) Bugs (c) Cockroaches (d) None.
- 2) Which of the following in relation to bugs is not correct (a) Head bears antennae (b) Pair of well developed eyes (c) 5 nymphal stages (d) Flask shaped operculated eggs.
- 3) Prevention & control of bed bugs can be achieved by all except (a) Malathion @2% (b) Chlorpyrifos @ 0.5% (c) Debugging of bed stands (d) Fipronil Gel.
- 4) Sticky traps and Visual assessment method are used for surveillance of (a) Bed bugs (b) Cockroaches (c) Simulium (d) All of these.

### Fill in the Blanks

- 5) Simulium flies are known vectors of \_\_\_\_\_
- 6) Nasty, pungent or offensive odour associated with bugs due to the presence of \_\_\_\_\_
- 7) \_\_\_\_\_ gel is an effective insecticide against cockroaches and has a cascade effect.

### True or False

- 8) Black flies are black in colour.
- 9) A female bed bug lays 2 to 10 eggs a day with a total up to 200 to 300 in her life time of 6 to 8 months.
- 10) The mouth parts in cockroaches are adapted for biting and chewing.

**Answers :** (1) b; (2) c; (3) d; (4) b; (5) Onchocerciasis; (6) Stink glands; (7) Fipronil; (8) False; (9) True; (10) True.

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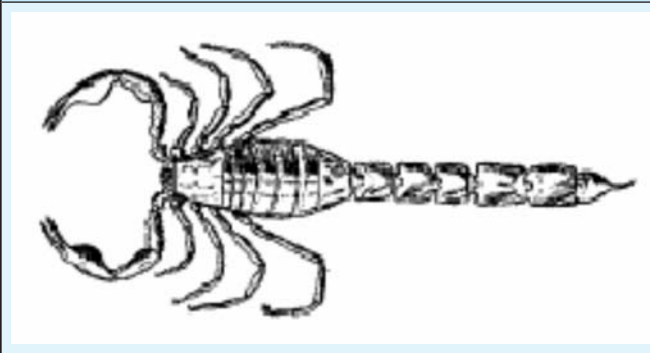
## Envenomizing Pests

Rina Tilak

### Scorpions

Scorpions are one of the commonly encountered venomous arthropods of the class Arachnida (Fig. - 1). At least 1000 species of scorpions have been described, but only 20 species are of medical importance. The last segment of their bodies is modified to form a flexible tail, with a vesicle holding poison gland and a sharp spine. They vary in size from about 2 to 20 cm and are cryptozoic and nocturnal, spending the day concealed under stones or fallen tree branches or in burrows and venturing out after sunset in search of food. The common Indian species belongs to the genera *Buthus* (*Mesobuthus*) and *Palamnoeus*; the former are more poisonous.

Fig. - 1 : Scorpion



Scorpion sting as a rule is not more dangerous than bee or wasp sting as the chemical nature of the poison is similar to

formic acid. It is, however, much more painful, and if sufficient poison has been injected, may cause distressing symptoms which may take twenty four hours to pass off. Stings of red scorpion (*Mesobuthus tamulus*) can be serious with massive release of catecholamines, producing raised BP, arrhythmias, cardiac failure and pulmonary oedema. Profuse sweating, dilated pupils and priapism can occur.

#### Box - 1 : Prevention of Scorpion Sting

Do not encroach their hiding places especially if ill equipped (i.e. barefoot or wearing loose / open sandals in areas with loose stones, fallen debris etc.)

Scorpions are active at nights. Always carry a torch while moving in infested areas at night.

Erect barrier up to 20 cm by means of tiles at the base of walls and steps to prevent scorpion encroachment.

Fill cracks and crevices to deny hiding places.

In infested areas, people should sleep with mosquito nets properly tucked. It is advisable to use treated bed nets.

Clear all junk and rubbish from around the house.

Shake the shoes / clothes well before putting them on.

Lastly use chemicals if problem still remains unresolved.

A Scorpion sting case needs immediate medical attention. A local anaesthetic (1% Lignocaine) at the site of sting or a strong oral pain killer is advised. For stings with less pain, ice therapy works well.

There is no commercially available antivenin for treatment of *Mesobuthus tamulus* stings in India. The effects are more marked in children, it is, however, very rare that a fatal dose of the venom is injected. If the sting is on the extremities, an immediate ligature may be helpful. Application of a strong



solution of ammonia relieves pain in a majority of cases; a series of injections of 1% Novocaine or Lignocaine and Adrenaline at the spot and along the nerve may be necessary in others. Barbiturates in large doses are useful in reducing restlessness. Patients developing priapism, dilated pupils, sweating and bradycardia may require early energetic treatment with vasodilators. Preventive measures include alertness in avoiding contact with scorpions in infested areas, putting on clothes and shoes after shaking them well and proper housekeeping. Propoxur 2% or Chlorpyrifos @ 0.2-0.5% may be used. Synthetic pyrethroids are generally not used as they irritate the scorpions and risk is increased further.

## Ants

Ants are common annoying insects. They have also been experimentally incriminated in the mechanical transmission of excremental infections. They should therefore be kept away from foodstuffs by placing the legs of food safes, tables etc. in anti-formicas viz. bowls or tins containing water or waste crude oil. Insecticidal sprays like Pyrethrum or Malathion are effective. Ordinarily, the ant-bite causes only a sharp stinging; the bites of some of the larger ants may be very painful involving faintness and shivering. Dilute ammonia or any other alkaline solution applied relieves the pain.

## Bees, Wasps and Hornets

In bees and wasps, venom is produced in glands at the posterior end of the abdomen and is expelled by contraction of muscles of the venom sac, which has a capacity of up to 0.1 ml. Uncomplicated stings cause immediate pain, a wheal-and-flare reaction and local edema and swelling that subside in a few hours. In sensitized individuals there may be alarming symptoms.

Honeybees often lose their stinging apparatus and the attached venom sac in the act of stinging and subsequently die, it should be removed gently by pulling it out, care being taken not to squeeze the venom in the wound. The site should be cleansed and disinfected and ice packs applied to slow the spread of venom. Elevation of the affected site and administration of analgesics, oral antihistamines and topical calamine lotion relieve symptoms. Local application of an alkaline solution of sodium bicarbonate or ammonia or soap and applying pressure with a moistened piece of lint are useful in relieving pain. Papain diluted roughly 1:5 with tap water is said to produce immediate relief of pain. Disturbing the honey-comb may bring the whole swarm on the person responsible or any one who happens to be in the vicinity. Their stings may cause serious allergic symptoms requiring adrenaline and/or morphine administration. Wasp's nests should not be destroyed in the daytime; they are generally destroyed at night when all wasps are inside. Insecticidal treatment includes use of 1% Dichlorvos, 0.015% Deltamethrin or 0.5% Chlorpyrifos.

## Centipedes

Centipedes (Myriapoda) possess a pair of legs to each apparent segment of the body; the first pair is modified to form poison claws. The bites of small centipedes gives rise to mild local inflammation but the larger centipede *Scolopendra gigantia* may cause a severe painful bite with marked local and general

reaction (usually swelling, erythema and lymphangitis; dizziness, nausea and anxiety are occasionally described and rhabdomyolysis and renal failure have also been reported).

Solution of ammonia is useful for local application and in bites of the larger centipedes morphia may be necessary to allay the pain. 2-4% Malathion as spot application is very useful.

## Leeches

Leeches (Hirudinea) are a class of annelid worms that attach to their hosts with chitinous cutting jaws and draw blood through muscular suckers. They are particularly troublesome near streams and rivers, in leafy forests and marshy jungles.

The two important species are:

- *Haemadipsa zeylanica*, which is a small land leech, about 2.5 cm long with great power of penetration into the interstices of clothing, putties or laced boots. They often drop from tree leaves onto man or animals passing by and suck blood.
- The other variety is *Limnatis nilotica* - the large aquatic leech which on being ingested, fastens itself to the mucus lining of the mouth, pharynx, larynx or nasal cavities of man or animal producing prolonged bleeding unless removed. Leech bites are painless but the bleeding may be prolonged (after the leech has detached) due to a powerful anti-coagulant, hirudin, present in its saliva.

Gum boots or jungle boots are very effective in protecting from leech bite. A frequent search of the body for the presence of leeches should be made. The leech should not be dragged or pulled off the skin because of the risk of breaking and leaving behind its suction apparatus which is liable to cause inflammation and suppuration. Salt, vinegar or a tobacco infusion application or a touch of the lighted end of a cigarette induces the leech to relinquish its hold; tincture of iodine should be applied to the bitten spot and a piece of adhesive plaster may be applied on it. Internally attached leeches may detach on exposure to gargled saline or may be removed by forceps. Repellents DEET & DEPA can be used to provide protection. The repellents can be applied on to the clothing as well as topically over the skin. At night a properly adjusted mosquito net, preferably insecticide treated bed net provides good protection. Aquatic leeches can be removed from drinking water by filtering through a sieve or a piece of muslin.

## Spiders

There are more than 30,000 recognized species of spiders, however, only about 100 can defend themselves aggressively and have fangs sufficiently long to penetrate human skin. The true spiders (Arachnida) have poison glands and inject venom into their prey. The common species of spiders as a rule do not bite man. If by chance it happens to bite, the bite amounts to no more than a pin prick. Envenomations of the brown or fiddle spiders (*Loxosceles* species) and widow spiders (*Latrodectus* species) may be life-threatening. Some spiders, especially those belonging to the genus *Latrodectus* produce severe effects in man. Important species are *L hasselti*, the 'red-backed' spider and *L mactans* the black widow and the allied species. The acute symptoms generally subside after a few days, but pain may persist for some time. In *Latrodectus* bites, the death rate

may amount to 6% or higher.

Identification of the offending spider should be attempted, both because specific treatments exist for bites of spiders. Initial management includes local cleansing, application of sterile dressings and cold compresses, and elevation and loose immobilization of the affected limb. Analgesics, antihistamines, antibiotics, and tetanus prophylaxis should be administered if indicated. Use of sedative is contraindicated. Intra venous administration of widely available equine antivenom rapidly relieves pain and can be life-saving. Because of the risk of anaphylaxis and serum sickness, antivenom should be reserved for severe cases involving respiratory arrest, uncontrollable hypertension, seizures, or pregnancy. Intravenous Calcium gluconate or Magnesium sulphate also gives dramatic relief to cramps. Spot (Infested area) treatment with 3% Malathion, 0.03% Deltamethrin, Chlorpyrifos @ 0.2-0.5% has been found to be effective against spiders.

### Summary

Scorpions are one of the commonly encountered venomous arthropods of the class Arachnida. The common Indian species belongs to the genera *Buthus* (*Mesobuthus*) and *Palamnoeus*. Scorpion sting (chemically similar to formic acid) is much more painful than bee or wasp sting, though not more dangerous. Hypertension, arrhythmia, cardiac failure and pulmonary oedema may be encountered following stings of *Mesobuthus tumulus* (Red scorpion). Prevention includes avoiding hiding place of scorpions especially when ill equipped, erecting barriers & filling up of cracks & crevices. There is no commercially available antivenin for treatment of *Mesobuthus tumulus*. Application of a strong solution of ammonia relieves pain in a majority of cases; in others, injections of 1% Novocaine or Lignocaine and Adrenaline bring relief. Preventive measures include alertness in avoiding contact. Propoxur 2% or Chlorpyrifos @ 0.2-0.5% may be used.

Ants are common annoying insects; need to be kept away from food stuffs. Ants have been involved in mechanical transmission of diseases & their bites may sometimes also be very painful. Dilute ammonia relieves pain. Other means of prevention are use of anti-formicas & Pyrethrum or Malathion spray.

Bee, Wasps & Hornet stings are often painful, the honey bee often leaves sting along with poison gland in the puncture, this should be promptly removed and pain relief may be obtained by applying alkaline solution of sodium bicarbonate or ammonia. Insecticides which can be used are Dichlorvos & Deltamethrin.

Centipedes possess a pair of legs on each segment of the body. Bites can cause mild reaction to severe pain. Ammonia and Morphine is used for treatment.

Leeches are a class of Annelid worms; the two important species are the land leech & the aquatic leech. Leech bites are painless but bleeding may be prolonged due to presence of anti-coagulant. Ideally, leech should not be dragged or pulled off the skin. Prevention is by wearing gum boots and searching the body for leeches. DEET & DEPA can be used to provide protection.

The true spiders (Arachnida) have poison glands. Important species are the red backed spider & black widow spider. Treatment of a bite is immediate washing and ligation. Aspirin or morphine is used for pain relief. Intravenous Calcium gluconate or Magnesium sulphate gives relief from cramps.

### Study Exercises

#### MCQs & Exercises

- 1) *Buthus* (*Mesobuthus*) and *Palamnoeus* are common Indian species of (a) spiders (b) scorpions (c) bugs (d) flies
- 2) Hypertension, arrhythmia, cardiac failure and pulmonary oedema may be encountered following stings of (a) Scorpion (b) Spider (c) Wasps (d) All of these
- 3) Scorpion sting can be treated by (a) Ammonia (b) Lignocaine (c) Barbiturates (d) All
- 4) This should not be used to treat stings of bees, wasps & hornets (a) Magnesium sulphate (b) Adrenaline (c) Morphine (d) Papain
- 5) *Scolopendra gigantia* is a species of (a) Spider (b) Scorpion (c) Centipede (d) None

#### Fill in the Blanks

- 6) Stings of red scorpion can be serious due to release of \_\_\_\_\_
- 7) Class of annelid worms which suck blood, cause painful bites \_\_\_\_\_

#### True or False

- 8) Erecting a barrier up to 20 cm by means of tiles at the base of walls to prevent scorpion encroachment.
- 9) Stings of Bees, Wasps & Hornets should not be removed.

**Answers :** (1) b; (2) a; (3) d; (4) a; (5) c; (6) Catecholamines; (7) Leeches; (8) True; (9) False.

### Further Suggested Reading

1. Anthony S. Fauci, Eugene Braunwald, Harrison's, Principles of Internal Medicine, Seventeenth Edition, 2008, Volume 2 ISBN 978-0-07-147693-5, the McGraw-Hill Companies, United States of America.

Rina Tilak

Ticks and mites belong to class Arachnida, which are characterized by the presence of two distinct body parts - cephalothorax and abdomen and four pairs of legs. Antennae are absent and eyes may or may not be present. Metamorphosis is incomplete and the adults resemble the nymphs except for the fact that nymphs lack genital aperture while in the adult the sexes are distinct. The larvae are morphologically distinct with three pairs of legs.

## Ticks

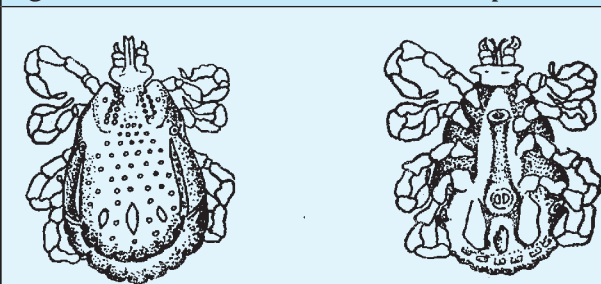
### Taxonomy & Morphology

Ticks belong to the super-family Ixodoidea. They are distinguished from other acarines by their relatively large size and absence of prominent hairs on the body. They are oval in shape and of varying colours and dorsoventrally compressed. Females are larger than males and are capable of great distention. Both sexes as well as the other stages i.e. nymphs and larvae thrive on blood alone and lead an intermittent parasitic life during a major part of their life cycle. They are free living on the ground in between various moults during development. There are two families, Family Ixodidae which is the hard tick and Family Argasidae which is the soft tick. The hard tick is more a jungle tick while the soft tick is a domestic or household tick like a bedbug.

### Ixodidae or Hard Ticks

The dorsum of the adult male is covered by a dark shield, like that of the tortoise, called the scutum. This may be ornate with grey or white 'patterns'. In females and immature males, it covers only the anterior part behind 'the capitulum' which is the false head, actually formed by the mouthparts anteriorly and therefore visible from above (Fig. - 1).

Fig. - 1 : Hard Tick - Dorsal and Ventral Aspect



### Argasidae or Soft Ticks

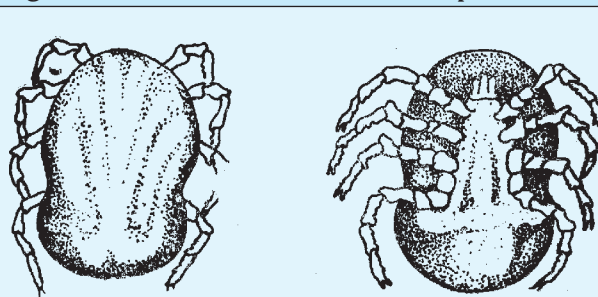
These are oval with leathery cuticle and devoid of scutum. Their mouth parts are placed ventrally and hence not visible from above and they possess no festoons (Fig. - 2).

### Life History

All species of ticks pass through four stages during their development viz. egg, larva, nymph and adult. The total period

required for full development of a tick is from six weeks to 2 years. Fully engorged fertilized female drops off to the ground and lays eggs in cracks and crevices in the soil under stones or among roots of shrubs and grass and such other sheltered spots. Hard ticks deposit all their eggs in a single act of oviposition after which they die. Eggs take a few weeks to several months to hatch. Larvae are six legged and do not feed for about a week after emergence. Thereafter, they become hungry and active and climb on vegetation for attachment to passing hosts (this is called questing). They feed for about three days and drop off when engorged and remain quiescent for digestion of blood. After the first moulting, the nymphs emerge with their fourth pair of legs and seek a new host in the same manner as the larvae, feed and again drop off. They again moult and become sexually mature. The adults are also parasitic and exhibit questing. Copulation takes place after the last moult and the male dies after fertilizing the female. The female engorges and then deposits eggs.

Fig. - 2 : Soft Tick Dorsal and Ventral Aspect



### Bionomics

Hard ticks are open jungle dwellers and thrive on animal hosts; hence they do not attach themselves to human beings voluntarily, except when a person comes across them accidentally. Argasidae (soft ticks), on the other hand, although preferentially parasitic on animals and birds attack man voluntarily. These are found in human dwellings and cattle sheds and attack man and animals during their sleep. They however, live away from their hosts, like bedbugs, in cracks and crevices and only emerge at night to feed on the host. Ticks can survive starvation for a long time.

### Vector Potential

Ticks produce diseases in man by transmitting the viruses, rickettsiae, spirochaetes and bacilli of infectious diseases and through toxin present in their saliva. Some of the factors which account for high vector potential are that all the stages are essentially haematophagous and are persistent blood suckers and while feeding they attach firmly and cannot be easily removed. They are resistant to varying environmental conditions and relatively protected from natural enemies. The trans-stadial and transovarian transmission of infection helps in maintaining infection for several years. Ticks have the power to regenerate lost parts such as amputated legs and also the ability to repair mutilated mouth parts, which conserves them for long.



### Soft Ticks

Soft ticks of the genus *Ornithodoros* transmit various types of spirochaetae causing relapsing fevers in certain parts of the world. *O. moubata* is the vector of *Borrelia duttoni* in Africa; *O. lahorensis* has a very wide distribution in Central Asia and North West India. In India, they are found in Kashmir and are known as *O. crossi*.

### Hard Ticks

These are much more ubiquitous and produce larger varieties of human diseases. The most important of all are the various rickettsial infections transmitted by the hard ticks of the genera *Ixodes*, *Dermacentor*, *Amblyomma*, *Haemaphysalis*, *Rhipicephalus*, *Hylomma* and *Boophilus*. Viruses causing Kyasanur Forest Disease, Colorado tick fever and other Haemorrhagic fevers and Encephalitides are transmitted. These also transmit *P. tularensis*, the causative organism of Tularaemia. Tick paralysis is an acute ascending flaccid paralysis due to an unknown toxin the tick's saliva introduces through the bite of certain species of ticks of the genera *Dermacentor*, *Ixodes* and *Amblyomma*. It affects mostly children and young domestic animals in Australia, South Africa, North America, Southern U.S.A. and N.W. Pacific. Even a single tick bite may cause fatal paralysis. In certain cases, reaction from improper or partial removal of ticks or due to the bite itself may cause itching, swelling and ulceration at the site of the bite. Otoacariasis is an invasion of the auditory canal by ticks.

### Mites

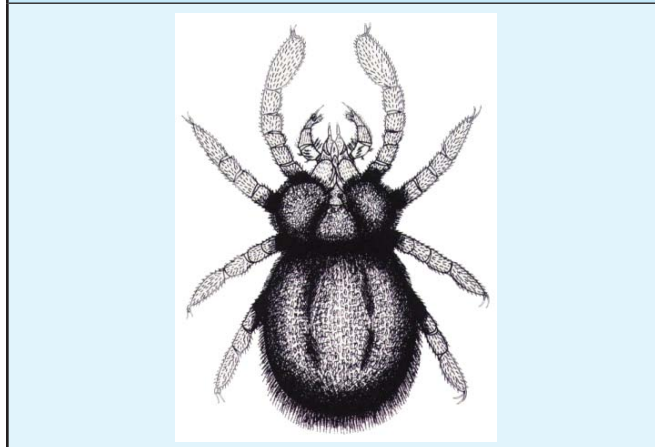
The vector mites belong to the order Acarina and family Trombiculidae which comprises many hundreds of species of world wide distribution. They are found in great abundance in areas with hot, humid climate, thick vegetation and presence of small vertebrates like rodents. The foothills in subtropical and temperate regions offer them ideal conditions. In the tropics, they are found even at heights in mountain valleys. These have also been found in the Alpine-subarctic terrain in the Himalayas as well as at the level of coniferous forest-glacial valleys in Pakistan. They are known by various names such as chiggers, harvest mites, kedany or scrub mite. Important species of the genus *Leptotrombidium* are *akamushi* which is distributed widely in Japan, South East China, Korea, Malaysia and Philippines and *L. deliense* which is vastly distributed in the tropical regions of South East Asia, Indian sub-continent, Sri Lanka and Maldive Islands. In India, it is present in the whole of the Shivalik range from Kashmir to Assam, the Eastern half of the plains adjoining the foothill ranges, the Eastern and Western ghats and the Vindhya range in Central India.

### Morphology

The adult is about 3-4mm in size, is densely covered with hair and has a figure of eight (Fig. - 3). The mouth parts consist of a pair of chelicerae and a pair of palps, together giving the mite an appearance of having a false head. The adult resembles the nymph except that it is larger and more densely covered with hairs; 'Kedany' meaning hair in Japanese language. The larva is pale yellow to orange-red in colour with a circular body bearing three pairs of legs and branched hairs on the body and on the legs. They are found in nature in the interior of ear

cusps or on rumps of rats, mice, shrews, bandicoots and other small mammals, reptiles and birds in orange coloured clusters of as many as 50 to 200 larvae. A cluster of 5 to 6 larvae is as big as a pin-head. When the cluster detaches, a scab is formed showing an evidence of recent infestation.

Fig. - 3 : Trombiculid Mite (Adult)



### Life History

The stages in the life history of a mite are egg, larva, nymph and adult. The eggs are laid singly on the surface of the soil. The larva leaves the egg-shell and becomes very active. Moving quickly over the surface of the soil and low lying vegetation, it seeks a suitable host such as rat, mouse, bandicoot and shrew and so on. While feeding, it buries the whole length of its chelicerae in the host's skin and injects an irritant secretion which causes tissue lysis. The larva feeds on the lymph and the tissue fluid but not on blood of the host. The orange red colour of the larva is therefore not due to ingested blood. The larvae feed for 2 to 3 days and then drop off to the ground concealing themselves in loose soil, and here they develop into nymphs and finally into adults. Generally, it takes 6 to 12 weeks for its development from egg to adult stage. Only the larval stages are parasitic; the nymphs and adults are never parasitic and feed on small insects in the soil or their eggs.

### Bionomics

The mites are distributed in areas ideal for their survival called as "Mite Islands". Mite Islands are patches of ground characterized by thick vegetation cover, mainly the scrub jungles or other tall grasses offering protection from direct sunrays and desiccation, nearly 100% relative humidity at ground level and ideal ambient temperature of  $27 \pm 5^\circ\text{C}$ . Such conditions also provide sanctuaries for small vertebrate life such as rats, mice, bandicoots, and shrews which are hosts for larval mites (shrews are considered as the index animal for scrub typhus). These animals are also the reservoirs of rickettsiae for which the trombiculid mites are vectors. Hence, these mite islands may also become typhus endemic foci. Mites are most active during the whole rainy season and their prevalence in such mite islands is related to the intensity and length of the monsoons. In dry season, the adults migrate deeper into the soil, the egg laying ceases and the mite islands shrink; during monsoon,



there is prolific activity and the mite islands expand. Patchy distribution of mite islands and their selective choice of locality explain the patchy nature of typhus endemic foci. The typical terrains favourable for the mites to thrive and propagate are as under :

- Man-made rural and urban wastelands like overgrown clearings produced by shifting cultivations.
- Domestic sub-urban waste lands produced around neglected patches in and around villages and even big towns, such as neglected gardens and plantations or overgrown clearings therein; deserted villages are heavily infested.
- Around the edges of moist depressions, water meadows, grassy but not swampy river banks and moist sites such as seepages along over ground canal areas.
- The hedgerow types of features ranging from a simple bushy hedgerow to belts of forests following water courses and ravines which are commonly left in deforested areas in and below the foothills.
- The scrub at the outskirts of the forests and low lying patches overgrown with elephant grass in sunny clearings inside thick forests.

### Vector Potential

Larval mites belonging to several genera attack man but only the Genus *Leptotrombidium* contains species of medical importance. In India, *Leptotrombidium deliense* is the vector of *Orientia tsutsugamushi* causing Scrub typhus; in Japan, the closely related variety *L. akamushi* (kedani mite) transmits Scrub typhus. Rickettsiae taken up by larvae while feeding on rodents are carried through its nymph, adult stages and then its eggs (trans-stadial transmission). The larvae hatching out of these infected eggs are capable of transmitting the rickettsiae to the next host. The infection is thus trans-ovarially transmitted for some generations and hence the mite also acts as a reservoir of infection. Larvae feed only once during their life time. Therefore, transmission of infection occurs in second or subsequent generations. When a larva lying on the ground comes in contact with a human being (instead of a rodent as would happen in the normal course), it attaches on to him and feeds on his lymph; in the process, the rickettsiae contained in the mouth parts are injected into the lymph of the human being thereby causing scrub typhus.

### Control of Ticks and Mites

#### A. Insecticidal Control

**a. Area Treatment :** This is the only reliable Acarine control method in camp sited areas or areas amenable for such treatments. Before the application of an insecticide to the areas infested with hard ticks and mites, clearing of bushes by cutting them is advantageous. If possible a bulldozer should be employed. When the top soil is bare and dry, an area becomes considerably safe and more suitable for insecticidal action. Initial coverage of the area should be thorough. It may require repetition after 8 weeks and occasionally a third time during the hot-humid season. If people have to go to some nearby stream for bathing or washing their clothes, the selected area should be similarly treated as the stream edges covered with vegetation are favourite sites for acarines. "Malathion 50% EC" (as 5% solution) should be sprayed in a dosage of 4 kilograms

of active ingredient (a.i.) per hectare of ground surface area, or else "Cyfluthrin EC" applied in dosage of 0.1 Kg (100 grams) of active ingredient per hectare. Malathion 5% may also be used (4 Kg of active ingredient of malathion will be present in 8 litres of 50% EC commercial supply; this 8 litres will be mixed with 72 litres of water to get 80 litres of 5% solution which should then be sprayed over one hectare of ground surface area).

**b. On Vegetation :** In areas where vegetation cannot be removed for various reasons, control of ticks on vegetation can be achieved by insecticide dusting or spraying from the ground or air at the dosage varying from 0.5 to 2 Kg/hectare. In woody and bushy areas, the dosage is increased proportionately. Malathion, Fenthion, Propoxur and Permethrin are suitable.

**c. Premises :** Against soft ticks, application of insecticide to floors and walls of infested premises on alternate days after initial scraping and scorching are necessary. Treatment for 2 weeks before occupation gives good control. During this period sweeping of floors should be discontinued. Such a series of applications repeated 6 weeks afterwards gives adequate protection to people staying in such habitations as camps during disasters or migratory labour camps, etc. The insecticides should also be applied to beds, mattresses, rugs and furniture. In known tick infested areas, particularly where there is a history of relapsing fever, infested houses/ areas should be avoided as far as possible. Organophosphorus compounds like Malathion and Fenitrothion or Carbamate compounds like Propoxur can be used either as 0.5 to 1.0% spray or as 5 to 10% dust.

**d. Domestic Animals :** Dogs and other domestic animals can be freed of ticks by a wash or spray containing 2% Malathion, 1% Propoxur, Deltamethrin (0.025%) etc. Only half these concentrations should be used if the animal is to be dipped and the entire animal should be immersed except the head. Dusts containing 5% Malathion, Propoxur (1%), Cyfluthrin (0.1%), Deltamethrin (0.05%), Temephos (2%), Fenthion (2%) etc. may also be used. The premises which animals visit or is tied in, should also be treated.

#### B. Personal Protection

- The repellent materials used for personal protection against ticks and mites are Dibutyl-phthalate (DBP), Diethyl phenyl acetamide (DEPA) and Diethyltoluamide (DEET). These are more effective when applied to the clothing than to the skin. The effect may last for nearly six washings or weeks which ever is earlier. However, if it is ironed, the concentration falls below effective limits. DEET/ DEPA may be used for application on the exposed parts of the body to reinforce the use of protective clothing treated with DEET/ DBP/DEPA when working in an uncontrolled area or under acute emergency when application of repellent on the clothing prior to entry in an unknown or uncontrolled area is absolutely impossible. The persistence of DEPA on clothes post ironing is superior to that of DEET, whereas both are equally effective when applied topically. Permethrin may also be used for treatment of clothing.
- Wearing shirts with rolled down sleeves tightly buttoned at the cuffs, the lower ends of trousers tucked in socks and wearing of proper boots considerably reduces the risk against ticks and mites.

- c. Clothes for drying should be hung on ropes especially fixed for the purpose and not on the vegetation. Bush and grass on the periphery of a camp becomes infested by larval mites and ticks brought in by the rats migrating into the camp. Therefore, purposeless wandering in such areas should be discouraged.
- d. More mites and ticks are picked up by standing or sitting than by walking over the infested ground. Therefore, while in such areas it is unsafe to lie down on a grassy ground. The immediate vicinity of a tree base should be avoided for resting, so also the green edges of a stream or an irrigation channel. Open grassy grounds should be avoided in tick infested areas.
- e. Before retiring at night or after leaving a tick infested area one should take a bath and carefully search one's body and clothing for presence of ticks. If a tick is found attached to the body it should be removed immediately, because every added moment of its attachment increases the danger of transmission of infection. Pulling of a tick has the danger of breaking off its parts, therefore, it should be removed by making the surrounding skin taut, slipping the point of a flat needle or a scalpel under the mouth parts and then removing the mouth parts by raising the point of the needle with a minimum of tissue damage. Iodine or any other antiseptic should then be applied to the site.
- f. Use of Insecticide treated mosquito net gives some protection against soft ticks.

**C. Habitat Management** : Vegetation management is another control option for ticks. Removal of shrubs, trees, or tall grass can be useful in recreational areas. Wherever this is not possible, area treatment with insecticide may be the only viable option.

### Anti-Rodent Measures

Persistent anti-rat hygiene is of great value in reducing the risk of diseases conveyed to man through ticks and mites. The main objective should be to reduce ingress of rodents by proper disposal of camp and kitchen refuse and removal of overgrown vegetation and rubble which afford them shelter. Rat destruction requires forethought; because if the feeding of larval ticks and mites is interrupted by the death of rodent hosts, a number of released acarines may reattach themselves to another host, which may be man. Active rat destruction may be adopted when the first infestation is at its peak i.e. a month or so after the rain starts. It is better to trap and then destroy them so that their parasites do not escape. When dead rats are collected from any endemic foci, the soil under and immediately around them should be treated with insecticide. Soft tick control is further achieved by rat-and-tick-proofing of dwellings. All cracks and crevices, fissures and other points of ingress should be closed and all doors should be made tight fitting to keep away rodents.

### Camp Siting

In civil life, camps may need to be sited for temporary settlements of labour population when large industrial / urbanization projects are being launched in possibly infested areas or during disaster like situations. Before any area in the known endemic tract is selected for camping or before the

insecticide treatment is undertaken, the degree of risk should be assessed by determining the prevalence of adult and larval Acari.

**(a) Mite Survey** : Superficial layers of earth are scraped from moist areas around the roots of scrub and mixed with water in a bowl. Adult mites resembling a figure of 8 float in a few minutes. For non parasitic larvae, pieces of dark cardboard are placed edge wise forming tent fashion structures on the ground at intervals, larvae crawl up the cardboard and congregate at its top edge within a few minutes. Rats caught from the area should be examined for the clusters of larvae or scabs in ear-cusps and shrews for clusters on their rumps. If the ears or rump is infested, they should be carefully cut with fine scissors and placed in 70% alcohol vials. Rodent trapping is done in field (Camps, fringe areas) by specialized traps called Sherman traps, whereas in peri-domestic areas, Wonder traps may also be used. The trapping procedure is described in a subsequent chapter on rodents. Once the traps are brought to the laboratory, the rats are transferred in to large polythene bags, anaesthetized and thereafter ectoparasite screening is undertaken. While carrying out the survey, one must protect oneself adequately with protective clothing and repellents.

As a rough guide, it can be said that the Scrub typhus risk in any area during the monsoon is considered low if only up to 10% of the rats have been found infested on consecutive two surveys unless cases have occurred already; if 20-40% of rats have been found infested the contraction of infection is very probable; and if 50% or more rats have been found infested the risk is high and the site should be considered as dangerous. Similarly, even if a single rat is found infested with more than 100 larval mites, the area should be avoided, being a very high risk area.

**(b) Tick-Survey** : Ticks are collected by sweeping flags made of white flannel across the vegetation (Flagging/dragging method). The larvae, nymphs and adults get attached to them and are easily detected against the white background of the flag. They should be picked up by forceps and placed in 70% alcohol vials. Parasitic stages of ticks on various animals can be collected by catching rodents, shrews and other animals. Physical examination of a volunteer for ticks attached on his body after he has travelled for a stipulated / fixed period of time in an area delineated for survey also provides information on tick presence/ abundance. Dry ice traps are one of the most effective means of sampling ticks.

### Summary

Ticks and mites belong to class Arachnida; body is divided into cephalothorax & abdomen with 4 pairs of legs. Ticks belong to two families : Ixodoidea (hard tick) and Argasidae (soft tick). All stages thrive on blood & lead an intermittent parasitic life. Dorsum of hard tick is covered by scutum which is replaced by the leathery cuticle in soft ticks. All species of ticks pass through 4 stages - egg, larva, nymph & adult. Eggs are laid in cracks & crevices. Hard ticks deposit all their eggs in a single act of oviposition, after which they die. Larvae are six legged and do not feed for about a week, thereafter they attach to passing hosts. They feed on blood & drop off. The nymphs and adults (both sexes) are parasitic and exhibit questing. Male dies after

fertilizing the female. Hard ticks thrive on animal hosts & soft ticks attack man voluntarily. Ticks produce diseases in man by transmitting viruses, rickettsiae, spirochaetes and bacilli of infectious diseases. Rickettsial infections are transmitted by the hard ticks of the genera *Ixodes*, *Dermacentor*, *Amblyomma*, *Haemaphysalis*, *Rhipicephalus*, *Hyalomma* and *Boophilus*. Hard ticks also transmit virus causing KFD and *P. tularensis*, the causative organism of Tularaemia. Soft ticks transmit various types of spirochaetes causing relapsing fever.

The vector mites belong to the order Acarina, family Trombiculidae. Found in great abundance in areas with hot, humid climate, thick vegetation and presence of small vertebrates like rodents (*Mite Island*). They are known by various names such as chiggers, harvest mites, Kedany or scrub mite. Important species of the genus *Leptotrombidium* are *akamushi* and *deliense*. They possess a figure of eight shaped body with eight legs. They are found in nature in the interior of ear cusps or on rumps of rats, mice, shrews, bandicoots and other small mammals. The stages in the life history of a mite are egg, larva, nymph and adult. The eggs are laid singly. The larva seeks a suitable host such as rat, mouse, bandicoot or shrew and feeds on the lymph and tissue fluid. Mites are vectors for various rickettsial diseases. *Leptotrombidium deliense* transmits *Orientia tsutsugamushi* causing Scrub typhus.

Control of ticks & mites can be achieved by clearing of bushes in areas infested by ticks & mites followed by application of insecticides. Malathion 50% EC (@ 5% solution) should be sprayed in a dosage of 4 kg of active ingredient (a.i.) per hectare. In areas where vegetation cannot be removed, dusting can be done by Malathion or Fenthion. Insecticides should also be applied to beds, mattresses, rugs and furniture. Dogs and other domestic animals can be freed of ticks by a wash or spray containing 2% Malathion or 1% Propoxur. The repellants used for personal protection against ticks and mites are Dibutyl-phthalate (DBP), Diethyl phenyl acetamide (DEPA) and Diethyltoluamide (DEET). Clothes for drying should be hung on ropes. Before retiring at night or after leaving a tick infested area, one should take a bath and carefully search one's body and clothing for presence of ticks. Anti rodent measures like proper disposal of refuse & removal of overgrown vegetation helps in reducing the risk of diseases conveyed to man through ticks and mites. It is better to trap and then destroy rats so that their parasites do not escape.

Mite survey for nymphs and adults is done by soil sampling method, whereas larvae are sampled by rodent trapping. Ticks are surveyed by flagging/ dragging method as well as by direct host collection method through rodent trapping or by screening the host body for attached tick stages. Scrub typhus risk is considered low if only up to 10% of the rats have been found infested on consecutive two surveys unless cases have occurred already.

## Study Exercises

### MCQs & Exercises

- Which of these regarding ticks is not true (a) Females are larger than males (b) Both sexes thrive on blood alone (c) They are free living on the ground in between various moults (d) All are true.
- Soft ticks are involved in transmission of which of these (a) Relapsing fever (b) Kyasanur forest disease (c) Tick paralysis (d) Tularaemia.
- Mite island is an area having (a) 100% relative humidity (b) Temperature of  $27 \pm 5^\circ\text{C}$  (c) Scrub jungles or other tall grasses (d) Rats, mice, bandicoots, and shrews (e) All of these
- Which is the parasitic stage in mites (a) Egg (b) Larva (c) Nymph (d) Adults

### Fill in the Blanks

- Ticks & mites belong to the class \_\_\_\_\_
- Hard ticks deposit all their eggs in a single act of \_\_\_\_\_ after which they die.
- The most important vector species of trombiculid mite transmitting scrub typhus is \_\_\_\_\_
- The most effective means of sampling ticks is \_\_\_\_\_

### True or false

- Hard ticks belong to Family Ixodidae and soft tick to Family Argasidae.
- The total period required for full development of a tick is from six weeks to 2 years.
- Copulation in case of ticks takes place after the last moult & the male dies after fertilizing the female.
- The mite larva feeds on lymph and the tissue fluid but not on blood.
- Only the adult stages of ticks are parasitic, whereas the larvae and nymph feed on plant juice.

**Answers :** (1) d; (2) a; (3) e; (4) b; (5) Arachnida; (6) Oviposition; (7) *Leptotrombidium deliense*; (8) Dry ice collection; (9) True; (10) True; (11) True; (12) True; (13) False.

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Rina Tilak

Rodents are the largest order of mammals with over 2000 living species placed in about 30 families. The word 'Rodent' has been derived from "rodere", which means to gnaw; the incisors of the rodents keep growing and to keep them in check, the rodents gnaw continuously. Rodents range in size from 5 gm (pygmy mice) to over 70 kg (capybaras). They have a world wide distribution with the exception of Antarctica. The habitat of the rodents is equally diverse with some preferring terrestrial life, while some live underground, others are adapted to desert life while some have inhabited the aquatic environment.

### Public Health Importance

Rodents are capable of transmitting a large number of diseases to man through transfer of ectoparasites, which are vectors of diseases like murine typhus, plague, scrub typhus etc. (Table - 1 & 2) besides consuming and contaminating stored food with their urine and droppings, destruction to immovable property, gnawing on wiring and electrical insulations etc., which at times may lead to fire hazard.

### Bionomics

Rodents use their sense of vision, hearing, touch, smell and taste for exploring new areas or food with certain senses more developed amongst rodents based on their needs for e.g. diurnal rodents have better vision as compared to their counterparts who are active at night. The rodents also possess the ability to perceive ultrasounds and use chemical, tactile, visual, auditory cues and intraspecific chemicals viz. pheromones for communication. Rats tend to be cautious and mice are more curious. Most rodents are omnivorous with few exceptions. They reproduce rapidly and exhibit crepuscular to nocturnal habit.

### Types of Rodents

Rodents may be classified broadly into two types : viz. commensal (domestic rodents) and sylvatic or wild rodents.

Three species of urban rodents, *Mus musculus* (house mouse), *Rattus norvegicus* (Norway or brown rat) and *Rattus rattus* (roof or black rat) are the principal rodents encountered in peridomestic and domestic environments.

**Table - 2 : Diseases transmitted through ectoparasites being harboured by the rodents.**

Disease	Agent	Vector
Murine typhus	Rickettsia	Flea
Plague	Bacteria	Flea
Scrub typhus	Rickettsia	Trombiculid mite
Indian tick typhus	Rickettsia	Hard Tick
Rickettsial Pox	Rickettsia	Mouse mite
Kyasanur Forest Disease	Virus	Hard Tick
Rocky Mountain Spotted Fever	Rickettsia	Hard Tick
Colorado tick fever	Virus	Hard Tick
Lyme disease	Spirochaete	Hard Tick
Human Granulocytic Anaplasmosis	Bacteria	Hard Tick
Babesiosis	Parasite	Hard Tick
Relapsing fever	Bacteria	Soft Tick
Western Equine Encephalitis	Virus	Mosquito
Cutaneous Leishmaniasis	Parasite	Sandfly

***Rattus norvegicus* - (Sewer rat)** : It generally frequents the sewers. It is a burrowing rat and is easily identified by its heavy body, coarse brownish to reddish grey fur with greyish belly. It is a good climber, nocturnal in habit and eats anything which is edible. It has poor vision but keen senses of smell, touch, taste and hearing and usually lives within 150 feet of food and water source. It feeds on familiar food, preferring meats and grains and has been found to be cautious of new items or food.

**Table - 1 : Diseases transmitted directly by rodents or through contaminated water, food or animal.**

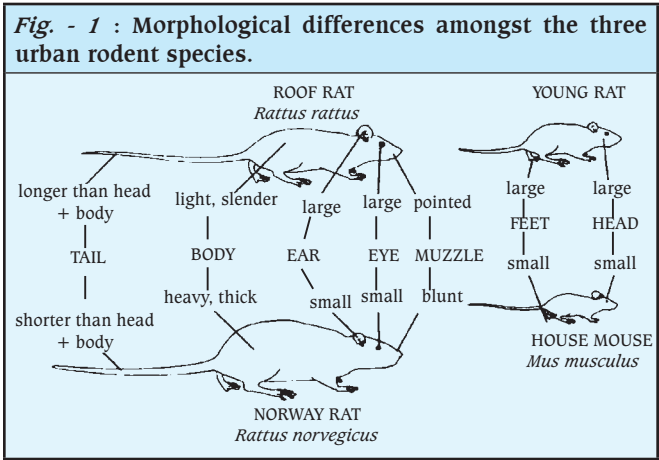
Disease	Agent	Mode of spread
Rat bite fever	Bacteria ( <i>Spirillum minus</i> )	Bite or scratch from an infected rodent or contact with a dead rodent, eating or drinking food or water that is contaminated by rat faeces
Leptospirosis	Spirochaete ( <i>Leptospira icterohaemorrhagica</i> )	Water & food contaminated with urine from infected animals
Salmonellosis	Bacteria ( <i>Salmonella spp</i> )	Water & food contaminated with faeces from infected animals
Tularaemia	Bacteria ( <i>Francisella tularensis</i> )	Handling infected animal carcasses, eating or drinking contaminated food or water, breathing in the bacteria
Haemorrhagic fever with renal syndrome	Virus	Breathing in dust that is contaminated with rodent urine or droppings, direct contact with rodents or their urine and droppings
Lymphocytic Chorio Meningitis (LCM)	Virus	Breathing in dust that is contaminated with rodent urine or droppings, direct contact with rodents or their urine and droppings
Plague	Bacteria ( <i>Yersinia pestis</i> )	Direct contact with infected animal



**Rattus rattus** : It is a slender rat and is a very agile climber thus earning its common name - the roof rat. It usually nests indoors in roof and wall cavities. It exhibits a strong fear of new things (neophobic). It is nocturnal and an omnivorous feeder with preference for fruits and propensity to hoard food.

**Mus musculus** : It resembles the roof rat, though smaller in size. It can be distinguished by its dusky grey fur and smaller feet. It commonly inhabits man made structures and therefore called house mouse. It has poor vision and is colour-blind, but has a well developed sense of smell which is used to locate food items and recognize other mice and an acute sense of hearing to respond to unusual noises as a means of detecting and escaping danger. Mice are omnivorous and known nibblers, eating small amounts of food at a time with preference for cereals or foods rich in fat and protein. They are poor swimmers and their normal activity range is usually within 10-30 feet from nest. Mice are habitual gnawers, curious and avid collectors of nesting materials; a habit which can be exploited while trapping them by attaching nesting material to traps.

The morphological differences amongst the three commensal or urban rodents are depicted in Fig. - 1.



**Detection of Rodent Infestation**

It is important to ascertain presence and level of rodent infestation prior to undertaking control measures. Following methods of detection may be employed for assessment :

**Rub marks** : During movement of rodents along rat runs, the oil and dust from the body of the rodents leaves rub marks especially in case of roof rats.

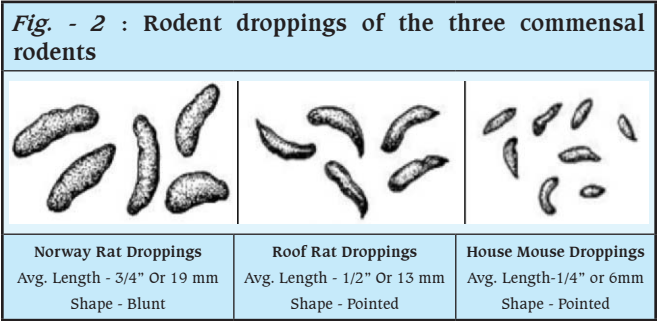
**Gnawing marks** : Due to the continuous gnawing habit of rodents, wood scrapings around doors, windows and frames may be the obvious visible signs of rodent activity.

**Droppings** : By seeing the droppings, it is possible to identify the type of rodent infesting a given structure. The same has been presented in Fig. - 2. Droppings are ideally visible along rat runs, near rodent burrows and at the feeding sites.

**Run Ways** : Rodents generally use the same path for travelling; the common runways or rat runs are seen along walls, behind stored objects and similar places.

On inspection, when no signs are visible, it is presumed that

there is no rodent infestation. In low to medium infested areas, no daytime rodent sightings or activity is noticed however, their presence is detected by the above mentioned methods of detection. The high-density infestation levels are detected by daytime sightings, active gnawing, droppings and heightened night time sightings.



**Prevention and Control**

The best method of prevention is to deny rodents a place to live / nest and food to eat. This is achieved by the following methods :

**Eliminating the Hiding and Nesting Sites** : The rodents prefer to breed in dark and undisturbed areas, which are available in plenty by the debris / garbage/ clutter present in the houses/ surroundings. The following measures will ensure denial of breeding / hiding place for the rodents.

- Keep surroundings clean and free from debris to prevent rodents entry and breeding in the premises.
- Good housekeeping will deny hiding and nesting places to rodents.
- Deny dark, sheltered and undisturbed places in the house by routinely displacing furniture.
- Make all openings to constructions rodent proof through engineering methods. The following measures can be adopted by individuals to make their houses rodent proof:
  - Install doors to fit tightly.
  - Rodent proof a door by placing sheet metal channel at bottom and cuffs at sides, over channel.
  - Reinforce doors with thick aluminium sheets of 22 gauze or thicker.
  - Steel wool and copper mesh can be packed tightly into holes to close openings or protect other areas from gnawing.
  - Make the drainage points rodent proof by using sieves secured with cement.
  - Use materials such as mortar for sealing holes in concrete buildings.
  - Fill all gaps in basements/ building or holes in walls with cement or steel wool.
  - Rodent proof utility wires to limit access to buildings using rolling plastic tubes made from rectangular sheets of plastic. The tube rolls when the rodent tries to walk over it.
  - Rodent proof air vents and chimneys using 1/4" hardware cloth.

### Eliminating Food Sources

- Spillage should be cleaned daily.
- Garbage should not be stored outside in plastic bags as plastic garbage bags are not rodent-proof, instead metal bins or heavy duty plastic bins with tight-fitting lids should be used.
- Fallen fruits and nuts from the ground should be promptly disposed of.
- Pet food dishes and leftovers should also be promptly removed after feeding.
- Animal waste should be cleaned frequently.
- Food scraps should not be placed in compost piles.
- Food grains or other food materials should be stored in rodent proof containers and wherever feasible be placed in cupboards.

In situations where preventive measures have failed to address the problem of rodent nuisance effectively, control of rodent infestation is achieved through the following three methods :

- Trapping
- Baiting
- Fumigation

**Trapping** : Trapping can be an effective method of controlling rodents, but it requires more skill and labor than most other methods. Trapping is recommended where poisons seem inadvisable and is the preferred method to try first in homes, garages and other small structures, where only a few rodents

may be present. Traps should be laid out at or before dusk along rat runs, near their feeding areas, areas of high activity or potential entry points. Traps should be placed at 3-10 ft apart for mice and about 20 ft for rats. It is also pertinent to use the correct trap for the rodents; larger rodents may require larger traps as compared to traps used for mice. For successful trapping, it is advisable that baited traps should be placed.

**Types of Traps** : There are various types of traps available in the market for use. The traps either trap live rats or kill the rats. Commonly available traps are :

#### Cage Traps (Fig. - 3)

- Used for capturing rodents live.
- These traps are designed to catch and hold one or more animals by means of a falling or sliding door, triggered when the rodent enters or nibbles at a bait.

#### Sherman Traps (Fig. - 4)

- Are foldable box traps made of Aluminium.
- Used for trapping rodents for research purposes or during epidemic investigation (Procedure of trapping is presented in Box - 1).
- Traps live rodents.
- Have an added advantage of ensuring that ectoparasites are not lost, even if the trapped rodent dies.
- Generally baited with freshly made baits rich in fat e.g. *pakor*as (fried snack of onion mixed with gram flour) or fried fish, chicken etc.

<b>Box - 1 : Trapping Procedure for Rodents using Sherman Traps</b>
Number the Sherman traps with marking pens starting from 1-40.
Prepare flags bearing the same numbers i.e. 1-40 with cardboard pieces.
Carry freshly prepared <i>pakor</i> as for the traps.
The laying of traps should be carried out in the late afternoons and should be completed before dusk.
Personnel involved in laying/ collecting of rodent traps should wear trousers tucked in boots/anklets and full sleeved shirt. Wear heavy duty gloves while laying/ collecting traps and use repellents on exposed skin.
Identify suspected mite islands (a patch of ground with vegetation, temp in the range of $27 \pm 5^{\circ}\text{C}$ , Relative Humidity in the range of 80-100% and which provides an ideal place for rodents to hide).
Check the working condition of Sherman trap before placement.
Place <i>pakor</i> a in traps; ensure it is placed at the closed end of the trap.
Place the trap in the bushes or where rodent is likely to frequent. Place the trap with its opening facing the likely direction of rodent entry. Ensure that the trap opening is not obstructed. The trap should be placed on flat ground so that it does not tumble if approached by rodent or any other movement in the area.
Place flag bearing the same number as the trap, close to the trap so that it is visible from a distance.
Tie a bandage to the nearby bush to indicate the site of trap placement to enable retrieval in the poor light conditions of dawn - the time for trap collection.
Make a spot map of trapping area with the trap numbers indicated on the map.
Collect the trap before dawn next day.
Use heavy duty gloves and a torch for collection of traps at dawn. (All protective measures as followed earlier should be ensured). If a trap is closed, do not try to open the trap, put the trap in a cardboard carton for transportation to the lab.
If a trap is open, fold it and place in carton/ plastic bags.
Once the traps are brought to the laboratory, the rats are transferred in to large polythene bags, anaesthetized, blood collected for testing for presence of rodent borne diseases by conventional serology/ PCR, rodent identified and thereafter subjected to ectoparasite screening.

**Fig. - 3 : Cage Trap**



**Fig. - 4 : Sherman Trap**



#### **Trigger or Snap Traps**

- These traps are generally more effective than cage traps.
- Simple, inexpensive, wood-based snap traps are readily available.
- For rats, bait the traps with fried food items like chicken, pakoras etc. tied securely to the trigger.

#### **Break Back Traps**

- These traps are similar to snap traps but have a quicker killing action and hence there are no misses.
- These traps are considered more humane as the rats die instantaneously.
- They are generally used in fields by farmers.
- Not preferred indoors.
- Traps need to be baited with food similar to that used for other traps.

**Advantages :** Trapping is an effective rodent control option when permanent rodent control measures are not in place or inappropriately implemented. It is one of the most preferred and safer rodent control options in domestic and peri-domestic environments. It has an advantage that it allows user satisfaction in terms of success of the trapping procedure being obvious. Trapping as a rodent control option also ensures proper disposal of carcasses or live trapped rodents thereby preventing odour nuisance from the dead rodents. Traps are especially effective indoors where use of rodenticides may pose threat to the non target organisms viz. people or pets and in kitchens, pantries or food serving areas due to possibility of contamination of food.

**Limitations :** This is a temporary control option as after initial success, the rodents become 'trap wise' (a phenomenon wherein rodents avoid traps as they are able to associate traps and their getting trapped in them) and the efficacy of the trapping process is then compromised. The trapping process should be stopped when rodents are sighted but are not being trapped.

**Glue Boards :** Glue boards are an alternative to rodent traps and may control rodents in low infestation areas. They are effective options for rodent control in areas where food is commercially prepared, where the use of rodenticides is unsafe and for monitoring rodent population. A combination of traps and glue boards may prove more advantageous than a single method. The mode of action of rat glue boards is the same as

that of fly papers. It entangles mice and rats in much the same manner as flypaper catches houseflies. Like traps, glue boards need to be placed along walls where mice and rats travel. It is however important to place the glue boards in dust free areas and away from direct sunlight or extremes of temperature so that the tackiness of the glue is maintained.

**Baiting :** In the event of emergency rodent control or at times when there is a failure to achieve effective rodent control through non chemical strategies mentioned in the preceding paragraphs, baiting emerges as an attractive alternative to address the problem. The process of baiting utilises special chemicals called rodenticides for killing the rodents. The use of rodenticides or the process of baiting should be undertaken by trained individuals and requires utmost care as they pose threat to non target organisms, as well as hazards of accidental/ deliberate poisoning.

**Factors Influencing Baiting :** The adaptive behavioural responses of rodents for selecting palatable and nutritious food, while rejecting palatable though harmful food poses one of the biggest challenges in making the rodents consume the toxic baits. This is further challenged by the phenomenon of 'neophobia' exhibited by rats and their learned food aversions. It is thus essential to undertake 'prebaiting' (the food material without the bait is placed for 3-5 days to remove fear of new food amongst the rodents) prior to actual baiting. It is further important that the rodenticide should preferably be tasteless and odourless in lethal concentrations and have a delayed effect.

**Time & Place of Baiting :** Baiting should be done in the evenings along rat runs, feeding and activity areas etc which are generally frequented by the rodents as evidenced by the signs of infestation elicited through the procedure given earlier.

**Types of Rodenticides :** Rodenticides are classified as acute rodenticides and anticoagulants. They are used mostly mixed with food or as contact poisons in the form of dusts (tracking powder).

**Acute Rodenticides :** These kill the rodents on ingestion of a single dose of the toxic bait. There are a large number of acute rodenticides, however, not all are considered ideal for use in domestic environments due to safety concerns. The acute rodenticides are Red squill, Norbromide, Sodium fluoroacetate,



Strychnine, ANTU etc. Some commonly available acute rodenticides are Zinc phosphide and Barium carbonate.

**Zinc Phosphide** : It is a black powder with a garlic odour. The garlic odor attracts rodents but has a repulsive effect on other mammals, though, birds cannot perceive the smell and unintentionally feed on them leading to unwarranted death. It is mixed in the proportion of 1 : 8 or 1 : 10 with wheat flour and made into pellets with a little edible oil. Upon ingestion, Zinc phosphide reacts with dilute acids in the gastrointestinal tract and produces phosphine which enters the blood stream and causes death within four hours of consumption of a single dose of the bait.

**Barium Carbonate** : It is a white powder mixed in the proportion of 1 : 4 with wheat flour. A single dose consumption of the product causes kill within eight to twenty four hours.

**Advantages** : Being highly toxic, these rodenticides bring about a rapid kill with a single dose consumption of the bait, which is one of the greatest advantages especially when the rodent populations are very high.

**Limitations** : These rodenticides need to be used with care as they may cause toxicity to non target organisms. The consumption of a single dose of the bait leads to very painful death of the rodent, which when sighted by the other rodents is quickly registered as an association of the new bait with these deaths, thus leading to avoidance of the bait - i.e. development of the phenomenon termed as "bait shyness". Once this develops, baiting with acute rodenticides is rendered ineffective and needs to be discontinued.

**Anticoagulants** : These substances kill by preventing normal blood clotting and causing internal haemorrhage through effective blocking of vitamin K cycle, which results in inability to produce essential blood-clotting factors (mainly coagulation factors II (prothrombin), VII (proconvertin), IX (Christmas factor) and X (Stuart factor)). The antidote to anticoagulant poisoning is therefore Vitamin K itself. Anticoagulants are of two types, multiple dose and single dose anticoagulants.

**(a) Multiple Dose Anticoagulants** : These are the earliest known anticoagulants also called the *first generation anticoagulants*. Multiple dose consumption of the product kills the rodents, which generally takes about 1-2 weeks post ingestion of lethal dose. The common examples in this category are :

- **Warfarin** : It is the earliest product used for rodent control from this category. The product is not a very popular product now for rodent control as it has a delayed action. This product requires a higher concentration of the toxicant (usually between 0.005 and 0.1%) and consecutive intake over days in order to accumulate the lethal dose. The product is mixed in the proportion of 1 : 19 with wheat flour and made into baits.
- **Coumatetralyl** : Is an anticoagulant of the Warfarin type. The toxicity of the product is known to increase with continued ingestion or exposure to the bait. For the product to be toxic, it should constantly remain present in the blood for more than 1 to 2 days. A single exposure, even though relatively large, may not produce toxic symptoms as the compound is quite rapidly metabolized. It is marketed in India as tracking powder (0.0375%) which

can be mixed with wheat flour and made into baits as in case of Warfarin.

**Advantages** : The greatest advantage of these products are that they cause apparently painless deaths and hence do not result in the development of 'bait shyness' and therefore can be used wherever continuous rodenticiding is required e.g. granaries, ships etc.

**Limitations of Multiple Dose Rodenticides** : As multiple dose consumption of the bait is required for the desired kill; single dose consumption of the bait will lead to sublethal dosing thereby giving rise to development of resistance.

**(b) Single Dose Anticoagulants** : Are derivatives of 4-hydroxycoumarin and are referred to as *second generation anticoagulants* or as "*superwarfarins*". These are far more toxic and lethal than their first generation counterparts and are applied in lower concentrations in baits (0.001 - 0.005%). The rodents die after ingestion of a single dose of the bait as in case of the acute rodenticides, however, the cause remains haemorrhage. Single dose anticoagulants commonly used are Bromadiolone, Difethialone, Brodifacoum etc. *Bromadiolone* is used in the form of ready-to-use baits of low concentration containing 0.005% bromadiolone. Single dose consumption of the bait kills the rodents. Bromadiolone kills all the commensal rodents viz. sewer rats, roof rats, house mice and is also effective against Warfarin resistant sewer rats.

**Advantages** : These single dose anticoagulants are effective against strains of rodents that have developed resistance to first generation anticoagulants. A single dose is lethal to cause kill and hence development of resistance also may not take place readily.

**Limitation** : As a single dose of these rodenticides is lethal to rodents; the use of this class of products may pose threat to non target organisms and hence needs to be used with care and under supervision.

**Fumigation** : Fumigation is the choice method for killing rodents in burrows, enclosed structures / places. It is however, carried out by trained professionals due to the risk posed by the noxious gases released during the process. The fumigants commonly used are Aluminium phosphide and Calcium cyanide. Sulphur dioxide, Carbon disulphide, Carbon monoxide and Methyl bromide are also used especially in godowns, granaries and aircrafts.

Fumigation with Aluminium phosphide and Calcium cyanide involves identification of burrows, locating the exit and entry points and then sealing one of the ends. The fumigants in the form of tablet (Aluminium phosphide) or in the form of powder (Calcium cyanide - 30 g /rodent burrow) are introduced in the burrows and the burrow closed with wet soil to release the gas - (Phosphine in case of Aluminium phosphide and Cyano gas in case of Calcium cyanide). Fumigation with Cyano gas has been extensively used in India for fumigating rat burrows in fields during Plague outbreaks, whereas Aluminium phosphide tablets are generally preferred for use in peri-domestic areas and agricultural fields.

**Ultrasonic Repellent Device** : The ability of rats to perceive ultrasonic sound has been exploited by using devices generating ultrasonic sounds. These are electrical devices and are popular



gadgets claiming efficacy in repelling rodents from infested rooms. Ultrasonic sounds, however, have very limited use in rodent control as they are directional, don't penetrate behind objects and lose their intensity with distance. They can be used in small rooms in a limited area.

## Summary

Rodents are the largest order of mammals with over 2000 living species. 'Rodent' has been derived from "rodere", which means to gnaw. Rodents range in size from 5 gm to over 70 kg. Rodents are capable of transmitting a large number of diseases to man through transfer of ectoparasites, which are vectors of diseases like murine typhus, plague, scrub typhus. Rodents use their sense of vision, hearing, touch, smell and taste for exploring new areas or food. The rodents also possess the ability to perceive ultrasounds and use chemical, tactile, visual, auditory cues and intraspecific chemicals like pheromones for communication.

Rodents are broadly classified into domestic & wild rodents; principal rodents encountered in peridomestic and domestic environments are *Mus musculus* (house mouse), *Rattus norvegicus* (Norway or brown rat) and *Rattus rattus* (roof or black rat). *Rattus norvegicus* or the sewer rat generally frequents the sewers. It is a burrowing rat and is easily identified by its heavy body. *Rattus rattus* is a slender rat & is a very agile climber. *Mus musculus* has dusky grey fur and smaller feet. Detection of rodent infestation can be done by rub marks, gnawing marks, droppings & runways. Rodents are mostly omnivorous with preference for cereals or foods rich in fat and protein.

Prevention is achieved by denying rodents a place to live/ nest and food to eat, keeping surroundings clean and making all openings to constructions rodent proof etc. Food source need to be eliminated and garbage should not be stored outside, animal waste should be cleaned and food grains / other food materials should be stored in rodent proof containers.

Control of rodent infestation is achieved through trapping; The traps used are Cage traps, Sherman traps, Snap traps & Break back traps. Traps should be laid out at or before dusk along rat runs, near their feeding areas, areas of high activity or potential entry points. Traps are the most preferred and safe rodent control options in domestic and peri-domestic environments as success of the trapping procedure being obvious, they however have the limitation of being temporary control options as the rats become trap wise.

Other alternative are use of glue boards, baiting & use of rodenticides. The acute rodenticides are Red squill, ANTU, Zinc phosphide & Barium carbonate (advantage of rapid kill but can lead to development of bait shyness.), the other rodenticides are the anticoagulants. Multiple dose anticoagulants are Warfarin & Coumatetralyl; They have the advantage of causing painless deaths but multiple dose consumption is required for the desired effect. Single dose anticoagulants (bromadiolone) have the advantage of killing the rodents by consumption of a single dose with the added advantage of anticoagulants i.e. no development of bait shyness takes place, thus making them ideal for continuous use. Fumigation can be done using Aluminium phosphide and Calcium cyanide.

## Study Exercises

### MCQs & Exercises

- 1) Which of these is known as roof rat (a) *Mus musculus* (b) *Rattus norvegicus* (c) *Rattus rattus* (d) All of these.
- 2) Rodents are capable of transmitting which of these diseases to man through vectors (a) Murine typhus (b) Leptospirosis (c) Rat bite fever (d) All of these.
- 3) Detection of rodent infestation prior to deciding control measures can be done by (a) Rub marks (b) Gnawing marks (c) Droppings (d) All of these.
- 4) This trap is generally used for trapping rodents for research purposes / outbreak investigation (a) Cage traps (b) Sherman traps (c) Trigger trap (d) Break back traps.
- 5) Acute rodenticides are all except (a) Red squill (b) ANTU (c) Zinc phosphide (d) Warfarin.

### Fill in the Blanks

- 6) Burrowing rat which is easily identified by its heavy body, coarse brownish to reddish grey fur with greyish belly & frequents sewers is \_\_\_\_\_
- 7) These traps have a quick killing action & are generally used in fields \_\_\_\_\_

### True or False

- 8) Rodents range in size from 5 gm (pygmy mice) to over 70 Kg.
- 9) Mice are omnivorous and known nibblers, eating small amounts of food at a time with preference for cereals or foods rich in fat and protein.
- 10) Traps should be placed at 3-10 ft apart for mice and about 20 ft for rats.

**Answers :** (1) c; (2) a; (3) d; (4) b; (5) d; (6) *Rattus norvegicus*; (7) Break back traps; (8) True; (9) True; (10) True.

Rina Tilak

Snakes are one of the most widely distributed animals spanning across continents (with the exception of Antarctica), inhabiting the sea and present as high as 16,000 feet (4900m) in the Himalayan Mountains, though conspicuous by their absence from Ireland and Iceland (1). There are over 3000 species of snakes distributed world wide and about 275 species are found in the Indian sub-continent (2).

### Morphology & Biology

Snakes, which belong to the class Reptilia, are limbless reptiles characterized by elongated body which is divided into head, body and tail. The whole body of the snake is covered with scales which are an important tool for their identification. A thin skin, in turn covers the scales which is periodically shed or cast off during the process of moulting; during this period the snake is blind (as the skin covers the eyes as well) and lethargic.

Snakes locate their prey by their senses of vision, smell or thermo-sensitivity. The remarkable vision of some snakes enables them to detect movement; snakes smell by using their forked tongue which collects airborne particles and then passes them to the Jacobson's organ or the vomeronasal organ in the mouth for examination. The body of the snakes which is in direct contact with the ground is also very sensitive to vibration, thus enabling snakes to sense other approaching animals by detecting vibrations on the ground. Some snakes like pit vipers and pythons have infrared-sensitive receptors present between the nostril and eye or have labial pits on their upper lip just below the nostrils (common in pythons) which allow them to "see" the radiated heat and thus locate prey especially warm-blooded mammals.

Of the roughly 725 species of venomous snakes worldwide, only 250 are able to kill a human with one bite. The official records state about 2, 50,000 snakes bite cases occur in India every year, of which, over 50,000 die due to inadequate first aid or unscientific treatment methods (3). The Indian snake bite statistics are alarming as the figures are highest in the world, though India does not host the largest number of snakes in the world.

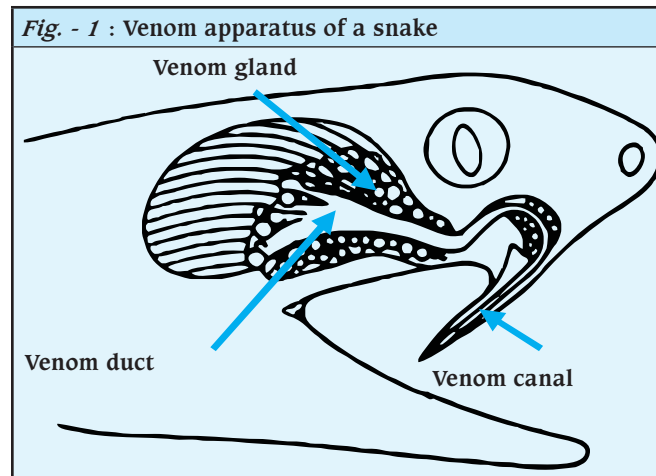
### Venom Apparatus

The Venom apparatus of a snake (Fig. - 1) comprises a venom gland which opens through the venom duct into fangs located in front of the upper jaw which have a venom canal along which venom is introduced while biting into the tissues of the prey. If a human is bitten, venom is injected either subcutaneously or intramuscularly.

### Classification of snakes

The venomous snakes of the Indian continent may be broadly classified into two important families i.e. Elapidae and Viperidae. Snakes belonging to family Elapidae are the Cobras, Kraits and Coral snakes. This group is characterized by the presence of short permanently erect fangs. Sea snakes belong

to family Hydrophilidae. The members of family Viperidae are divided into two subgroups viz. the pit vipers and the typical vipers; they possess long fangs which are normally folded up against the upper jaw and are erected while striking.



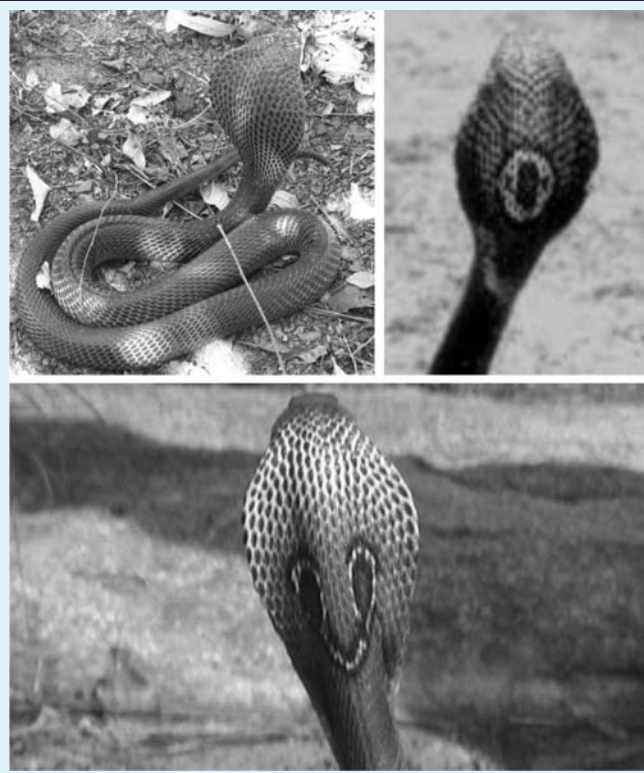
**Venomous Indian Snakes** : The important venomous snakes in India are Cobra (*Naja naja*), Common Krait (*Bungarus caeruleus*) and three types of vipers i.e. Russell's (*Daboia russelii*), Saw scaled (*Echis carinatus*) and the Hump nosed viper (*Hypnale hypnale*). The polyvalent antivenom available as of now in India, however, has the antivenom targeted against poisoning by only the first four types of snakes. The identification of snakes is a very specialized task and is best left to the herpetologists, however, certain common identification marks and distribution of the venomous snakes of India is presented below:

- a) **Cobra**: Found all over India, are active during day and night. Raises a hood which may have no mark e.g. king cobra (*Ophiophagus hannah*), or hood may be spectacled or bicellate (*Naja naja*) or monocled (monocellate i.e. single circular mark) - *Naja kaouthia* (Fig. - 2).
- b) **Krait**: Found all over India, are generally encountered at night. It is the most venomous of all land snakes. The common krait or *Bungarus caeruleus* is identified by paired white lines on the body, whereas the other variety is the banded krait *Bungarus fasciatus* (Fig. - 3).
- c) **Saw Scaled Viper**: Found all over India and prefers dry scrub or desert. *Echis carinatus* is identified by the White loop marks along body and arrow or birds foot mark on head (Fig. - 4)
- d) **Russell's Viper**: Found throughout India up to 3000 m altitude. *Daboia russeli* is identified by the black edged chain like marks and white V on head (Fig. - 5)
- e) **Hump Nosed Viper**: *Hypnale hypnale*, the hump nosed viper is found in the Western ghats. It is identified by its characteristic hump nose, whereas the other features resemble *Echis carinatus* (Fig. - 6).

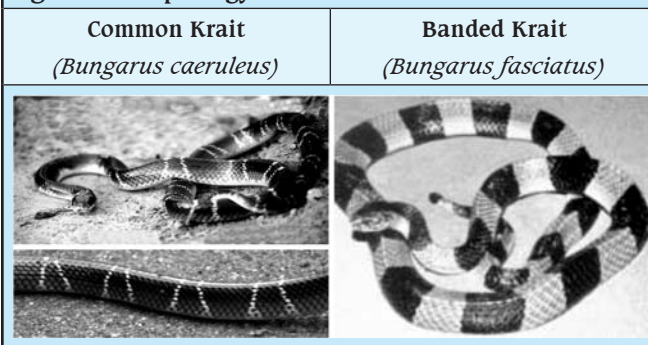
### Snake Venom

Snake venom contains more than 20 different constituents which evoke varied responses in the body. These constituents are: procoagulant enzymes, haemorrhagins, cytolytic or

**Fig. - 2 : Hoods of Cobra**



**Fig. - 3 : Morphology of Kraits**



necrotic toxins, haemolytic and myolytic phospholipases A2, pre-synaptic neurotoxins and post-synaptic neurotoxins. It is important to note that not all venomous snake bites lead to clinical effects as most of the time insufficient or no venom enters the wound.

**Envenomation Symptoms :** The local symptoms and signs of snake bite are fang marks, local pain and bleeding, bruising, lymphangitis, lymph node enlargement, inflammation (swelling, redness and heat), blistering, local infection, abscess formation and necrosis. The systemic action of snake venom is either on the nervous system (Neurotoxic) or on the haematological system (anti-haemostatic). It may also cause local damage or reaction as a result of the constituents of venom which primarily function to spread the venom throughout the body. Symptoms seen in neurotoxic type (due to elapid bites) are drooping eyelids, vision disturbances, difficulty in breathing,

**Fig. - 4 : Saw scaled Viper**

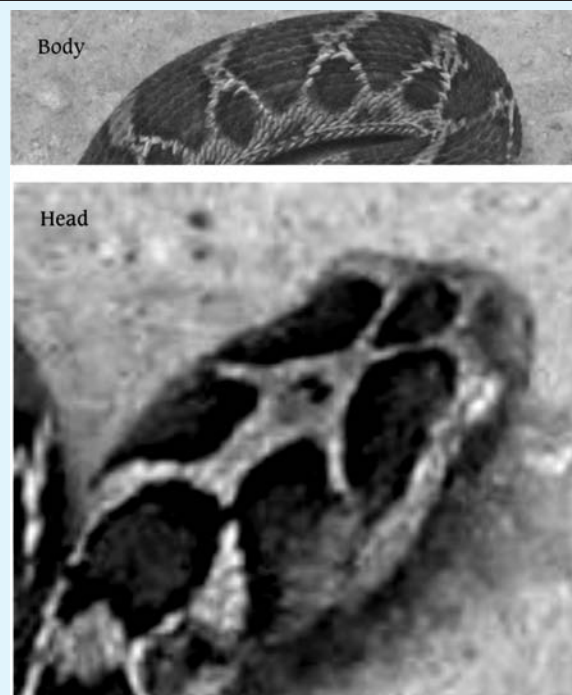


Photo courtesy Ian Simpson

**Fig. - 5 : Russell's viper**



Photo courtesy Ian Simpson

**Fig. - 6 : Hump nosed Viper**





difficulty in speaking, opening of mouth or protruding the tongue, difficulty supporting the neck and head and difficulty in swallowing. The presentation in haematotoxic type (due to vipers) is continuous bleeding from bite site, bleeding from gums or nose, appearance of bruises and dark urine.

### Syndromic Approach as Guidelines

A “syndromic approach” as laid down by WHO may be useful in prompt and effective management of snake bite especially when the snake has not been identified; the envenomation symptoms provide the relevant guidelines as presented in Table - 1.

Table - 1 : Snake identification based on Envenomation Syndrome	
Envenomation Syndrome	Snake species
<b><i>Local swelling with bleeding/ clotting disturbance</i></b> <ul style="list-style-type: none"> <li>Above + Shock or renal failure</li> <li>Ptosis, external ophthalmoplegia, facial paralysis and dark brown urine</li> <li>Paralysis with dark brown urine and renal failure along with bleeding/clotting disturbance</li> </ul>	<b><i>All Viper species</i></b> <ul style="list-style-type: none"> <li>Russell's &amp; Saw scaled viper</li> <li>Russell's viper - reported from South India</li> <li>Russell's viper - reported from South India</li> </ul>
<b><i>Paralysis with minimal or no local envenoming</i></b>	<b><i>Krait</i></b>
<b><i>Local envenoming (swelling etc) with paralysis</i></b>	<b><i>Cobra or King cobra</i></b>

### Prevention of Snake Bites

Snake bites can be effectively prevented by following certain simple preventive measures; the following do's and don'ts should be followed to prevent snake bites:

- Do not try to kill a snake. Many people are bitten because they try to kill a snake or get too close to it- leave snakes alone.
- While trekking/ hiking, stay out of tall grass unless you are wearing thick leather boots and remain on hiking paths as much as possible.
- Keep hands and feet out of areas you cannot see. Do not pick up rocks or firewood unless you are out of a snake's striking distance.
- Be cautious and alert when climbing rocks.
- Wear boots and avoid moving barefoot in snake infested areas.
- Always carry a torch while moving in darkness.
- Remove garbage or any other junk material lying in and around the house - keep surroundings rubble free.
- In snake infested areas, shake shoes well before wearing.
- Dust bedding before sleeping, use mosquito nets while sleeping in camp sited areas and preferably avoid sleeping on ground.

### First Aid

Whenever dealing with a snake bite case, it is pertinent to remember that a substantial proportion of all snake bites are actually due to non-poisonous snakes; secondly, almost 50% of bites by venomous snakes do not inject enough poison and hence it is important to reassure the person. The following measures (Do's & Don'ts) can save lives even in case of venomous snake bites, if timely action is taken (See Box - 1).

Box - 1 : Snake Bites - Do's and Don'ts
<b>Do's</b>
Calm the patient down to slow down blood circulation and retard the spread of venom.
Have the victim lie down with the affected limb lower than the heart.
Immobilize the bitten limb, using a splint if possible and position it below the level of the heart.
Get the victims to hospital urgently, lying flat, if possible - do not wait for the symptoms to develop.
<i>Start Artificial Respiration</i> , this can be life saving in Cobra and Krait bites as the victim may stop breathing, however they are not dead.
Remove any rings, bracelets, boots, or other restricting items from the bitten extremity as it may swell.
Start antivenin in hospital after assessment of envenomation symptoms by a qualified medical person.
<b>Don'ts</b>
Do not apply any tourniquet or compression bandage (4).
Do not give incision or attempt to suck out venom as it is ineffective at removing venom; and in Viper bites will cause serious bleeding.
Do not give the victim alcoholic drinks or Aspirin.
Do not wash the bitten area as it may increase the venom flow.
Do not cool the area of the bite.
Do not try to catch the snake; we do not need another victim. If the snake has been killed, take it to the hospital.
Do not give antivenin in any other place other than in a hospital.



**Acknowledgement:** The author gratefully acknowledges the inputs by Ashok Captain, a well known Indian Herpetologist and Ian Simpson for the photographs.

## Summary

Snakes are one of the most widely distributed animals. There are over 3000 species of snakes distributed worldwide and about 275 species are found in the Indian sub-continent. Snakes belong to the class Reptilia, are limbless and characterized by elongated body which is divided into head, body and tail. The whole body is covered with scales, which are covered by skin. The skin is shed or cast off during the process of moulting. Snakes locate their prey by their senses of vision, smell or thermo-sensitivity, body is also very sensitive to vibration. Of the roughly 725 species of venomous snakes worldwide, only 250 are able to kill a human with one bite.

The snakes are classified into families: Elapidae and Viperidae. Elapids are the Cobras, Kraits and Coral snakes. Viperidae are further divided into two subgroups- the pit vipers and the typical vipers. The important venomous snakes in India are Cobra, Common Krait and the three types of vipers i.e. Russell's, Saw scaled and the Hump nosed viper.

Not all venomous snake bites lead to clinical effects as most of the time insufficient or no venom enters the wound. The local symptoms and signs of snake bite are fang marks, local pain and bleeding, bruising, lymphangitis, lymph node enlargement, blistering, local infection, abscess formation and necrosis. The systemic action of snake venom is either on the nervous system or on the haematological system. Neurotoxic symptoms due to elapid bites are drooping eyelids, vision disturbances, difficulty in breathing, difficulty in speaking and opening the mouth. Haematotoxic symptoms (due to vipers) are continuous bleeding from bite site, bleeding from gums or nose, appearance of bruises and dark urine.

Prevention of snake bite is by avoiding snake infested areas, staying out of tall grass, while hiking-keeping hands and feet out of areas one cannot see, wearing boots, keeping surroundings rubble free & dusting the beds before sleeping.

First aid involves reassurance, making the victim lie down with the affected limb lower than the heart. It is important to start artificial respiration and remove any rings, bracelets, boots etc.

Antivenom should only be given in a hospital after assessment of envenomation. It is not advisable to apply any tourniquet or compression bandage or give incision. The victim should not be given any alcoholic drinks or Aspirin nor should the bitten area be washed.

## Study Exercises

### MCQs & Exercises

- 1) The common poisonous snakes of India are (a) Cobra (b) Common Krait (c) Russell's vipers (d) All of these.
- 2) Which of these should not be done in case of snake bite (a) Victim should be made to lie down with affected limb lower than the heart. (b) Give incision (c) Start artificial respiration (d) Start antivenom

### Fill in the Blanks:

- 3) Snakes belong to the class \_\_\_\_\_
- 4) The most venomous of all land snakes, identified by paired white lines on the body is \_\_\_\_\_
- 5) The skin which covers the scales of snakes is periodically shed of & the process is called as \_\_\_\_\_

### True or false:

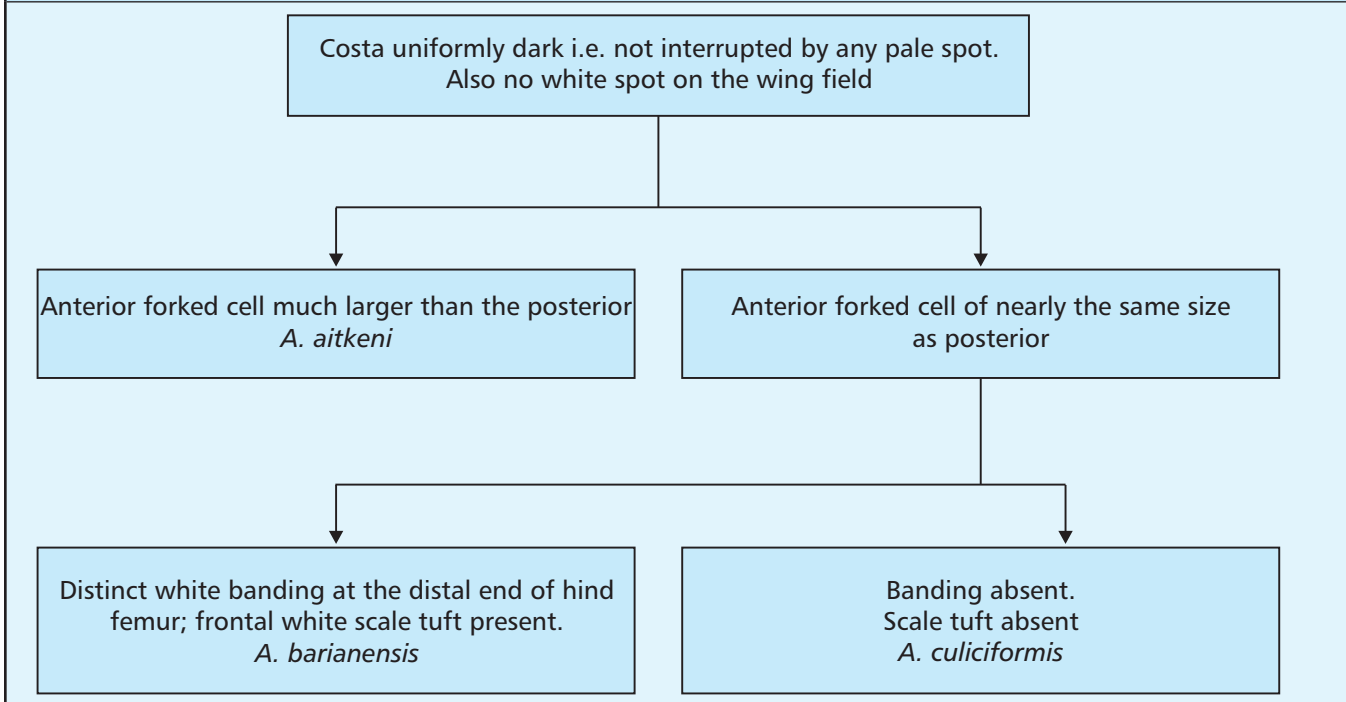
- 6) The body of the snakes which is in direct contact with the ground is not very sensitive to vibration.
- 7) Drooping eyelids, vision disturbances, difficulty in breathing, difficulty in speaking are symptoms seen in bite due to elapids.

**Answers:** (1) d; (2) b; (3) Reptilia; (4) Krait; (5) Moulting; (6) False; (7) True.

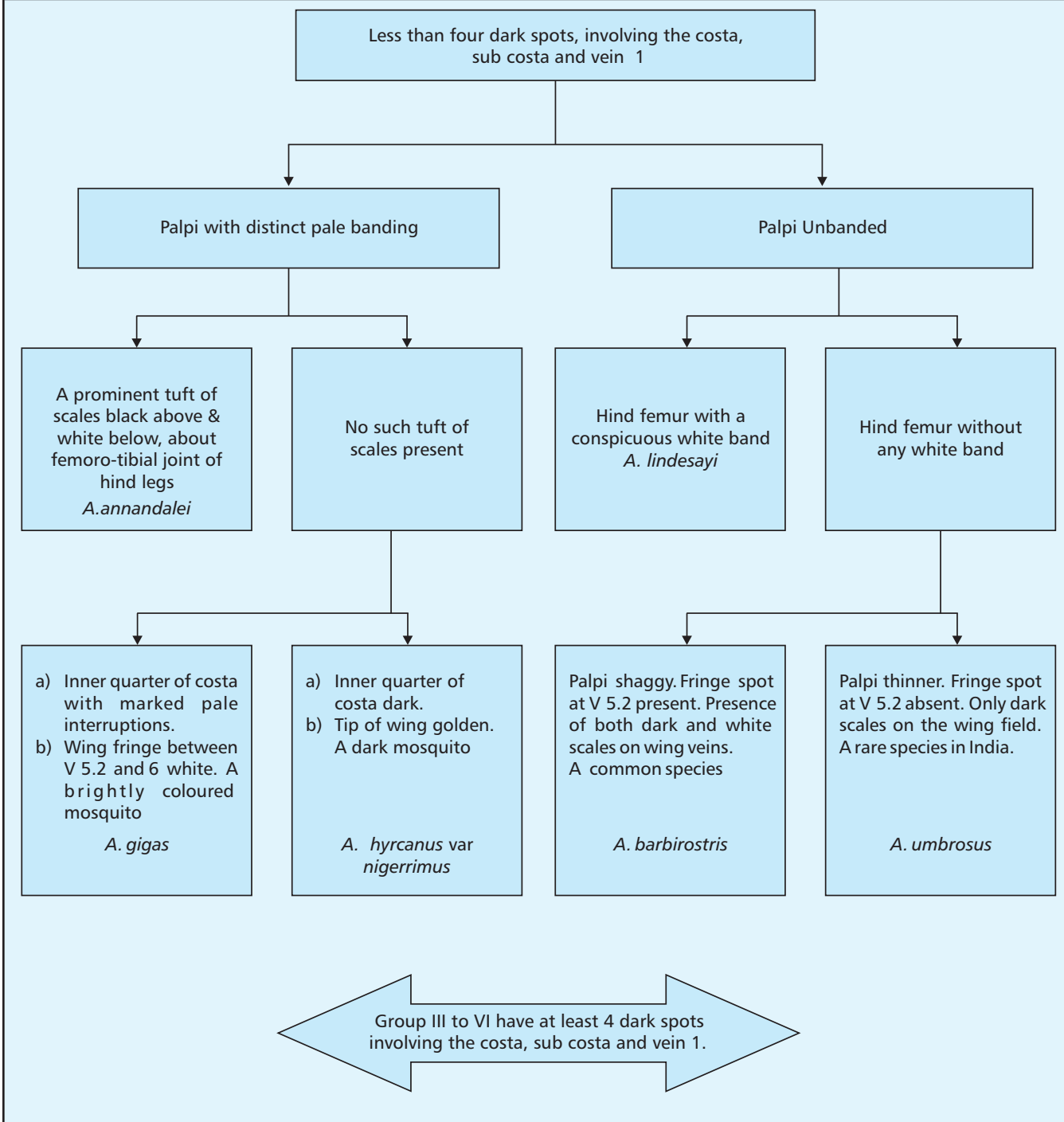
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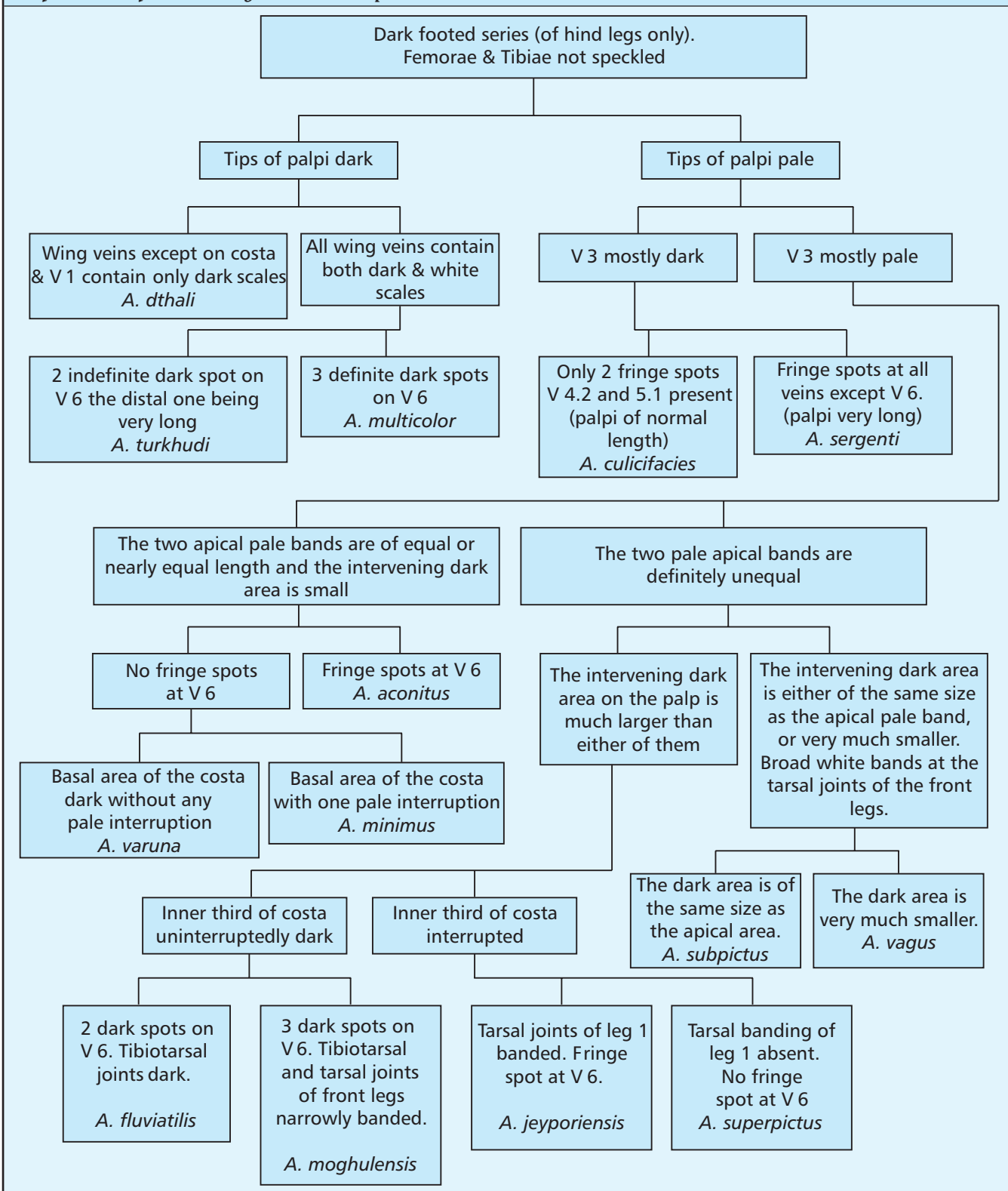
*Anopheles Mosquitoes Identification : Group - I*



**Anopheles Mosquitoes Identification : Group - II**

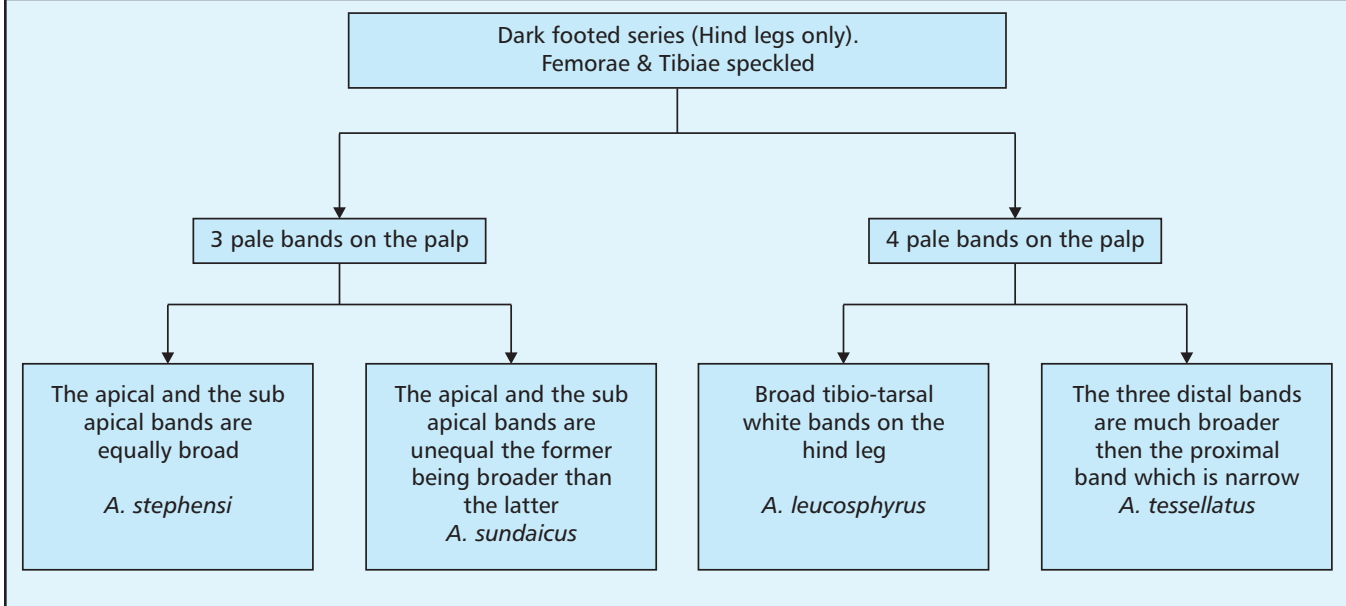


**Anopheles Mosquitoes Identification : Group - III**

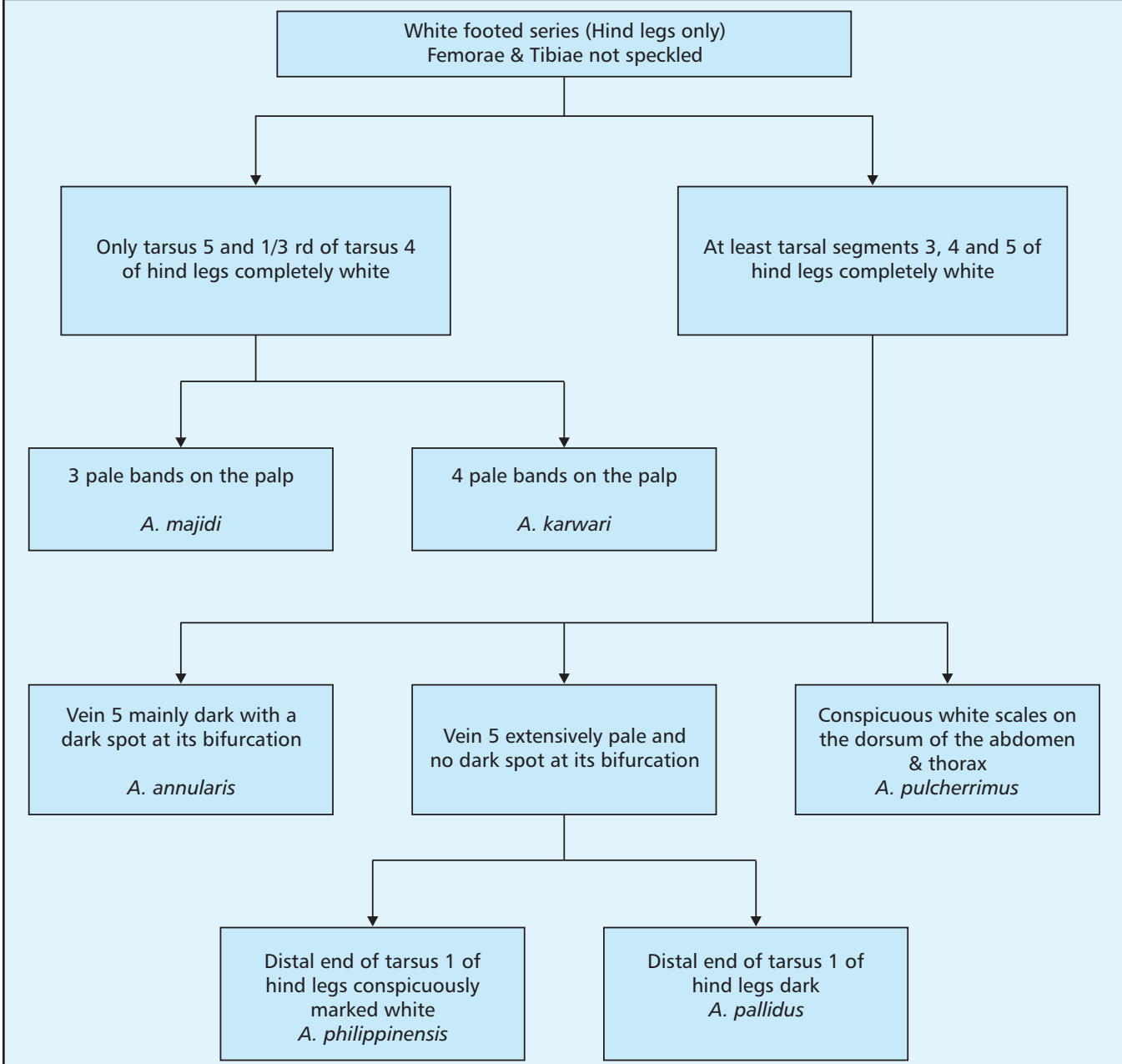




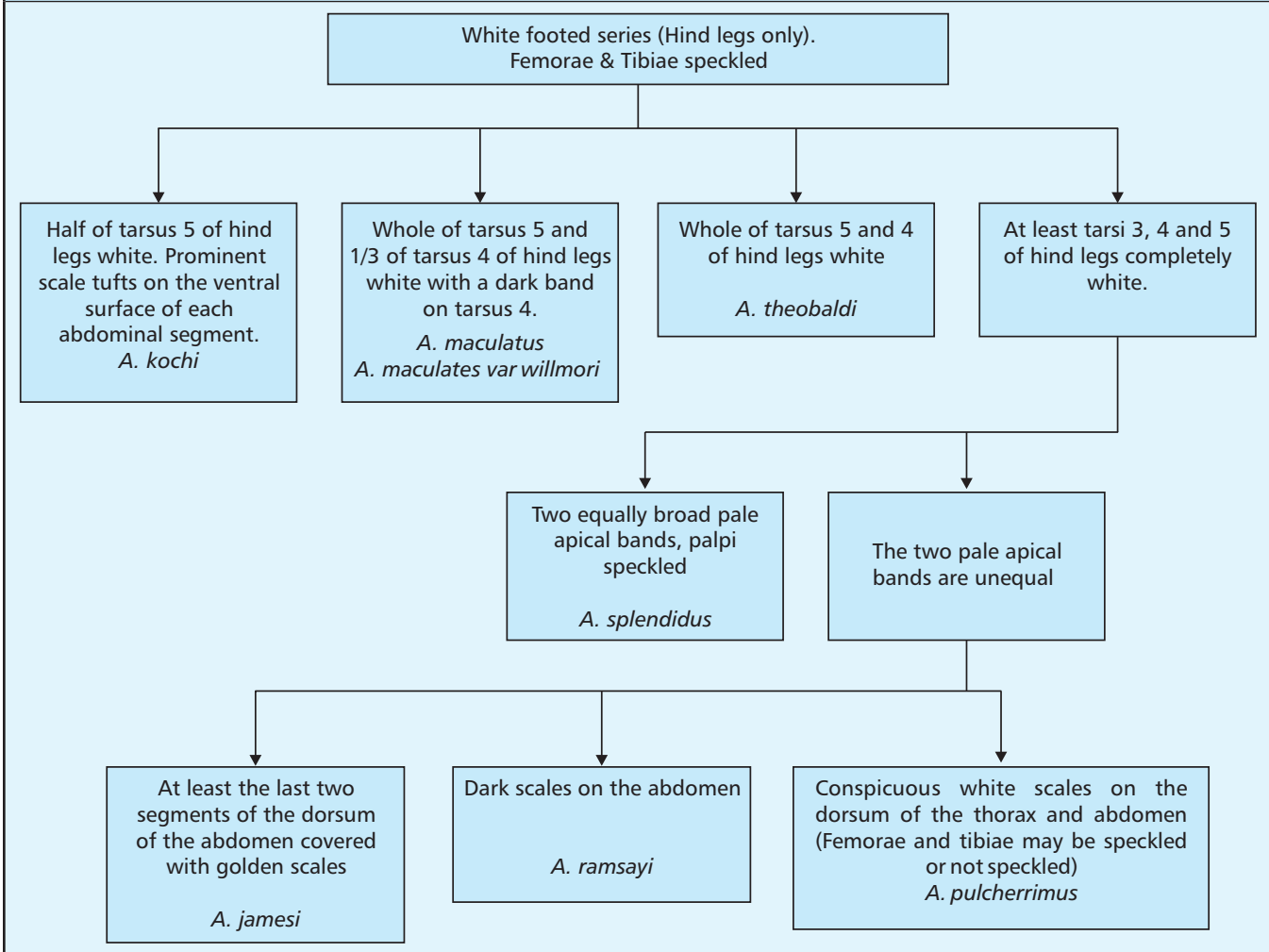
*Anopheles* Mosquitoes Identification : Group - IV



*Anopheles* Mosquitoes Identification : Group - V



*Anopheles* Mosquitoes Identification : Group - VI







## EXANTHEMATOUS FEVERS



Chickenpox rash



Herpes Zoster



Maculopapular rash in measles



Petechial rash in meningococcal meningitis



Chickenpox rash showing pleomorphism:  
papule, vesicle & crust



Petechial rash in meningococcal meningitis

(Photo courtesy: S Grover, M Chatterjee, Command Hospital, SC & AS Kushwaha - Dept of Community Medicine, AFMC, Pune)

## LEPROSY



Lepromatous Leprosy



A leprosy patch



Lepromatous Leprosy



Thickened supra-orbital nerve in leprosy



Thickened nerve in leprosy



Type 1 Reaction in Leprosy



ENL reaction

(Photo courtesy: RS Grewal, S Grover, & M Chatterjee - Command Hospital, Southern Command Pune)



## SEXUALLY TRANSMITTED DISEASES (STDs)



Syphilis



Secondary Syphilis



Gonococcal Urethritis



Secondary Syphilis



Herpes Zoster in a case of AIDS



Bubo in LGV



Extensive Genital Herpes in a case of AIDS

*(Photo courtesy: RS Grewal, S Grover, & M Chatterjee - Command Hospital, Southern Command Pune)*

## COMMON SKIN INFECTIONS & INFESTATIONS



Scabies



Interdigital Scabies



Tinea barbae



Tinea corporis



Pediculosis

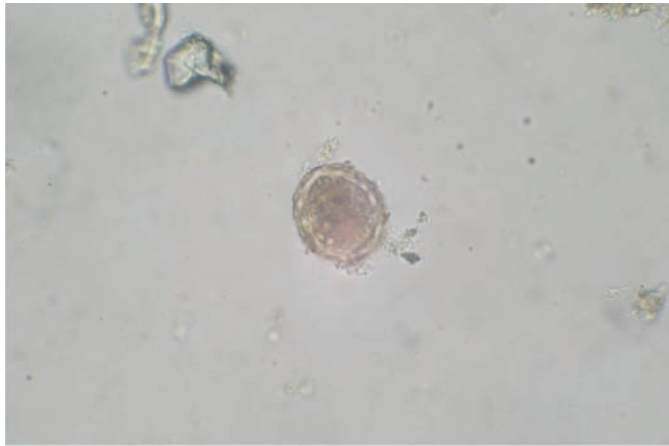


Herpes simplex:  
Vesicular lesions on nose & Keratoconjunctivitis

*(Photo courtesy: S Grover & M Chatterjee - Command Hospital, Southern Command Pune)*



## EGGS AND LARVA OF HELMINTHS IN STOOL



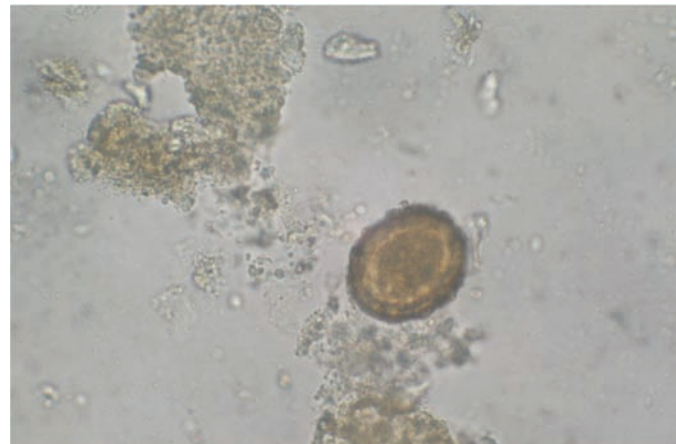
*Ascaris lumbricoides* ova (100X)



Egg of *Ancylostoma*



*Ascaris lumbricoides*:Unfertilised egg (100x)



*Ascaris lumbricoides*:Fertilised egg (100x)



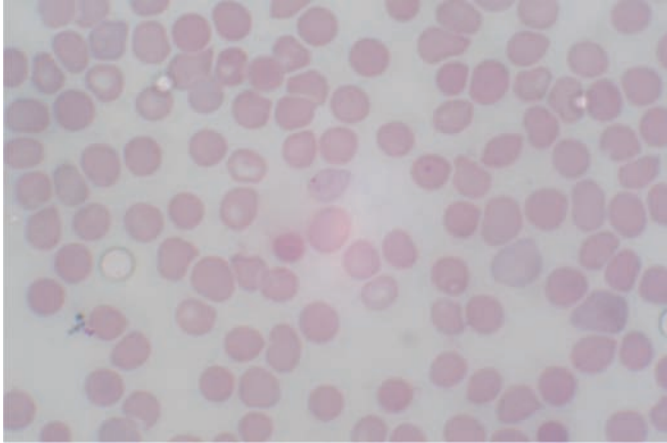
Egg of *Hymenolepis nana* (100x)



*Strongyloides stercoralis* larva (100x)

*(Photo courtesy: K Kapila & Nandita Hazra - Dept of Microbiology, AFMC, Pune)*

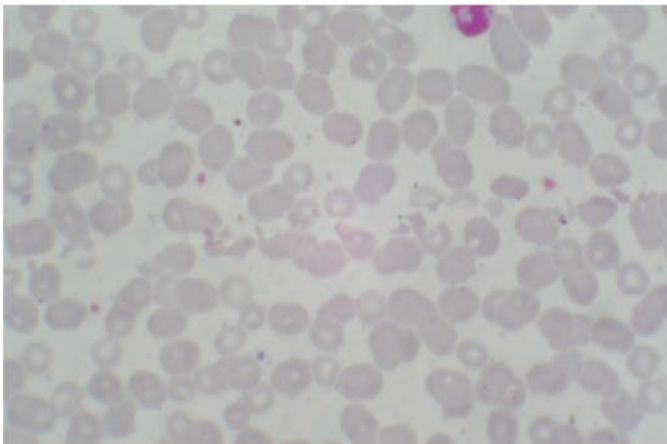
## MALARIAL PARASITES, LD BODY AND MICROFILARIA



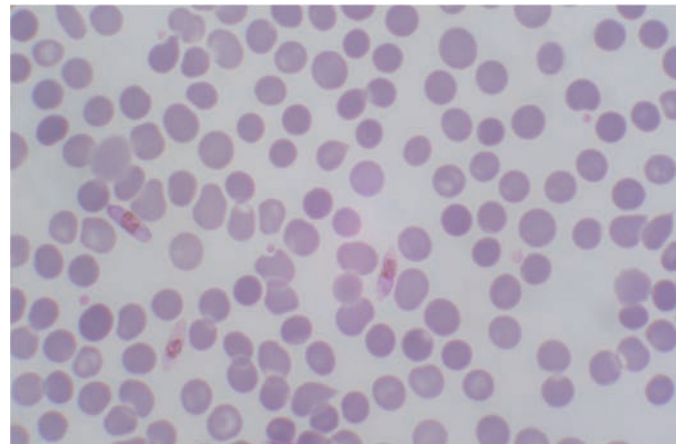
Plasmodium vivax: Ring form (100x)



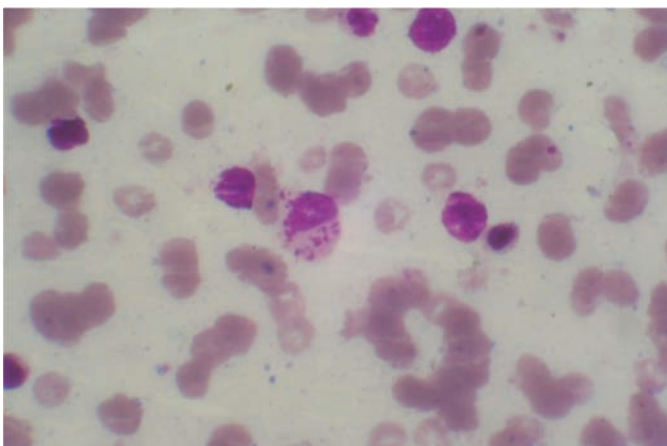
Plasmodium vivax: Immature schizont (100x)



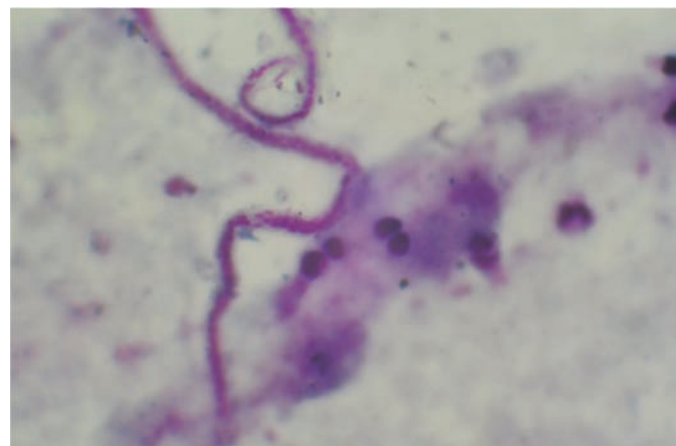
Plasmodium falciparum: Ring form (100x)



Plasmodium falciparum: Gametocytes (100x)



LD bodies in bone marrow (100x)



Microfilaria in buffy coat (100x)

(Photo courtesy: K Kapila & Nandita Hazra - Dept of Microbiology, AFMC, Pune)



## COMMON NUTRITIONAL DEFICIENCY DISORDERS



Marasmus



Kwashiorkor



Iodine Deficiency Disorder



Rickets



Rickets



Ricket rosary and Harrison's Sulcus



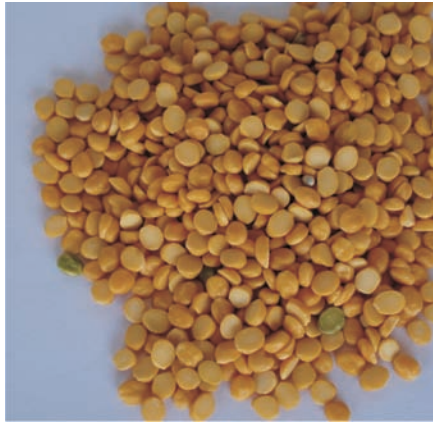
Rickets

(Photo courtesy: Madhuri Kanitkar & RK Gupta - Dept of Paediatrics, AFMC, Pune)



## COMMON PULSES, LEGUMES, CEREALS & MILLETS

### COMMON PULSES & LEGUMES



Bengal Gram *dal*  
*Channa Dal (Cicer arietinum)*



Bengal Gram (whole)  
*Chana (Cicer arietinum)*



Lentil (whole)  
*Masure Dal (Lens culinaris)*



Pea  
*Mutter (Pisum sativum)*



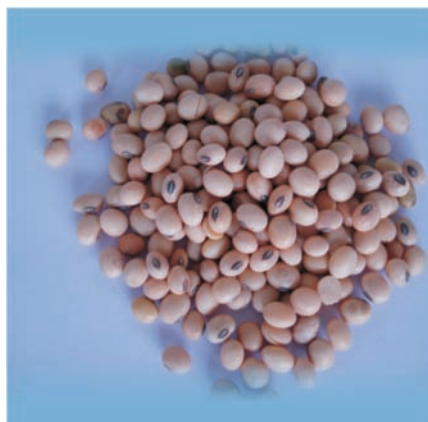
Green Gram whole  
*Moong Dal (Phaseolus aureus)*



Green gram  
*Moong Dal (Phaseolus aureus)*



Moth Bean  
*(Phaseolus aconitifolius)*



Soyabean  
*(Glycine max)*



*Rajmah*  
*(Phaseolus vulgaris)*

(Photo courtesy: Kumar Pushkar & Sumit Lathwal - Dept of Community Medicine, AFMC, Pune)



## COMMON PULSES, LEGUMES, CEREALS & MILLETS

### COMMON PULSES & LEGUMES (CONTD)



Black Gram  
*Udad Dal (Phaseolus mungo)*



Black Gram (whole)  
*Udad (Phaseolus mungo)*



Cow pea  
*Lobia (Vigna catjang)*

### COMMON CEREALS



Maize  
*Bhutta (Zea mays)*



Rice raw  
*Chawal (Oryza sativa)*



Wheat  
*Ghaun (Triticum aestivum)*

### COMMON MILLETS



Pearl millet  
*Bajra (Pennisetum typhoideum)*



Sorghum  
*Jowar (Sorghum vulgare)*



Finger millet  
*Ragi (Eleusine coracana)*

(Photo courtesy: Kumar Pushkar, Diva Reddy & Avinash Surana - Dept of Community Medicine, AFMC, Pune)



## DOTS: ANTI TB DRUGS

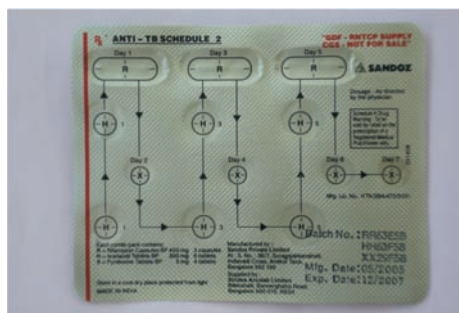


Anti TB Schedule 1

Anti-TB Schedule 1 containing two tabs of Pyrazinamide (Z) 750 mg, two tabs of Ethambutol (E) 60mg, two tabs of Isoniazid (H) 300mg & one cap of Rifampicin (R) 450 mg



Anti TB Schedule 1

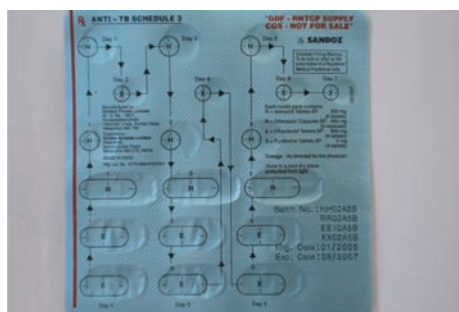


Anti TB Schedule 2

Anti-TB Schedule 2 containing 3 cap of Rifampicin(R) 450, 6 tabs of Isoniazid (H) 300mg & 4 tabs of pyridoxine 5mg



Anti TB Schedule 2



Anti TB Schedule 3

Anti TB Schedule 3 containing 6 tabs of Isoniazid 300 mg, 3 caps of Rifampicin (R) 450mg, 6 tabs of Ethambutol (E) 600mg & 4 tabs of Pyridoxin 5mg



Anti TB Schedule 3



Anti TB Schedule 4

ANTI-TB SCHEDULE 4 containing 2 tabs of Pyrazinamide (Z)750mg, 2 tabs of Isoniazid (H) 300mg & 1 cap of Rifampicin (R) 450mg



Anti TB Schedule 4

(Photos courtesy: Yaduveer Singh - Dept of Community Medicine, AFMC, Pune)

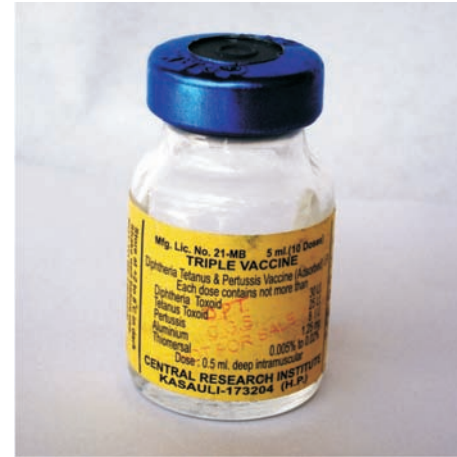
## VACCINES



BGC Vaccine



Oral Polio Vaccine



DPT Vaccine



Hepatitis B Vaccine



Measles Vaccine



MMR Vaccine



Typhoid Vaccine



Hib Vaccine



Ice Lined Refrigerator

(Photo courtesy: Yaduveer Singh - Dept of Community Medicine, AFMC, Pune)



## WATER TREATMENT PLANT



Screening



Aeration Chamber



Flocculation Chamber



Sedimentation Tank



Filtration Tanks



Filtration Tanks

*(Photo courtesy: Puja Dudeja)*



## SEWAGE TREATMENT PLANT



Screening



Grit Chamber



Primary Sedimentation Tank



Aeration Tank



Secondary Sedimentation Tank



Chlorination

*(Photos courtesy: Seema Sharma, Kumar Pushkar, Atul Puthia - Dept of Community Medicine, AFMC, Pune)*

## SPRAY EQUIPMENTS



ASPEE BOLO (Mist Blower)



Cold fogger



Flit Gun



Hand-held Thermal Fogger



Knapsack Sprayer.



Pneumatic Compression Sprayer

(Photo courtesy: Seema Sharma, Kumar Pushkar & Shabeena Tawar - Dept of Community Medicine, AFMC, Pune)

# 9

## Communicable Diseases





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RajVir Bhalwar

One way of broadly classifying human diseases is according to whether they are “infectious (communicable)” or else, “non - communicable”. Out of these two, infectious diseases account for lion's share of death, ill - health and suffering in the developing countries. For this reason an epidemiologist must have a sound understanding of the epidemiologic principles concerning infectious disease practice.

### General Terms and Definitions

**Infection & Infectious Disease** : This refers to the entry and development or multiplication of an infectious agent in the human (or, animal) body, with an implied response (e.g. immunological response) on the part of the human or animal. It must be remembered that “infection” by itself does not mean “infectious disease”. An infectious disease is that part of the spectrum of “infection” which is clinically apparent. In fact, this is the basic difference between epidemiologic practice and clinical practice as regards infectious disease - the clinician is mainly interested in “infectious disease” while the epidemiologist is interested in “infection” and its dynamics - including the subclinical cases, the carriers, the reservoirs or the infectious agent and its modes of transmission.

**Colonisation** : Colonisation indicates presence of infectious agent in the human body but without any evidence of specific host immune responses to the agent. In short, colonization means “infection less specific immune response”.

**Endogenous Infection** : Infection due to a colonizing agent; e.g. *E Coli* normally colonises the human GIT; however, under certain circumstances, it may enter the blood stream and cause endogenous infection.

**Contamination** : Refers to an infectious agent being present in inanimate articles like food, water, linen, patient care items or routine usage items like cutlery, toys etc. often, the term is also used to denote presence of infectious agent on skin surface, particularly on hands.

**Pollution** : Refers to presence of either infectious agent or such other disease causing noxious agents (as industrial effluents) or mechanical agents (as sound), usually in the general environment, air or water (e.g. sound pollution, water pollution, air pollution).

**Infestation** : Infestation may refer to human beings, animals or personal usage items, wherein it implies either the presence and development of insect vectors on the body or linen (e.g. louse infestation) or else on the mucus membranes (e.g. roundworm infestation). Infestation is also sometimes used for describing a state wherein an accommodation or such articles as containers have the presence of arthropods or vectors (e.g. cockroach or rat infestation in the houses).

**Communicable Disease** : A communicable disease is one that is caused by an infectious agent (or its toxic products, e.g. preformed toxins of *B cereus* or *C botulinum*) which can

be transmitted to a human being either directly, or indirectly (through food, water, insect vectors, soil), or else a disease which can be transmitted between humans and animals. All infectious diseases are not necessarily communicable; e.g. osteomyelitis or brain abscess are infectious diseases but not communicable. Similarly, an infectious disease may be communicable in one form (e.g. pneumonic plague) but not in the other form (e.g. bubonic plague).

**Dead-End Infection** : A state when an infectious disease, which is usually “communicable”, cannot be transmitted any further between human beings or from humans to animals or vice versa, for various agent, host and environmental reasons. Examples are Japanese Encephalitis, Rabies, Tetanus, Bubonic plague, Scrub typhus in humans.

**Subclinical Infection (Inapparent infection)** : It is a state when there is a host immune response following entry of the infectious agent; the agent may also multiply in the host body, but there are no clinical manifestations of the disease. Thus, the presence of infection cannot be recognized clinically though the infectious agent is constantly passed out of the human body and hence a person with subclinical infection is a greater health hazard for community than those having apparent disease (since the latter can be identified, treated and isolated if required). Diseases like Viral hepatitis A, have large number of subclinical infections; on the other hand, diseases like measles hardly have any subclinical infections. Thus, infections which have a large proportion of subclinical infections in their spectrum are less amenable to prevention; on the other hand, diseases which have very few or no subclinical infections are more amenable to prevention by surveillance methods.

**Latent Infection** : This refers to a state when the infectious agent lies “dormant” within the host body, without any clinical manifestations but does not come out of the human body (thus it is different from subclinical infection). After a period of time, under certain circumstances, the agent which had been lying dormant, reactivates and produces a different type of disease (e.g. Herpes Zoster; Brill - Zinsser disease) or else the same type of disease (e.g. reactivation Tuberculosis).

**Zoonoses** : Zoonoses are infections which are normally transmitted between vertebrate animals, either directly, or indirectly through a vehicle or insect vector. Those which are of health importance are the ones that are transmitted to man from vertebrate animals, either directly, or indirectly through vehicle or vectors. These are called “anthropozoonoses” and include a long list of infections like Rabies, Plague, Bovine TB, Salmonellosis, Japanese Encephalitis, Scrub and Murine typhus, Echinococcosis, Anthrax, Brucellosis and so on. The second group are infections which primarily infect man but can be transmitted to animals; these are called as zooanthroponoses. The third group is amphixenosis which includes infections that may be transmitted from man to animals and vice versa.

**Opportunistic Infections** : The term refers to disease, caused by infectious agents, which are normally not pathogenic, due to a decline in the general or specific immune status of the host. The term has assumed greater importance following identification of HIV infection whose clinical manifestations comprise of a wide variety of such opportunistic infections like *P carini*, *T gondi*, CMV etc.

**Nosocomial Infection** : This is an infection contracted while in hospital, as a result of health care or related procedure. Such infections would include those whose clinical presentation may start after discharge from the hospital but NOT those which were “incubating” in the patient’s body at the time of admission. The field of “Nosocomial Epidemiology” is fast becoming a specialized one. Hospital epidemiologists should ensure prevention and control of such hospital infections.

**Eradication** : The term refers to a complete cessation of transmission of the infectious agent. Usually this would imply that the infectious agent as well as the disease has also been completely reduced to zero. Small pox is the only example wherein eradication has been achieved.

**Control** : This refers to reducing the transmission of a disease to a level when it no longer remains a “public health problem”. Control is more pragmatic than eradication but needs ongoing preventive measures, and consequently continuing expenditure, along with an efficient surveillance system to give an early warning of increase in the level of transmission.

**Elimination** : Elimination implies either a ‘regional eradication’ (say from a country or continent), or else reduction of disease to zero without total removal of infectious agent.

### Epidemiologic “Chain” of Infection

There are 4 inter - related factors, which together are referred to as the “epidemiologic chain of infection” :

- The infectious agent and its characteristics.
- The human host who is susceptible to the infectious agent, and various factors which determine such susceptibility.
- Characteristics of the infectious process which are determined by the interactions between agent and the host.
- Inter - connecting the agent and host are the “channels (or modes) of transmission of the agent to the host. Let us discuss the details of each of these components of the chain of infection.

### Agent

There are three broad groups of characteristics that are important in respect of infectious disease agent viz. the reservoir and immediate sources of the agent; the characteristics of an agent that are connected with its survival in environment; and the characteristics of agent which determine the production of infection and consequent to infection, the production of disease.

**Reservoir and Immediate Source of Agent** : Any infectious agent has a primary habitat, called the “reservoir of infectious agent” which can be defined as “a person, animal, or inanimate environment (like soil), where an infectious agent lives, depending primarily for its survival, and where it propagates itself so that it can be transmitted to a human host”. On the other hand, a source of infection is the person, animal, or their excretions or inanimate environment from where the infective form of the agent is immediately available to the susceptible human host. Let us take the example of hookworm. The adult forms live in human gut, depending primarily on the human being for their survival; they multiply there and propagate themselves, the eggs being passed out for further transmission

to another human so as to further propagate the species. The worms do not depend primarily for survival and multiplication on any other animal, soil, plants, etc. Thus, the “reservoir of infection” is “human being, infected with Hookworm”, (human reservoir). On the other hand, infection of another human being occurs due to skin contact with soil contaminated with infective stage larvae. Thus, the “source” is “soil contaminated with infective stage larvae”.

**Types of “Reservoir of Infection”** : The most important “reservoir” for large majority of human infectious agents is the human being himself. The “human reservoir” of infectious agents can occur in two forms, viz. Cases and Carriers :

**a) Cases** : Those who have clinically apparent disease.

**b) Carriers** : A carrier is a human being who harbours an infectious agent and sheds it, thus becoming a potential source of infection for other human beings, but does not exhibit any manifestation of the disease. The fact that they cannot be detected despite being a potential source of infection for other makes carriers extremely important from epidemiological point of view. Depending on the stage of disease in its natural progression, a person may be a carrier either during the incubation period (incubatory carriers) as occurs in measles, mumps, Hepatitis A, etc. The importance of the incubatory carrier state lies in the fact that after the incubation period is over and the disease manifestations come up, we may isolate and treat the person, but the damage has already been done by him, by transmitting the infection during incubation period. Secondly, he may be having subclinical or clinically inapparent disease (contact or healthy carrier) e.g. Hepatitis A, Cholera, Poliomyelitis, Diphtheria etc. A subclinical carrier should be differentiated from a subclinical case, which refers to a person who has the infection beyond the incubation period but does not show clinical manifestations and *do not shed the organisms* so that the infection cannot be transmitted to other human hosts; e.g. subclinical case of Japanese Encephalitis in which the infectious agent is present in the body, but the low titer viraemia is inadequate to infect the mosquito vector. Thirdly, the person may continue to shed the infectious agent even after apparent recovery, during the convalescent stage, and hence known as convalescent carrier as occurs in cholera, typhoid and bacillary dysentery. Such “convalescent carriers” may be short term or temporary carriers (lasting upto 4 weeks or so) or chronic carriers (lasting beyond 4 weeks; may be upto years as in chronic typhoid infection of gall bladder) (103).

**Animals and Other Forms of Reservoir** : Besides human beings, animals form another reservoir wherein the infectious agent lives primarily, thrives, multiplies and is available for being transmitted to the human host. Such diseases fit in the scope of “zoonoses” as has been already described. Finally some infectious agents like fungi may primarily thrive and multiply in the contaminated soil.

**Characteristics of Agent Concerned with Survival in Nature**: The capability of an agent to thrive outside the reservoir and withstand adverse environmental effects like drying, heat, acidity, etc is known as “survival capacity in nature”. Some agents can hardly survive outside the human body (e.g. measles, chicken pox). Others may survive for limited time

provided conditions are favourable (e.g. cholera vibrio, polio virus, Hepatitis A, etc. can survive in water, ice, sewage, milk, etc; HIV can survive in blood and blood products; however all of them are quite vulnerable to drying, heat and disinfectants). Finally some organisms or their intermediate forms are quite sturdy and can withstand adverse environment very well (e.g. clostridal spores, cysts of intestinal protozoans, ova of helminthes etc). Usually, agents which have very poor survival in nature tend to adopt the direct modes of transmission like droplet infection or direct mucous contact. Survival in nature becomes all the more crucial for the agent, if human being is the only reservoir.

**Characteristics of Agent Involved in Production of Infection and Disease** : The various characteristics of an infectious agent which determine the production of infection, as well as the causation of disease are (104) :

**Infectiousness** : this is the relative ease with which the agent is transmitted to the host. Infectiousness is more of function of environmental factors; e.g. infectiousness of measles would be higher in overcrowded conditions but lesser in affluent communities.

**Infectivity** : This is the ability of the agent to cause infection, i.e. to enter, survive and multiply in the host. A useful epidemiologic measure of infectivity is *Secondary Attack Rate (SAR)*. It is defined as the number of susceptible persons who, within the duration of one incubation period, following exposure, develop the disease out of the total susceptibles who were exposed. SAR is usually measured by conducting studies in closed communities or families wherein the first case which brings in the infection is called the index case.

Thus,

$$SAR = \frac{\text{No. of susceptible exposed to index Case, who develop the disease, within the duration of maximum incubation period of the disease}}{\text{Total number of susceptibles exposed to the Index case}} \times 100$$

**Pathogenecity** : It is the ability of the agent to produce manifest disease out of those who have been infected. Generally, agents which have high pathogenecity have features which protect them from non - specific host defenses, and elaborate toxins or similar products (e.g. Diphtheria, Tetanus) or else, may cause such host immune response that leads to disease (e.g. Rheumatic fever, Glomerulonephritis).

**Virulence** : Higher in order, from infectivity and pathogenecity, is virulence. It is the ability of the agent to produce severe disease. If "serious" infection is being measured in terms of death, then Case Fatality Ratio (CFR) becomes a reasonably good measure of virulence.

**Infective Dose** : Infective dose is important for certain infectious disease agents like *V cholera* and *S typhi* in which, if the inoculum is not adequate, then infection may not settle, or at least, manifest disease may not occur. On the other hand, in infections like plague, even a very small dose may be enough to cause infection.

## Host Factors

Like the agent is on one end of the epidemiological chain of infection, the "HOST" is at the other end of the chain. The host factors which determine the dynamics of infection fall into two broad categories :

**(a) Host Attributes which Affect the Probability of Being Exposed to the Infectious Agent** : These include *age* (e.g. young children, because of hygienic innocence and habit of "orally exploring" the items, are more susceptible to exposure to soil transmitted helminthic infections); *Sex* (e.g. females, by virtue of leading a mainly indoor life may be less exposed to sylvatic zoonoses like Kyasanur Forest Disease), *Economic status* (poverty, squalor and infection form an almost invincible trinity and this needs no further highlighting), *Occupation* (e.g. agricultural workers and veterinarians are much more likely to be exposed to certain zoonoses), *Education* (by way of improving the knowledge regarding causation and prevention of infection, may help in reducing the chances of exposure), *Living conditions* (Poor housing, overcrowding, lack of sanitary eating and drinking facilities will all increase the chances of exposure), *Life style and behavioural factors* (e.g. permissive attitude toward sex will increase the probability of exposure to reservoir of STDs), and *use of Personal protective measures* (e.g. use of mosquito nets and repellents decrease the chances of exposure to mosquito borne diseases).

**(b) Host Factors that Influence Occurrence of Infection and Disease** : Once the host has been "exposed" to the infectious agent, certain factors will determine whether disease will actually occur and the severity of the same. These include "*status of host immunity*", whether actively or passively (or naturally or artificially) acquired; *Age* (In general, extremes of age viz. the very young, i.e. < 2 years and the old, > 65 years are more susceptible); *Genetic make up* (known to occur in respect of diseases like tuberculosis and malaria); and *Availability & utilization of health services* (by providing chemoprophylaxis, immunization and health education at the primary preventive level and early diagnosis and prompt treatment)

**Herd Immunity** : Herd immunity refers to the level of immunity that is present in a population against an infectious agent. It is, thus, concerned with the protection of a "population" from infection, the protection being brought about by the presence of immune individuals. It may be defined as "the resistance of a group to attack by a disease to which a large proportion of the members are immune, thus decreasing the probability that a person having the infectious agent will transmit it to another susceptible person in the same population". In general, while dealing with childhood infectious diseases amenable to prevention by immunization, vaccination coverage of about 85% is likely to provide adequate herd immunity, which will effectively block the disease transmission, even if remaining 15% children are not immunized (though there may be many exceptions to this generally held belief).

## Factors Affecting the Process of Infection as a Result of Interaction Between Agent and Host

There are certain features which are peculiar to each infectious disease as follows :

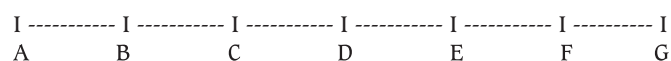


**Incubation Period** : Incubation period is the time period between the entry of infectious agent (or its toxin) into the human body to the point when the earliest clinical manifestations of the disease are apparent. During this period, the host does not exhibit any outwardly clinical manifestations, though immunological and histopathological changes within the body would definitely occur. If, during this period, the organism is also shed from the body of the host, the host qualifies to be an “incubatory carrier”. Incubation period is usually measured in terms of “median incubation period”, i.e. the time in which half of the infected subjects will develop clinical manifestations, following entry of the organism into the body. Along with the median incubation period, a “range” is also given which indicates the minimum and maximum incubation periods. Incubation period of a disease is found out by studying the time taken for onset of secondary cases following exposure to the index case, in family groups or in closed communities, or else during investigation of “common - vehicle, point source epidemics”. Different diseases have different values of median incubation period and range, and a specialist in Public health should remember them well.

**Latent Period** : In infectious disease epidemiology, latent period refers to the time that elapses between the entry of the agent in the human body to the point when the shedding of organism starts.

**Period of Communicability (Infectious Period)** : This is the duration for which the host sheds the agent, i.e. remains infectious. This may be very long in case of diseases like leprosy and HIV infection.

**Generation Time** : The generation time is the duration between the entry of infectious agent into the body to the peak infectivity of the host. As a crude calculation, generation time (G) is equal to (latent period + period of maximum communicability). The relationship between the various landmarks of a typical infectious disease is depicted as follows :



Landmarks : A = Entry of agent into host; B = Shedding of agent starts; C = Clinical manifestations start; D = Maximum infectivity of host; E = Clinical disease ends; F = Shedding of agent ends; G = Convalescence ends; A to B = Latent period; A to C = Incubation period; A to D = Generation time; C to E = Clinical phase; E to G = Convalescence phase; B to F = Period of communicability; B to C = Incubatory carrier phase; E to F = Convalescent carrier; E to G = convalescent phase; C to F = Subclinical (healthy) carrier phase (if clinical disease did not occur).

**Biological Gradient (Gradient of Infection)** : Biological gradient of a disease refers to the range of manifestations that may occur in the host as a result of infection. Thus, it is like a “spectrum”, ranging from inapparent infection at one end, and passing through mild illness, clinical disease, serious forms of disease, to death at the other extreme of the spectrum. Diseases like viral Hepatitis - A, poliomyelitis and cholera have a classically wide biological gradient with all varieties of severity as outlined above being present. On the other hand, measles and chicken pox tend to have only the middle part of the spectrum with either subclinical cases or deaths being uncommon. Diseases like rabies occupy only the other extreme of the spectrum, having a very serious biological gradient, with certain death being the only outcome.

**Frequency of Disease** : As has been repeatedly stressed in this chapter, the epidemiologist should not go simply by observed number of cases of a disease but convert it into some form of frequency measure (like incidence or prevalence) by relating the number of cases to a denominator (the population at risk). Depending on the “frequency” of the disease, the occurrence may be

- **“Epidemic”** : This is the occurrence of disease frequency, in a defined population or area, which is clearly in excess of the normal expectation.
- **“Endemic”** frequency refers to continued transmission of a disease, in a defined population or area, at a relatively low level (without any importation from an outside area or population). It would also be appreciated that the difference between an epidemic and an endemic situation is dependent on two factors - firstly, the high frequency and the “abrupt increase” which occurs in epidemic situation, compared to “continued transmission” in endemic settings. Depending on the “frequency” with which this continued transmission is going on in an endemic scenario, the endemicity could be described as “hypoendemic” or “low endemic”, (incidence being low), mesoendemic, hyperendemic, and holoendemic. In both hyperendemic as well as holoendemic situations, the transmission continues at a very high frequency; however in the latter situation, exposure to infection generally occurs during early childhood so that by the time adulthood is achieved, the population becomes immune and a high level of herd immunity occurs. For this reason, epidemic outbreaks of the disease are not likely in holoendemic situations (the classical example being “stable malaria” situations). The epidemiologist should note that half - hearted or unscientific measures (e.g. sudden introduction of insecticidal spray programs without full coverage and without concurrent coverage with surveillance for prompt diagnosis and treatment for a disease like Malaria) would tend to convert a “stable”, holoendemic situation into an “unstable” meso - endemic one, thus increasing the propensity to epidemic outbreaks.
- **“Sporadic”** frequency which refers to few, scattered cases of infection, which do not have any relation to each other temporally or spatially (i.e. according to place or time). The difference between a “low endemic” disease and sporadic disease is based on this fine dividing line - that in a low endemic disease, the frequency of disease is low but the cases would show a reasonable relation to each other according to place or time which will not be the case in sporadic situations.

### Channels of Transmission

The two end points in the epidemiological chain of infection are the infectious agent and the (susceptible) host. Now, to complete this link, the infectious agent must be transmitted to the susceptible host. Such establishment of the link between agent and host is of two types, viz “direct” and “indirect” modes of transmission.

**(a) Direct Modes of Transmission** : A direct mode of transmission is one in which the infectious agent has to be in a state of actual physical or physiological proximity with the susceptible host, or even if not in such proximity, should be



within a very close distance so as to be able to directly come in contact with the host. There are five methods of such direct transmission

- Contact of host skin or mucous membranes with the infectious agent contained in a living tissue; e.g. sexually transmitted diseases.
- Contact of skin or mucous membranes with the infectious form of the agent contained in inanimate environment. The examples include transmission of hookworm (infective form in soil) and leptospirosis (infective form in water or soil contaminated with urine).
- Inoculation of the agent, directly from the *reservoir* into the skin or mucous as in Rabies.
- "Vertical transmission" from mother to child, through the placenta, e.g. HIV, syphilis, "TORCH" agents etc.
- Direct transmission due to the agent being within a reasonably close distance of the host, as occurs in "*droplet infection*". Droplets are actually very finely dispersed aerosol containing the infectious agent, which are formed when a person harbouring the agent in his respiratory tract undertakes such activities like coughing, sneezing, talking etc. if another susceptible host is within a 'reasonably close' distance (usually taken to be 1 meter at the most), such infective droplets can be directly deposited on to the mucous membrane of oral cavity or respiratory passage (i.e. the relevant portal of the respiratory tract infections). TB, common cold, influenza, measles, mumps, pertussis, diphtheria, meningococcal infection, leprosy etc. are transmitted by such mode.

**(b) Indirect Modes of Transmission** : An indirect mode of transmission can be defined as one in which its infectious agent requires an "intermediary agency" to convey it from the source of infection to the susceptible host. Like for direct modes, there can be five types of indirect modes of transmission :

**Vehicle Borne** : The various types of "vehicles" which can convey the infectious agent, from the source of infection to the susceptible host include anything which is eaten (e.g. food, sweets, milk products, confectioneries and so on, or anything which is drunk (e.g. milk, ice, water, beverages etc). Infections of the gastrointestinal tract are classically transmitted by this mode and include such common examples as cholera, typhoid, hepatitis - A, ascariasis, amoebiasis and so on. A vehicle also would include anything which can be "injected" (e.g. blood and blood products, drugs, vaccines, diluents; examples are HIV, Hepatitis B, Malaria etc).

**"Fomites"** : These are defined as inanimate objects of general use by the infected person (e.g. utensils, linen, fountain pens, tooth brushes etc.) The infectious agent may remain on the surface of such fomites and may be transmitted to the susceptible host usually when such objects are put into the mouth or come in contact with conjunctiva.

**Fingers** : Fingers form a very important mode of indirect transmission. If Contaminated, they can transport a number of gastrointestinal infection (especially, shigella, *Salmonella typhi*, vibrio and Entamoeba).

**Air** : Often droplets containing the infectious agent may dry up, or may settle down on the dust. Now, if the agent can

survive environmental adversaries like drying or heat, it can be carried for long distances by air currents, alongwith the dust or droplet nuclei; and if deposited on the portal of entry of a susceptible host, can initiate infection. Important examples are legionnaires disease, 'Q' fever, tuberculosis, nosocomial infections. Air borne infected nuclei and dust should be differentiated from "droplet infection". As explained, the latter is a 'direct' method of transmission in which the agent is directly deposited from the immediate source of infection onto the portal of entry of a susceptible host, the intervening distance being very short (maximum 1 meter). On the other hand, in an air borne transmission the agent is not directly deposited from the source of infection on to the portal of entry of susceptible host but transported indirectly by air over long distances.

**Vector Borne Indirect Transmission** : A vector is a living invertebrate which transfers the infectious agent from the source of infection to another susceptible host. Usually the term encompasses arthropods, and to a smaller extent, molluscs like snails. Such transmission by a vector could be either "mechanical", in which the vector simply acts as a "fomite", transferring the infectious agent from the host on to another vehicle like food, by carrying the agent on its body surface or in the gut (finally excreting them in the faeces). The common example is of the housefly, which mechanically transmits a number of oro - faecal disease agents from the faeces to the food. Secondly, it could be a "biological" transmission, wherein the infectious agent is transmitted, not simply in a mechanical form, but undergoes, within the body of the vector, one or more of the biological changes pertaining to the stages in its life cycle. Such biological changes may occur in one of the following three ways :

- Take the example of plague bacillus. After being taken up by the rat flea following a blood meal on the rodent, the bacilli so taken up with the blood, multiply enormously, increasing in number, in the mouth parts of the rat flea. However, there is no developmental change as regards stages of life cycle of the bacillus. Such a method of biological transmission in which the agent "multiplies" but does not "develop" in the body of the vector before being finally transmitted to the susceptible host, is known as "*propagative*" mode.
- As another example, once a female culex mosquito takes in a microfilaria along with the blood meal, the microfilaria so taken up will undergo developmental changes of life cycle in the body of the mosquito (the three larval stages, finally becoming the infective stage larva). However, there is no multiplication and for each one microfilaria taken up with blood meal, there will be, finally, only one infective form larva. Thus, if the agent undergoes developmental changes in the body of the vector but no multiplication, the same is known as "developmental" or "*cyclo developmental*" method.
- Finally, let us consider the sequence of events that occur following ingestion of malarial male and female gametocytes along with blood meal by a mosquito. The gametocytes transform into gametes, form a zygote, followed by oocyst and sporozoites. Thus, there are developmental changes

pertaining to the life cycle of the agent. In addition, for one each of male and female gametocyte taken in by the mosquito, there will be formed, not one but thousands of sporozoites; thus, if in addition to developmental changes, there is multiplication, it is known as "*cyclo - propagative*".

## Summary

Infection/ Infectious disease refers to the entry and development or multiplication of an infectious agent in the human (or animal) body, with an implied response (e.g. immunological response) on the part of the human or animal. An infectious disease is that part of the spectrum of "infection" which is clinically apparent. Colonization indicates presence of infectious agent in the human body but without any evidence of specific host immune responses to the agent. Infection due to a colonizing agent is called endogenous infection. Contamination refers to an infectious agent being present on inanimate articles.

Pollution refers to presence of either infectious agent or such other disease causing noxious or mechanical agents, usually in the general environment, air or water. Infestation may refer to human beings, animals or personal usage items, wherein it implies either the presence and development of insect vectors on the body or linen or on the mucous membranes.

A communicable disease is one that is caused by an infectious agent or its toxic products which can be transmitted to a human being either directly, or indirectly. Dead-end infection is a state when an infectious disease, which is usually "communicable", cannot be transmitted any further between human beings or from humans to animals or vice versa, for various agent, host and environmental reasons. Subclinical infection is a state when the agent may also multiply in the host body, but there are no clinical manifestations of the disease; whereas Latent infection refers to a state when the infectious agent lies "dormant" within the host body, without any clinical manifestations but does not come out of the human body. Zoonoses are infections which are normally transmitted between vertebrate animals, either directly, or indirectly through a vehicle or insect vector. Opportunistic infection refers to disease, caused by infectious agents, which are normally not pathogenic, due to a decline in the general or specific immune status of the host.

Nosocomial infections are those contracted while in hospital, as a result of health care or related procedure. The term Eradication refers to a complete cessation of transmission of the infectious agent. Control refers to reducing the transmission of a disease to a level when it no longer remains a "public health problem". Elimination implies either a "regional eradication" or else reduction of disease to zero without total removal of infectious agent.

Four inter-related factors are together referred to as the "epidemiologic chain of infection" - these are : agent, host, interaction between agent and host; and modes of transmission. There are three broad groups of characteristics that are important in respect of infectious disease agent, viz. the reservoir and immediate sources of the agent; the characteristics of an agent that are connected with its survival in environment; and, the characteristics of agent which determine the production of infection and, consequent to infection, the production of disease.

The "human reservoir" of infectious agents can occur in two forms, viz. Cases and Carriers. Those who have clinically apparent disease are cases, whereas a carrier is a human being who harbours an infectious agent and sheds it, thus becoming a potential source of infection for other human beings, but does not exhibit any manifestation of the disease. Carriers are of various types - subclinical, incubatory and so on. Infectiousness is the relative ease with which the agent is transmitted to the host ; whereas Infectivity is the ability of the agent to cause infection, a useful measure being Secondary Attack Rate (SAR). Pathogenicity is the ability of the agent to produce manifest disease out of those who have been infected. Virulence is the ability of the agent to produce severe disease.

The host factors which determine the dynamics of infection fall into two broad categories - Host attributes which affect the probability of being exposed to the infectious agent (like age, sex, SES etc.) and host factors that influence occurrence of infection and disease ( like status of host immunity, genetic make - up etc.). Herd immunity refers to the level of immunity that is present in a population against an infectious agent.

Certain features which are peculiar to each infectious disease are as follows : *Incubation period* is the time period between the entry of infectious agent (or its toxin) into the human body to the point when the earliest clinical manifestations of the disease are apparent; whereas, *Latent period* refers to the time that elapses between the entry of the agent in the human body to the point when the shedding of organism starts.

*Infectious period* is the duration for which the host sheds the agent. *Generation time* is the duration between the entry of infectious agent into the body to the peak infectivity of the host. Depending on the "frequency" of the disease, the occurrence may be either *Epidemic*, which is the occurrence of disease frequency, in a defined population or area, which is clearly in excess of the normal expectation; or *Endemic* frequency refers to continued transmission of a disease, in a defined population or area, at a relatively low level (without any importation from an outside area or population). Depending on the "frequency" with which this continued transmission is going on, the endemicity could be described as *hypoendemic*, *mesoendemic*, *hyperendemic* and *holoendemic*. Sporadic frequency refers to few, scattered cases of infection, which do not have any relation to each other temporally or spatially.

There are two broad modes of disease transmission - direct and indirect; A direct mode of transmission is one in which the infectious agent has to be in a state of actual physical or physiological proximity with the susceptible host (for example, inoculation or vertical transmission), whereas an indirect mode of transmission can be defined as one in which its infectious agent requires an "intermediary agency" to convey it from the source of infection to the susceptible host (for example, vehicle or vector - borne). Vector - borne transmission may be of many types - cyclo - developmental, propagative or cyclo - propagative, depending on whether only development or multiplication or both (of the causative organism) occurs in the vector.

## Study Exercises

**Long Question :** Discuss, with suitable examples, the various modes of transmission of infectious diseases.

**Short Notes :** (1) Herd Immunity (2) Survival of infectious agent in nature (3) Nosocomial infections (4) Incubation period (5) Carriers.

### MCQs & Exercises

1. Presence of an infectious agent in an inanimate article or on skin surface, particularly hands, is called (a) pollution (b) contamination (c) infection (d) infestation
2. Which mode of transmission is followed in transmission of microfilaria through female culex mosquito (a) cyclo - propagative (b) propagative (c) cyclo - developmental (d) vehicle - borne
3. Malaria and Filariasis are mainly transmitted through vehicle - borne mode of transmission . Yes/ No
4. All of the following are examples of direct modes of transmission except (a) Fomites (b) inoculation into skin or mucus membranes (c) droplet infection (d) vertical transmission
5. Latent period + period of maximum communicability will give a crude estimate of the (a) lead time (b) lag time (c) generation time (d) incubation period
6. The level of immunity that is present in a population against an infectious agent is known as (a) innate immunity (b) acquired immunity (c) selective immunity (d) herd immunity
7. In calculation of secondary attack rate, exposure to which case is being taken into account (a) primary case (b) index case (c) secondary case (d) subclinical case
8. Case Fatality Ratio (CFR) is a reasonably good measure of (a) Pathogenicity (b) Infectivity (c) Virulence (d) Infectiousness
9. Epidemiologic chain of infection usually involves all of the following factors except (a) Disinfectants (b) Infectious agent (c) Human host (d) Modes of transmission
10. The presence and development of insect vectors on the body or linen e.g. louse is known as (a) Infection (b) Infestation (c) Infectiousness (d) Infectivity
11. A significantly large amount of subclinical infection occurs in all of the following diseases except (a) Hepatitis A (b) Hepatitis B (c) Rubella (d) Measles
12. All of the following diseases are examples of Anthroponoses except (a) *Trypanosoma cruzi* (b) Hydatid disease (c) Trichinosis (d) Plague.
13. All of the following organisms are quite sturdy and can withstand adverse environment very well, except (a) Clostridal spores (b) Cysts of intestinal protozoans (c) Ova of helminths (d) Hepatitis A virus
14. The time in which half of the infected subjects will develop clinical manifestations, following entry of the organism into the body, is known as (a) Lead time (b) Median Latent period (c) Median Incubation Period (d) Generation time
15. That subset of Endemic frequency, wherein exposure to infection generally occurs during early childhood so that by the time adulthood is achieved, the population becomes immune and a high level of herd immunity occurs, is known as (a) Hyper - endemic (b) Holo - endemic (c) Meso - endemic (d) Hypo - endemic

**Answers :** (1) b; (2) c; (3) No; (4) a; (5) c; (6) d; (7) b; (8) c; (9) a; (10) b; (11) d; (12) a; (13) d; (14) c; (15) b.

### History

The concept of immunity has intrigued mankind for thousands of years. According to the prehistoric views, disease was caused by supernatural forces and illness was a form of punishment for “bad deeds” or “evil thoughts” visited upon the soul by the Gods or by one’s enemies (1). The first written descriptions of the concept of immunity may have been made by the Athenian Thucydides who, in 430 BC, described that when the plague hit Athens “*the sick and the dying were tended by the pitying care of those who had recovered, because they knew the course of the disease and were themselves free from apprehensions. For no one was ever attacked a second time, or not with a*

*fatal result*” (3). The term “*immunes*”, is also found in the epic poem “Pharsalia” written around 60 B.C. by the poet Marcus Annaeus Lucanus to describe a North African tribe’s resistance to snake venom (2). The first clinical description of immunity which arose from a specific disease causing organism is probably *Kitab fi al-jadari wa-al-hasbah* (4) written by the Islamic physician Al-Razi in the 9th century. However, it was with Louis Pasteur’s Germ theory of disease that the fledgling science of immunology began to explain how bacteria caused disease, and how, following infection, the human body gained the ability to resist further insults (3).

Burnet and Medawar, Nobel Prize winners in 1960 put forth the concept that man had learnt to tolerate his own tissues (self) and was intolerant to foreign tissues (i.e. not self). The concept of ‘self’ and ‘not self’, therefore, means that under normal conditions the body tolerates its own tissues (immunological tolerance), and recognizes and destroys foreign tissues. In the



modern sense, therefore, immunity has been defined as the ability of the body to recognize, destroy and eliminate antigenic material foreign to its own (5, 6).

## The Immune System

The *immune system* is a collection of mechanisms within an organism that protects against infection by identifying and killing pathogens and tumour cells.

### Structure and Function of Immune System

Tissues and organs important for the immune function include:

- Cells derived from stem cells : liver, bone marrow
- Cells that are stored, multiply, interact and mature in : thymus, spleen, lymph nodes, blood
- Transport : lymphatic vessels
- Accessory organs
- Appendix, tonsils, intestines

The immune system protects organisms from infection with layered defenses of increasing specificity. Most simply, physical barriers prevent pathogens such as bacteria and viruses from entering the body. If a pathogen breaches these barriers, the innate immune system provides an immediate, but non-specific response. Innate immune systems are found in all plants and animals. However, if pathogens successfully evade the innate response, vertebrates possess a third layer of protection, the adaptive immune system. Here, the immune system adapts its response during an infection to improve its recognition of the pathogen. This improved response is then retained after the pathogen has been eliminated, in the form of an immunological memory, and allows the adaptive immune system to mount faster and stronger attacks each time this pathogen is encountered (7,8).

### Antigen

Antigen is defined as a substance which when introduced into the tissues stimulates the production of specific antibodies and combines specifically with the antibody so produced (3). By far the best antigens are proteins (e.g. diphtheria toxin, tetanus toxin); others are polysaccharides (e.g. blood group antigens), lipids and nucleic acids. There are also incomplete antigens called 'haptens' which by themselves are not antigenic but can provoke an immune response by combining with one of the body's proteins in such a way that the protein becomes 'foreign' to the body. Penicillin is an example of 'hapten'. On contact with an antigen the host can respond in three different ways :

- (a) Circulating antibody is formed.
- (b) A delayed-type cell mediated hypersensitivity reaction may result on second contact with the antigen.
- (c) Tolerance, which means that on second contact with the same antigen no response will be provoked.

The type of response in a particular case will depend largely on the antigen itself, the dosage, and the route of application and possibly on other lesser-known factors (9).

### Antibody

Antibody is a protein substance that appears in the body as a result of invasion of antigen. It is capable of reacting specifically

with the same antigen, which provokes its production. The sites of maximum antibody formation are the lymph nodes and spleen. Smaller collections of antibody producing cells are widely scattered in various tissues throughout the body. Plasma cells also produce antibodies. Antibodies may be antitoxic such as diphtheria and tetanus, antibacterial like typhoid or antiviral such as polio.

### Immunoglobulins

These comprise of families of closely related globulin molecules, which are synthesized by cells of reticulo-endothelial system (RES). The human immunoglobulin system is divided into five major classes IgG, IgA, IgM, IgD and IgE. The molecule of each immunoglobulin is understood to consist of K (Kappa) and L (Lambda) polypeptide chain (10).

**(a) IgG** : Repeated exposure to antigen leads to its accumulation in serum. It comprises about 80 per cent of serum antibodies in an adult. Antibodies to gram positive pyogenic bacteria, antiviral and antitoxic antibodies are found exclusively among IgG globulins. This is the immunoglobulin, which is transported across the placenta. Maternally derived IgG is slowly replaced by actively synthesized IgG which appears at 1-3 months of age and then rapidly rises and adult level is reached by the age of one or two years. Normal adult serum level of IgG is 600-1800 mg/100 ml.

**(b) IgA** : This fraction has been found to contain isohaemagglutinins, anti-brucella, anti-diphtheria antibodies and comprises about 10 per cent of the serum antibodies. Saliva, colostrum and tears are relatively rich in this fraction. Nasal and bronchial secretions, bile, intestinal juices and prostatic fluid also contain IgA. It seems to play a decisive role in local immunity. IgA synthesis begins two weeks after birth. Normal adult serum level is 70-380 mg/100 ml.

**(c) IgM** : This fraction is found to have high agglutinating and complement fixation ability. Wasserman antibodies and bactericidal antibodies against Gram negative organisms (endotoxins) are almost exclusively found in IgM. It accounts for 5 to 10 per cent of serum antibodies. It cannot pass through placenta. Normal adult serum level is 20-130 mg/100 ml.

**(d) IgD** : Not much is known about it. Normal adult serum level is 4-40 mg/100 ml.

**(e) IgE** : The antibodies in this fraction have the ability to fix themselves firmly to tissues and remain so. They are likely to play an important role in allergic reactions.

### Immunity

The word "immunity" derives from the latin *immunis*, meaning exemption from military service, tax payments or other public services and is defined as "Ability of an organism to recognize and defend itself against specific pathogens or antigens (11) (Box - 1).

#### Types of Immunity

The normal individual has two levels of defence against foreign agents. *Natural or innate immunity*, - which is present in neonatal animals and in invertebrates. Adaptive or acquired immunity - that is confined to vertebrates (Box - 2).

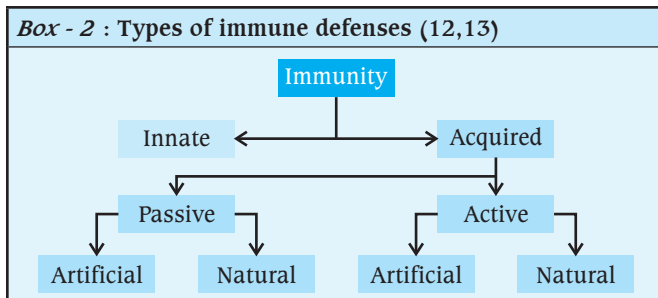


Box - 1		
Nonspecific Defense Mechanisms		Specific Defense Mechanisms (Immune System)
First line of defense	Second line of defense	Third line of defense
<ul style="list-style-type: none"> <li>• Skin</li> <li>• Mucous membranes</li> <li>• Secretions of skin and mucous membranes</li> </ul>	<ul style="list-style-type: none"> <li>• Phagocytic White blood cells</li> <li>• Antimicrobial proteins</li> <li>• The inflammatory response</li> </ul>	<ul style="list-style-type: none"> <li>• Lymphocytes</li> <li>• Antibodies</li> </ul>

**Acquired (Adaptive) immunity** : This develops only after exposure to inducing agents such as microbes, toxins, or other foreign substances.

#### Active Immunity

**Naturally acquired active immunity** : It occurs when a person is exposed to a live pathogen, and develops a primary immune response, which leads to immunological memory. This type of immunity is “natural” because it is not induced by man.



**Innate (natural) Immunity** : This is made up of several components.

- *Physical barriers* are the first line of defense against infection. The skin and mucous membranes provide a continuous surface which must be breached and back this up with mechanical protection through cilia and mucous.
- *Physiological factors* such as pH, temperature and oxygen tension limit microbial growth. The acid environment of the stomach combined with microbial competition from the commensal flora inhibits gut infection.
- *Protein secretions* into external body fluids such as lysozyme also help resist invasion. Soluble factors within the body such as complement, interferons and other molecules such as C-reactive protein are of considerable importance in protection against infection.
- *Phagocytic cells* are critical in the defense against bacterial and simple eukaryotic pathogens. Macrophages and Polymorphonuclear leucocytes (PMN) can recognise bacterial and yeast cell walls through broadly specific receptors (usually for carbohydrate structures) and this recognition is greatly enhanced by activated complement (opsonin) (7).

**Artificially acquired active immunity** : It can be induced by a vaccine, a substance that contains antigen. A vaccine stimulates a primary response against the antigen without causing symptoms of the disease.

**Passive Immunity** : Passive immunity is the transfer of active immunity, in the form of readymade antibodies, from one individual to another.

**Naturally acquired passive immunity** : Passive immunity can occur naturally, when maternal antibodies are transferred to the fetus through the placenta or through breast milk (14,15).

**Artificially acquired passive immunity** : This is a short-term immunization induced by the transfer of antibodies, which can be administered in several forms; as human or animal plasma or serum, as pooled human immunoglobulin (16).

**Active versus Passive Immunity** : Some differentiating points between active and passive immunity are given in Table - 1.

#### Host Defenses

There are two different types of host defenses that the body exhibits as a result of exposure to an antigen. These are :

- The humoral immune response involves the activation and clonal selection of B cells, resulting in the production of antibodies.
- The cell-mediated immune response involves the activation and clonal selection of cytotoxic T cells (17).

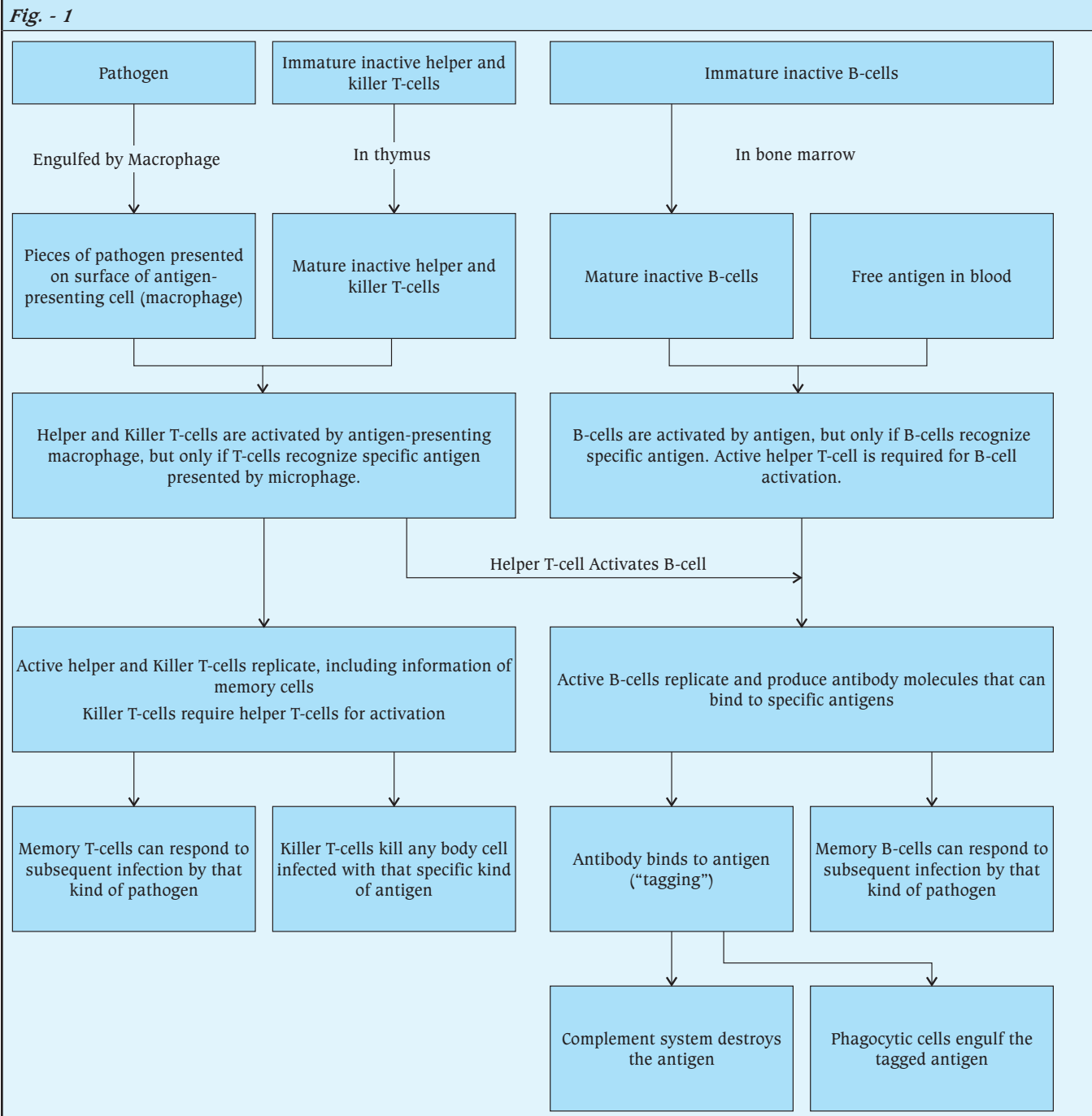
**Humoral Immunity** : An immunocompetent but as yet immature B-lymphocyte is stimulated to maturity when an antigen binds to its surface receptors and there is a T helper cell nearby (to release a cytokine). This sensitizes or primes the B cell and it undergoes clonal selection. Most of the family of clones becomes plasma cells. These cells, after an initial lag, produce highly specific antibodies at a rate of as many as 2000

Table-1: Comparison between Active & Passive Immunity	
Active Immunity	Passive Immunity
Usually produced in response to bacteria, viruses, toxins or toxoids.	Produced by serum containing already prepared antibodies
Body cells take an active part in the production of immunity.	Cells of body do not take part in the production of antibodies.
It takes sometime to develop the antibody in the system.	No time is lapsed to get the antibodies circulating in the system.
Immunity lasts long	Immunity lasts for a short period, usually 10-14 days.
Used for pre-pathogenic prophylaxis and treatment of sub-acute or chronic infections in order to increase	Used for treatment of acute infection and for tiding over the crisis or incubation period.

molecules per second for four to five days. The other B cells become long-lived memory. Humoral immunity is active when the organism generates its own antibodies and passive when antibodies are transferred between individuals. Similarly, cell mediated immunity is active when the organisms' own T-cells are stimulated and passive when T cells come from another organism (17, 18).

**Cell-mediated Immunity** : Macrophages engulf antigens and process them internally. This sensitizes the T cells to recognize these antigens. T cells are primed in the thymus, where they undergo two selection processes. The first positive selection

process weeds out only those T cells with the correct set of receptors that can recognize the MHC molecules responsible for self-recognition. Then a negative selection process begins whereby T cells that can recognize MHC molecules complexed with foreign peptides are allowed to pass out of the thymus. Cytotoxic or killer T cells (CD8+) do their work by releasing lymphotoxins, which cause cell lysis. Helper T cells (CD4+) serve as managers, directing the immune response. The process by which T cells and B cells interact with antigens is summarized in Fig. - 1.



**Local Immunity** : Local immunity is believed to be produced by fixation of various specific humoral antibodies in tissues, cells; or it may be nonspecific response of local tissues, induced by a local application of antigen, against a subsequent infection threatening systemic disease e.g. oral poliomyelitis vaccine (OPV) used for producing immunity against poliomyelitis.

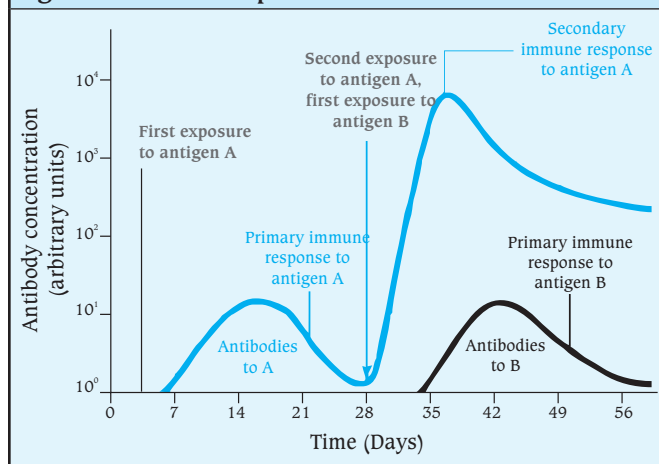
**Herd Immunity** : Herd Immunity is the immunity of a group of people or a community taken as a whole. In the epidemiology of infectious diseases, consideration of herd immunity is of greater importance than that of individual immunity. Epidemics disappear from a community long before 100 per cent of its members become immune, either naturally or artificially through mass immunization. Epidemiological immunity is usually established even when, say only 80 to 85 % people in the community become immune. The other 20 % people enjoy freedom from infection by virtue of their belonging to the 'herd'. Herd immunity can also develop through the process of natural selection by weeding out of the susceptible successive generations due to death from disease. The level of herd immunity at a given time depends on the herd structure which is constantly changing. (19).

### Types of Immune Response

The first encounter with an antigen is known as the *primary response*. Re-encounter with the same antigen causes a *secondary response* that is more rapid and powerful (20) (Fig. - 2). Immune response depends on

- Nature and dose of antigen
- Route of administration
- Type of adjuvants used
- Nutritional status of the recipient

**Fig. - 2 : Immune Response**



### Immunisation

Immunisation is the process by which an individual is exposed to an agent that is designed to fortify his or her immune system against that agent. The material is known as an *immunogen*. Immunization is the same as inoculation and vaccination in that inoculation and vaccination use a viable infecting agent like immunization does.

**History of Immunization** : While Dr. Edward Jenner (1749-1823) has been recognized as the first doctor to give sophisticated

immunization, it was British dairy farmer Benjamin Jestey who noticed that "milkmaids" did not become infected with smallpox, or displayed a milder form. Jestey took the pus from an infected cow's udder and inoculated his wife and children with cowpox, thereby making them immune to smallpox. By injecting a human with the cowpox virus (which was harmless to humans), Jenner swiftly found that the immunized human was then also immune to smallpox.

**Vaccines** : These are immunobiological substances designed to produce specific protection against diseases by stimulating production of protective antibody or other immune mechanisms. A number of agents can be used to provide protection against diseases. This protection can be active where antibodies are produced by our own body in response to vaccines or passive where antibodies are received in ready made form of immunoglobulins or non-human antisera (See Box - 3).

Box - 3 : Milestones in vaccination	
1798	Smallpox
1885	Rabies
1897	Plague
1923	Diphtheria
1926	Pertussis
1927	Tuberculosis (BCG)
1927	Tetanus
1935	Yellow Fever
After World War II	
1955	Injectable Polio Vaccine (IPV)
1962	Oral Polio Vaccine (OPV)
1964	Measles
1967	Mumps
1970	Rubella
1981	Hepatitis B

**Immune Response to Vaccination** : The vaccine mimics infection with the respective pathogen, but without risk of the disease. The consequent immune response may be manifested through antibody (humoral immunity) or cell mediated immunity (CMI), or both. Maternal CMI is not transferred to the foetus. Therefore BCG can be given at birth, OPV is given by mouth; it establishes local infection in a proportion of children. Maternal antibody in the infant's circulation is a very weak inhibitory factor; hence OPV also can be given at birth. Hepatitis B surface antigen is an excellent immunogen, overcoming, to a large extent, the inhibiting effect of maternal antibody; hence that too can be given at birth. On the other hand, live measles vaccine may be completely inhibited in the presence of detectable maternal antibody in the infant's circulation. Therefore measles vaccine is given after a delay of 9 months from birth and MMR only after 12 months (8).

The goal of all vaccines is to promote a primary immune reaction so that when the organism is again exposed to the antigen, a much stronger secondary immune response will

be elicited. Any subsequent immune response to an antigen is called a secondary response and it exhibits the following features :

- A shorter lag time
- More rapid buildup
- A higher overall level of response
- A more specific or better "fit" to the invading antigen
- Utilizes IgG instead of the large multipurpose antibody IgM

**Types of vaccines** : Traditionally, there are four types of vaccines (Table - 2).

- Live (attenuated)
- Inactivated (killed)
- Toxoids
- Subunit and recombinant

**Live Vaccines** : These are prepared from live attenuated organisms. They are very potent immunizing agents because :

- Live organisms multiply in the host
- All major and minor antigenic components are present
- Target organs may be colonized
- May replace wild strains in the community

**Drawbacks** : Safety is an issue because mutation may take place resulting in disease. Live vaccines can not be used for immuno-deficient patients as well as during pregnancy.

**Precautions** : Two live vaccines are usually not used together. They are to be given at different sites or three weeks apart. Besides, live vaccines have exacting storage requirements.

**Example** :

- Bacterial
  - BCG
  - Typhoid oral
- Viral
  - Measles, Mumps, Rubella
  - Oral Polio
  - Yellow fever, Influenza
- Rickettsial
  - Epidemic typhus

**Inactivated (Killed) Vaccines** : These are prepared from organisms killed by heat or chemicals. Killed vaccines are very safe but less efficacious than live vaccines. They require multiple doses which may be administered as a series of primary doses followed by regular booster doses. The only absolute contraindication is hypersensitivity.

**Example** :

- Bacterial
  - Typhoid, Pertussis, Cholera
- Viral
  - Rabies, Hepatitis B, Japanese encephalitis

**Toxoids** : These are produced from detoxicated toxins. The body produces antibodies against the toxin in response to toxoids. They offer no protection against infection. Toxoids are very safe and highly effective.

**Example** : Diphtheria, Tetanus

Table - 2 : Immunizing Agents	
Live attenuated Vaccines	
BCG	Bacterial
Typhoid, oral	
Plague	
Oral polio (Sabin)	Viral
Yellow fever	
Measles	
Rubella	
Mumps	
Influenza	
Chickenpox	Rickettsial
Epidemic Typhus	
Inactivated or Killed Vaccines	
Typhoid	Bacterial
Cholera	
Pertussis	
C.S. meningitis	
Plague	
Hepatitis A	Viral
Hepatitis B	
Rabies	
Salk (polio)	
Influenza	
Japanese Encephalitis	
KFD	
Toxoids	
Diphtheria	Bacterial
Tetanus	
Human Immunoglobulins	
Hepatitis A	Human normal Immuno-globulin
Measles	
Rabies	
Tetanus	
Mumps	
Hepatitis B	Human specific Immuno-globulin
Varicella	
Diphtheria	
Non Human (Antisera)	
Diphtheria	Bacterial
Tetanus	
Gas gangrene	
Botulism	
Rabies	Viral



**Passive Immunisation** : Passive immunization may be administered using human or animal products. Conventionally human products are called *immunoglobulins* and animal products are called *anti-sera*. Animal products are cheaper but suffer from the disadvantage of greater chances of immediate or delayed hypersensitivity.

**Human Immunoglobulins** : Non-specific or generalized protection is offered by normal immunoglobulins while protection against specific diseases is given by using hyper-immune immunoglobulins.

**Normal Immunoglobulins** : These provide non specific immediate ready made protection for upto three weeks. No live vaccine should be given for 12 weeks following administration of immunoglobulins. They should be administered at least two weeks after a live vaccine

*Example* : Measles, Hepatitis A

**Specific Hyperimmune Immunoglobulins** : These are made from plasma of recently recovered patients. They are to be given immediately after exposure. Peak blood levels are usually achieved in two days. They have a half life three to five weeks

*Example* : HBIG, VZIG, Rabies, Tetanus

**Animal anti-sera or anti-toxin** : Animal anti-sera are generally equine in origin. Their biggest draw back is that they may cause anaphylactic reactions or serum sickness.

*Examples* : Diphtheria, Tetanus, Rabies, Botulism, Gas gangrene, Snake Bite.

### National Immunization Schedule


Any immunization schedule is drawn up keeping two important factors in mind. Firstly the vaccines need to be administered in doses and schedules which produce an adequate immunological response in the recipient. Secondly the schedule should be administratively convenient and one which is likely to be most acceptable to the target population. The National Immunization Schedule drawn up for India factors in both these aspects (21) (Table - 3).

**Table - 3 : Schedule**


Infants	At Birth	BCG, OPV - 0 (Institutional delivery)
	6 weeks	BCG (If not given at birth) DPT - 1, OPV - 1
	10 Weeks	DPT - 2, OPV - 2
	14 Weeks	DPT - 3, OPV - 3
	09 months	Measles
Children	16 - 24 mths	DPT and OPV
	5 - 6 yrs	DT*
	10 yrs	TT*
	16 yrs	TT *
(If there is no clear evidence of previous immunization two doses one month apart to be given)		
Pregnant Women	Early pregnancy	TT - 1
	One month later	TT - 2
(In case of clear evidence of primary immunization or two doses during previous pregnancy, only single dose to be given)		

### Storage of Vaccines

**Sensitivity to heat** : All vaccines are sensitive to heat to some extent, but some are more sensitive than others. The commonly used EPI vaccines may be ranked according to their sensitivity to heat as given in Box - 4.

Box - 4 : Sensitivity to Heat	
Most Sensitive	
	OPV
	Measles
	DPT, Yellow Fever
	BCG
	Hib, DT
	Td, TT, Hepatitis B
(Note : However, that all freeze-dried vaccines become much more heat-sensitive after they have been reconstituted, and it is then even more important that they are not exposed to heat.)	

**Sensitivity to Cold** : Some vaccines are also sensitive to being too cold. For these vaccines, freezing or exposure to temperatures < 0°C can also cause loss of potency, and again, the vaccine will become useless. For these vaccines, it is therefore essential to protect them not only from heat, but also from freezing. The vaccines sensitive to freezing (as well as to heat) are as given in Box - 5.

Box - 5 : Sensitivity to Cold	
Most Sensitive	
	Hep B
	Hib (Liquid)
	DTP
	DT
	Td
	TT
Least Sensitive	

**Sensitivity to Light** : Some vaccines are also very sensitive to strong light, so they must always be protected against sunlight or fluorescent (neon) light. BCG, measles, MR, MMR and rubella vaccines are sensitive to light (as well as to heat). Normally, these vaccines are supplied in vials made from dark brown glass, which gives them some protection against light damage, but care must still be taken to keep them covered and protected from strong light at all times (22,23).

### Recommended Storage Temperatures

The recommended conditions for storing vaccines are shown in Table - 4. This table indicates the maximum times and temperatures in each case (24).

Each time some damage due to heat occurs, the loss of potency accumulates, and eventually, if the cold chain is not correctly

**Table - 4 : WHO recommended vaccine storage conditions**

	Primary	Intermediate		Health Centre	Health Post
		Region	District		
	6 months <sup>a</sup>	3 months	1 month	1 month	Daily use
OPV	-15°C to -25°C		+2°C to +8°C		
BCG	WHO no longer recommends that freeze-dried vaccines be stored at -20°C. Storing them at -20°C is not harmful but it is unnecessary. Instead, these vaccines should be kept in refrigeration and transported at +2°C to +8°C.				
Measles					
MMR					
MR					
Yellow Fever					
Hib freeze-dried					
HepB	+2°C to +8°C				
DTP-HepB					
Hib liquid					
DTP					
DT					
TT					
Td					
Diluent vials must NEVER be frozen. When the manufacturer supplies a freeze-dried vaccine packed together with its diluent, ALWAYS store the product at between +2°C and +8°C. Where space permits, diluents supplied separately from the vaccine may safely be stored in the cold chain at between +2°C to +8°C Note a : 6 months is the maximum recommended storage time at primary level. This includes the period required to obtain clearance from the National Regulatory Authority.					

maintained, all potency will be lost, and the vaccine becomes useless.

**Expiry Date** : Even when stored at the correct temperature, vaccines do not retain their potency forever, and therefore all vaccines have an expiry date (24).

**Diluents for Vaccines** : Diluents for vaccines are less sensitive to storage temperatures than the vaccines with which they are used, but may be kept in the cold chain between +2°C to +8°C if space permits. When vaccines are reconstituted, the diluent should be at same temperature as the vaccine, so sufficient diluent for daily needs should be kept in the cold chain at the point of vaccine use. However, diluent vials must never be frozen. This will risk cracking the glass and allowing contamination of the contents, so diluent vials must never be kept in a freezer, or allowed to be in contact with any frozen surface (25). Each vaccine requires a specific diluent and therefore, diluents are not interchangeable. Likewise, diluent made by one manufacturer for use with a certain vaccine cannot be used for reconstituting the same type of vaccine produced by another manufacturer.

### Cold Chain

Cold chain is a system of transporting and storing vaccines at recommended temperature from manufacturer to the point of use. All the vaccines can be stored at temperatures between +2°C to 8°C. However for long term storage, OPV and measles can be stored at sub zero temperatures in deep freezers. DPT, DT and TT should never be frozen. BCG and diluent ampoules should not be frozen. Diluents required for measles and BCG should be stored at +2°C to +8°C in the refrigerator.

Cold chain includes :

- Walk in cold rooms (WICs)
- Deep freezers
- Ice - lined refrigerators (ILRs)
- Refrigerators
- Cold box
- Vaccine carrier
- Day carrier
- Ice packs

**Walk In Cold Rooms** : These are used for the storage of large quantities of vaccines. They require constant electric supply. Vaccines can be stored up to 3 months. They serve a region of 4-5 districts.

**Deep Freezers and ILRs** : These are provided at the district and CHC level and can store up to 1 month supply of vaccines. Capacity is 300/240 L. They can be used for storing OPV and measles. Ice packs are also prepared.

**Small Deep Freezers and ILRs** : These are provided at the PHC and can store up to 1 month supply of vaccines. Capacity is 140L. They do not have a freezer compartment.

**Refrigerators** : While using a refrigerator for the purpose of keeping vaccines, certain Do's and Don'ts have to be followed as shown in the box.

**Vaccine Carriers** : Used for transporting small quantity of vaccines to sub center. These are made of insulating material. Each carries four ice packs. The vaccines should be used on the same day. They should be kept away from direct sunlight.

**Day Carriers** : These are made of insulating material and carry two ice packs. They can keep few vials for 6-8 hrs at a time.

<i>Using refrigerator to keep vaccines - Do's and Don'ts</i>	
<b>Do's</b>	
<ul style="list-style-type: none"> <li>• Keep in cool room away from sunlight</li> <li>• At least 10 cm away from the wall</li> <li>• Keep ice pack in freezer</li> <li>• Defrost periodically</li> <li>• Check temp. and maintain record</li> </ul>	
<b>Don't's</b>	
<ul style="list-style-type: none"> <li>• Open unless necessary</li> <li>• Keep vaccine in the door</li> <li>• Keep food inside</li> <li>• Keep more than one month's requirement</li> <li>• Keep expired vaccines</li> </ul>	

**Ice Packs :** These are flat plastic water bottles filled with water. They are available in three capacities : 400ml, 500ml and 600ml. They are prepared by keeping in freezer.

**Quality of Cold Chain :** The quality of the cold chain is monitored by the National Quality Control Lab located at Kasauli. The quality check is done before release of the vaccines. Reverse Cold Chain is also maintained to check vaccines for their potency.

**Vaccine stock management :** Vaccine stock management is done at three points :

- When vaccine consignments arrive at the storage point
- While vaccines and diluents remain in storage
- When vaccine & diluent stocks leave a storage point (26).

## UIP Vaccines

### BCG Vaccine

The BCG vaccine was first used to immunize humans in 1921. Following its introduction into the WHO Expanded Programme on Immunization in 1974, the vaccine soon reached global coverage rates exceeding 80% in countries endemic for TB. At present, about 100 million children receive BCG vaccine each year. Although the oldest of currently used vaccines, BCG is still controversial in that there are conflicting data on its protective efficacy. (27). A number of BCG vaccine strains are available, although the French Pasteur strain 1173 P2, the Danish strain 1331, the Glaxo strain 1077 and the Tokyo strain 172 account for about 90% of BCG vaccinations worldwide.

**Administration of the Vaccine :** WHO recommends intra-dermal application of the vaccine, preferably on the deltoid region of the arm using special syringe as early as possible after birth. Newborn vaccinees should receive half the dose given to older children. Within a few months of vaccination, the local reaction is replaced by a small scar. Presence of a typical scar is used as a marker of previous BCG vaccination but is not a marker of protection against TB.

**Vaccine Efficacy :** Vaccine efficacy ranges from 0 to 80 percent.

**Duration of Protection :** The duration of protection after neonatal BCG vaccination is not well known but commonly believed to decline gradually to non-significant levels after 10-20 years.

**Adverse Events :** Complications following BCG vaccination are rare : Significant local reactions, such as extensive local ulceration and regional lymphadenitis occur in <1 : 1000 persons (31).

### Indications and Contraindications as recommended by WHO

- For all infants living in areas where TB is highly endemic
- For infants and children at particular risk of TB exposure in otherwise low-endemic areas
- For persons exposed to multi-drug-resistant Mtb BCG vaccination is contraindicated
- For persons with impaired immunity (symptomatic HIV infection, known or suspected congenital immunodeficiency, leukaemia, lymphoma or generalized malignant disease);
- For patients under immunosuppressive treatment (corticosteroids, alkylating agents, anti-metabolites, radiation);
- In pregnancy.

**New vaccines against TB :** In recent years, there has been a dramatic increase in the number of candidate TB vaccines evaluated in research laboratories. Currently, the most favoured research strategies include recombinant modified BCG vaccines, attenuated strains of MTB, subunit vaccines and DNA vaccines.

<i>BCG Vaccine (Summary)</i>
<ul style="list-style-type: none"> <li>• Attenuated <i>M. tuberculosis var bovis</i> developed in 1921.</li> <li>• Protects against TB Meningitis, Miliary TB especially in Children</li> <li>• Maternal antibodies do not interfere with BCG vaccine as CMI is not transferred trans-placentally, hence should be given as early as possible after birth</li> <li>• Vaccine efficacy ranges from 0 to 80 percent. Neonatal immunization induces long term protection</li> <li>• Supplied freeze dried, store frozen or refrigerated</li> <li>• Use reconstituted BCG within 4-6 hours</li> <li>• Inject intra-dermally over left shoulder at the insertion of deltoid.</li> <li>• Local lesion due to bacterial multiplication; Heals leaving scars; If no scar, repeat BCG</li> </ul>

### Polio Vaccine

An effective IPV (Salk vaccine), comprising all three serotypes, was licensed after large-scale field trials in 1955. Starting in 1963, trivalent OPV (Sabin vaccine) replaced IPV as the primary means of prevention of poliomyelitis in most countries, because of the ease of administration, enhanced mucosal immunity providing a more effective barrier to transmission and community wide circulation of wild poliovirus, secondary spread of Sabin-derived vaccine virus from vaccinees to close contacts thus immunizing some unvaccinated contacts and lower cost (32).

**Oral Polio Vaccine :** The oral polio vaccine is a suspension of over 1 million particles of polioviruses type 1, 2 and 3 together. It is supplied with a stabilizing agent - magnesium chloride. The virus survives the acidity of the stomach and confers local immunity. However, for reasons not clearly understood,

the 'take' rate is relatively low in our children. For the above reason, multiple doses of OPV are necessary before 90 - 95% of children develop immune responses to all 3 poliovirus types. In addition to the "Routine OPV doses", "Pulse OPV doses every year on National Immunization days (NID's) till the age of 5 years are also mandatory. The risks due to OPV comprise cases of Vaccine-Associated Paralytic Poliomyelitis (VAPP), outbreaks of circulating vaccine-derived polioviruses (cVDPVs) and long-term carriers of VDPVs identified among immunodeficient persons (iVDPVs) (33).

**Eradication** is defined as no case of paralytic poliomyelitis by wild polio virus in last 3 calendar years along with absence of wild polio virus in the community, where excellent clinical and virological surveillance exists and the coverage of routine OPV is more than 80%.

**Polio elimination** is defined as zero case of paralytic poliomyelitis by the wild polio virus in one calendar year with other criteria same as in eradication.

**Pulse Polio Immunization** : On National Immunization Days (NIDs), pulse doses of oral polio vaccine has to be administered, simultaneously to all susceptible infants and children which would produce immunity to all.

**Injectable Killed Polio Vaccine (IPV)** : IPV is formaldehyde killed poliovirus grown in monkey kidney cell/human diploid cells containing 20, 8 & 32 D antigen against type 1, 2 and 3 poliovirus, respectively. It is highly immunogenic. Seroconversion is 90-95%, after 2 doses and 99% after 3 doses. It produces excellent humoral immunity as well as local pharyngeal and possible intestinal immunity. The vaccine is very safe. However, it is not available at present in the Indian market for routine use and is licensed only for use in immunocompromised children.

#### Oral Polio Vaccine (Summary)

- Live attenuated Poliovirus types 1, 2 and 3 developed by Sabin, 1961
- Temperature sensitive, store frozen or refrigerated
- Can be given simultaneously with any other vaccine
- Multiple doses necessary to ensure vaccine virus take and antibody response to all 3 types of polioviruses
- First dose is recommended in the newborn period or as early as possible
- IAP recommends additional doses of OPV as a part of Pulse Polio programme every year till the age of 5 yrs.

#### Injectable (Killed) Oral Polio Vaccine (Summary)

- Formaldehyde Killed Polio Virus grown in monkey kidney or human diploid cell
- Contains 20, 8 and 32 D antigen units against type 1, 2 and 3 Polio Viruses respectively
- Seroconversion 90-95% after 2 doses and 99% after 3 doses
- Thermostable and is indicated in immunocompromised individuals, HIV infection and disease.

### DPT Vaccine

Diphtheria is a potentially acute disease caused by exotoxin producing *Corynebacterium diphtheriae*. The combination

of diphtheria toxoid, whole cell killed pertussis vaccine and tetanus toxoid is popularly known as the triple antigen. While the two toxoids are highly immunogenic and antibodies to them are almost completely protective, the pertussis vaccine, given in 3 doses, has a protective efficacy of about 70-80% only.

**Administration of the vaccine** : DPT must be injected IM. The preferred site is the antero-lateral aspect of the thigh. Immunization should begin by six weeks of life and completed before the ninth month at the latest, although it can be given at any period before 5 years of age. Initially three doses at monthly intervals are injected intramuscularly. Booster doses are given during the second year and just before the child starts going to school (34).

**Adverse events and Contraindications** : Local pain, redness and fever after DPT are almost entirely due to the pertussis component. Convulsions following DPT vaccine are rare, and when occur they may be the earliest signs of some incipient neurological disease in the infant. For these reasons, progressive neurological diseases are the only contraindication to first dose of DPT immunization (35-39).

#### DPT Vaccine (Summary)

- Diphtheria toxoid (Ramon & Glenny, 1923)
- Killed *Bordetella pertussis* (Madsen, 1923)
- Tetanus toxoid (Ramon & Zoeller, 1927)
- Toxoids adjuvanted (Aluminium hydroxide/phosphate)
- DPT vaccine supplied as liquid, store refrigerated
- Aluminium adjuvanted vaccines should not be frozen
- Inject intramuscularly, antero-lateral thigh
- Alert parents about local reaction and fever; Paracetamol to be given to reduce pain/fever
- Progressive neurological disease or serious adverse reaction to earlier dose are contraindications for DPT; replace with DT Vaccine

### Tetanus Toxoid

Indian Academy of Paediatrics recommends TT at 10 and 16 years. After completing the full course of 7 doses, there is no need for additional doses during pregnancy, at least for the next 10 years. Thereafter a single booster would be sufficient to extend immunity for another 10 years. For pregnant women who have not had previous immunization, at least 2 doses should be given during pregnancy so that protective antibody would be transferred to the infant in order to prevent neonatal tetanus. Td is the preferred preparation for active tetanus immunization in wound management of patients greater than or equal to 7 years of age.

### Tetanus Immunoglobulin (TIG)

It is a liquid or freeze-dried preparation containing immunoglobulins, mainly IgG obtained from plasma or serum containing specific antibodies against the toxin of *Clostridium tetani*.

**Adverse Effects** : Local pain, fever, flushing, headache and chills may occur.

**Indications** : Subjects already sensitized with serums of animal origin, existence of prior or present allergic manifestations



(asthma, eczema etc.), burns, injuries, open and compound fractures, unimmunised or inadequately immunised mothers.

**Dosage** : Prophylaxis 250 - 500 I.U. IM. Therapeutic : Tetanus neonatorum 500 - 1000 I.U. intramuscular or 250 I.U. intrathecal. In adults and children : 500 - 1000 I.U. IM and / or 250 - 500 I.U. intrathecally.

### Measles Vaccine

Measles vaccine consists of live attenuated Measles virus, developed by Enders, in 1960. The original virus strain was isolated from a child by the name Edmonston; therefore the virus strain was also named Edmonston. In liquid suspension the vaccine virus is very heat-labile; in the freeze-dried state the shelf life of the vaccine is one to two years. The vaccine may be stored frozen or refrigerated. But, after reconstitution, the vaccine should be injected within 4-6 hours. During such interval the liquid vaccine should be kept cold, either in the refrigerator or vaccine carrier.

**Administration of the vaccine** : The vaccine should be injected subcutaneously. The preferred site is right upper arm. It can also be injected over the antero-lateral thigh, but SC. The vaccine induces both humoral and cellular immune responses comparable to those following natural infection.

**Vaccination schedule and vaccine efficacy** : The optimum age for measles vaccination depends on the local epidemiological situation and on programmatic considerations. Given the immaturity of the immune system as well as the presence of neutralizing maternal antibodies, vaccination of infants before or at 6 months of age may often fail to induce immunity. In most developing countries, children are vaccinated against measles at 9 months of age, when seroconversion rates of 80-85% may be expected. A single dose of live, attenuated measles vaccine is generally felt to provide lifelong protection (40,41).

**Adverse Reactions** : Adverse reactions following measles vaccination, alone or in fixed combinations, are generally mild and transient. Slight pain and tenderness at the site of injection may occur within 24 hours, sometimes followed by mild fever and local lymphadenopathy. Thrombocytopenia purpura occurs in approximately 1 in 30,000 vaccinated individuals.

#### Measles Vaccine (Summary)

- Live attenuated Measles virus vaccine developed by Enders, 1960
- Vaccine further attenuated (e.g. Schwarz, Edmonston-Zagreb)
- MV supplied freeze dried, Store frozen or refrigerated
- Use reconstituted vaccine within 4-6 hours (Refrigerate, do not freeze)
- Inject SC, preferably right upper arm
- Recommended age 9 months (270 days) plus
- During Measles outbreak, may be given at 6 months Plus
- If given at < 9 months, repeat dose after interval of at least 3 months
- Alert parents of fever 5-10 days later; Paracetamol may be given

## Non UIP Vaccines

### Mumps Vaccine

Mumps can be prevented by vaccination given either as a monovalent vaccine or as part of MMR vaccine. A live attenuated monovalent mumps vaccine was first developed by Hilleman in 1966. The mumps component in MMR vaccine contains live attenuated mumps virus. Mumps vaccines are recommended for use in a 1-dose schedule, given at age 12-18 months (42)

**Adverse Reactions** : In general, adverse reactions to mumps vaccination are rare and mild. The most common adverse reactions following mumps vaccination are parotitis and low-grade fever.

### Rubella Vaccine

A live attenuated Rubella vaccine was developed by Waller in 1962. The current rubella vaccine available commercially is derived from RA 27/3 vaccine strain grown in human diploid cell cultures. It is available either as a monovalent vaccine or as a part of combination vaccine - MMR. It contains live attenuated virus not less than 1000 TCID<sub>50</sub>. It is a highly immunogenic vaccine with positive antibody response in 95% of susceptible vaccinees. It provides long term and probably life long protection (43, 44, 45,46).

The primary purpose of rubella vaccination is to prevent the occurrence of congenital rubella infection including CRS. Two approaches are recommended by WHO :

- (a) Prevention of CRS only, through immunization of adolescent girls and/or women of childbearing age
- (b) Elimination of rubella as well as CRS through universal vaccination of infants and young children (with/ without mass campaigns), surveillance, and assuring immunity in women of childbearing age.

### MMR Vaccine

MMR Vaccine is available as single as well as multidose (5 dose) vial. The diluent for injection is available separately. The dose of the reconstituted vaccine is 0.5 ml per dose, to be administered subcutaneously in the upper arm. The vaccine should be stored between +2 to +8°C in the ordinary compartment of the fridge. Reconstituted vaccine should be used within 6 hours.

IAP recommends a dose of MMR vaccine to all children. For infants given measles vaccine at 9 months, MMR vaccine may be given between 12-15 months of age. If measles vaccine is given later, a 3 months gap is advisable. If measles vaccine was missed altogether, one MMR dose should be given at or after 12 months. The vaccine can be given along with any other vaccine like DPT, OPV but at different sites using different syringes and needles (47).

### Hepatitis B Vaccine

The main objective of hepatitis B immunization strategies is to prevent chronic hepatitis B virus (HBV) infection and its serious consequences, including liver cirrhosis and hepatocellular cancer (HCC) (49). Younger the age at infection, higher the chance of becoming chronically infected as carrier. The World Health Organization recommends universal Hepatitis B vaccination.

### Administration of the Vaccine

Two types of hepatitis B vaccines are available - plasma derived vaccines and recombinant vaccines. The two vaccines show no differences in terms of reactogenicity, efficacy or duration of protection. The complete vaccine series induces protective antibody levels in >95% of infants, children and young adults. Hepatitis B vaccine should be given IM at antero-lateral thigh in infants. In older children/adults it should be administered at deltoid region. The minimum recommended interval between the doses is four weeks. Longer dose intervals may increase the final anti-HBs titres but not the seroconversion rates (49). As an adjuvanted vaccine, it should not be frozen. If frozen accidentally, the vaccine should be discarded.

Using the principles described, the IAP recommends the commencement of HB immunization at birth. Two alternate schedules are available :

#### a) Infants

1. Birth, 6 and 14 weeks
2. 6, 10 and 14 weeks. (Combined DTPw/Hepatitis B vaccine can be preferred)

b) *For older children, adolescents and adults* : The recommended schedule is elected date, 1 month and 6 months. Booster dose is not recommended as of date.

**Adverse Events** : In placebo-controlled studies, with the exception of local pain, reported events such as myalgia and transient fever have not been more frequent than in the placebo group. Reports of severe anaphylactic reactions are also very rare.

**Contraindications and Precautions** : Hepatitis B vaccination is contraindicated for persons with a history of hypersensitivity to yeast or to any vaccine component. Pregnancy is not a contraindication to vaccination. Limited data indicate no apparent risk for adverse events to developing fetuses when hepatitis B vaccine is administered to pregnant women (50).

**Passive immunization against hepatitis B** : Temporary immunity may be obtained using hepatitis B immune globulin (HBIG) for post-exposure prophylaxis. HBIG prophylaxis may be indicated :

- (i) For newborn infants whose mothers are HBsAg-positive.
- (ii) Following percutaneous or mucous membrane exposure to HBsAg-positive blood or body fluids.
- (iii) Following sexual exposure to an HBsAg-positive person.
- (iv) To protect patients from recurrent HBV infection following liver transplantation.

HBIG does not interfere with generation of antibody response to hepatitis B vaccine. As a rule, HBIG should be used as an adjunct to hepatitis B vaccine. However, in full-term newborns, the protection against perinatally acquired infection achieved by immediate (<24 hours) hepatitis B vaccination is not significantly improved by the addition of HBIG.

**Dosage** : Following exposure to HBsAg.

**Adults** : 1000 - 2000 I.U., IM.

**Children** : 32-48 I.U./kg body wt. This should be administered within 7 days (preferably within 48 hrs) after exposure to HBsAg.

**Neonates** : Initial dose is 100 - 200 I.U. The first dose should be administered within 5 days after birth. The booster dose should be 32 - 48 I.U./kg of body wt., between 2 & 3 months after initial dose.

#### Hepatitis B Vaccine (Summary)

- Safe, immunogenic, effective HB vaccine available since 1982
- Highly purified preparation of HBsAg
- HBsAg is a glycoprotein that makes up outer envelope of HBV
- Two types of vaccine : Plasma derived and Recombinant DNA
- To be shipped and stored at 2° C - 8° C
- IM Injection at deltoid in adults, adolescents and children and antero-lateral thigh in neonates and infants upto 2 years
- Immunogenicity is > 95% in a variety of vaccination schedules
- No booster dose recommended

### Typhoid Vaccine

The choice of vaccine depends upon the age of commencement of the vaccine and the availability.

**1. The Whole Cell Typhoid Vaccine** : The heat-killed phenol-preserved and the acetone killed lyophilized whole cell *Salmonella typhi* vaccine was developed one century ago. This typhoid vaccine is extremely safe from serious reactions and is reasonably effective.

Primary course include 2 doses, 4 or more weeks apart and a single booster dose is recommended every 3 years. In field trials the vaccine has been associated with fever and systemic reactions in 9%-34% of the recipients, and with short absences from work or school in 2%-17% of cases. This vaccine is extremely cheap and well suited for giving to children of families who cannot afford more expensive vaccines (51).

**2. The Vi Polysaccharide Vaccine** : The Vi polysaccharide, purified and adjuvanted is another satisfactory typhoid vaccine with reasonable efficacy & low reactogenicity. As polysaccharide antigens are T cell independent, this vaccine is non-immunogenic below 2 years of age, induces IgM response without IgG response, not able to induce immunological memory; hence not able to induce booster effect. When a dose is repeated 3-5 years later, it induces response similar to the first dose. Adverse reactions seem limited to fever (0%-1%), headache (1.5%-3%) and erythema or induration >1 cm at the site of injection (7%) (52).

**3. Oral Ty21a Vaccine** : This is a live attenuated strain of *S. typhi* Ty21a that was developed in the early 1970s by chemical mutagenesis. It is genetically stable, and does not revert to virulence. Indeed it does not induce a true "infection" as only very limited multiplication occurs in the gastrointestinal tract after oral feeding. It is not excreted in large numbers and is non-transmissible under natural conditions. Very large number of bacteria are necessary as oral doses in order to achieve sufficient degree of local immunity, which is the main basis of protection afforded by this vaccine. The bacteria are acid-

labile. Hence the stomach acidity has to be either neutralised or bypassed when Ty21a is fed orally. The vaccine is administered orally as enteric coated capsules and is registered for use from 6 years of age. The vaccine is to be given in three sittings, on alternate days. The protective efficacy is as good as other available typhoid vaccines. Immunization needs to be repeated every 3-5 years (53,54).

<b>Typhoid Vaccines (Summary)</b>
<b>Whole Cell</b> <ul style="list-style-type: none"> <li>• Killed <i>S. typhi</i>, often with <i>S. paratyphi</i> A (TA)</li> <li>• Developed by Wright, 1896</li> <li>• Liquid, store refrigerated, inject subcutaneously</li> <li>• Primary course : 2 doses 4 weeks</li> <li>• Boosters : Once in 3-5 years</li> <li>• Dose : 0.5 ml SC</li> </ul>
<b>Vi polysaccharide</b> <ul style="list-style-type: none"> <li>• Vi polysaccharide, developed by Robbins, 1984</li> <li>• Liquid, adjuvanted, store refrigerated</li> <li>• Inject IM; give at or after 2 years of age</li> <li>• Dose 0.5 ml</li> <li>• To be repeated 3 years later</li> </ul>
<b>Oral</b> <ul style="list-style-type: none"> <li>• Live attenuated <i>S. typhi</i>, developed by Germanier, 1975</li> <li>• Strain name : Ty 21 a</li> <li>• Enteric coated capsules : store refrigerated, administered orally on alternate days, 3 doses</li> <li>• To be repeated 3-5 years later</li> <li>• Recommended age : 6 years and above</li> </ul>

### Hib Conjugate Vaccine

*Haemophilus influenzae* type b vaccine is a very effective and safe vaccine. Both PRP-T and PRP - CRM 197 conjugate Hib vaccine are now available in India. All Hib-containing vaccines should be stored at between +2°C and +8°C. Liquid Hib vaccine should never be frozen (55).

**Vaccine Administration** : As Hib disease is age dependant and Hib immunization involves boosting of natural immunity, 3 doses when initiated below 6 months, 2 doses between 6 to 12 months and 1 dose between 12 to 15 months should be given. A booster is recommended at 15 to 18 months. Beyond 18 months, a single dose is recommended up to 5 years of age and above 5 years Hib vaccination is not recommended (56,57).

Hib vaccine has not been associated with any serious adverse effects. However, redness, swelling and pain at the site of injection may occur in as many as 25% of those who have been vaccinated (58).

<b>Hib Vaccine (Summary)</b>
<ul style="list-style-type: none"> <li>• <i>H. influenzae</i> b capsular polysaccharide</li> <li>• Conjugated to protein antigens to improve immunogenicity</li> <li>• Monovalent or DPT / Hib conjugate</li> <li>• 3 doses 1-2 months apart</li> <li>• Booster at 15-18 months</li> <li>• Beyond 18 month a single dose up to 5 years</li> </ul>

### Japanese B Encephalitis Vaccine

Currently, the three types of JE vaccines in large scale use are (59) :

- The mouse brain-derived, purified and inactivated vaccine, which is based on either the Nakayama or Beijing strains of the JE virus and produced in several Asian countries
- The cell culture-derived, inactivated JE vaccine based on the Beijing P-3 strain
- The cell culture-derived, live attenuated vaccine based on the SA 14-14-2 strain of the JE virus.

Both the mouse-brain derived and the cell culture-based vaccines are considered efficacious and to have an acceptable safety profile for use in children. However, with the mouse-brain derived vaccine, rare cases of potentially fatal acute disseminated encephalomyelitis and hypersensitivity reactions have been reported among vaccinated children in endemic regions and in travellers from non endemic locations (60-62).

Many Asian countries have adopted a schedule of 2 primary doses preferably 4 weeks apart, followed by a booster after 1 year. In some countries, subsequent boosters are recommended, usually at about 3-year intervals up to the age of 10-15 years (59).

This vaccine is based on the genetically stable, neuro attenuated SA 14-14-2 strain of the JE virus, which elicits broad immunity against heterologous JE viruses. Case control studies and numerous large-scale field trials in China have consistently shown an efficacy of at least 95% following 2 doses administered at an interval of 1 year (63).

The Indian strain of the Japanese B Encephalitis vaccine produced by Central Research Institute, Kasauli, is available through central and state health authorities for use in endemic areas during epidemic situation in the specific regions of the country where the infection is prevalent.

### Meningococcal Vaccine

Meningococcal meningitis and septicaemia are caused by various sero groups of *Neisseria meningitidis*. Endemic disease occurs worldwide and is mostly caused by meningococci of serogroups A, B or C. The group A meningococcus is the predominant cause of large epidemics. Vaccines are available against four serogroups of meningococci A, C, W-135 and Y. No effective serogroup B vaccine is presently available. The vaccines are either monovalent i.e. A, C, etc. or polyvalent i.e. A-C, A-C-Y, A-C-Y-W135 etc. The efficacy rate of a single dose of serogroup A or serogroup C vaccine is 90% in adults and children over 2 years of age. The four polysaccharide antigens (A, C, Y and W135) have been combined into a tetravalent vaccine. It is available in single-dose and multi-dose vials distributed as lyophilized powder that contains 50 micrograms of each component per dose. The vaccine should be stored at -20°C (64, 65).

**Dosage and Route of Administration** : For both adults and children, vaccine is administered s.c. as a 0.5 ml dose. Protective levels of antibody can be expected after 7-10 days.

#### Indications

- Routine immunisation of recruits may be considered (66).
- In household contacts, as an adjunct to chemoprophylaxis.



- (iii) Routine immunization for asplenic people and those with previously described immunodeficiencies.
- (iv) Vaccination is recommended for outbreak control for disease caused by any of the serotypes carried by the vaccine.
- (v) Travellers to hyperendemic or endemic areas.

**Precautions and Contra-indications** : Adverse reactions are mild and consist of pain and tenderness at the site of injection for 1-2 days (67,68). No adverse effects have been documented among women vaccinated during pregnancy or their newborns. There are no known contraindications. The vaccine is not recommended for use in children under 2 years of age (69,70).

**Revaccination** : The need for revaccination of older children and adults has not been determined, antibody levels decline rapidly over 2 to 3 years and if indications still exist for immunisation, revaccination may be considered within 3 to 5 years (71).

### Varicella Vaccine

Takahashi et al developed a live attenuated vaccine for varicella from Oka strain in Japan. The recommended dose is 0.5 ml which provides at least 1350 plaque forming units of the virus. The vaccine is administered SC in the upper arm/thigh region. It is recommended after the age of 1 year. Up to the age of 12 years, one dose is required and if given after 12 years, 2 doses are needed at an interval of 1 month. Both humoral and cell mediated immunity develops in more than 95% cases after a single dose between 1-12 years and 99% after 2 doses in children 13 years and above (72-74).

#### Varicella Vaccine (Summary)

- Developed by Takahashi in 1971 in Japan
- Live attenuated Oka Strain
- Vaccine available as lyophilized powder
- Dissolve in 0.5 ml diluent
- SC Injection
- Single dose 12 months - 12 years
- Two doses beyond 13 years; 1 month apart
- Efficacy 95- 99%
- No booster dose recommended

### Hepatitis A Vaccine

Several inactivated or live attenuated vaccines against hepatitis A have been developed, but only 4 inactivated hepatitis A vaccines are currently available internationally. All 4 vaccines are similar in terms of efficacy and side-effect profile. The vaccines are given parenterally, as a 2-dose series, 6-18 months apart. The dose of vaccine, vaccination schedule, ages for which the vaccine is licensed, and whether there is a paediatric and adult formulation varies from manufacturer to manufacturer. No vaccine is licensed for children aged < 1 year (75, 76). Vaccine efficacy is 94-100% and the duration of protection is long lasting, hence no booster dose is recommended at present. The current vaccines are well tolerated and no serious adverse events have been statistically linked to their use. Contraindications to hepatitis A vaccination include a known allergy to any of the vaccine components (77).

#### Hepatitis A Vaccine (Summary)

- Inactivated vaccine containing HM 175 strain grown in MRC5 cell line
- 2-dose series, 6-18 months apart.
- Efficacy - 94-100%
- No booster dose

### Pneumococcal Vaccine

Two types of vaccine are currently available - a 23 valent polysaccharide vaccine (available in India) and a 7 valent conjugate polysaccharide vaccine in some countries of the world (78). 23-valent polysaccharide vaccine is capable of prevention of 85% of meningitis and bacteremia caused by pneumococcus. Each dose is 0.5 ml containing 25 µg of individual serotype polysaccharide. A single IM injection is recommended after the age of 2 years with booster every 3-5 years till the age of 10 years (79, 80). The 7 valent conjugate polysaccharide vaccine manufacturer recommends three IM injections in infants aged under 6 months, the first dose usually given at 2 months of age, with an interval of at least 1 month between doses.

### Influenza Vaccine

Both inactivated and live, attenuated influenza vaccines are available. There are 3 types of inactivated influenza vaccine, namely whole virus vaccines, split virus vaccines and subunit vaccines. In most countries, whole virus vaccines have been replaced by less reactogenic split virus and subunit vaccines. The multivalent vaccine usually contains 3 virus strains (usually 2 type A and 1 type B) with composition changed periodically in anticipation of the prevalent influenza strains expected to circulate in the country (81, 82). The vaccine is given in 2 doses in children 6 months to 9 years of age and one dose above 9 years of age. The dose is 0.25 ml between 6 months to 3 years IM and 0.5 ml after the age of 3 years (83).

**Live, Attenuated Influenza Vaccines** : For several years, live, attenuated influenza vaccines for nasal application have been used successfully in the Russian Federation. The temperature-sensitive vaccine virus will replicate well in the relatively cool environment of the nasopharynx, but poorly in the lower respiratory tract. This vaccine is reported to be safe and highly efficacious following 1 single dose in adults and children >3 years of age (84-86). Based on data from industrialized countries, and listed in order of priority, the following groups of individuals may be targeted for vaccination in order to reduce the incidence of severe illness and premature death.

1. Residents of institutions for elderly people and the disabled.
2. Elderly, non-institutionalized individuals with chronic heart or lung diseases, metabolic or renal disease, or immunodeficiencies.
3. All individuals >6 months of age with any of the conditions listed above.
4. Elderly individuals above a nationally defined age limit, irrespective of other risk factors.

### Rabies Vaccine

There are 2 types of rabies vaccines available in India :

1. Nerve tissue vaccine



2. Tissue culture vaccines
  - Human diploid cell vaccine
  - Purified chick embryo cell vaccine
  - Vero cell vaccine

Nerve tissue vaccine is no longer recommended because of its poor efficacy and life threatening adverse reactions in the form of neuromuscular conditions of 1 : 2000 to 1 : 8000 doses (87,88).

#### Tissue Culture Vaccines

All tissue culture vaccines are having almost equal efficacy and any one of them can be used.

**Post exposure prophylaxis :** After thoroughly cleaning the wound with soap and water and appropriate tetanus prophylaxis, rabies immunoglobulin either human or equine in the dose of 20 IU and 40 IU/kg body weight respectively is infiltrated around the wound in case of severe bite or bites in the upper extremities, trunk, head and face. Currently IM injection of RIG is not recommended (89,90).

**Pre-exposure prophylaxis :** 1 ml of any of the tissue culture vaccine is given IM over the deltoid region on day 0, 7 and 28 for the high risk group.

In order to reduce the cost of post-exposure treatment, intradermal multisite regimens using a fraction of the intramuscular volume per intradermal inoculation site have been developed (91).

#### Rabies Vaccine - Tissue Culture Vaccine (Summary)

##### Post exposure Prophylaxis

- 1 ml per dose irrespective of age in deltoid region in infants >2 years; and in anterolateral aspect of thigh in infants < 2 years.
- Schedule Day 0, 3, 7, 14 and 28
- Re-exposure within 5 years - 2 doses - day 0 and 7; after 5 years full course. Earlier if anti rabies antibody titer falls below 0.5 IU / ml

##### Pre exposure Prophylaxis

- 1 ml per dose, any Tissue Culture Vaccine, IM
- Schedule Day 0, 7 and 28
- Indicated for High Risk Group
  - Laboratory staff working with Rabies Virus
  - Veterinarians
  - Wild life staff

**Rabies Immunoglobulin :** It is a liquid or freeze dried preparation containing immunoglobulins mainly IgG obtained from plasma or serum of donors immunised against rabies and contains specific antibodies that neutralise the rabies virus. It provides passive protection when given immediately to individuals exposed to rabies virus with minimum interference of active immunization with human diploid - cell vaccine (92).

**Adverse Effects :** Local tenderness, muscle soreness or stiffness at the injection site, low grade fever, sensitization to repeated injections of human globulin in immunoglobulin deficient patients.

**Indications :** All injuries, even licks, on mucous membranes by wild animals (or even pet animals) suspected to be suffering from rabies.

#### Immunization against Cholera

Until recently, the only available cholera vaccine was phenol-killed whole cell killed vaccine, administered in 2 doses, 2 weeks apart. Unfortunately, the protective efficacy of vaccine is only about 50%; duration of protection hardly exceeds 6 months.

**Live, Attenuated CVD 103-HgR vaccine :** A live, attenuated oral cholera vaccine containing the genetically manipulated Classical *V. cholerae* strain CVD 103-HgR has been available since 1994 which confers a high level of protection (> 90%) against moderate and severe cholera. Both the whole cell killed and the CVD 103-HgR vaccines may be recommended for travellers to high-risk regions (93).

#### Development of New Vaccines : Current Situation

##### Rotavirus Vaccine

Acute diarrhoea is responsible for nearly 1.9 million deaths per year in children under age five. Rotavirus is responsible for as much as one fourth of these casualties, almost all of which occur in developing countries.

**Status of vaccine development :** RotaRix, a vaccine developed by GlaxoSmithKline (GSK), and RotaTeq vaccine developed by Merck against rotavirus diarrhoea are now licensed in many countries. In addition to being available in the private market, it has now been introduced in the public sector immunization programmes of many countries (94).

**Recommendations :** Routine immunization of all infants without contraindications. It is provided as a single 2ml oral dose in a buffered stabilizer solution. It is stored at 36-46°F (2-8°C), and administered at 2, 4, and 6 months of age. Minimum age of first doses is 6 weeks. First dose should be administered between 6 and 12 weeks of age (until age 13 weeks). Minimum interval between doses is 4 weeks. Maximum age for any dose is 32 weeks (95).

**Challenges :** A vaccine must be effective against numerous rotavirus strains (serotypes), including those prominent in developing countries. These vaccines, since they are live, oral ones, must be shown not to interfere with oral polio vaccine & must be efficacious. Even more importantly, they must be shown to be safe in general, and in HIV-infected children in particular. Price will also be an issue for large-scale introduction (94).

##### Human Papillomavirus (HPV) Vaccine

Sexually transmitted HPV is the major cause of cervical cancer, the most common cause of cancer deaths among women in developing countries. About 500,000 cases occur each year, 80% of them in developing countries. Cervical cancer kills some 240,000 women annually.

**Status of vaccine development :** Gardasil, an HPV vaccine recently licensed by Merck, covers four types of HPV, including the cancer-causing types 16 and 18 and types 6 and 11 for non-cancerous genital warts. A second vaccine, developed by GSK, covers HPV types 16 and 18 alone and is expected to be licensed in 2007.

**Challenges :** HPV types 16 and 18 cause around 70% of HPV cervical cancers globally, but the vaccines in development will

not cover the 30% of cancers attributed to other HPV types. Because these other types are numerous and individually only contribute a small percentage, significantly expanding vaccine coverage against them may present technical challenges for manufacturers. The duration of the immunity conferred by the vaccines is not yet known, and only time and follow up studies will provide this critical information. Access to the vaccines is likely to be an issue in developing countries due to limited resources for the implementation of vaccination programmes (94).

## International Vaccination Requirement

### Immunization Against Yellow Fever

Yellow fever (YF) is endemic in tropical regions of Africa and South America. Vaccination is the most effective method for the prevention of spread of the disease by international travel (96). Two types of vaccines are available (97).

(i) **17 D Vaccine** : This is the approved vaccine for international travel. It is a live, attenuated chick embryo grown 17D-strain freeze-dried vaccine. For storage at WHO approved centers, the vaccine can be kept for 3 months at +4°C. If the storage is for a longer duration, a temperature of -25°C is to be maintained. After reconstitution, it should be used within half an hour.

(ii) **Dakar Vaccine** : It is also called French Neurotropic Vaccine developed at the Pasteur Institute Dakar. It is thermostable and can be easily transported. However, it has produced post-vaccinal encephalitis in children. WHO has not approved use of this vaccine for international travel.

**Administration of vaccine** : 17-D vaccine is given SC at the insertion of deltoid in a single dose of 0.5 ml. Immunity begins within 10-12 days and lasts for at least 10 years however the persistence of neutralizing antibody 30-35 years after immunization with 17D yellow fever vaccine has been observed (98). Yellow fever vaccination is available at designated centers certified by the Government of India. Armed Forces Clinic, New Delhi is one of such centers.

International certificate of vaccination is required only for one disease i.e. yellow fever. The period of validity of the certificate is shown in Table - 5.

Protection is recommended against certain other diseases for international travellers although the international certificate is not required. These diseases are as under :

(a) **Cholera** : Cholera vaccine may be taken by all travellers proceeding to endemic areas. It offers partial protection against the disease.

(b) **Enteric Infections** : Vaccination and revaccination against typhoid is strongly advised for all travellers proceeding to endemic areas.

(c) **Hepatitis A** : A single IM injection of human normal immunoglobulin 500 mg or 1.2 mg/kg body weight is effective

almost immediately and its efficacy lasts for six months. Active immunisation with HAVRIX is available in our country.

**Table - 5 : Validity of International Certificate of Vaccination**

Type of vaccination	Certificate	
	Valid for	Valid from
Yellow fever-primary vaccination	10 years	10 days after vaccination
Yellow fever-re-vaccination	10 years	at once after revaccination

(d) **Tetanus** : A booster dose of Tetanus toxoid should be taken if 5 years or more have elapsed since the last injection of a complete course or booster.

### Immunization in Special Circumstances (99)

**1. Immunization in preterm infants** : All vaccines should be administered as per schedule irrespective of birth weight or period of gestation except Hepatitis B. If the weight of the baby is less than 2 kg and mother is HBsAg negative, then Hepatitis B vaccine is postponed till the baby attains a weight of 2 kg or 2 months of age. However, if the mother is HBsAg positive, then both Hepatitis B vaccine and Hepatitis B immunoglobulin is administered within 12 hours of birth followed by 3 more doses at 1, 2 and 6-12 months.

**2. Children receiving corticosteroids** : Children receiving corticosteroids at the dose of 2 mg/kg/day for more than 14 days should not receive live virus vaccines until steroid has been discontinued for at least 1 month.

**3. Vaccination in HIV/AIDS** : Following table summarizes the recommendation of WHO and Advisory Committee on Immunization Practices and American Academy of Paediatrics. Vaccination recommendations in HIV infected symptomatic and asymptomatic Children (Table - 6).

**Table - 6 : Vaccination recommendations in HIV infected symptomatic and asymptomatic Children**

Vaccine	Known Asymptomatic		Known Symptomatic	
	WHO	ACIP / AAP	WHO	ACIP / AAP
BCG	Yes*	No	No	No
DPT/DtaP	Yes	Yes	Yes	Yes
OPV	Yes	No	No	No
Measles / MMR	Yes	Yes	Yes	Yes
IPV	-	Yes	-	Yes
Hepatitis B	Yes	Yes	Yes	Yes
Hib	-	Yes	-	Yes
Pneumococcal	-	Yes	-	Yes
Influenza	-	Yes	-	Yes
Varicella	-	Consider	-	Consider
Hepatitis A	-	Yes	-	Yes

\* For regions where risk of TB is high

**4. Vaccination schedule for children not immunized in time :** Table - 7 depicts the schedule which should be followed in case of unimmunized child.

<b>Table-7: Vaccination schedule of an Unimmunized Child</b>		
<b>Age</b>	<b>Less than 5 years</b>	<b>More than 5 years</b>
First Visit	BCG, OPV, DPT, HB	TT/ Td, HB
2nd visit (1 month later)	OPV, DPT, HB	TT/ Td, HB
3rd visit (1 month later)	OPV, DPT, MMR, Typhoid	MMR, Typhoid
1 Year later	OPV, DPT, HB	HB
Every 3 years	Typhoid booster	Typhoid booster

**5. Lapsed Immunization :** A lapse in the immunization schedule does not require reinstitution of the entire series. Immunizations should be given at the next visit as if the usual interval had elapsed and the immunization schedule should be completed at the next available opportunity. In case of an uncertain immunization status, it is appropriate to start the schedule of unimmunized child.

**6. Immunization of Adolescents :** Reasons for adolescent immunization fall into the following broad categories :

- To boost the waning immunity by giving booster doses.
- To counter a specific risk e.g. due to travel, life style etc.

<b>Table - 8 : Vaccination Schedule in Adolescents</b>	
<b>Vaccine</b>	<b>Age</b>
Tetanus Toxoid	Booster at 10 and 16 years
Rubella vaccine	As part of MMR vaccine or (Monovalent) 1 dose to girls at 12-13 years of age, if not given earlier
MMR Vaccine	1 dose at 12-13 years of age. (if not given earlier)
Hepatitis B. Vaccine	3 Doses (0, 1 and 6 m) if not given earlier
Typhoid Vaccine	TA, Vi or Oral typhoid vaccine every 3 years
Varicella Vaccine*	1 dose upto 12-13 years, and 2 doses after 13 years of age. (if not given earlier)
Hepatitis A Vaccine*	2 doses (0 and 6 months) if not given earlier
Varicella* and Hepatitis A* vaccine are additional vaccines. These vaccines are recommended depending upon the epidemiology of these diseases especially in the adolescent age group where fatal complications are likely to occur.	

**International Certificate of Vaccination :** These are individual certificates and should not be used collectively. Certificates are printed in English and French; an additional language may be used. The dates should be recorded in the following sequence; Day, Month, Year, the month to be written in letters e.g. 20 March 1999. A certificate issued to a child who is unable to write should be signed by the parent or guardian. The signature of

an illiterate person should be indicated by his left thumb mark certified by another person. The certificates requires signature of medical practitioner; his official stamp is not accepted as a substitute nor is the signature of the clinical nurse. The correct procedure for the doctor is to do the vaccination himself and sign the certificate as the vaccinator. On all international vaccination certificates, name of manufacturer of vaccine as well as the batch number must be given. Medical officers are also advised to refer to standard WHO publication on requirements for international travellers (100).

## Summary

The modern word "immunity" derives from the latin *immunis*, meaning exemption from military service, tax payments or other public services and is defined as "Ability of an organism to recognize and defend itself against specific pathogens or antigens". The immune system is a collection of mechanisms within an organism that protects against infection by identifying and killing pathogens and tumour cells. The physical barriers prevent pathogens entering the body. If a pathogen breaches these barriers, the innate immune system provides an immediate, but non-specific response. However, if pathogens successfully evade the innate response, vertebrates possess a third layer of protection, the adaptive immune system.

An antigen is defined as a substance which when introduced into the tissues stimulates the production of specific antibodies and combines specifically with the antibody so produced. By far the best antigens are proteins; others are poly-saccharides, lipids and nucleic acids. There are also incomplete antigens called 'haptens' which by themselves are not antigenic but can provoke an immune response.

An antibody is a protein substance that appears in the body as a result of invasion by an antigen. It is capable of reacting specifically with the same antigen, which provokes its production. The sites of maximum antibody formation are the lymph nodes and spleen. Immunoglobulins comprise of families of closely related globulin molecules, which are synthesized by cells of reticuloendothelial system. The human immunoglobulin system is divided into five major classes IgG, IgA, IgM, IgD and IgE.

Types of immune defenses can broadly be divided into Innate and Acquired Immunity. Acquired Immunity can further be divided into Active and Passive immunity with Artificial and Natural types in each. Active immunity : (a) Naturally acquired active immunity occurs when a person is exposed to a live pathogen, and develops a primary immune response, which leads to immunological memory. (b) Artificially acquired active immunity can be induced by a vaccine, a substance that contains antigen. Passive immunity is the transfer of active immunity, in the form of readymade antibodies, from one individual to another.

Two different types of Host defenses that the body exhibits as a result of exposure to antigen : (a) The humoral immune response (b) The cell-mediated immune response. The cells of the tissue attacked are as much concerned in offering resistance to the infecting agent as the antibodies or phagocytes; this is the local immunity. Herd Immunity is the immunity of a group of people or a community taken as a whole. The first encounter with an



antigen is known as the primary response. Re-encounter with the same antigen causes a secondary response that is more rapid and powerful.

Immunisation is the process by which an individual is exposed to an agent that is designed to fortify his or her immune system against that agent. The material is known as an immunogen. Immunization is the same as inoculation and vaccination. Vaccines are immunobiological substances designed to produce specific protection against diseases by stimulating production of protective antibody or other immune mechanisms. The Vaccine mimics the infection with the respective pathogen, but without risk of the disease. The goal of all vaccines is to promote a primary immune reaction so that when the organism is again exposed to the antigen, a much stronger secondary immune response will be elicited.

There are four types of traditional vaccines : Live (attenuated), Inactivated (killed), Toxoids, Subunit and recombinant. Live Vaccines are prepared from live attenuated organisms and are very potent immunizing agents. Safety is an issue and they cannot be used for immunodeficient patients and during pregnancy. Examples include BCG, Typhoid oral, Measles, Mumps, Rubella and Oral Polio. Inactivated (Killed) Vaccines are prepared from organisms killed by heat or chemicals, are very safe but less efficacious than live vaccines. They require multiple doses. The only absolute contraindication is hypersensitivity, e.g. Typhoid, Rabies, Hepatitis B. Toxoids are produced from detoxicated toxins. The body produces antibodies against the toxin in response to toxoids. They offer no protection against infection, are very safe and highly effective, e.g. Diphtheria, Tetanus.

Passive immunization may be administered using human or animal products. Conventionally human products are called immunoglobulins and animal products are called anti sera. Non specific or generalized protection is offered by normal immunoglobulins while protection against specific diseases is given by using hyperimmune immunoglobulins.

Immunization schedule drawn up keeping two important factors in mind - the vaccines need to be administered in doses and schedules which produce an adequate immunological response in the recipient; and secondly the schedule should be administratively the most convenient and one which is likely to be most acceptable to the target population. The National Immunization schedule drawn up for India factors in both these aspects.

Cold chain is a system of transporting and storing vaccines at recommended temperature from manufacturer to the point of use. All the vaccines can be stored at temperatures between +2 to +8°C. However, long term storage of OPV and Measles requires them to be stored at sub zero temperatures in deep freezers. DPT, DT and TT

should never be frozen. BCG and diluent ampoules should not be frozen, as ampoules are likely to crack. Diluents required for measles and BCG should be stored at +2 to +8°C in the refrigerator. Cold Chain includes Walk in cold rooms (WICs), Deep freezers, Ice - lined refrigerators (ILRs), Refrigerators, Cold box, Vaccine carrier, Day carrier and Ice packs. The quality

of the cold chain is monitored by the National Quality Control Lab at Kasauli. The quality check is done before release of the vaccines. Reverse Cold Chain is also maintained to check vaccines for their potency.

UIP VACCINES includes BCG Vaccine, Oral PolioVaccine, DPT Vaccine and Measles Vaccine. NON UIP VACCINES includes Mumps Vaccine, Rubella, MMR, Hepatitis B Vaccine, Typhoid Vaccine, Japanese B Encephalitis, Meningococcal Vaccine, Hepatitis A, Varicella, Pneumococcal, Rabies and Influenza Vaccine. International Vaccination Requirement is for Yellow fever (YF) which is a mosquito-borne, viral haemorrhagic fever that is endemic in tropical regions of Africa and South America.

## Study Exercises

### MCQs & Exercises

1. Wasserman antibodies and bactericidal antibodies against Gram negative organisms (endotoxins) are almost exclusively found in (a) IgG (b) IgM (c) IgA (d) IgE
2. Cytotoxic or killer T cells (CD8+) do their work by releasing \_\_\_\_\_, which cause cell lysis.
3. Antibody binds to antigen & this is called \_\_\_\_\_.
4. Influx of susceptible people and occurrence of new births increase the herd immunity. True/ False
5. Tuberculosis (BCG) was discovered in (a) 1923 (b) 1927 (c) 1935 (d) 1943
6. Hepatitis B (a) 1963 (b) 1971 (c) 1981 (d) 1993
7. World Health Organization (WHO) certified the eradication of smallpox in (a) 1975 (b) 1977 (c) 1979 (d) 1981
8. The immunization against quarantinable disease under the International Health Regulations, is carried out for which disease? (a) Polio (b) Yellow fever (c) Plague (d) Malaria
9. When vaccines are reconstituted, the diluent should be at same temperature as the vaccine. True/ False
10. The vaccines must be kept in the cold chain between \_\_\_\_\_ at all times, or optionally, at -15 to -25°C if cold chain space permits. (a) 0 and +4°C (b) +2 and +6°C (c) +2 and +8°C (d) +6 and +10°C
11. While vaccines and diluents remain in storage it is necessary to follow the principle of "EEFO" which stand for \_\_\_\_\_.
12. The BCG vaccine was first used to immunize humans in (a) 1971 (b) 1941 (c) 1931 (d) 1921
13. Eradication is defined as no case of paralytic poliomyelitis by wild polio virus in last \_\_\_\_\_ years along with absence of wild polio virus in the community, where excellent clinical and virological surveillance exists and the coverage of routine OPV is more than 80%.
14. Polio elimination is defined as \_\_\_\_\_ cases of paralytic poliomyelitis by the wild polio virus in one calendar year with other criteria same as in eradication.
15. Indian Academy of Paediatrics recommend \_\_\_\_\_ at 10 and 16 years

**Answers :** (1) b; (2) lymphotoxins; (3) Tagging; (4) False; (5) b; (6) c; (7) c; (8) b; (9) True; (10) c; (11) "earliest expiry first out"; (12) d; (13) 3 calendar; (14) Zero; (15) TT.



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The fields of preventive medicine and public health share the goals of promoting general health, preventing specific diseases, and applying the concepts and techniques of epidemiology to attain these goals. Preventive medicine seeks to enhance the lives of individuals by helping them improve their own health, whereas public health attempts to promote health in populations through the application of organized community efforts.

### Classification of Diseases

Diseases can broadly be classified as communicable and non - communicable. Communicable Diseases are illnesses caused due to invasion by specific microorganisms or their toxic products. The transmission of the agent or its products

occurs from a source reservoir by direct or indirect means. Non - communicable Diseases are diseases, which are not caused by specific microorganisms and are not spread from one person to the other. These diseases may be metabolic, degenerative, neoplastic, mental, allergic, constitutional or accidental.

### Principles of Prevention and Control

The practical application and aim of epidemiological investigation and intelligence are to prevent and control the entry and spread of diseases in communities. The amenability of a disease to prevention and control depends upon the knowledge of its aetiology, epidemiology, mode of contraction, route and mode of transmission of the aetiological agent, the natural history or course of the disease and the incubation period. The better the knowledge of these factors, the greater is the amenability of the disease to prevention and control. The principles of prevention and control are applicable to non - communicable diseases as well as communicable diseases. However, a better knowledge of the specific aetiological agent and epidemiology makes it easier to apply the principles of

prevention and control to most communicable diseases. The ever increasing knowledge of the aetiological and epidemiological factors involved in the causation of non communicable diseases has now made the control and prevention of many non communicable diseases possible as well.

### Natural History of Disease

The disease process is a dynamic one and is initiated by a disturbance of the balance between man and environment. The term 'natural history of disease' is applied to its course in man. Disease as seen in the hospital is but an episode in the natural history. The natural history of disease can be seen as having three stages : The pre disease stage, the latent (asymptomatic) disease stage, and the symptomatic disease stage. Another classification of the natural history is the pre pathogenesis phase (pre disease phase), the pathogenesis phase (the latent and symptomatic disease stage) and the post pathogenesis phase. In the pre disease stage the individual possesses various factors that promote or resist disease, these include genetic make up, demographic characteristics (especially age), environmental exposures, nutritional history, social environment, immunologic capability and behavioural patterns. Over time, these and other factors may cause a disease process to begin. Thus potentially man is always in the midst of disease but only when the agent, host and environmental factors, the three components of the epidemiological triad, interact that the disease process is initiated. The pathogenic period begins with the entry of disease agent in the human host as a result of the disease provoking stimuli. If the disease producing process is underway but no symptoms of disease are apparent, the disease is said to be in the latent stage. This stage represents a window of opportunity during which detection followed by treatment provides a better chance of cure or at least of effective treatment. Once the agent becomes established and multiplies, there are tissues or physiologic changes in the host and the disease process is advanced enough to produce clinical manifestations, it is said to be in the symptomatic stage. The end result of the disease process may be complete recovery, chronicity, disability or death. (1 - 3).

### Levels of Prevention and Control

The modern concept of health as 'the state of complete physical, mental and social well being and not merely the absence of disease or infirmity' warrants the application of preventive and control measures in the three phases in the natural history of disease discussed above. Prevention of disease means barring or preventing its initial entry into man or a community while 'control' means arresting the further progress and propagation after its entry in an individual host or a community at large. Prevention entails anticipatory action to remove the possibility that a disease will ever occur. Control entails action to prevent invasion of the non - affected but exposed individuals in the affected community. As far as the non - communicable diseases are concerned, some are amenable to simple means of protection e.g. ill effects of cold and heat, while others require more intricate and elaborate preventive and control measures. The natural history and epidemiology of the non - communicable diseases such as cancer, cardiovascular diseases, accidental injuries and occupational diseases, have to be studied in detail to detect vulnerable points or links where preventive or control

measures can be applied (1 - 3).

The objective in the pre - pathogenic phase is to achieve primary prevention, firstly through health promotion by socio - economic improvement and providing healthful housing, adequate nutrition, clothing, healthy living & working environments, and secondly by giving specific protection through immunization, environmental sanitation, use of specific nutrients, protection against occupational hazards, accidents, protection from carcinogens or allergens and so on. In the pathogenic phase, secondary prevention aims at early case detection & treatment as well as uncovering the vulnerable community in the submerged part of the iceberg. It limits dissemination of infection and prevents occurrence of secondary cases in the community by reducing the infectious pool. The methods employed in early case detection are :

- Case finding measures - individual or mass or by contact tracing.
- Screening surveys.
- Surveillance techniques and
- Selective examination of high risk groups.

In the post - pathogenic phase, disability limitation helps early rehabilitation of the patients. The objective is to halt the further progress of the disease process by instituting adequate therapy to limit the disability, prevent further complications through physiotherapy and other techniques of physical medicine. A rapid rehabilitation prevents the recovered individual from lapsing back into ill health, both physical and mental and protects the community from social disruption and diseases. Rehabilitation aims not only at restoring and retraining a patient to live and work within the limits of his disability but to the maximum of his residual capacity. This is termed as the tertiary prevention. The various levels and stages of prevention in relation to the periods in the natural history of disease are shown in Table - 1.

<b>Table 1 : Levels of Prevention</b>		
<b>Levels of prevention</b>	<b>Appropriate response</b>	<b>Period in the natural history where applied</b>
Primary prevention	Health promotion (e.g. encourage healthy lifestyle changes, balanced nutrition and clean environment) Specific Protection (e.g. immunization, Occupational and automobile safety measures)	Pre - pathogenesis
Secondary prevention	Early Diagnosis & treatment	Pathogenesis
Tertiary prevention	Disability limitation (i.e. institute medical or surgical treatment to limit damage from the disease) Rehabilitation (i.e. identify and teach Methods to reduce physical and social disability)	Pathogenesis and Post - pathogenesis



Communicable diseases can be classified according to the aetiological agent or as per the route and mode of transmission. Usually both methods are employed. However, as they have a definite chain of transmission from the reservoir or source through a route upto the susceptible host or recipient, it is more convenient from the point of view of prevention and control, to classify them according to their mode of transmission.

The later, which also indicates the portal of entry & venue of exit of the infecting organism is as follows :

- (a) Contact transmission - direct and indirect.
- (b) Vehicle transmission - water, food, milk etc.
- (c) Vector transmission - by arthropods.
- (d) Air-borne transmission - droplet, droplet nuclei and infected dust.
- (e) Animal-borne transmission - zoonoses
- (f) Trans placental transmission

### Control Measures

These aim at exterminating the causative agent in its reservoir at the source of its production, its destruction soon after exit and before it starts its spread by interrupting its path of transmission. Action at these levels requires knowledge of the multifarious factors concerned with the inanimate or animate reservoir or source, various links in the chain of transmission and different approaches to the recipient susceptible host. The practical measure of control broadly fall under three main heads. One or all of these measures may be applied according to the circumstances of the case (1, 4 - 6).

**Control of Reservoir and Source of Infection** : The first link in the chain of causation is the existence of infected persons, cases (clinical or subclinical) or carriers, who constitute the primary source of infection. The general measures of control of the reservoir of infection are :

- (a) Early detection of cases.
- (b) Notification
- (c) Isolation
- (d) Treatment.
- (e) Quarantine.
- (f) Surveillance.
- (g) Disinfection.

**Block the channels of Transmission** : This may be achieved by general environmental control, specific control measures such as safe water supply, sanitary disposal of sewage & other waste products, high standard of food hygiene, vector control, personal hygiene, proper ventilation, prevention of overcrowding and dust control.

**Protection of Susceptible Population** : This is carried out by immunization, chemoprophylaxis, good nutrition, health education and personal protection.

### Control Measures on the Occurrence of an Infectious Disease

In public health practice, the action to control the communicable diseases has to be crystallized into the form of a 'drill' which should involve no elaborate thought or preparation because the etiological agents travel fast and gain momentum and invasive force as they proceed from person to person. The usual sequence of action to control the spread of an infectious disease is as follows :

- (a) Early detection of case.
- (b) Isolation of the case for the entire period of infectivity.
- (c) Prompt and effective treatment of case.
- (d) Disinfection of discharges and fomites.
- (e) Notification.
- (f) Surveillance of contacts.
- (g) Mass immunization of the vulnerable community.
- (h) Investigation of the current outbreak.
- (i) Survey to assess endemicity.

**Immunization** : One of the most satisfactory control measures is that it renders the host immune from infectious disease by an infectious agent. Active immunization is a cornerstone of public health measures for the control of many infectious diseases and is considered one of the most cost - effective methods of individual, institutional, and community protection from many infectious diseases. Immunization is dealt with in detail in other sections of this book.

**Chemoprophylaxis** : Chemoprophylaxis is the prevention of infection or its progression to clinically manifest disease through the administration of chemical substances, including antibiotics. Chemoprophylaxis may be specifically directed against a particular infectious agent or it may be non - specifically directed against many infectious agents. The use of antibiotics before surgical procedures is an example of non - specific Chemoprophylaxis to prevent wound infections in the postoperative period. Examples of specific Chemoprophylaxis are as follows (9) :

### Use of Chemoprophylaxis to prevent development of infection

- Using chloroquine to prevent malarial parasitaemia.
- The use of silver nitrate, erythromycin or tetracycline instilled into the eyes of a newborn to prevent gonococcal ophthalmia by transmission of *Neisseria gonorrhoeae* from an infected mother during birth.
- To use of tetracycline, sulfonamides or streptomycin in close contacts of confirmed or suspected cases of plague pneumonia to prevent plague.
- Use of Rifampicin in close contacts of meningococcal meningitis patients.

### Chemoprophylaxis to prevent the progression of an infection to active manifest disease

- Use of co - trimoxazole or pentamidine to prevent subclinical latent infection with *Pneumocystis carinii* from progression to clinically manifest pneumocystis pneumonia in immunosuppressed persons such as HIV - infected individuals.
- Use of pyrimethamine - sulfadiazine - folinic acid to prevent asymptomatic infants congenitally infected with *Toxoplasma gondii* from clinically manifest chorioretinitis and other sequelae of congenital toxoplasmosis.

### Chemoprophylaxis to treat an infectious disease to prevent complications of the disease

- Penicillin to treat streptococcal sore throats caused by *Streptococcus pyogenes* group A to prevent acute rheumatic fever.
- Benzathine penicillin for treatment of syphilis in its primary, secondary, or early latency period to prevent



late manifestations of the disease such as cardiovascular syphilis.

## Disinfection

### Definitions (4)

(a) **Disinfection** : This means destruction outside the body, of specific microorganisms, which cause communicable diseases.

(b) **Disinfectants** : These are the agents used for disinfection.

(c) **Antiseptics** : These are the chemical agents, which inhibit the growth and multiplication of microorganisms, but are not strong enough to destroy them completely. A sufficiently diluted or weakened disinfectant becomes an antiseptic.

(d) **Disinfestations** : This means destruction of undesirable animal forms, especially arthropod ectoparasites present upon the persons or on domestic animals. The term also includes destruction or avoidance of endoparasites like helminthes, and rodent destruction. However, in practice this term mainly refers to the destruction of ectoparasites like lice, sarcoptes, bugs and fleas and their ova and eggs.

(e) **Disinfestants** : These are the agents used for disinfestation. Disinfestants which are specially used against arthropods are called 'insecticides' and 'acaricides' depending on their special values in practice. A number of disinfectants are disinfestants if used in adequate strength, but all disinfestants or insecticides are not disinfectants.

(f) **Detergents** : These are surface cleansers and degreasers. They dissolve grease and oily matter and thereby help removal of dirt etc., from any material when rinsed or washed with water consequently removing the micro - organisms sheltered by grease and dirt.

(g) **Deodorants** : These are substances, which mask the unpleasant odours without having disinfecting or antiseptic powers. Many disinfectants and antiseptics mask putrefactive odours also.

### Objective

The object of these processes is to cut the links in the chain of the spread of communicable diseases and reduce nuisance. They can, therefore, be considered as supplementary to environmental sanitation. The main objective can be achieved with minimum effort and maximum success if the aetiology and mode of transmission of each disease is clearly understood, ecology and bionomics of their agents are known, procedures are rational and specifically directed against the paths of its spread and not employed merely as placebos to appease the ignorant mind. Much time, energy and money are wasted on disinfection of places which only require ventilation and cleansing. Some situations may need only the disinfection and other may need only disinfestation while a few may need both. Agents and procedures adopted will, therefore, depend upon the situation as well as nature of the problem. Disinfection is discussed hereunder.

### Disinfection Procedures

**Concurrent Disinfection** : It means the disinfection of the patient himself, of his excreta & discharges & of all articles used by him or likely to have been contaminated during the course of his illness, including hands and clothing of attendants.

**Terminal Disinfection** : It means the disinfection of the room or premises and their contents after the patient has recovered, died or has been removed elsewhere. This includes the vehicle or ambulance, the wheel chairs and stretcher used by the patient. This is either 'local' or 'complete'.

(i) **Local** : It is the disinfection of the bedding and the bedsheet occupied by the patient, the walls, floor, furniture including the kit box, shelf, lockers and their contents and all other surfaces or articles within 2 meters all round the bed.

(ii) **Complete** : It is the disinfection of the whole room and all its contents.

**Prophylactic Disinfection** : It means chemical treatment or boiling of water, pasteurization of milk, washing of hands and so on.

**Classification of Disinfecting Agents** : Disinfecting agents can be classified as follows :

(a) Natural Agents

- Fresh air
- Sunlight

(b) Physical Agents

- Dry Heat : Burning; Hot dry air; Contact heat - ironing
- Moist Heat : Boiling (with or without chemical agent); Steaming - current steam and steam under Pressure.
- Radiation : Ionizing radiation; Ultraviolet rays.

(c) Chemical Agents

- Solids
- Liquids
- Gases
- Aerosols

It will not, however, be correct to suppose that the action of any agent is circumscribed in or confined to its particular group only. Many disinfectants act both by physical action and chemical action e.g. soap acts by physically removing the grease and dirt which shelter the organisms as well as by its chemical action. Often, in practice, disinfection by chemical agents can be complemented or supplemented by physical agents. Thus clothing can first be soaked in a chemical agent, then steamed and finally washed, dried in the sun and ironed. Similarly disinfection by boiling can be accelerated or aided by the addition of a chemical or soap.

### Natural Agents

Fresh air dilutes the bacterial content in enclosed places and desiccates micro - organisms by dehumidification. Sunlight disinfects due to the desiccating effect of its heat rays and the action of its ultraviolet rays. Indeed, this disinfecting power of the sun has made life possible in the unsanitary tropical and subtropical environments. Although these agents are slow in action and frequently unreliable owing to the resistance of certain organisms, they are valuable adjuncts to artificial methods. In their absence the saprophytic life of all germs is prolonged. Thus, during epidemics, cinema theatres act as foci for the dissemination of infection since they usually admit no direct sunlight and little fresh air, whilst respiratory moisture delays desiccation.

### Physical Agents

Heat kills ectoparasites and micro - organisms by coagulating

their protoplasm. It may be employed in a dry or moist form. To ensure perfect sterility, the former demands a higher temperature and / or longer exposure than the latter. Heat, especially in the moist form, is the only physical agent that is reliably used for artificial disinfection and disinfestation in preventive medical practice.

**Dry Heat :** Burning is a certain and rapid method of disinfecting and disinfestation but has only a limited scope. It may, however, be the only available method on active service. For example, clothing contaminated by excreta of cholera patients may be burnt, or the ground which has been contaminated by an anthrax carcass may be disinfected by burning straw or oil on the top of it. Contact heat applied by pressing irons over clothing may be used to disinfest louse and mites. Hot air ovens are used to disinfect glass ware such as petridishes, sharp instruments, swabs, dressing, chalk, Vaseline etc. The temperature of the air in the oven should be maintained at 160°C for at least one hour.

**Moist Heat :** Boiling is quite effective in killing all non-spore forming organisms, spores being very resistant require boiling for an hour and a half. Boiling is largely used for sterilizing instruments and is useful for disinfecting bed clothing, underwear and similar articles. Blood stains become fixed by boiling owing to the coagulation of protein; these should, therefore, be first removed by soaking in cold soapy water. Another disadvantage of boiling is that it is unsuitable for thick bedding of woollens. The effect of boiling can be enhanced by adding soap or washing soda to water. Steaming is the most efficient procedure of disinfection and disinfestation. The usual method is to expose the infected articles to 'saturated steam' in 'current steam' or 'under pressure'.

#### Radiation

**Ionizing Radiation :** Gamma radiation or electron beams have the advantage of combining great penetrative power with little or no effect on the object to be sterilized. Bandages, catgut, dressing and surgical instruments may be sterilized by ionizing radiation. These methods are used commercially. The isotope used is Cobalt 60.

**Ultraviolet Rays :** Ultraviolet rays delivered from an apparatus hung in the ceiling at the entrance of special purpose rooms like the one in which premature infants are kept or in operation theatres, temporarily disinfect the objects and air entering inside.

**Steam Disinfection :** Steam in contact with boiling water from which it is generated has the temperature of 100°C and is called as 'saturated steam'. When it comes in contact with colder objects it immediately condenses and every gram of it transfers a latent heat of 537 calories to that object and it contracts to about 0.0015<sup>th</sup> of its volume and creates a partial vacuum. To fill the empty space more steam immediately rushes, condenses, releases the latent heat and again creates a partial vacuum. Continued repetition of this process achieves penetration of steam throughout the mass of the fabric. Heat is thus transferred to the exposed articles until its temperature is raised to 100°C. Intimate contact with saturated steam is instantly fatal to all non - spore forming organisms.

Steam introduced at atmospheric pressure is known as 'current'

or 'unconfined' steam; and at pressure in excess of that is called 'pressure' or 'confined steam'. The penetration of the pressure steam is no better than the current steam unless the chamber is vacuumised. By increasing pressure after creating vacuum much higher temperatures can be attained than the 100°C obtained with current steam. This renders 'pressure steam' disinfection more effective. This temperature of steam with a 0.33 kg per square cm rise of pressure above the atmosphere is 109°C, at 0.66 kg it is 115°C, at 1 kg 121°C, at 1.33 kg 126°C, and at 2.66 kg per square cm it goes upto 141°C and so on.

#### Chemical Agents

Chemical disinfectants may be solid, liquids, gases or aerosols. Solids act as disinfectants only in solution. A few disinfectants as powders, act better when dissolved. Gases like sulphur dioxide and formaldehyde also act as better disinfectants in the presence of adequate moisture. The disinfecting power of a chemical depends upon its basic toxicity, concentration, penetrating power, the medium in which it is to act, the resistance of organism required to be killed, the extent to which the organism is protected by organic matter like pus or faeces, and the period of contact allowed. The ideal chemical disinfectant should be capable of destroying all micro - organisms in all probable media within half an hour; it should be harmless to man and higher animals; it should not spoil metals, clothing and other household goods in the concentration usually employed; for convenience of transportation. It should be obtainable in a highly concentrated form; it should be capable of forming a solution or stable emulsion in water (even in hard water); and finally it should be cheap. The main problem with any disinfectant, however, is the ability of its particles to gain contact with bacteria. Capsulated organisms resist penetration to a marked degree; the organisms locked up even in microscopic masses of pus, mucus, faeces etc. are protected against most disinfectants unless the time of contact is long and the concentration high. Disinfection by chemicals is thus a complex process and the estimation of the true disinfecting power of any chemical agent is difficult (7, 8).

**Estimation of Germicidal Power :** The best known test for assessing germicidal power is the 'Rideal - Walker phenol coefficient test' (RW). In this test the bactericidal power of any chemical is compared with that of phenol under identical conditions. This is done by observing the comparative sterilizing effects of a series of dilutions of the particular chemical and those of phenol against a standard dose of a standard culture of the Lister strain of *B. typhosum*, in a standard time, at a standard temperature. The RW coefficient is obtained by dividing the highest sterilizing dilution of the agent under test by the highest dilution of phenol sterilizing in the same time. For example, if cresol diluted 1 : 1200 and phenol diluted 1 : 100 both produce sterility, say, in 15 min, the RW coefficient of cresol would be 12 i.e. cresol has 12 times the disinfecting power of phenol. The test, however, does not indicate the disinfecting powers of disinfectants under natural conditions. For example, the mercurial salts show a high RW coefficient but their disinfecting action is arrested by albuminous materials. Chlorine and potassium permanganate lose a great deal of potency in the presence of organic matter, while others like cresol are only slightly handicapped. Various

modified tests, like Chick - Martin's test, take into account the effects of extraneous material. However, the unmodified Rideal - Walker test is useful for comparing the germicidal power of different batches of the same disinfectant.

### Solids

**Quicklime** : It is used in the burial of animals dead of anthrax; for disinfecting byres and stables after the occurrence of a case of anthrax; and as 25 per cent lime wash for walls, ceiling and floors of barns, sheds, stables, kitchen, stores and so on. Slaked lime is used as a deodorant in and around urinals, soakage pits, grease traps; to promote bacterial growth by retarding acidity in deep trench latrines; and as a final spread over shallow trenches.

**Chlorine Compounds** : Bleaching powder, water sterilizing powder, sodium hypochlorite and many other kindred substances containing chlorine are used to sterilize water and vegetables. Bleaching powder in combination with boric acid has been used as eusol in surgery. The practice of sprinkling bleaching powder in drains, gutters, latrine pails etc. is wasteful and useless.

### Liquids

**Coal Tar Derivatives** : These are obtained by its fractional distillation and are most widely used of all the liquid disinfectants. This group includes the aniline dyes, the phenols and the cresols.

**Cresol** : It is a dark brown, oily, readily emulsifiable liquid. Liquor cresoli fortis, known in the Armed Forces as 'disinfecting fluid black' or simply as cresol, is the most convenient and the most useful general disinfectant. It turns white on dilution with water and is extremely stable. Liquor cresoli fortis has a RW coefficient of 12, but cresol commercially supplied may have a 10 RW. All containers are marked with the RW of the contained cresol so that, by increasing or decreasing the amount of dilution with water a final disinfectant liquid of known strength can be made. For general use, like scrubbing bedsteads the dilution of 1 per cent of RW 10 cresol is enough. In this dilution it is not dangerously toxic if swallowed, is only mildly irritating to the skin, and possesses high germicidal power. For disinfecting bedpans, sputum or excreta a dilution of 2.5% of RW 10 cresol is needed. Even in this dilution cresol does not destroy fabrics. Although it is rapidly fatal to micro-organisms when it comes in contact with them, its penetration into a mass of sputum or faeces is not good. Therefore, as a measure of greater safety, a 5 per cent emulsion is used for disinfecting sputum of tuberculosis cases and faeces of some excremental disease cases. Cresol is of great value in the disinfection of the receptacle after the contained infective material has been disposed of.

**Izal** : This is saponified cresol, officially known as 'disinfecting fluid white (Izal)'. This correct nomenclature should always be used. It is used in 3 per cent strength for disinfecting mouthpieces of telephones and microphones, of RT sets and PA sets and the face pieces of respirators. It should not be used for any other purpose.

**Dettol** : This is chloroxylenol. It is non - irritating but inactivated by organic matter. It is active against streptococci but has no effect on some gram - negative bacteria.

**Commercial Formalin** : This is a 40 percent aqueous solution of formaldehyde. It is a powerful disinfectant, but since it is very irritating to the hands, eyes and respiratory passages, it is not used as a general disinfectant. It can be used in a 5 per cent dilution for disinfecting rooms, tents, huts, or vehicles and for spraying fur - coats, leather, rubber, metal and similar articles which are destroyed by steam. It is used for disinfecting valuables like jewellery, gold and ornaments and watches. It is used for preserving tissues required to be sent to the laboratory for examination.

### Gases

**Sulphur Dioxide** : This gas has been used for fumigation against rats in ships and warehouses by the Clayton apparatus in which a forced draft from a blower ensures complete combustion of sulphur. By means of pipes led from the generator, a concentration of 15 per cent sulphur dioxide is attained in the air in enclosed places. Sulphur dioxide is not dangerous to human life, but tarnishes metals, discolours paints, destroys pictures, spoils grain and entails a risk of fire.

### Formaldehyde

The gas is generated popularly by pouring liquid formalin over crystals of potassium permanganate placed in a deep pan. About 300 ml of formalin and 150 gm of potassium permanganate are required for 1000 cft of space. The room is to be kept closed for 6 to 12 hours to allow disinfection.

### Aerosols

Aerosols are mists released into the air by a special atomizer to disinfect the air in enclosed places. Their action is believed to be either due to collision with and absorption by organisms or condensation of vapour on bacteria - carrying particles, quickly destroying their bacterial content. The ideal aerosol should be non - irritating to the mucosa, non - toxic even after prolonged exposure, invisible, inodorous, non - corrosive, non - inflammable, highly bactericidal in low concentrations, and capable of penetrating organisms in dried secretions such as saliva. The most effective and irritating particles have a diameter of less than 1 micron and act at dilution ranging 1 in 100 million to 500 million volume of air. Aerosol has an advantage over ultra violet rays in the disinfection of air in enclosed places due to their penetration to the remote corners of rooms. Aerosols so far tried for killing bacteria suspended in the air, fall into three groups viz. hypochlorites, resorcinols and glycols. Insecticide aerosols are effective against insects only. They contain Freon gas, Pyrethrum and DDT in solutions.

### General Recommendations

To summarize, disinfection of the following must always be considered in all cases of infectious illness :

- (a) The patient's excreta and discharges, linen, utensils and other articles used by the patient.
- (b) The quarters occupied by the patient before removal to hospital and their contents.
- (c) The vehicle in which the patient is conveyed to hospital.
- (d) On recovery of the patient, the ward/ room in which the patient was treated and its contents.
- (e) In the case of carriers or contacts disinfection should be carried out at the discretion of the officer in medical charge.



### Details of Procedures to be followed

**(a) Concurrent Disinfection :** It should always be considered as extremely important. Concurrent disinfection of various infective materials in appropriate cases should be carried out as follows :

- (i) Sputum should be received directly into sputum cups containing 2.5 per cent cresol and afterwards burnt.
- (ii) Nasal, aural and eye discharges should be received directly into small pieces of linen, cotton or cotton wool, and immediately burnt. Vaginal or urethral discharges and those from open sores should also be similarly received on pads left in situ under dressings and burnt after removal at frequent intervals. Handkerchiefs should be soaked in 2.5 percent cresol solution before washing with soap and ironing.
- (iii) Contents of bed pans and urine bottles used by patients suffering from gastro - intestinal diseases as well as their vomits should be thoroughly mixed with an equal quantity of 2. 5 per cent cresol and allowed to stand for 2 hours before throwing down the sluice or water closet or incinerated. Bed pans and bottles should subsequently be steeped in 2. 5 per cent cresol for 15 min to half an hour and then washed.
- (iv) Bed linen, blankets etc. which have been soiled with infectious discharges, exudates or excreta should be steeped in 2.5 percent cresol for half an hour before removal from the ward. Special bedding and clothing marked with 'I' are reserved for use of patients suffering from infectious diseases.

**(b) Terminal Disinfection :** It is complementary to the concurrent disinfection. All clothing, mattresses, bedding, linen, personal wear and similar articles within the specified areas for local or complete disinfection as indicated are packed in sacks, or sheets soaked in 2. 5 per cent cresol and removed to the disinfection center for steam disinfection. After disinfecting, the articles of clothing and linen are washed with soap, dried in the sun and ironed. The floor, the walls and wall - skirting, bedsteads, shelves and any other metal or wooden article, other than those which are removed for steam disinfection, are disinfected in situ by scrubbing or spraying with 2.5 per cent cresol. After a suitable period of contact with the disinfectant, these may be washed.

#### (c) Some Special Disinfections

**(i) Vehicle or Aircraft :** Spray or swab with 5 per cent formalin or 2. 5 per cent cresol followed by washing in hot water with soda.

**(ii) Crockery and Cutlery :** Steep for half an hour in 2. 5 per cent cresol followed by washing in hot water with soda.

**(iii) Toys, Book and Papers :** If of small value, they may be burnt. If valuable, spray or swab with 5 per cent formalin followed by exposure to the air for two to three days.

**(iv) Shaving Brushes :** Thoroughly wash in 5 per cent soap solution containing one per cent soda ash at 50°C. Allow to stand in one per cent soda ash at 50°C for half an hour. Soak for half an hour in 10 percent formalin solution at 50°C. Allow to dry in the shade, bristles downwards.

**(v) Latrine Seats :** Scrub with 2.5 per cent cresol, which should then be allowed to dry on the seat.

### Summary

The fields of preventive medicine and public health share the goals of promoting general health, preventing specific diseases. The amenability of a disease to prevention and control depends upon the knowledge of aetiological agent, the natural history or course of the disease and the incubation period. The disease process is a dynamic one and is initiated by a disturbance of the balance between man and environment. The natural history of disease can be seen as having three stages the pre pathogenesis phase (pre disease phase), the pathogenesis phase (the latent and symptomatic disease stage) and the post pathogenesis phase. The objective in the pre - pathogenic phase is to achieve primary prevention. In the pathogenic phase, secondary prevention aims at early case detection & treatment. In the post - pathogenic phase, disability limitation helps early rehabilitation of the patients. Control Measures aim at exterminating the causative agent in its reservoir at the source of its production, its destruction soon after exit and before it starts its spread by interrupting its path of transmission. The practical measure of control broadly fall under three main heads; these are : Control of Reservoir and Source of Infection comprising of Quarantine, Surveillance, Disinfection etc.; Blocking the channels of Transmission, which may be achieved by general environmental control, specific control measures such as safe water supply, sanitary disposal of sewage etc., Disinfection means destruction outside the body, of specific microorganisms, which cause communicable diseases. It must always be considered in all cases of infectious illness. Disinfection Procedures involves Concurrent Disinfection, Terminal Disinfection and Prophylactic Disinfection. The various Disinfecting agents can be classified as Natural Agents, Physical Agents and Chemical Agents.

### Study Exercises

**Long Question :** (1) Discuss Natural History of Disease and Levels of Prevention and Control of diseases. (2) Classify and discuss various disinfecting agents

**Short Notes :** (1) Control Measures used in infectious diseases (2) Chemoprophylaxis (3) Terminal Disinfection (4) Physical Agents of Disinfection (5) Rideal - Walker phenol coefficient test

#### MCQs

1. The objective of Prevention and Control measures in the pre - pathogenic phase is to achieve (a) Primary prevention (b) Secondary prevention (c) Tertiary prevention (d) None of the above
2. Broad categories of Disinfecting Agents are all except (a) Natural Agents (b) Physical Agents (c) Chemical Agents (d) Gaseous Agents
3. The temperature of the air in the oven should be maintained at (a) 160°C for at least one hour (b) 170°C for at least one hour (c) 180°C for at least one hour (d) 190°C for at least one hour



4. Steam introduced at pressure in excess of atmospheric pressure is known as (a) Current Steam (b) Unconfined Steam (c) Saturated steam (d) Confined steam
5. Contents of bed pans used by patients suffering from gastro-intestinal diseases should be thoroughly mixed with an equal quantity of \_\_\_\_ per cent cresol and allowed to stand for \_\_\_\_ hours before throwing (a) 0.5% for 1hr (b) 0.5%, 2hr (c) 2.5%, 1hr (d) 2.5%, 2hr

**Answers :** (1) a; (2) d; (3) a; (4) d; (5) c.

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## Public Health Laboratory : Microbiological Procedures

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Outbreaks of communicable diseases are public health emergencies which result in increased morbidity and mortality and place acute demands on the health system. A surveillance network, including available laboratory support and aimed at a simplified syndromic surveillance of priority communicable disease syndromes is important for early detection, control and prevention of outbreaks. Laboratory support is an integral component of any disease surveillance system as well as outbreak investigation system (1, 2).

## Syndromic Approach to Investigation of Outbreaks

The underlying principle of the "*Syndromic Approach*" to communicable disease surveillance and field investigation of an outbreak is that the case definition is based on a syndrome and not on a specific disease e.g. acute diarrhoeal syndrome. Syndromic surveillance may be the ideal type of public health surveillance to detect outbreaks whether they are intentional or naturally occurring events. These systems monitor for disease by tracking symptom complexes that are representative of most diseases. The system looks for significant increases in the frequency of a given syndrome against a baseline and provides timely notification of any increase (3). Syndromic surveillance is already being practiced in India e.g. Acute Flaccid Paralysis Surveillance.

### Disease Syndromes according to Clinical Criteria

For the purposes of routine disease surveillance as well as field investigation of priority communicable diseases, the syndromes based on clinical criteria are as given below (2) :

- Acute Diarrhoeal Syndrome
- Acute Haemorrhagic Fever Syndrome
- Acute Jaundice Syndrome
- Acute Neurological Syndrome
- Acute Respiratory Syndrome
- Acute Dermatological Syndrome
- Acute Ophthalmological Syndrome
- Acute "Systemic" Syndrome

Some of the diseases or pathogens which cause outbreaks are enumerated in Table - 1. The list is not exhaustive as many illnesses are restricted geographically or may present with unexpected clinical features.

## Planning for Clinical Specimen Collection

Proper collection of an appropriate clinical specimen is the first step in obtaining an accurate laboratory diagnosis of an infectious disease. The important considerations for specimen collection and handling are :

- Based on the preliminary information on the syndrome responsible for the outbreak, decide on the possible differential diagnosis for further investigations.
- The quantity and nature of the supplies required in the field such as containers, reagents, rapid kits, transport media etc. and the level of expertise of the personnel required in the field must be considered before setting out to investigate the outbreak.
- Keep *outbreak investigation kit* always ready with the team (see Table - 2).
- Specimens obtained in the acute phase of the disease, preferably prior to administration of antimicrobial drugs, are more likely to yield the infective pathogen.
- Once in the field, ensure proper collection, storage and transport of the specimen in leak - proof containers labeled properly and accompanied by complete patient information in standard formats.
- Universal safety precautions require that workers should

Table - 1 : Diseases and pathogens encountered in outbreak investigations	
Syndrome	Diseases / Pathogens
Acute Diarrhoeal Syndrome	<b>Possible Diseases/ Pathogens :</b> (a) <i>Watery Diarrhoea</i> : Cholera, Viral gastroenteritis (Norwalk - like and Rotavirus), Enterotoxigenic <i>E.coli</i> , Giardiasis, Cryptosporidium (b) <i>Dysentery</i> : Shigellosis, Salmonellosis, Enterohaemorrhagic <i>E. coli</i> , Amoebic dysentery, Campylobacteriosis, <i>Clostridium difficile</i>
	<b>Other Causes :</b> Ebola and other haemorrhagic fevers*
Acute Haemorrhagic Fever Syndrome	<b>Possible Diseases / Pathogens :</b> Dengue haemorrhagic fever and shock syndrome, Malaria, Relapsing fever
	<b>Other Causes :</b> Yellow fever, other arboviral haemorrhagic fevers
Acute Jaundice Syndrome	<b>Possible Diseases / Pathogens :</b> Hepatitis A to E, Leptospirosis
	<b>Other Causes :</b> Yellow fever
Acute Neurological Syndrome	<b>Possible Diseases/ Pathogens :</b> Poliomyelitis or Guillain Barré syndrome, Japanese encephalitis, Meningococcal meningitis, Leptospirosis, Malaria
	<b>Other Causes :</b> Rabies and other lyssaviruses, Tick - borne encephalitis viruses, Trypanosomiasis
Acute Respiratory Syndrome	<b>Possible Diseases / Pathogens :</b> Influenza, Diphtheria, Streptococcal pharyngitis, Bacterial pneumonias including : Pneumococcal pneumonia, <i>Streptococcus pneumoniae</i> , <i>Haemophilus influenzae</i> , Mycoplasma, Respiratory anthrax, Pertussis, Pneumonic plague, Legionellosis
	<b>Other Causes :</b> Hantavirus pulmonary syndrome, Respiratory Syncytial Virus (RSV), Q fever, SARS
Acute Dermatological Syndrome	<b>Possible Diseases / Pathogens :</b> Chickenpox, Measles, Rubella, Typhus, Cutaneous anthrax
	<b>Other Causes :</b> Monkeypox, Parvovirus B19
Acute Ophthalmological Syndrome	<b>Possible Diseases / Pathogens :</b> Epidemic adenoviral keratoconjunctivitis, Haemorrhagic conjunctivitis (adeno - or enteroviral), Trachoma ( <i>Chlamydia trachomatis</i> )
Acute "Systemic" Syndrome	<b>Possible Diseases / Pathogens :</b> Dengue fever and other Arboviral fevers, Viral Hepatitis, Typhoid fever, Malaria, Leptospirosis, Brucellosis, Anthrax, Bubonic Plague, Typhus
	<b>Other Causes :</b> Hantaviral disease, Lassa fever, Lyme disease, , Relapsing fever, Rift Valley fever, Yellow fever, Borreliosis
* NOTE : Ebola and other haemorrhagic fevers may initially present as bloody diarrhoea. If such aetiology is suspected, refer to "Acute Haemorrhagic Fever Syndrome" for appropriate specimen collection guidelines. Source : Adapted from (2)	

handle all clinical specimens as if they were infectious.

- Ensure that appropriate bio - safety and waste management measures are followed.
- Inform the receiving laboratory about the tentative date and time of arrival of the specimen.
- The aim should be to reduce the time to confirmation so that timely public health actions can be taken. Only, a few initial cases need confirmation. Rest with similar clinical manifestations should be treated as confirmed.

#### Collection & Transportation of Clinical Specimens

The appropriate clinical specimens that should be collected in various disease syndromes for the laboratory confirmation of the pathogen responsible for the outbreak are summarized in Table - 3.

The general guidelines for collection and transportation of clinical specimens are given in the successive paragraphs.

**Blood Specimen Collection :** Blood and separated serum are the most common specimens taken to investigate outbreaks

of communicable disease. Venous blood is to be collected for identification of the pathogen in culture and serum for PCR, specific antibodies, antigens, or toxins and viral pathogens. For specific antibodies, paired sera are required to be collected. Finger prick method is to be used for slides for microscopy or for absorption onto special filter paper discs for analysis. Whenever possible, blood specimens for culture should be taken before antibiotics are administered to the patient.

#### Handling and transport

- Blood culture bottles and blood sample tubes should be transported upright and secured in a screw cap container or in a rack in a transport box. Cushion or suspend bottles during transport over rough terrain to prevent lysis of red cells. They should have enough absorbent paper around them to soak up all the liquid in case of a spill. If the specimen will reach the laboratory within 24 hours, most bacterial pathogens can be recovered from blood cultures transported at ambient temperature.

<b>Table - 2 : Proposed Components of the Outbreak Investigation Kit</b>	
<b>Generic Outbreak Investigation Kit</b>	
Disposable storage vials (5ml & 10 ml)	Rubber bands
Disposable sample collection vials	Ziploc plastic bags
Vacuutainer (plain and EDTA)	Absorbent material (tissue paper, cotton wool, newspaper)
Cryovials	Filter paper
Syringes and needles disposable (5ml & 10 ml)	Vaccine carrier with ice - packs
Tuberculin syringes and needles	Dry ice packs
Lancets	Glass marking pen
Slides, cover slips and slide holding box	Specimen labels
Tourniquet	Adhesive tape
Gloves	Scissors
Masks (triple layer surgical mask)	Scalpel/ blade
Disposable caps	Spatula
Goggles	Forceps
Disposable gowns	Loop holder
Swabs & gauze pads	Parafilm (small rolls)
Povidone iodine 10%	Leak proof screw capped containers
Isopropyl alcohol 70%	Pasteur pipettes/ pipettes and pipette aids (rubber teats)
Band - aid	Sodium hypochlorite concentrate (4%)
Spirit lamp/ gas lighter	Hand disinfectant
Match - box	Stationary (writing pads, pens, pencils, erasers, sharpeners etc.)
Test tube rack	Calculator
Centrifuge tubes	Torch with spare batteries/ rechargeable batteries
Puncture proof discarding bags (disposable)	OT test kit
Thermometers	Water sampling kits
Tongue depressors (disposable)	Distilled water (100ml)
CSF collection kit	Normal saline in dropper bottle
Stool culture bottle	Magnifying glass
Throat swabs	Patient register book
Blood culture bottles	Laboratory request forms
Viral transport medium (VTM)	Epidemiological survey formats
Cary Blair medium/ Stuart's transport medium	Epidemiological reporting formats
Rapid diagnostic kits (e.g. H2S method kit for water testing, latex agglutination for meningitis, card test for dengue etc.) wherever possible	Outbreak investigation guide/ module
Sharps disposal boxes	Laptop Computer with case
<b>Selected Entomological &amp; Vector Dissection Equipment</b>	
Aspirator and flashlight for indoor/ outdoor mosquito collection	WHO susceptibility kit for adult & larvae with reagents
Kit for outdoor mosquito collection	Bioassay kit
Ladle bottles for keeping larvae, strainer, dropper, trays and funnel net for wells	Charts/ synoptic keys for identification of vectors
White bed sheet to spread on floor	Pyrethrum spray with flit gun
Dissecting microscope	Staining equipment & material
Dissection needle	Filter paper
Petridishes	Mosquito net
Slides, coverslips	Physiological saline
Note : Any other item, as per the requirements of the outbreak. Source : Adapted from (1, 2, 4, 5)	

Table - 3 : Clinical Specimens needed and Laboratory Tests to be Performed in Various Disease Syndromes			
Syndrome	Specimens Required	Laboratory Tests To Be Done	
		Field / Peripheral Lab	Zonal/ Referral Lab
<b>Acute Diarrhoeal Syndrome*</b> *(including suspected food-borne outbreaks)	<ul style="list-style-type: none"> <li>Freshly passed stool</li> <li>Rectal swab</li> <li>Faecal swab</li> <li>Environmental sampling especially water for available chlorine and bacteriological examination</li> </ul> <p><i>If food-borne outbreak is suspected:</i> Refrigerate all remaining food items for further testing if necessary.</p>	<ul style="list-style-type: none"> <li>Hanging drop / Iodine &amp; wet mount of stool specimen</li> <li>Parasite : Macro- and microscopic examination</li> <li>OT test for available chlorine in water</li> <li>Rapid H<sub>2</sub>S test for bacteriological examination of water</li> </ul>	Earlier tests, plus <ul style="list-style-type: none"> <li>Faecal leukocytes</li> <li>Toxin detection test for cholera toxin (if kit available)</li> <li>MPN test for bacteriological examination of water</li> <li>Stool culture for enteropathogens; sensitivity testing, if available</li> <li>Serotyping</li> <li>Referral of samples for further characterization and testing, if required</li> </ul>
<b>Acute Haemorrhagic Fever Syndrome</b>	<ul style="list-style-type: none"> <li>Blood</li> <li>Blood smear</li> <li>Serum</li> <li>Post - mortem tissue specimens (e.g. skin biopsy and/ or liver biopsy)</li> </ul>	<ul style="list-style-type: none"> <li>Peripheral smear for malarial parasite</li> <li>Total leukocyte count</li> <li>Differential leukocyte count</li> <li>Platelet count</li> <li>Rapid diagnostic tests for diagnosis of dengue fever</li> </ul>	Earlier tests, plus <ul style="list-style-type: none"> <li><i>Viral</i> : Culture; Antigen detection; Antibody levels (IgM/ IgG)</li> <li><i>Parasitic</i> : Demonstration of pathogen</li> <li><i>Yellow fever</i> : post-mortem liver biopsy</li> <li>Referral of samples for further characterization and testing, if required</li> </ul>
<b>Acute Jaundice Syndrome</b>	<ul style="list-style-type: none"> <li>Blood</li> <li>Serum</li> <li>Urine</li> <li>Environmental sampling especially water for available chlorine and bacteriological examination</li> </ul>	<ul style="list-style-type: none"> <li>OT test for available chlorine in water</li> <li>Rapid H<sub>2</sub>S test for bacteriological examination of water</li> <li>Dark ground microscopy of peripheral blood for leptospirosis</li> <li>Rapid test kit for diagnosis of viral hepatitis (HbsAg antigen detection and anti-HCV)</li> </ul>	Earlier tests, plus <ul style="list-style-type: none"> <li>MPN test for bacteriological examination of water</li> <li>Urine microscopy</li> <li>Rapid tests for detection of antibodies to <i>Leptospira</i></li> <li>Blood for <i>Leptospira</i> : Culture; Serotyping</li> <li><i>Yellow fever</i> : post-mortem liver biopsy</li> <li><i>Viral</i> : Culture; Antigen detection; Antibody levels (IgM/ IgG)</li> <li>Referral of samples for further characterization and testing, if required</li> </ul>
<b>Acute Dermatological Syndrome</b>	<ul style="list-style-type: none"> <li>Vesicular fluid</li> <li>Crust</li> <li>Serum</li> <li>Lesion swab (vesicular exudate)</li> <li>Tzanck smears (vesicle floor scrapings)</li> </ul>	<ul style="list-style-type: none"> <li>Giemsa stain for Tzanck smears (scrapings of floor of vesicles)</li> </ul>	Earlier tests, plus <ul style="list-style-type: none"> <li>Electron microscopy of vesicle fluid</li> <li><i>Bacterial</i> or <i>Viral</i> : Culture; Antibody levels (IgM/ IgG); Immunofluorescence</li> </ul>
<b>Acute Ophthalmological Syndrome</b>	<ul style="list-style-type: none"> <li>Conjunctival swab and smear</li> <li>Throat swab</li> <li>Serum</li> </ul>	<ul style="list-style-type: none"> <li>Giemsa stain for HP bodies (<i>C.trachomatis</i>)</li> </ul>	Earlier tests, plus <ul style="list-style-type: none"> <li>Chlamydial : Microscopic examination, Culture, Antigen detection</li> <li><i>Viral</i> : Antigen detection Antibody levels (IgM/ IgG)</li> </ul>



Table - 3 (Contd..)

Syndrome	Specimens Required	Laboratory Tests To Be Done	
		Field / Peripheral Lab	Zonal/ Referral Lab
<b>Acute Neurological Syndrome</b>	<ul style="list-style-type: none"> <li>CSF</li> <li>Blood</li> <li>Serum</li> <li>Stool</li> <li>Urine</li> <li>Throat swab</li> <li>Post - mortem tissue in suspected rabies (e.g. corneal impressions, brain tissue, skin biopsy from neck)</li> <li>Environmental sampling especially water for available chlorine and bacteriological examination</li> </ul>	<ul style="list-style-type: none"> <li>Gram stain of CSF &amp; CSF cytology</li> <li>India ink mount of CSF</li> <li>Dark ground microscopy of peripheral blood for leptospira</li> <li>OT test for available chlorine in water</li> <li>Rapid H<sub>2</sub>S test for bacteriological examination of water</li> </ul>	Earlier tests, plus <ul style="list-style-type: none"> <li>MPN test for bacteriological examination of water</li> <li>Latex agglutination tests for detection of capsular antigen in CSF (if kit available)</li> <li>Rapid tests for detection of antibodies to Leptospira</li> <li>CSF for bacterial culture (if facilities available)</li> <li>Blood for bacterial culture</li> <li>ELISA for JE virus</li> <li><i>Polio</i>myelitis : Stool culture, Antigen detection, Intratypic differentiation</li> <li><i>Rabies</i>: Demonstration of <i>Negri</i> bodies by Seller's stain in post-mortem tissue, virus isolation, fluorescent antibody test</li> <li>Referral of samples for further characterization and testing, if required</li> </ul>
<b>Acute Respiratory Syndrome</b>	<ul style="list-style-type: none"> <li>Throat swab</li> <li>Per-nasal swab / nasopharyngeal swab (for suspected pertussis)</li> <li>Sputum</li> <li>Bronchoalveolar lavage/ tracheal aspirate</li> <li>Blood for culture</li> <li>Serum</li> <li>Urine (for <i>Legionella</i>)</li> </ul>	<ul style="list-style-type: none"> <li>Gram stain of throat swab and sputum*</li> <li>Albert's stain of throat swab*</li> <li>Inoculation of blood culture bottles and swabs in appropriate transport media</li> </ul> <p><i>* For diphtheria &amp; other organisms</i></p>	Earlier tests, plus <ul style="list-style-type: none"> <li>Bacterial culture (and antimicrobial susceptibility, wherever applicable) from throat swab, sputum, blood</li> <li>Toxin detection tests for bacteria</li> <li><i>Viral</i> : Culture; Antigen detection; Antibody levels (IgM/ IgG)</li> <li>Serotyping</li> <li>Referral of samples for further characterization and testing, if required</li> </ul>
<b>Acute "Systemic" Syndrome</b>	<ul style="list-style-type: none"> <li>Blood smears (thick and thin)</li> <li>Blood Serum</li> <li>Bubo aspirate</li> <li>Post-mortem tissue specimens (e.g. liver biopsy)</li> <li>CSF (if meningeal signs present)</li> <li>Urine</li> <li>Stool</li> <li>Clotted blood (5 or 10 ml)</li> <li>Tracheal or lung aspirate</li> </ul>	<ul style="list-style-type: none"> <li>Peripheral smear for malarial parasite</li> <li>Rapid diagnostic tests for diagnosis of malaria, dengue fever and typhoid (Typhidot test)</li> <li>Platelet count</li> <li>Total leukocyte count</li> <li>Differential leukocyte count</li> <li>Gram stain (bacteria)</li> <li>Bubo aspirate: stab deeply into Cary Blair transport medium</li> <li>OT test for available chlorine in water</li> <li>Rapid H<sub>2</sub>S test for bacteriological examination of water</li> </ul>	Earlier tests, plus <ul style="list-style-type: none"> <li>Widal test</li> <li>Weil-Felix reaction</li> <li>Stool culture for enteropathogens</li> <li>Blood culture and sensitivity</li> <li><i>Viral</i> : Culture; Antigen detection; Antibody levels (IgM/ IgG)</li> <li>Serotyping</li> <li>Yellow fever: post-mortem liver biopsy</li> <li>MPN test for bacteriological examination of water</li> <li>Referral of samples for further characterization and testing, if required</li> </ul>

- If serum will be required for testing, separation from blood should take place as soon as possible, preferably within 24 hours at ambient temperature and ideally as soon as clot formation occurs. If the specimen will not reach a laboratory for processing within 24 hours, serum should be separated from blood prior to transportation. Sera may be stored at 4 - 8°C for up to 10 days. If testing is delayed for a long period, serum samples may be frozen.
- If separation on site is not possible, or is inadvisable for safety reasons, the blood sample should be stored at 4 - 8°C and protected from excessive vibration while transporting. Unseparated blood samples should not be frozen.

**Method of Preparation of Blood Films :** Blood films should be made by trained personnel. If this is not possible, they can be spread from heparinized or EDTA blood specimens sent to the laboratory.

#### Steps for making thick films for microscopy

- Label the slide with patient identification number and name.
- Disinfect and prick site with a lancet.
- Touch one or more large drops of blood onto the centre of the slide making sure that the slide does not touch the skin.
- Spread the blood in a circle about 1 cm in diameter using the corner of another glass slide or with a needle. Thickness of the film should be such that it is possible to read newsprint through it.
- Air dry the film in a horizontal position. Do not dry the film by heating over a flame or other heat source.

#### Steps for making thin films for microscopy

- Label the slide with patient identification number and name.
- Touch another drop of blood to the glass slide about 2 cm from one end making sure that the slide does not touch the skin.
- Place the slide horizontally on a flat surface.
- Hold the side of a second clean glass slide (the spreader) on to the center of the specimen slide and move it back until it touches the drop and the blood spreads along its base.
- At an angle of about 45°, move the spreader firmly and steadily across the specimen slide and air dry the film quickly. Do not dry over a flame or other heat source.
- Fix the dried film by dipping the glass slide in methanol or other fixative for a few seconds and air dry.

**Handling and Transport :** Air dried and/ or fixed films are transported at ambient temperature, preferably within 24 hours of specimen collection. They must not be refrigerated. Thick and thin films are usually kept in separate slide boxes.

**Cerebrospinal Fluid (CSF) Specimen Collection :** The specimen must be taken by a physician or a person experienced in the procedure. Standard lumbar puncture tray is needed. CSF is used in the diagnosis of viral, bacterial, parasitic, and fungal meningitis.

#### Handling and transport

- CSF specimens for bacteriology are transported at ambient temperature, generally without transport media. They must

never be refrigerated as many of the relevant pathogens do not survive at low temperatures.

- CSF specimens for virology do not need transport medium. They may be transported at 4 - 8°C for up to 48 hours or at - 70°C for longer periods.

**Eye Specimen Collection :** Conjunctival and corneal swabs and smears are the usual specimens collected. Strict aseptic technique is essential when collecting and processing these specimens.

**Method of collection of conjunctival swabs :** Clean the skin around the eye with a mild antiseptic. Moisten a swab in sterile saline and roll over the conjunctiva in a circular manner. Insert the swab into a sterile screw - cap tube containing the appropriate transport media for bacteria e.g. Stuart's transport media.

#### Handling and transport

- Specimens for detection of bacterial pathogens are transported at ambient temperature in appropriate bacterial transport medium.
- Specimens for viral detection are transported at 4 - 8°C in virus transport medium.
- Microscopic slides are air dried and transported at ambient temperature in a slide box.

**Faecal Specimen Collection :** Stool specimens are most useful for microbiological diagnosis if collected soon after onset of diarrhoea (for viruses < 48 hours and for bacteria < 4 days), and preferably before the initiation of antibiotic therapy. If required, two or three specimens may be collected on separate days. Stool is the preferred specimen for culture of bacterial, viral, and parasitic diarrhoeal pathogens. Rectal swabs showing faeces may also be used from infants. In general, rectal swabs are not recommended for the diagnosis of viruses.

#### Method for collecting a stool specimen

- Collect freshly passed stool, 5ml liquid or 5g solid (pea - size), in a container
- Label the container.

#### Method of collecting a rectal swab from an infant

- Moisten a swab in sterile saline
- Insert that swab tip just past the anal sphincter and rotate gently
- Withdraw the swab and examine to ensure that the cotton top is stained with faeces
- Place the swab in sterile tube/ container containing the appropriate bacterial or viral transport medium
- Break off the top part of the stick without touching the tube and tighten the screw cap firmly
- Label the vial with patient's name type of specimen and date of collection.

#### Handling and transport

- Stool specimens should be transported at 4 - 8°C. Bacterial yields may fall significantly if specimens are not processed within 1 - 2 days of collection. Shigella are particularly sensitive to elevated temperatures. If the laboratory is at a distance, samples should be transported in Cary Blair medium in cases of diarrhoea. In cases of suspected cholera samples should be transported in Alkaline peptone water or Thiosulphate Citrate Bile salt Sucrose Agar. (TCBSA).

- Specimens to be examined for parasites should be mixed with 10% formalin or Polyvinyl Alcohol; three parts stool to one part preservative. Transport at ambient temperature in containers sealed in plastic bags.

**Bedside Microscopy** : In cases of suspected cholera “darting motility” can be demonstrated if a slide and microscope are available. A hanging drop preparation of the sample is ideal for making this diagnosis.

#### Method of preparation of Hanging Drop

- Take a clean glass slide & make a thin ring of plasticine (good quality) and apply it over the slide.
- Thickness of the ring should not be more than 1mm, so that there is no difficulty in focusing the slide with 40X high power objective.
- Take a clean coverslip & put on small drop of liquid culture over the coverslip with the help of a small sized inoculating loop (about 1mm diameter).
- Put the slide containing plasticine ring over the coverslip containing the drop of liquid culture without touching the drop and then invert the slide so that the drop hangs.
- Put the condenser low and focus the slide in low power (10X objective) and try to focus the edge of the drop.
- Examine next in high power i.e. 40X objective for checking the motility against the stationary background.

**Respiratory Tract Specimen Collection** : Preferably, specimens should be taken within the first 3 days after onset of symptoms for most respiratory infections. Specimens are collected from the upper or lower respiratory tract, depending on the site of infection. Upper respiratory tract pathogens (viral and bacterial) are found in throat or nasopharyngeal specimens. Lower respiratory tract pathogens are found in sputum specimens.

**Method of collecting a throat swab** : Hold the tongue down with the depressor. Use a strong light source to locate areas of inflammation and exudate in the posterior pharynx and the tonsillar region of the throat behind the uvula. Rub the area back and forth with a Dacron or calcium alginate swab. Withdraw the swab without touching cheeks, teeth or gums and insert into a screw - cap tube containing transport medium.

#### Method of collecting per - nasal and post - nasal swabs (for suspected pertussis)

- Seat the patient comfortably, tilt the head back and insert the nasal speculum.
- Insert a flexible calcium alginate/ Dacron swab through the speculum parallel to the floor of nose without pointing upwards. Alternately, bend the wire and insert it into the throat and move the swab upwards into the nasopharyngeal space.
- Rotate the swab on the nasopharyngeal membrane a few times, remove it carefully and insert it into a screw - cap tube containing transport medium.

**Method of collecting sputum** : Instruct patient to take a deep breath and cough up sputum directly into a wide - mouth sterile container. Avoid saliva or postnasal discharge. Minimum volume should be about 1 ml.

**Handling and transport** : All respiratory specimens except sputum are transported in appropriate bacterial/ viral media. Transport as quickly as possible to the laboratory to reduce

overgrowth by commensal oral flora. For transit periods up to 24 hours, transport bacterial specimens at ambient temperature and viruses at 4 - 8°C, in appropriate media.

**Collecting Specimens of Skin Lesions** : For most dermatological conditions, diagnosis may be established on the basis of physical examination and clinical history without the collection of diagnostic specimens.

#### Method of collection

##### 1. Vesicular or vesiculo - pustular rash (for diagnosis of viral infections)

- Pierce roof of fluid - containing vesicle with sterile lancet.
- Swab fluid with two sterile swabs. Try to get a good amount of fluid onto the swab.
- Take a clean labeled microscope slide and make a smear with one swab in the central area of the slide. Make two slides if possible. The slides should be left to dry in air.
- Place the second swab directly into virus transport medium.

##### 2. Crusting stage

- Gently ease off crust with a lancet or scalpel and a pair of disposable forceps.
- Take 5 - 10 crusts; place them in a plastic screw - cap vial. Make sure the lid is tightly closed.
- If cutaneous anthrax is suspected, the vesicular fluid under the eschar is a better diagnostic specimen than a piece of the eschar.

##### 3. Aspiration of abscesses

- Aspiration of abscesses should only be performed by experienced personnel
- Disinfect the skin overlying the abscess/bubo with 70% isopropyl alcohol
- Aspirate the fluid from the abscess with a sterile needle and syringe. Only enough fluid to perform the diagnostic tests is required to be sent even though all may be aspirated.
- Transfer the aspirate aseptically into a sterile tube with transport medium.

**Handling and transport** : Specimens for bacteriological analysis should be transported in Stuart's or Amies transport medium. Swabs for suspected viral pathogens should be transported in virus transport medium. If processing takes longer than 2 hours, bacteriology specimens can be maintained at ambient temperature for 24 hours. Specimens for virus isolation may be refrigerated at 4 - 8°C, and transported to the laboratory as rapidly as possible.

**Urine Specimen Collection** : Give the patient clear instructions to pass urine for a few seconds, and then to hold the cup in the urine stream for a few seconds to catch a *midstream clean catch* urine sample. This should decrease the risk of contamination from organisms living in the urethra.

**Handling and transport** : Transport to the laboratory within 2 to 3 hours of collection. If this is not possible, do not freeze, but keep the specimen refrigerated at 4 to 8°C. Keeping the specimen refrigerated will decrease the risk of overgrowth of contaminating organisms.

**Post - mortem Specimen Collection** : Strict precautions, including respiratory protection from aerosolized particles, must be taken when carrying out post - mortem specimen

collection in communicable disease outbreaks. Collect the specimens as soon as possible, since viral titres decline while bacteria multiply rapidly after death. Thorough post - mortem examinations may only be accomplished by experienced medical personnel. Prior experience and training is also advised even for the minimal collection of specimens from cadavers.

#### Handling and transport

- Fixed specimens can be stored and transported at ambient temperature.
- Tissue specimens for isolation of bacterial pathogens can be transported at ambient temperature in transport media for up to 24 hours.
- Transport tissue specimens for isolation of viral pathogens in viral transport medium or sterile saline at 4 - 8°C for 24 - 48 hours. For longer periods, freeze and store at - 70°C.
- If rabies is suspected and brain samples are collected, freeze unfixed specimens immediately after collection. Formalin - fixed samples are also useful and may be transported at ambient temperature.

#### Labeling and Identification of Specimens

Adequate labeling ensures that the laboratory results can be linked to the correct patient. Each patient should be assigned a unique identification number. This unique identification number and the patient name should be present on specimens, epidemiological data forms, and the laboratory transmittal forms. Glass slides for microscopy must be labeled individually, using glass - marking pencil. This should not interfere with the staining process.

**Label on specimen :** The label may be a piece of paper attached to the specimen container. Alternatively, the information may be written directly on the specimen container with the following essential details :

Patient Name _____	Identification No. _____
Specimen Type _____	Date & Time of Collection _____

**Note :** Do not attach the label to the top of the specimen container.

#### Laboratory Investigation Form

A laboratory request form must be completed for each specimen and contain information to interpret the necessary tests. This may include :

- *Patient information :* Age (or date of birth), sex, complete address
- *Clinical information :* Date of onset of symptoms, clinical and immunization history, risk factors or contact history where relevant, antimicrobial drugs taken prior to specimen collection etc.
- *Laboratory information :* Acute or convalescent specimen, other specimens from the same patient.

For a large number of patients, it may be practical to submit the

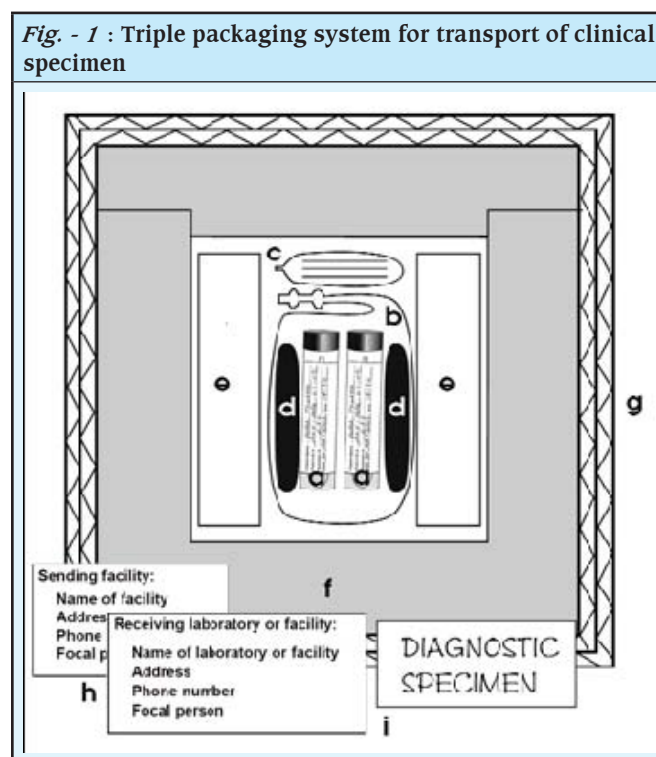
requests to each relevant laboratory as a 'line listing'.

#### Transport of Clinical Specimens Using the Triple Packaging System

The specimen should be transported in a basic triple packaging system (see Fig.1) to ensure biosafety, transient temperature and quality of the specimen (2, 8). EPI vaccine carriers or other commercially made containers may be used as a tertiary container to transport specimens. *Vaccine Carriers that have been used for specimen transport must never be reused for carrying vaccines.* Gloves should be worn at all times when handling the specimen.

#### Triple Packaging System for Transport of Clinical Specimens

See Fig. - 1, legend for the figure as follows :



- a Primary container
- b Secondary container (sealed plastic bag holding primary container)
- c Sealed plastic bag holding case investigation form
- d Absorbent material such as cotton wool
- e Four ice packs. Place ice packs at the bottom of the box and along the sides. Then place an ice pack on top of the specimen. If the specimen should remain cold, but not frozen, wrap the specimen in paper or cardboard to prevent direct contact with ice packs.

#### Points to Remember During Transport of Clinical Specimens

- Avoid repeated thawing and freezing of specimens.
- Freeze the specimen only if transport is assured at -20°C.
- Store and transport all specimens at 2 - 8°C, except CSF obtained from suspected cases of pyogenic meningitis.



- f Insulating material
- g Tertiary container (outer carton of double - ply corrugated cardboard or plastic)
- h Address labels on tertiary container
- i Diagnostic specimen label on tertiary container

## Common Staining Techniques Used in Field Investigations of Disease Outbreaks

**Gram Staining** : This is the most extensively used differential stain that divides bacteria into two major groups. Those which retain crystal violet dye after treatment with iodine and alcohol appear purple or bluish purple and are designated as Gram positive. Those bacteria which lose the crystal violet show the colour of the counter stain employed. The commonly - used counter stain is safranin which gives a pink/ red colour to bacteria and these organisms are labeled as Gram negative. Smear prepared from throat swab, nasal swab, ear discharge, pleural fluid, CSF, urethral discharge, sputum, centrifuged deposit of urine, bacterial culture, vaginal discharge etc. can be stained by this method.

### Reagents

- Crystal violet (*primary stain*)
- Gram's iodine (*mordant*)
- Acetone Iodine/ Acetone alcohol (*decolouriser*)
- Safranin solution (*counterstain*)

### Staining procedure

- Make a thin smear on a clean glass slide, dry it in air and fix by passing through flame of a burner.
- Cover the smear with crystal violet, keep for one minute.
- Wash the slide with water, then cover with Gram iodine and let it stand for one minute.
- Wash the slide with water.
- Decolour with acetone / alcohol, rocking the slide gently for 10 - 15 seconds till the violet colour comes off the slide.
- Wash with water immediately.
- Counterstain with safranin. Let the counterstain stand for 30 seconds.
- Wash with water, blot dry and examine under the oil immersion lens of a microscope.

**Albert's Staining** : Albert's staining is most common staining technique used for examining the specimens, suspected to have *Corynebacterium diphtheriae*; which are gram positive rods of varying length and often containing volutin (polyphosphate) granules which appears purple black against the light green cytoplasm of the bacillus. The appropriate specimens are throat swab/ nasal swab smear or bacterial culture from suspected cases of diphtheria. *C. diphtheriae* appear as bacilli with dark green protoplasm and purple black granules, other bacteria will stain light green.

### Procedure for staining

- Make a smear, dry in air, and fix by heat.
- Cover slide with Albert's stain-I & leave for 4 - 6 minutes.
- Wash in water and blot dry.
- Cover the slide with Albert's stain-II and allow to act for 1-2 minutes.
- Wash, blot dry and examine under oil immersion lens of microscope.

## Staining For Malarial Parasite

- Prepare thick and thin smear from malaria case on a glass slide.
- Dehaemoglobinize the thick smear by placing the film in a vertical position in a glass jar containing distilled water for 5 minutes. When film becomes white, take it out and dry in upright position.
- Fix the thin smear in methanol for 15 minutes.
- Dilute the Geimsa's stain solution, one part with 9 parts of boric buffer pH 7.2.
- Immerse the smears in this stain for 1 hour.
- Wash the smear in buffer solution.
- Blot dry.
- Examine the slide under oil immersion of microscope.

**Observation** : Examine thin film first. If no parasite is found then only examine thick film. If parasite are seen in the thick film but the identity is not clear, thin film should be re - examined more thoroughly so as to determine the nature of infection.

### Thin film examination

- Area of the film examined should be along the upper and lower margins of tail end film as parasites are concentrated over there.
- A minimum of 100 fields should be examined in about 8 - 10 minutes.

**The following stages of the parasite can be observed in a peripheral blood thin smear :**

- Ring, trophozoite, schizont and the gametocytes in case of *Plasmodium vivax*.
- The infected erythrocytes are usually enlarged in *P. vivax*.
- However, in case of *P. falciparum* infection, it is mainly the ring stages which are seen and occasionally schizonts and trophozoites. During the late stages of the disease even crescent shaped gametocytes can be seen in the peripheral blood.

### Observations on thick smear

- Only elements seen are leucocytes and malarial parasites.
- Morphology of malarial parasites is distorted.
- Species of parasites cannot be identified.

### Appearance in thick film

- Trophozoites appear as streaks of blue cytoplasm with detached nuclear dots. The ring forms are rarely seen.
- Schizonts and gametocytes, however, retain their normal appearance and are seen if present in the smear (the pigments are seen more clearly).

**Negative (India Ink) Staining** : Negative staining is sometimes a very useful technique for demonstrating the capsulated organisms like Meningococcus/ Pneumococcus/ Cryptococcus, the causative agents of meningitis. After the staining procedure the background will appear dark. The bacterial cells will be stained purple. The capsule (if present) will appear clear against the dark background.

### Procedure

- Using a Pasteur pipette, put a drop of CSF sediment (obtained after centrifuging the CSF at 2000 - 3000 rpm for 10 - 15 min) or any other appropriate specimen on a clean glass slide.

Table 4 : Priority communicable diseases and their laboratory diagnosis			
Disease	Sample	Laboratory Test	Result
Chickenpox	Vesicle scrapings	Tzanck smear of scrapings from base of vesicles	Multinucleated giant cells & intranuclear inclusion bodies.
		Electron microscopy (EM)	Herpes virus particles in fluid.
		Antigen or nucleic acid detection	Varicella-zoster virus detected.
		Culture	Human fibroblasts cell line used. Confirmed by Immunofluorescence using Monoclonal Ab on cell line ( <i>time consuming</i> ).
		Immunofluorescence (IF)	Viral antigens detected. <i>More labour intensive but more sensitive than EM.</i>
		Virus isolation	Culture by inoculating into human amnion, fibroblast, HeLa cells, Vero cells.
Measles	Blood /Nasal / throat swabs	Immunofluorescence and capture RIA or EIA	Detection of Varicella Zoster Virus (VZV)-specific IgM.
		ELISA & PCR	Detection of Varicella Zoster Virus antigen/ nucleic acid.
		Giemsa-stained smears	Multinucleated giant cells.
		Viral isolation	Measles virus is present in acute stage in throat and nasopharyngeal secretions. It is also excreted in urine intermittently for at least 7 days after rash onset. At least one specimen for virus isolation, along with blood for serology is required.
		Immunofluorescence	Viral antigens detected ( <i>more labour intensive</i> ).
		Serological tests (ELISA)	Capture ELISA for measles IgM (reference gold standard test). Measles specific IgM antibodies detected using IgM capture ELISA. A single blood specimen collected 3 to 28 days after rash onset is usually satisfactory for IgM serology.  Indirect ELISA for measles IgM. For IgG serology, the first (acute) sample is obtained as soon as possible after appearance of rash and no later than 7 days afterwards. The second (convalescent) sample is collected 10 to 20 days after the first sample. Both paired sera tested simultaneously.

Disease	Sample	Laboratory Test	Result
Rubella	Blood (within 2-3 days of onset of symptoms); Nasopharyngeal washings / throat garglings	Virus isolation	<i>Viral culture is labour intensive.</i>
	Serum	Serological tests (ELISA)	IgM & IgG antibodies (IgM alone indicates current acute infection & IgG indicates past infection or vaccination). Rubella-specific antibodies are detectable in the IgM fraction within two days after onset of the rash, or even earlier. The titre of rubella specific IgM antibodies remains higher than those in the IgG fraction for about five days after the appearance of the rash.
		Immunofluorescence for Rubella specific IgM antibodies	The test is useful from about one to two days before the rash, prior to the appearance of a detectable level of HI antibody, to about four weeks afterwards.
		Immunofluorescence (Direct Fluorescent Antibody Staining)	Demonstration of viral antigen.
Influenza	Nasopharyngeal aspirate/ washings using saline; lower nasal swab/ nasopharyngeal swab/ throat swab; bronchoalveolar lavage	Reverse transcriptase PCR	Detection of nucleic-acid sequences.
	Serum (Acute phase serum and convalescent phase serum)	Haemagglutination inhibition	Rise in antibody titres in paired (acute and convalescent) serum samples.
	Nasopharyngeal aspirate, washings using saline, lower nasal swab/ nasopharyngeal swab/ throat swab; sputum; bronchoalveolar lavage	Viral culture	Virus identification by immunofluorescence of cell cultures or Haemagglutination-Inhibition (HI) assay of cell culture medium (supernatant).
	Throat swabs	Albert's stain	<i>Corynebacterium diphtheriae</i> appears as green rods containing green-black volutin granules. The rods may be arranged in rows or in V-formation or joined at angles, giving the appearance of Chinese characters.
Meningococcal disease		Culture of throat swab/ swab from membrane at any other site (inoculated on Loeffler's serum slope)	Bacilli showing cuneiform (Chinese letter) arrangement on Gram stain with metachromatic granules (seen in smears stained with methylene blue or Albert's stain).
	CSF	Gram stain	Meningococci appear as gram-negative intracellular diplococci (inside polymorphs).
		Ag detection by Latex Agglutination/ <i>Immunofluorescence</i>	Demonstration of meningococcal antigen.
		Molecular Diagnosis by PCR	Detection of meningococcal DNA sequences.
	Blood	Culture	Isolation of meningococci.

Disease	Sample	Laboratory Test	Result
Avian Influenza	Nasopharyngeal aspirate; Nasopharyngeal swabs; Throat swab washings; Throat swab	Immunofluorescence; Enzyme immunoassay (for influenza A nucleoprotein)	Rapid antigen detection.
	Serum (Acute phase serum and convalescent phase serum)	Serology	IgM & IgG antibodies (IgM alone indicates current acute infection & IgG indicates past infection or vaccination).
		Virus culture	Virus identification by immunofluorescence of cell cultures or Haemagglutination-Inhibition (HI) assay of cell culture medium (supernatant). Detection of nucleic-acid sequences.
SARS (new strain of corona virus)		Polymerase chain reaction and Real-time PCR assays.	
	Throat and nasal swabs; rectal swab; nasopharyngeal aspirate; throat washings and urine	Reverse transcription PCR for viral RNA	Detection of nucleic-acid sequences.
	Serum (paired samples)	ELISA; Immunofluorescence Viral isolation	Demonstrates rising antibody titres. Vero E6 cell monolayers examined daily for diffuse, refractile, rounding cytopathic effects characteristic of SARS-CoV confirmed on staining by the indirect immunofluorescence technique and RT-PCR.
Hepatitis A	Serum	Antibody detection: ELISA	Anti HAV IgM & IgG antibodies (IgM alone for current/acute infection & IgG for past infection).
Hepatitis B	Serum (Acute & Chronic phase sera)	Serological demonstration of viral markers	HBsAg in blood; anti-HBc IgM indicates recent infection; anti HBc IgG indicates remote infection; HBeAg denotes high infectivity.
	Blood in sterile container (serum)	Viral loads by Real time PCR & HBV DNA by PCR	Molecular analyses to detect HBV DNA are rarely required and should be performed only in a well-defined clinical context.
Hepatitis C	Serum	ELISA	Antibody detection.
	Serum	Viral loads by Real time PCR & HCV RNA by PCR	HCV RNA in blood detected. Molecular analyses to detect HCV RNA are rarely required and should be performed only in a well-defined clinical context.
Hepatitis E	Serum	ELISA	Anti HEV IgG & IGM antibodies ( <i>IgM in the bile &amp; faeces during incubation period</i> ).
	Whole blood in EDTA/ Serum	HEV RNA by PCR	Molecular analyses to detect HEV RNA are rarely required and should be performed only in a well-defined clinical context.



Disease	Sample	Laboratory Test	Result
Leptospirosis	Serum	Detection of group specific anti Leptospiral IgG & IGM antibody by latex agglutination test and a sensitive test such as ELISA	Specific IgM antibody detection confirms recent infection.
		Detection of species specific anti Leptospiral IgG & IGM antibody using Microscopic Agglutination Test (MAT) is the Gold Standard	Live Leptospira strains seen to be immobilized and agglutinated by patient's serum.
	CSF/ Urine/ Body fluid (freshly passed urine sample alkalized to pH 9 with Sodium bicarbonate)	Dark ground illumination	Motile leptospira.
Cholera	Blood in EDTA; Urine (alkalinized)	Culture in EMJH medium. Isolation facility available at Leptospira Surveillance Centres	Motile leptospira seen in dark ground illumination.
	Faeces (rice water) OR Rectal swab moistened with transport medium OR Lubricated catheter to pass sample directly into screw capped container OR Strips of blotting paper soaked in stool and sent in plastic envelopes OR Bedside inoculation onto media	Hanging Drop preparation -darting motility	Demonstration of <i>Vibrio cholerae</i> .
		Dark ground illumination or phase contrast	Demonstration of immobilization by antiserum (may be observed under a simple microscope too using a hanging drop preparation)
		Isolation of cholera vibrios (in a stool specimen or sample by rectal swab) after enrichment for 6 hours. Venkatramanliquidmedium( <i>Holding medium</i> ) or Cary - Blair medium ( <i>Transport medium</i> ); Alkaline peptone water or Monsur's media ( <i>Enrichment media</i> )	Non lactose fermenting colonies; catalase and oxidase positive with a positive cholera red reaction. Serogrouping into O1 and non O1, biotyping into Classical and El Tor strains and serotyping into Ogawa, Inaba and Hikojima can be done at centres where facility exists. Strains may be dispatched to a higher centre for confirmation.

Disease	Sample	Laboratory Test	Result
Typhoid	Blood for culture	Blood culture ( highest positivity if sent in first week of fever)	Pale non-lactose fermenting colonies of Salmonella. Organisms are motile, indole & urease negative, ferment glucose and mannitol but not lactose. Strains may be biochemically differentiated on the basis of H <sub>2</sub> S and acid with/without gas production.
	Serum ( <i>in first week</i> )	Widal Test	Baseline titres.
	Serum ( <i>in second week and thereafter</i> )	Widal Test	Demonstration of O & H agglutinins in a paired sera Significant one time titres: - O agglutinins > 100 H agglutinins > 200 OR Four fold rise in titres in paired sera
	Faeces	Stool enrichment with Selenite F or Tetrathionate broth followed by faeces culture on a selective medium like Wilson Blair media or DCA.	Black colonies with metallic sheen on Wilson Blair media.
	Urine	Urine culture ( 2nd & 3rd week)	Salmonella shed intermittently so requires repeated sampling.
FOOD POISONING			
Salmonella	Faeces & food specimens	Gram staining	Salmonella are gram-negative organisms.
		Culture	Isolation of salmonella from food macerated in sterile saline.
Botulism	Faeces & food specimens	Gram staining of food samples	Gram positive sporing bacilli.
		Isolation from faeces & food specimens	Food is macerated in sterile saline and filtrate is inoculated into mice/ guinea pigs intraperitoneally after protection with polyvalent antitoxin.
		Toxin detection	Retrospective diagnosis by demonstration in patient's serum.
<i>Cl. perfringens</i>	Faeces & food specimens	Isolation on selective media	Heat resistant <i>Cl. perfringens</i> Type A isolated.
<i>B. cereus</i>	Faeces & food specimens	Isolation on selective media (MYP - Mannitol egg Yolk Phenol red Polymyxin Agar media)	Isolation of <i>B. cereus</i> which produces lecithinase & ferments glucose but not mannitol.
<i>Enteropathogenic E coli</i> (EPEC)	Faeces	Plated on Blood agar & MacConkey media	Tested for agglutination by polyvalent & monovalent EPEC O antisera
<i>Enterotoxigenic E coli</i> (ETEC)	Faeces	In Vivo test (ligated rabbit ileal loop) In Vitro test (Tissue culture test, Serological test) Genetic test (DNA Probe)	Demonstration of enterotoxins.

Disease	Sample	Laboratory Test	Result
MALARIA <i>P. falciparum</i> <i>P. vivax</i> <i>P. malariae</i> <i>P. ovale</i>	Blood Smear (Thick smear and thin smear)	Blood Smear for Malaria parasite	Detection of malaria parasite & characteristic morphological changes in the RBCs to detect the plasmodium species. <i>The thick smear after dehaemoglobinisation is used for screening for malaria parasite and thin smear for speciation.</i>
	Blood in double oxalate, EDTA vacutainer; finger prick blood directly collected in the QBC capillary tube	Quantitative buffy coat	Detection of malaria parasite, both ring form (trophozoite) and gametocytes using the fluorescent microscope.
	Whole blood in EDTA; blood from finger prick	Rapid diagnostic tests(RDT) or Immunochromatographic tests	PfHRP2 or pLDH detection using monoclonal antibody against one of these antigens. PfHRP2 persists to be positive even after therapy unlike pLDH. Both these tests should be supplemented with microscopy.
	Serum	Serology for antibody detection by ELISA	This does not necessarily detect current infection.
Dengue (4 serotypes DEN 1,2,3,4)	Whole blood	Polymerase Chain Reaction for detection of gene or Multiplex PCR for all four species	Detection of relevant gene sequence.
	Acute phase serum; plasma; Buffy coat (leucocytes) washed to remove antibodies; CSF; autopsy tissue from fatal cases especially liver, spleen, lymph node.	Virus Culture	Isolation of dengue virus.
	Serum ( <i>three serial serum samples during acute, convalescent phase &amp; late convalescent phase, respectively</i> )	Serological Tests like Dengue IgM & IgG ELISA Dengue IgM & IgG Rapid strip Test(ICT)	Early dengue-IgM in 3-5 days of onset of infection, later a rise in IgG is seen. Test should be repeated at least once after 2-3 days if negative at first.
	Autopsy tissue or serum	Viral antigen detection	Demonstration of dengue virus antigen in autopsy tissue or serum samples by Direct fluorescence or viral nucleic acid detection using Immunohistochemistry (IHC).
	Whole blood	Platelet count	Thrombocytopenia (platelets less than or equal to 100,000/mm <sup>3</sup> ).
		Haematocrit	Evidence of plasma leakage documented >20% increase of PCV for age and sex.

Disease	Sample	Laboratory Test	Result
Japanese Encephalitis Group B Arbovirus (flavivirus)	CSF; autopsied brain in saline, whole blood (collected in initial 2-3 days)	Virus isolation can be performed using Vero, LLCMK2 and PS cells	Viral culture.
	Autopsy tissue in saline or serum samples	Viral antigen detection	Demonstration of JE virus antigen in autopsied brain tissue by fluorescence antibody test.
	Serum	PCR-based tests	Nucleic acid detection.
		Serological testing using IgM-capture ELISA or using Haemagglutination Inhibition Tests (performed at specialized centres)	Detects specific IgM.
Trachoma <i>C. trachomatis</i>	Conjunctival scrapings	Giemsa-stained	<i>C. trachomatis</i> inclusion bodies or Halberstaedter Prowazek (HP) bodies seen.
		Culture : Clinical specimens are inoculated onto McCoy cells, HeLa cell lines (Tissue culture)	Confirmed by demonstration of cytopathic effects in cell lines.
Poliomyelitis	Stool or nasopharyngeal washings	Viral isolation in cell lines	Demonstration of cytopathic effects in cell line.
	Serum	Serology	Neutralizing antibodies.
	Cerebrospinal fluid (CSF)	Cell count in cytology and biochemistry	Increased number of white blood cells (10 to 200 cells/mm <sup>3</sup> , primarily lymphocytes) and a mildly elevated protein from 40 to 50 mg/100 ml.
Plague	Whole blood; sputum; aspirates from buboes, body fluids or tissues	Confirmed by Gram stain/ culture	Gram stain shows bipolar staining Gram negative bacilli. Culture of <i>Y. pestis</i> confirmed by specific phage lysis of lawn cultures.
	Serum (Acute phase serum and convalescent phase serum)	Passive haemagglutination testing of paired serum samples	Four-fold change in antibody titre to the F1 antigen in paired serum specimens, confirmed by F1 antigen haemagglutination inhibition test.
	<p>Note : Blood should be collected in a sterile container for serology. If serum needs to be transported across a long distance, it should be centrifuged and separated into a sterile container and sent on ice (4°C), preferably with a human courier. Any material for culture should be sent in saline and not in formalin. 24-hour samples are not acceptable for culture. Tissue sent for culture or antigen detection tests should not be allowed to dry and may be placed into a sterile container with some saline in it. A second sample for serology (paired sera) is a must for evidence of rising titres.</p>		



- Add another smaller drop of Indian Ink (about 1/3rd the size of CSF drop) on the slide. Mix the two drops thoroughly using a match stick.
- Put a coverslip on the resultant mixture.
- Examine the preparation under the microscope first using 40x objective and then 100x objective to look for the characteristic encapsulated cells.

## Interpretation of Laboratory Tests

The interpretation of laboratory tests for some priority communicable diseases are listed in Table - 4.

## Summary

Outbreaks of communicable diseases are public health emergencies which result in increased morbidity and mortality. A surveillance network, including available laboratory support aimed at a simplified syndromic surveillance of priority communicable disease syndromes is important for early detection, control and prevention of outbreaks. The underlying principle of the “Syndromic Approach” to communicable disease surveillance and field investigation of an outbreak is that the case definition is based on a syndrome and not on a specific disease. When investigating outbreaks, it is important to keep an open mind about possible causes, and ensure that adequate clinical samples are taken to eliminate any uncertainty. Proper collection of an appropriate clinical specimen is the first step in obtaining an accurate laboratory diagnosis of an infectious disease. The specimen should be transported in a basic triple packaging system to ensure biosafety, transient temperature and quality of the specimen.

The effective control of a communicable disease outbreak depends upon early detection and reporting of suspect cases, adequate knowledge regarding collection of appropriate clinical specimens, their transportation under optimum conditions and specific diagnostic tests to facilitate rapid confirmation of the causative agent responsible for the disease outbreak.

## Study Exercises

**Short Notes :** (1) Syndromic surveillance (2) Laboratory diagnosis of Acute Jaundice Syndrome (3) Preparation of peripheral blood smear for diagnosis of malaria (4) Hanging drop preparation (5) Triple packaging system for transport of clinical specimens

## MCQs

1. The underlying principle of “Syndromic Approach” to communicable disease surveillance is that the case definition is based on (a) a specific disease (b) a group of diseases (c) a syndrome (d) None of the above
2. The possible pathogens in Acute Diarrhoeal Syndrome are all except (a) *Vibrio cholerae* (b) Rotavirus (c) *Leptospira* (d) *Cryptosporidium*
3. Albert's staining is used for the demonstration of metachromatic granules in (a) *Plasmodium falciparum* (b) *Corynebacterium diphtheriae* (c) *Chlamydia trachomatis* (d) *Clostridium difficile*
4. Serum should be separated from blood prior to transportation if the time taken to reach the laboratory is (a) > 6hours (b) > 12 hours (c) > 18 hours (d) > 24 hours

**Answers :** 1(c); 2 (c); 3 (b); 4 (d).

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Rajesh Vaidya

Malaria is the most important parasitic disease of man. It is defined as an acute and chronic disease caused by obligate intracellular protozoa of the genus *Plasmodium*. Four species of *Plasmodium* are capable of infecting humans : *Plasmodium malariae* (Laveran, 1881), *Plasmodium vivax* (Grassi and Feletti, 1890), *Plasmodium falciparum* (Welch, 1897) and *Plasmodium ovale* (Stephens, 1922). The parasites are transmitted to humans by female Anopheles mosquitoes. The illness that ensues is highly variable but is generally characterized by paroxysms of fever and chills, anaemia and splenomegaly (1). Approximately 5% of the world population is infected by malarial parasites and the disease is responsible for nearly one million deaths annually world wide. Although drugs against malaria have been available for many years, widespread drug resistant strains of parasite and insecticide resistant strains of mosquito vectors have made its treatment and control difficult.

### History

Few diseases have had a greater impact on human social and economic development than malaria. Fossil mosquitoes have been found in geologic strata 30 million years old. Malaria was linked with poisonous vapours of swamps or stagnant water on the ground since time immemorial. The disease was finally named by the Italians in the 18th century malaria (from the Italian *mala* "bad" and *aria* "air"). The first references to periodic fevers can be found in early Hindu and Chinese writings. In the fifth century B.C., the Greek physician Hippocrates described the clinical manifestations and some of the complications of malaria.

The first major breakthrough in understanding the etiology of the disease was in 1880, when Laveran, a French army surgeon in Algeria, described exflagellated gametocytes of *Plasmodium falciparum* in a fresh blood film from a patient with malaria. Even after that, transmission remained a mystery until the 1880s. It was only in 1897, that Ronald Ross, a British army surgeon in India, conclusively established the major features of the life cycle of plasmodia by a careful series of experiments in naturally infected sparrows. During the 20th century, progress was made in vector control technology and in the development of potent synthetic antimalarial compounds. One of the major landmarks was in 1955 when, encouraged by the high potency, low toxicity, ease of administration and low cost of DDT and other residual insecticides, the World Health Organization (WHO) launched a worldwide program of malaria eradication. This program was hindered by the development of DDT resistance in the mosquito populations and by the development of chloroquine resistance in some strains of *Plasmodium falciparum*. Soon it was realized by the world that "Malaria" was here to stay and subsequently in 1978, the World Health Assembly changed its focus from eradication to malaria control based on the assessment of localized control potential. This ranged from reducing morbidity and mortality with chemotherapy to comprehensive campaigns stressing

personal protection and vector control to community - based bioenvironmental interventions (1, 2).

### Epidemiology

**Global** : Malaria is endemic in over 105 countries and is responsible for over 300 - 500 million clinical cases and over a million deaths annually. Out of around 3000 deaths a day, over 90% are in Sub Saharan Africa. Out of the 11 countries of the South East Asian Region (SEAR) of WHO, 10 are malaria endemic. Maldives has no endogenous transmission since 1984. SEAR accounts for 30% of global morbidity and 8% of global mortality due to malaria. An estimated 82.8% of the total population here is at risk of malaria. Out of the total population, 41.5% are at moderate to high risk, 41.7% are at low risk while the remaining 16.8% are considered free from the risk of malaria.

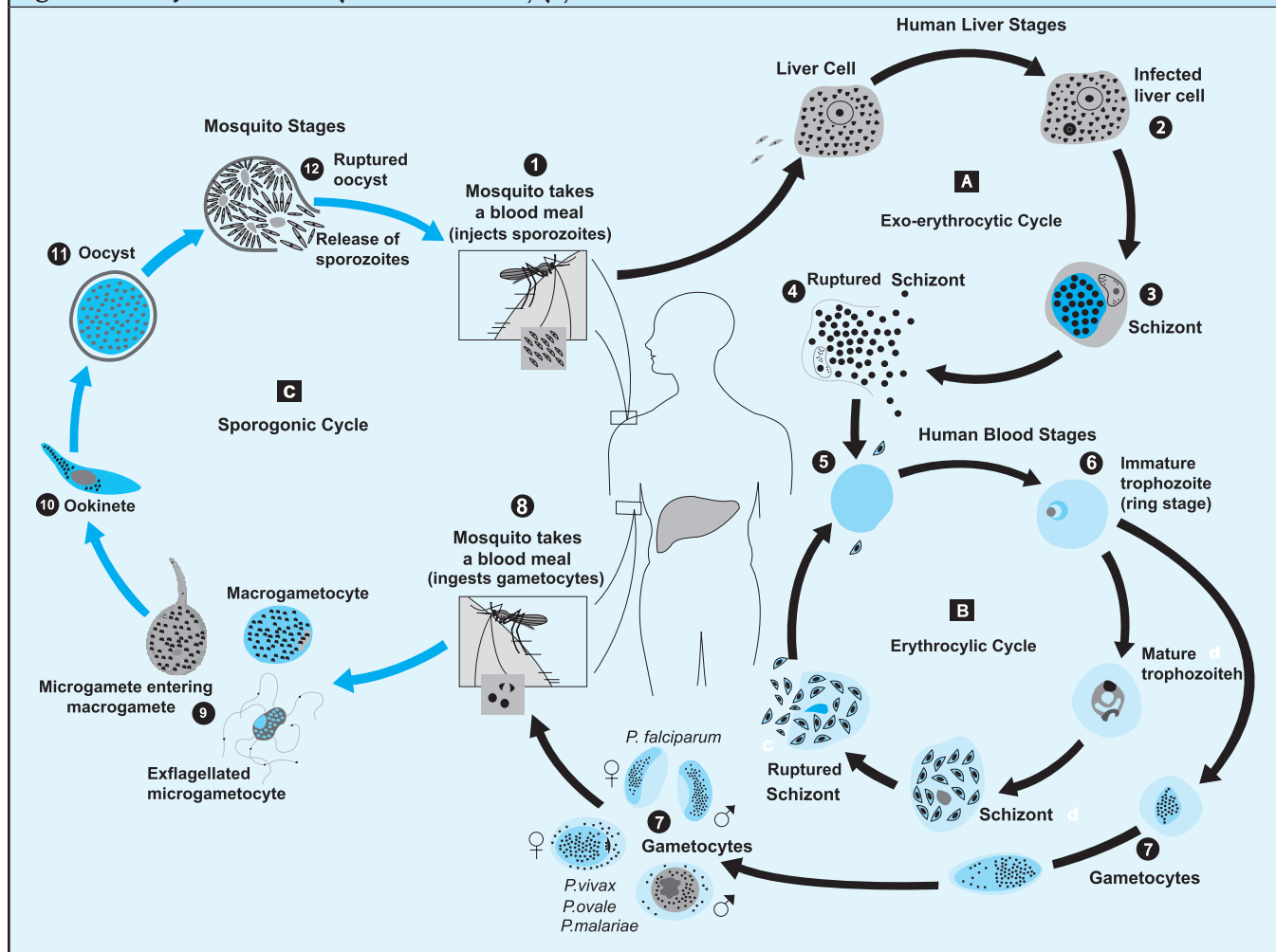
**India** : Malaria transmission occurs in almost all areas of India except areas above 1800 meters, above mean sea level. 95% of the Indian population lives in malaria risk prone areas. Malaria in India is unevenly distributed. In most parts of India about 90% malaria is unstable with relatively low incidence but with a risk of increase in cases in epidemic form every 7 to 10 yrs. This depends on the immune status of the population and the breeding potential of the mosquitoes, rainfall being the leading cause of malaria epidemic as it increases vector density. In North - East India, efficient malaria transmission is maintained during most months of the year. Intermediate level of stability is maintained in the plains of India in the forests and forest fringes, predominantly tribal settlements in eight states (Andhra Pradesh, Gujarat, Jharkhand, MP, Chattisgarh, Maharashtra, Orissa and Rajasthan). The reported incidence is between 2 and 2.5 million cases annually with some fluctuations every year for last over two decades. 44.3% of these are due to *Plasmodium falciparum*.

**Agent** : The causative organisms of the disease malaria are protozoa of the genus *Plasmodium*, family *Plasmodiidae*, suborder *Haemosporidiidae*, order *Coccidia*. There are 120 or so species of *Plasmodium* which are recognized taxonomically by the presence of two types of asexual division : schizogony, in the vertebrate host; and sporogony, in the insect vector. Within the vertebrate host, schizogony is found both within erythrocytes (erythrocytic schizogony) and in other tissues (exo - erythrocytic schizogony). However diseases in humans is caused by four parasites which have, in the recent past, been described as follows (3) :

- *Plasmodium vivax* : Benign Tertian, Simple Tertian, Tertian
- *Plasmodium malariae* : Quartan
- *Plasmodium falciparum* : Malignant Tertian (MT), Subtertian, Aestivo - Autumnal, Tropical, Pernicious
- *Plasmodium ovale* : Ovale Tertian.

The cyclopropagative life cycle of the *Plasmodium* occurs in two stages (Fig - 1). The sexual stage starts with the 'gametogony' in the human host and progresses through 'sporogony' in the mosquito. The asexual stage starts with injection of sporozoites by the infective mosquito into the human host and progresses through three phases of 'schizogony'. The broad outline of events occurring during the two stages is as follows (4).

Fig. - 1 : Life Cycle of malaria (*Plasmodium vivax*) (5)



### Sexual Cycle in Mosquito (Sporogony)

The vector female anopheline mosquito ingests male and female gametocytes from a malarial subject. In the mosquito's stomach the male gametocyte becomes rounded, its chromatin splits into 5 to 8 particles, which get arranged along its edge. Cytoplasm around each chromatin particle elongates into a 'flagellum' and together with chromatin separates from the main mass as a 'microgamete'. Female gametocyte extrudes polar bodies and becomes a 'macrogamete' ready to be fertilized. Syngamy of microgamete and macrogamete forms 'zygote'. This becomes an elongated, motile 'ookinete'. Penetrating the stomach wall, this comes to lie under its external basement membrane, becomes rounded & develops into 'oocyst'. As the oocyst matures, it increases in diameter and rapidly undergoes division and subdivision to form a large number of haploid sporozoites (varying from new hundreds to thousands). Finally, the oocysts rupture, releasing the elongated sporozoites into the body cavity, majority of which find their way into the salivary glands. Sporozoites injected in human host through the mosquito bite start schizogony.

### Asexual Cycle in man (Schizogony)

**Pre - erythrocytic Phase :** Sporozoites injected by infective mosquito into human body circulate for approximately 30 minutes and thereafter leave the peripheral blood. Fully matured, pigmentless schizonts, containing cryptozoites are seen in the parenchymal liver cells. The cycle lasts approximately 8 days in *Plasmodium vivax*, 6 days in *Plasmodium falciparum* and 9 days in *Plasmodium ovale*. On full maturity of the pre - erythrocytic schizonts, the liver cells rupture and cryptozoites enter the erythrocytes.

**Erythrocytic Phase :** The earliest intracorporeal form of parasite is the 'trophozoite' which has a fine ring of cytoplasm with a small chromatin dot. It grows in the parasitised RBC that becomes pale and, in some species, enlarged or distorted. The haemoglobin changes into haemozoin pigment and is seen in the cytoplasm of the parasite as black or brown granules. Fully developed trophozoite fills the RBC and undergoes segmentation. The chromatin divides into a number of particles which migrate towards the periphery. The cytoplasm around each particle separates off forming merozoites; the pigment concentrates in the centre of the RBC. This is called 'rosette' or 'schizont'. The parasitised RBC eventually ruptures releasing

merozoites which enter other RBCs repeating the asexual cycle. Each asexual cycle is completed in 48 hours in *Plasmodium falciparum*, *Plasmodium vivax* and *Plasmodium ovale* and in 72 hours in *Plasmodium malariae*.

**Gametogony** : After a few cycles of erythrocytic schizogony, male and female gametocytes appear in the blood. The female macrogametocyte has a dense and deeply staining cytoplasm and a small compact nucleus, while the male microgametocyte has a less dense and faintly staining cytoplasm and a relatively large and diffuse nucleus. The gametocyte of *Plasmodium vivax* is large and round filling the enlarged RBC, the gametocyte of *Plasmodium falciparum* is sausage or crescent shaped. Gametocytes remain within the corpuscles until taken up by the mosquito or their final disintegration.

**Persistent Tissue Phase (Exoerythrocytic phase)** : After the establishment of blood infection the initial tissue phase (pre - erythrocytic phase) disappears completely in *Plasmodium falciparum*, whereas in *Plasmodium vivax*, *Plasmodium ovale* and *Plasmodium malariae* it continues in the form of a persistent tissue phase in the liver. These exoerythrocytic forms never arise from the merozoites of erythrocytic schizogamy and are now considered responsible for relapses of vivax, ovale and quartan malaria.

Most of the severe morbidity and mortality in malaria is caused by *Plasmodium falciparum*. When compared with the three other species infecting humans, the incubation period is shortest, the exoerythrocytic schizonts release 2.5 to 20 times as many merozoites, and the duration of untreated infections is the least. By contrast, *Plasmodium malariae* has the longest duration of untreated infection and sometimes is almost a commensal infection in adults. Certain characteristics of the four species are given in Table - 1 (6).

**Reservoir and Source** : For human plasmodia the only reservoir is a malaria case. In some parts of Africa, Chimpanzees may act as reservoir of *Plasmodium malariae*. The source of infection is a malaria case with adequate number of mature viable gametocytes circulating in the blood. It has been estimated that

in order to infect a mosquito, the blood of a human carrier must contain at least 12 gametocytes per mm<sup>3</sup> and the number of female gametocytes must be more than the male gametocytes.

**Period of Communicability** : The human case of malaria becomes infective to mosquito when mature, viable gametocytes develop in the blood of the patient in sufficient density.

**Host** : All ages are equally affected. Children are usually effective carriers of gametocytes. Gender does not affect the incidence or severity of malaria infection and disease per se, but because they are often related to frequency of exposure (via occupation, social behaviour, and migration). Racial immunity against one or more species of malaria parasite has been observed in certain parts of the world. Negroes with sickle cell trait have been found to be relatively immune to *Plasmodium falciparum* infection. Individuals lacking the Duffy a and b blood group determinants (Duffy - negative blood type) are resistant to infection with *Plasmodium vivax*. Economic Status is inversely related to incidence of malaria mainly because of poor housing. Ill ventilated and poorly lighted houses provide ideal resting places for mosquitoes.

**Acquired Immunity** : In general, populations in endemic areas continuously exposed to infected mosquitoes develop immunity to malaria illness and, to a lesser degree, to malaria infection. Clinical manifestations, asexual parasitemia, and the production of gametocytes are all reduced by acquired immunity. In areas with high falciparum transmission, newborns will be protected during the first few months of life presumably by maternal antibodies transferred to them through the placenta. As these antibodies decrease with time, these young children become vulnerable to disease and death by malaria. If they survive to an older age (2 to 5 years) they will have reached a protective semi - immune status.

**Environment** : Optimal conditions for malaria transmission occur when the temperature is between 20°C and 30°C and the mean relative humidity is at least 60%. Sporogony does not occur at temperatures below 16°C or at temperatures higher than 33°C. Water temperatures regulate the duration of the

**Table 1 : Selected characteristics of four species of Human Malaria**

	<i>P. falciparum</i>	<i>P. vivax</i>	<i>P. ovale</i>	<i>P. malariae</i>
Exocrythrocytic cycle (days)	5 - 7	6 - 8	9	12 - 16
Erythrocytic cycle (hr)	48	42 - 48	49 - 50	72
Usual incubation period in days (range)	12 (9 - 14)	13 (12 - 17) or longer	17 (16 - 18) or longer	28 (18 - 40) or longer
Earliest appearance of gametocytes (days)	10	3	7	?
Secondary exoerythrocytic cycle	none	present	present	none
Average merozoites per tissue schizont	40,000	10,000	15,000	2000
Size of tissue schizont	60 µm	45 µm	70 µm	45 µm
Duration of untreated infection (yr)	1 - 2	1 - 4	1 - 4	3 - 50
Average parasitemia (per mm)	20,000 or greater	10,000	9000	6000
Minimum duration (and range) of sporogony cycle in mosquito in days	9 (9 - 22)	8 (8 - 16)	12 (12 - 14)	16 (16 - 35)
Usual periodicity of febrile attacks (hr)	none	48	48	72



aquatic breeding cycle of the mosquito vector. A high relative humidity increases mosquito longevity and therefore increases the probability that an infected mosquito will survive long enough to become infective. Malaria infections and malaria illness are often more common during rainy seasons because the number of breeding sites is increased and because female anophelines survive longer when the humidity is high. However, too much rainfall can be deleterious to vector larvae and pupae by washing them away, thus decreasing transmission; and prolonged droughts may be associated with increased transmission if they reduce the size and flow rates of large rivers sufficiently to produce suitable breeding sites.

The proximity of human habitation to breeding sites directly influences vector - human contact and, therefore, transmission. The stability of breeding sites is influenced by water supply, soil, vegetation, etc. Irrigation schemes, dams, and other man-made changes can alter the pattern of malaria transmission (6).

**Vectors** : There are 56 species of anopheline mosquitoes in India but only six are regarded as primary vectors and another three or four as secondary or local vectors. As per the global classification, India is covered by 3 out of the 12 epidemiological zones. The present distribution of malaria vectors in these zones is given below (7) :

#### Northern and Peninsular India

**(a) Main Vectors** : *Anopheles culicifacies*, *Anopheles stephensi*, *Anopheles fluviatilis*.

**(b) Local Vectors** : *Anopheles sundaicus*, *Anopheles annularis* and *Anopheles varuna*.

#### Eastern India

**Main Vectors** : *Anopheles dirus*, *Anopheles sundaicus*, *Anopheles philippinensis*, *Anopheles minimus*, *Anopheles maculatus*.

#### Andaman and Nicobar Islands

**(a) Main Vectors** : *Anopheles sundaicus*

**(b) New Vectors** : *Anopheles dirus*, *Anopheles maculatus* and *Anopheles tessellatus*.

A number of characteristics of vector mosquitoes play an important role in the epidemiology of malaria (8, 9). These include breeding habits, vectorial capacity, density, longevity, tropism, biting behaviour, and flight range.

**Breeding Habits** : The breeding habits of mosquitoes show a lot of variation. Hence, vector mosquitoes tend to be confined to certain geographical areas only. *Anopheles fluviatilis* breeds in slow moving water, seepages and terraced rice fields. *Anopheles sundaicus* prefers to breed in brackish waters. The main urban vector *Anopheles stephensi* commonly breeds in wells, cisterns and over head tanks. Tanks, pools, burrow pits and ditches are the preferred breeding spots for *Anopheles annularis* and *Anopheles philippinensis* while *Anopheles dirus* is usually found breeding in forest pools, streams and slit trenches.

**Vectorial Capacity** : Why only certain species and not others act as vectors is not exactly known. A complexity of factors determines the vectorial status of a mosquito. Certain new species are emerging as secondary vectors in different parts of

the country.

**Density** : For effective transmission of malaria in a locality, the mosquito vector must attain and maintain a certain density. This is called *critical density* and it varies from one mosquito to another and also under different environmental conditions. *Anopheles culicifacies* needs a very high density for transmission of malaria.

**Longevity** : A mosquito must live for at least 10 days after an infective blood meal, to complete the development of malaria parasites.

**Tropism** : Some mosquitoes like *Anopheles fluviatilis* prefer human blood and are called anthropophilic. Others like *Anopheles culicifacies* preferably feed on animal blood and are called zoophilic. This preferential feeding habit is called tropism. It has obvious bearing on the transmission of malaria.

**Biting Behaviour** : Some vector mosquitoes bite at or soon after dusk, others either during late night or early hours of the morning. However, some species may be active at two different periods during the same night.

**Resting Habits** : A female mosquito rests either indoors (endophilic) or outdoors (exophilic) after a blood meal for maturation of its eggs. Knowledge of these habits is necessary for organizing antiadult measures. The common resting places are either human dwellings, cattle sheds or mixed dwellings.

**Flight Range** : The range of flight and dispersion varies from one vector to another. Knowledge of this is important for planning control measures. Some have a short flight range e.g. *Anopheles dirus*, *Anopheles annularis* and *Anopheles fluviatilis*. The species with flight range upto Two km distance are *Anopheles culicifacies* and *Anopheles stephensi*. *Anopheles sundaicus* may fly upto 8 or 10 km.

**Mode of Transmission** : The most prevalent mode of transmission of malaria is through the bite of the infected female anopheles mosquito. The mosquito is infective only if the sporozoites are present in its salivary glands. However, Malaria can also be transmitted by intravenous or intramuscular injection of infected blood or plasma in an otherwise healthy person. The parasite can stay alive for nearly two weeks at - 4°C in bottled blood. Rarely transmission can also occur from infected mother to the newborn.

#### Epidemiologic Terminology (10)

A number of descriptive terms are used to describe the malaria situation in a given area. Stable endemic Malaria is said to be present when natural transmission occurs over many years and there is a predictable incidence of illness and prevalence of infection. Transmission is generally high and epidemics are unlikely. Unstable malaria describes the situation where malaria occurs in settings where transmission rates vary from year to year and collective immunity is low. Epidemics are more likely in this setting. Autochthonous (indigenous) malaria is malaria contracted locally. Secondary cases are those derived from imported cases and are referred to as introduced malaria. The term induced malaria is used for malaria infections acquired by blood transfusion, shared needles, intentional inoculation, or laboratory accidents.

A number of parameters are commonly used to classify

malaria in an area. Malaria incidence is the number of new infections or cases detected per time unit (e.g. annually) per unit of population (e.g. per 1000). Malaria prevalence is the total number of cases or infections at one point in time, per unit of population. When the measure used is microscopically proven parasitemia, malaria prevalence and parasite rate are synonymous.

**Annual Parasite Incidence** : Number of new parasitologically confirmed cases per 1000 population per year. This tool of evaluation has been introduced under the National Programme, which measures not prevalence but the incidence of malaria and based on this, areas are divided into high & low risk zones.

**Infant Conversion Rate** : Fraction of parasitologically negative infants becoming positive per time unit.

**Spleen Rate** : Proportion of individuals in a stated age range with enlarged spleens. The degree of endemic malaria is determined by examination of a statistically significant sample of a population and is assessed and classified as follows :

**Hypoendemic** : Spleen rate or parasite rate of 0 to 10% in children between the ages of 2 and 9.

**Mesoendemic** : Spleen rate or parasite rate of 11 to 50% in children between the ages of 2 and 9.

**Hyperendemic** : Spleen rate or parasite rate consistently over 50% in children between the ages of 2 and 9. Adult spleen rate is also high.

**Holoendemic** : Spleen rate or parasite rate consistently over 75% in children between the ages of 2 and 9. Adult spleen rate is low and the transmission index is high.

### Pathophysiology

A detailed description of pathophysiology is beyond the scope of this chapter. However in short, the pathophysiology of malaria results from destruction of erythrocytes, the liberation of parasite and erythrocyte (Cytokines, Nitric Oxide etc) material into the circulation, and the host reaction to these events. *P. falciparum* malaria differs from the other three human species of malaria parasite because infected erythrocytes also sequester in the microcirculation of vital organs, interfering with micro circulatory flow and host tissue metabolism, which results in severe organ damage.

### Clinical Features

**Uncomplicated Malaria** : The classical (but rarely observed) malaria attack lasts 6 - 10 hours. It consists of three typical stages. In the *Cold Stage*, there is a general sensation of cold followed by rigors. The temperature rises to 40°C and stays for nearly one hour. At this time parasites are demonstrable in the blood. This stage is followed by the *Hot Stage* which is characterized by fever, headaches and vomiting. The skin feels hot and dry. This lasts from 2 to 6 hours. The last stage is the *Sweating Stage*. The patient sweats profusely and temperature returns to normal. This stage lasts from 2 - 4 hours.

Classically, the attacks occur every second day with the "tertian" parasites (*Plasmodium falciparum*, *Plasmodium vivax*, and *Plasmodium ovale*) and every third day with the "quartan" parasite (*Plasmodium malariae*). More commonly, the patient presents with a combination of symptoms of fever, chills,

sweats, headaches, nausea, vomiting, body aches and general malaise. Physical findings may include elevated temperature, perspiration, weakness, enlarged spleen etc. In *Plasmodium falciparum* malaria, additional findings may include mild jaundice, enlargement of the liver and increased respiratory rate.

**Severe Malaria** : Severe malaria occurs when *Plasmodium falciparum* infections are complicated by serious organ failures or abnormalities in the patient's blood or metabolism. The manifestations of severe malaria include cerebral malaria, with abnormal behaviour, impairment of consciousness, seizures, coma, or other neurologic abnormalities, severe anaemia due to hemolysis, hemoglobinuria, pulmonary edema or Acute Respiratory Distress Syndrome (ARDS), which may occur even after the parasite counts have decreased in response to treatment, abnormalities in blood coagulation and thrombocytopenia, cardiovascular collapse and shock.

**Relapse** : In cases of *Plasmodium vivax* and *Plasmodium ovale* infections, recurrent attacks could be due to re - activation of hypnozoites in the liver. This can occur any time after 30 to 180 days of the primary attack. The relapses have the characteristic symptoms of malaria. Splenomegaly may be a prominent feature in these patients. Such long - term relapses commonly occur in patients who have either not taken primaquine or taken incomplete treatment.

**Recrudescence** : In *Plasmodium falciparum* and *Plasmodium malariae* infections, the parasites can remain in the blood for months or even years and cause recurrent symptoms from time to time. In falciparum malaria, such recrudescence can occur within 28 days of the primary attack and may indicate partial resistance to chloroquine. However, treating every case of recurrent *Plasmodium falciparum* as resistant malaria is unjustified. One should consider the possibility of re - infection in most of these cases.

### Diagnosis

Peripheral smear examination for malarial parasite is the gold - standard in confirming the diagnosis of malaria. Thick and thin smears prepared from the peripheral blood are used for the purpose. The thick smear of correct thickness is the one through which newsprint is barely visible. Thick smears are used to detect infection and to estimate parasite concentration. Thin film examination is the gold standard in diagnosis of malarial infection.

The QBC Test, developed by Becton and Dickenson Inc., is a new method for identifying the malarial parasite in the peripheral blood. It involves staining of the centrifuged and compressed red cell layer with acridine orange and its examination under UV light source. It is faster and easier.

The other tests include Para Sight F test, OptiMal Assay, the Immuno Chromatographic Test (ICT Malaria Pf. test), Polymerase Chain Reaction, detection of antibodies by Radio Immuno Assay, Immunofluorescence or Enzyme Immuno Assay (11, 12).

**Rapid Diagnosis of Malaria (Dipstick Test)** : The immunochromatographic tests for the detection of malaria antigens, developed in the past decade, have opened a new and

exciting avenue in malaria diagnosis. However, their role in the management and control of malaria appears to be limited at present. Immunochromatographic tests are based on the capture of the parasite antigens from the peripheral blood using either monoclonal or polyclonal antibodies against the parasite antigen targets. Currently, immunochromatographic tests can target the Histidine - Rich Protein 2 of *Plasmodium falciparum*, a pan - malarial Plasmodium aldolase, and the parasite specific lactate dehydrogenase. Pf LDH is cleared rapidly from blood, the test becomes negative within days of treatment, but P/HRP2 is cleared very slowly from the blood, and may remain positive for up to one month after the acute infection, particularly if the parasitaemia was high. This is a disadvantage in areas where transmission is high, and infections frequent. These RDTs are kit based, much faster, need only little training and diagnostic sensitivity similar to trained microscopists (13, 14).

### Treatment

WHO recommends that all malaria endemic countries should have their own national anti - malaria drug policy and defines it as 'An antimalarial treatment policy is a set of recommendations and regulations concerning the availability and rational use of antimalarial drugs in a country. It should be the part of the national essential drug policy and the national malaria control policy and in line with the overall national health policy'.

India's first national anti - malaria drug policy was drafted in 1982. Thereafter the policy has been reviewed periodically based on sensitivity studies and current National Drug Policy on Malaria has been revised in 2007. The main purpose of the national anti - malaria drug policy is to provide a framework for the safe and effective treatment of uncomplicated and severe malaria as well as prevention of malaria in travellers and vulnerable groups, such as pregnant women and young children. Detailed discussion of treatment of malaria is beyond the scope of this chapter. The main treatment guidelines based on national anti - malaria drug policy are as follows (15) :

#### Microscopically positive *Plasmodium falciparum*/ *Plasmodium vivax* cases :

- *Plasmodium falciparum* cases should be treated with chloroquine in therapeutic dose of 25 mg/kg body weight over three days and single dose of Primaquine 0.75 mg/kg bw on the first day only.
- *Plasmodium vivax* cases should be treated with chloroquine in full therapeutic dose of 25 mg/kg body weight over three days. Primaquine can be given in dose of 0.25mg/kg bw daily for 14 days.

When diagnosis by microscopy or Rapid Diagnostic Kits (RDK) is not possible, cases showing signs and symptoms of malaria without any other obvious causes should be considered as "clinical malaria" and treated with chloroquine in full therapeutic dose of 25 mg/kg body weight over three days in low risk area while in high risk area single dose of Primaquine 0.75 mg/kg bw should also be given on the first day.

*Plasmodium falciparum* in chloroquine resistant areas is treated with 4mg/kg body weight of artesunate daily for 3 days along with 25mg/ kg body weight of sulphadoxine/sulphalene + 1.25 mg per kg bw of pyrimethamine on the first day.

In severe and complicated malaria of *Plasmodium falciparum*

(clinically/microscopically confirmed), parenteral artemisinin or quinine is the drug of choice, irrespective of chloroquine resistance status of the area.

- Quinine salt : 10mg /kg body weight 8 hourly in 5% dextrose saline is preferred. Patients should be switched over to oral quinine as early as possible and oral dose is 10 mg/kg body weight eight hourly not exceeding 2gm in a day in any case. Minimum total duration for quinine therapy should be for 7 days including both parental and oral doses.
- Injectable form of artemisinin derivatives may be used for the management of severe and complicated malaria (For adults and non - pregnant only). Artesunate : 2.4 mg/kg bw IM/IV followed by 1.2 mg/kg body weight after 12 hours then 1.2 mg/kg body weight once daily for total duration of 5 days.

### Prevention and Control Measures

The malaria prevention and control measures aimed at breaking the 'man - mosquito - man' cycle of transmission include a number of methods which are complementary to each other. None of the measures will be successful if applied alone in any given environment. At the same time use of all of them together may not be feasible for technical or administrative reasons. Local environmental conditions, resources and feasibility will have to be studied before optimum measures may be implemented (16, 17). The various measures are described in greater detail in section of Entomology.

**Personal Protective Measures** : Individual personal protection against mosquito bites is achieved by use of mosquito nets, repellents and protective clothing. The feeding and resting habits of the vectors and the cultural practices and sleeping habits of people are important determinants of the efficacy of personal protective measures.

The use of mosquito net is the most effective personal protective measure. Net should be put up before dusk and tucked all round under the bedding. For making the mosquito nets more effective, the nets are now being treated/medicated with synthetic pyrethroids like deltamethrin, cyfluthrin etc. These nets can be used by pregnant women & small children. These nets are also effective against sand flies.

Commercially available repellants such as Odomos, Mosfree have been found to be very effective when applied on clothing or on exposed parts of the body. The wearing of long trousers and shirts with rolled down sleeves after dusk should be encouraged in all epidemic areas. Screening of houses and barracks as a measure is effective only when all doors, windows and ventilators in the building are screened by wire mesh of proper gauge and size (1.2 to 1.5mm).

**Anti - larval Measures** : Larval control is the only effective method of radical mosquito control. In urban areas, this method complements the adult mosquito control. Anti - larval work is carried out by preventing breeding and destruction of larvae and pupae. For long term and permanent mosquito control, greater emphasis should be placed on the prevention of breeding during non - transmission season than on larvicidal (chemical & biological) measures during breeding season.

**Anti - Adult Measures** : The principle of malaria control by intercepting its transmission, by shortening the life span of the



vector species to a period shorter than the extrinsic incubation period of the parasite, has come to be established. This principle has been successfully employed by the application of residual insecticides to the resting places of mosquitoes, viz. the inside of all the walls of habitations, this is known as Indoor residual spraying. Other methods of adult mosquitoes control include Space Sprays, Genetic Control etc.

**Vector Engineering** : Avoidance of man - made mosquitogenic conditions is of primary importance. A positive aspect of mosquito breeding prevention should be kept in view and deliberately incorporated in the planning and execution of all engineering constructions and town planning schemes. Drainage in water supply projects may lead to mosquitogenic conditions. Besides these, indiscriminate digging, disposal of discarded tins, containers and water collections, overhead storage tanks and septic tanks without covers are potential mosquito breeding places in urban areas. Clean edging and water deweeding, channelling, filling or draining, exposing to sunlight, shading or covering are the usual methods adopted. Underground drainage constitutes the best method of bio - engineering method for control of mosquito breeding (17).

**Environmental Management** : Environmental management approaches to vector control aim at modifying the environment to deprive the target vector population of its requirements for breeding, resting and feeding purposes. This reduces human - vector contact and renders conditions less conducive for disease transmission. These include periodic flushing in streams by means of small dams with siphons and sluice gates and changing the salinity of breeding habitats (17).

**Chemoprophylaxis** : Chemoprophylaxis is a valuable supplementary measure under high risk situations, but not a substitute for other control measures. Early colonists devised many indigenous methods of taking quinine regularly (including 'Indian tonic water'), which were generally neither pleasant nor fully effective. Quinine (a poor prophylactic) was relied upon by armies and colonists until after the Great War. But it was only after the introduction of chloroquine, the antimalarial biguanides and subsequently pyrimethamine that finally brought safe and effective antimalarial prophylaxis into existence. In the current age of increasing drug resistance, many prophylactic drugs can no longer be relied upon, particularly in areas of multiple drug resistance such as South - East Asia and South America. Therefore recommendations for each region vary depending upon the drug sensitivity studies. In India the current recommendations on Chemoprophylaxis as per National Drug Policy on Malaria (2007) is as follows (15) :

- In chloroquine sensitive areas - chloroquine 10 mg/kg body weight and followed by a weekly dose of 5 mg/kg body weight . This is to continue till 1 month after delivery in case of pregnancy and in travellers till one month after return from endemic area. The terminating dose should be radical treatment for *P. vivax* i.e. 25 mg/kg body weight over 3 days along with 0.25 mg/kg body weight of primaquine for 14 days.
- In chloroquine resistant areas - chloroquine 5 mg/kg body weight weekly supplemented with proguanil 200mg daily.
- Chemoprophylaxis with chloroquine is not recommended beyond 3 years because of its cumulative toxicity.

**Malaria Vaccine** : Despite considerable effort and expense, a generally available and highly effective malaria vaccine has till date not been developed. An ideal malaria vaccine is one that would prevent the infection at the first instance and if this is not possible, should decrease the intensity of infection and should be successful in preventing malaria transmission. The path of vaccine development has proved long and strewn with pitfalls, but there has been progress. Research is now concentrated on all stages of the parasite life cycle : the sporozoite, the liver stage, the asexual blood stage, and the gametocyte.

## Summary

Malaria is the most important parasitic disease of man. It is defined as an acute and chronic disease caused by obligate intracellular protozoa of the genus *Plasmodium*. Approximately 5% of the world population is infected by malarial parasites and the disease is responsible for nearly one million deaths annually world wide. The causative organisms of the disease malaria are protozoa of the genus *Plasmodium*, family *Plasmodiidae*, suborder *Haemosporidiidae*, order *Coccidia*. However diseases in humans is caused by four parasites namely *Plasmodium vivax*, *Plasmodium malariae*, *Plasmodium falciparum* and *Plasmodium ovale*. Most of the severe morbidity and mortality in malaria is caused by *Plasmodium falciparum*. The cyclopropagative life cycle of the *Plasmodium* occurs in two stages the sexual stage and the asexual stage. For human plasmodia, the only reservoir is a malaria case. All ages are equally affected. Optimal conditions for malaria transmission occur when the temperature is between 20°C and 30°C and the mean relative humidity is at least 60%. There are 56 species of anopheline mosquitoes in India but only six are regarded as primary vectors. The most prevalent mode of transmission of malaria is through the bite of the infected female anopheles mosquito. Clinical Features can be divided into Uncomplicated Malaria and Severe Malaria. Severe malaria occurs when *Plasmodium falciparum* infections are complicated by serious organ failures or abnormalities in the patient's blood or metabolism. Peripheral smear examination for malarial parasite is the gold - standard in confirming the diagnosis of malaria. However immunochromatographic tests for the detection of malaria antigens, have been developed in the past decade for Rapid Diagnosis of Malaria. Treatment is based on National Drug Policy on Malaria 2007. The malaria prevention and control measures aimed at breaking the 'man - mosquito - man' cycle of transmission include a number of methods which are complementary to each other; these are Personal Protective Measures, Anti - larval Measures, Anti - adult Measures, Environmental Management, Chemoprophylaxis and Malaria Vaccine.

## Study Exercises

**Long Questions** : (1) Discuss the epidemiology, diagnosis and treatment of Malaria (2) Discuss in detail Prevention and control measures against malaria.

**Short Notes** : (1) Spleen rate (2) Characteristics of vector mosquitoes in transmission of malaria (3) Life cycle of the *Plasmodium* (4) Rapid Diagnosis of Malaria (5) Chemoprophylaxis of malaria.



## MCQs

1. Malignant tertian malaria is caused by (a) *Plasmodium vivax* (b) *Plasmodium malariae* (c) *Plasmodium falciparum* (d) *Plasmodium ovale*
2. The cyclopropagative life cycle of the *Plasmodium* occurs in \_\_\_\_\_ stages (a) Two stages (b) Three stages (c) Four stages (d) Five stages
3. Most of the severe morbidity and mortality in malaria is caused by (a) *Plasmodium vivax* (b) *Plasmodium malariae* (c) *Plasmodium falciparum* (d) *Plasmodium ovale*
4. In order to infect a mosquito, the blood of a human carrier must contain at least \_\_\_\_\_ no. of gametocytes per mm<sup>3</sup> (a) 10 (b) 12 (c) 14 (d) 16
5. Main Vector of malaria in Andaman and Nicobar Islands is (a) *Anopheles dirus* (b) *Anopheles sundaicus* (c) *Anopheles maculatus* (d) *Anopheles stephensi*
6. A Hyperendemic area is defined as one in which (a) Spleen rate or parasite rate consistently over 10% in children between the ages of 2 and 9 years (b) Spleen rate or parasite rate consistently over 30% in children between the ages of 2 and 9 years (c) Spleen rate or parasite rate consistently over 50% in children between the ages of 2 and 9 years (d) Spleen rate or parasite rate consistently over 75% in children between the ages of 2 and 9 years
7. Rapid Diagnostic test of Malaria based on detection of antibodies against Histidine - Rich protein 2 is used for diagnosis of (a) *Plasmodium falciparum* (b) *Plasmodium vivax* (c) *Plasmodium ovale* (d) All of the above
8. Gold - standard in confirming the diagnosis of malaria is (a) Peripheral smear examination (b) Immuno chromatographic test (c) Polymerase Chain Reaction (d) Radio immuno assay
9. Drug of choice in severe and complicated malaria of *Plasmodium falciparum* (a) Artesunate (b) Quinine (c) Chloroquine (d) None of the above
10. In severe and complicated malaria recommended dose of Quinine is (a) 2.5mg /kg body weight 8 hourly (b) 5mg /kg body weight 8 hourly (c) 10mg /kg body weight 8 hourly (d) 15mg /kg body weight 8 hourly

Answers : (1) c; (2)a; (3) c; (4) b; (5) b;(6) c; (7) a; (8) a; (9) b; (10) c.

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Lymphatic Filariasis is widely known as Elephantiasis. More than a billion people in more than 80 countries are at risk of suffering from the disease. India accounts for one - third of the people infected with the disease (1). Filariasis is caused by three species of nematode worms belonging to the super family Filarioidea and family Onchocercidae which are transmitted

to man by the bite of infective mosquitoes. The three species are *Wuchereria bancrofti*, *Brugia malayi* and *Brugia timori*. *Wuchereria bancrofti* is the most widespread among these three species (2). Several mosquito species are known to transmit the infection. However, *Culex quinquefasciatus* and *Mansonia annulifera* are the two most important vectors in India. In tropical and subtropical areas the prevalence of infection is continuing to increase. The major reason for this increase is the rapid and unplanned growth of cities which greatly enhances breeding of the mosquitoes that transmit the disease. This painful and profoundly disfiguring disease is usually acquired

in childhood, but manifests its most disfiguring forms in adults (3, 4). The disease due to lymphatic filariasis is characterized by disfigurement of the limbs (elephantiasis) and genitalia (hydrocele and other anatomical changes in the male genitalia). Consequently, it often has adverse economic and psychosexual effects as well as medical consequences (5). Lymphatic filariasis is one of the six infectious diseases considered eradicable by WHO with the available tools (6).

In 1863, Demarquay first described the microfilariae that are the larvae which live in the blood stream. Microfilariae were found in urine by Wucherer in 1868. Patrick Manson was the first to speculate in 1878 that filariasis may be transmitted by mosquitoes (2). The disease has been known in India since ancient times. It finds mention in "*Susruta Samhita*" which dates back to the 6th century B.C. Madhavakara described the signs and symptoms of the disease in his treatise '*Madhava Nidhana*' in 7th century A. D. In 1709, Clarke called elephantoid legs in Cochin as 'Malabar legs' (7).

### Epidemiology

**Global** : According to the World Health Organization, about 1.25 billion people are at risk of suffering from lymphatic filariasis. As on 31 Dec 2006, 83 countries are considered endemic for filaria. The highest proportion of cases is in the WHO South - East Asia Region with 64% followed by the WHO African Region with 32%. The WHO European Region remains free of lymphatic filariasis transmission (8). Approximately one third of those at risk live in India, another one third in Africa and the remainder in other parts of Asia, the Pacific and the Americas. The most highly - endemic countries are Bangladesh, Democratic Republic of Congo, India, Indonesia, Madagascar, Nigeria and the Philippines (9). The total number of persons infected worldwide is estimated to be 120 million, one third of whom have serious disfigurement and incapacitation (1). Almost 25 million men suffer from genital disease, most commonly hydrocoele, while an estimated 15 million people, mostly women suffer from lymphoedema of the leg (elephantiasis). Among the three parasitic worms responsible for the disease, *Wuchereria bancrofti* is the most prevalent particularly in hot and humid climates of Asia, Africa, the Americas and the Pacific. *Brugia malayi* is found in Southern India, South East Asia and South and Central China. *Brugia timori* has only been found in parts of Indonesia (2). More than half of all cases of Lymphatic filariasis live in South East Asia. Of the estimated 700 million people living in endemic areas in the region, about 60 million are estimated to be infected or suffering from the disease (10).

**India** : One - third of the people infected with the disease live in India (1). The disease has been described as being second only to malaria as a major public health problem. The disease is endemic to most parts of the country. Indigenous cases have been reported from about 250 districts in 20 states / union territories. Local transmission is known to occur in Andhra Pradesh, Assam, Bihar, Chhattisgarh, Goa, Jharkhand, Karnataka, Gujarat, Kerala, Madhya Pradesh, Maharashtra, Orissa, Tamil Nadu, Uttar Pradesh, West Bengal, Pondicherry, Andaman & Nicobar Islands, Daman & Diu, Dadra & Nagar Haveli and Lakshadweep. The North Western and North Eastern parts of India appear to be free from indigenously acquired

filarial infection. These include the states of Jammu & Kashmir, Himachal Pradesh, Punjab, Haryana, Chandigarh, Rajasthan, Delhi, Uttaranchal Sikkim, Arunachal Pradesh, Nagaland, Meghalaya, Mizoram, Manipur and Tripura (7). Almost all the cases in India are caused by *Wuchereria bancrofti* (94%) while the remaining 6% are attributed to *Brugia malayi* (7).

Over 400 million people live in filariasis endemic areas in India. Three fourths of those at risk live in rural areas. An estimated 49 million individuals in India are infected. Of these, over twenty million people suffer from chronic forms of filariasis while another 28 million are thought to be microfilaria carriers (11 - 13).

**Agent** : The three species of nematodes causing lymphatic filariasis, *Wuchereria bancrofti*, *Brugia malayi* and *Brugia timori* are threadlike in appearance. They have five stages in their life cycle. Unlike other vector borne diseases, the infective stage of the parasite is not injected into the human body by the mosquito vector. The infective third - stage larvae are deposited on skin by the vector and penetrate on their own or through the opening created by mosquito bites within minutes to reach the lymphatic system. They then proceed to shed their cuticle and develop a new surface as they moult into the fourth stage larvae (10). These fourth - stage larvae migrate to central lymphatic vessels and develop into sexually mature adult male or female worms over a period of approximately 9 months. The adult worms are significantly larger than larval stages, with male worms being 20 - 40 mm in length and female worms 40 to 100 mm in length. The adults reside mostly in the afferent lymphatics. The preferred sites for the adult worms seem to be the lymphatics of the lower extremities, upper extremities and the genitalia.

The mean reproductive life span of adult worms is approximately 5 years. Following copulation female worms discharge large numbers (10,000 per day) of microfilariae measuring  $150 \times 7 \mu\text{m}$  into the blood stream via the lymphatics. The number of microfilariae in the peripheral blood is variable. There is usually a surge in their numbers during the night. These microfilariae are ingested by the mosquito vectors during feeding. The microfilariae exsheath in the mosquito stomach to become first stage larvae. They penetrate the stomach wall and move to the thoracic muscles of the mosquito where they moult twice to develop into the infective third stage larvae. The infective forms then move to the mouth parts of the mosquito and the cycle repeats. The extrinsic incubation period is usually two weeks (2, 3, 13).

**Vector** : A wide range of mosquitoes can transmit the parasite, depending on the geographic area. The primary vectors for Filaria are the night biting *Culex* and *Anopheles* mosquitoes. *Culex quinquefasciatus* is the principal vector in urban areas in South East Asia. In rural areas of both Asia and Africa, *Anopheles* species are the important vectors particularly *Anopheles gambiae* and *Anopheles funestes* (2). *Aedes* and *Mansonia* are also responsible for transmitting the infection in the parts of Asia and the Pacific region (3).

In India, the most important vector for lymphatic filariasis is *Culex quinquefasciatus*. It is the vector for *Wuchereria bancrofti*. It is a ubiquitous mosquito and is present all over the country.

*Culex* breeds in polluted water. Important breeding sites are wet pit latrines, septic tanks, drains, disused wells and paddy fields. *Mansonia annulifera* and *Mansonia uniformis* are the vectors for *Brugia malayi* in India. *Mansonia* lay eggs on the under surface of the leaves of plants (7).

Filarial nematodes are poorly transmitted by the vectors. A very small proportion; usually less than 1% of mosquitoes are infective even in endemic areas (14). Repeated mosquito bites over several months result in lymphatic filariasis. People exposed to intense transmission for a long period are at the greatest risk for infection. Visitors to endemic areas from non endemic areas for short periods rarely develop disease (2, 15).

**Host Factors :** Varied patterns of infection and disease are seen in different endemic areas. Infection is usually acquired in childhood (16). The prevalence of infection rises with age from 5 years to 30 years beyond which it stabilizes. Prevalence may decline somewhat among the elderly. Signs of disease start becoming apparent during late adolescence and rise steadily with age (2). Both sexes are equally susceptible. Minor differences, however, are shown by various groups. It has been postulated that females in the reproductive age group may be more resistant to infection than males because of hormonal factors (17).

Lymphatic filariasis is primarily a disease of the poor as it occurs mostly in rural areas or urban slums. The increase in lymphatic filariasis over the past few years has been attributed to the expansion of slum areas and poverty, particularly in India and Africa. As many filariasis patients are physically incapacitated, it has a significant economic impact. Lymphatic filariasis also exerts a heavy social burden. Among men, genital damage may be a severe handicap leading to physical limitations and social stigmatization. Enlargement of a leg or arm, the genitals, vulva and breasts may result in severe stigmatization of women (1).

**Environment :** Environmental conditions that enhance vector breeding and survival increase infection rates. The optimum conditions for the breeding of the vectors and the development of parasites in them are temperature between 15°C and 35°C and relative humidity above 60%. The density of *C quinquefasciatus* is at its minimum during the monsoon, but due to favourable atmospheric conditions, somehow the maximum infectivity rate in the mosquitoes occurs during this period. India presents areas of widely variable endemicity because of its large size and variable climates from region to region (18).

### Clinical Features

The incubation period is very variable stretching from 8 to 16 months or even longer. The adult worms induce an immunological reaction. A wide variety of clinical manifestations can be seen in lymphatic filariasis. A large proportion of infected persons remain asymptomatic despite the presence of microfilariae. The manifestations result from either acute inflammation or chronic lymphatic obstruction. Clinical manifestations range from those without apparent clinical disease to those with lymphedema and severe disfigurement of the limbs and genitalia. Fever may or may not be present in both the acute and chronic forms. The various presentations can include lymphangitis and adenitis, funiculitis and hydrocoele, abscess formation, lymphadoema and elephantiasis, chyluria and monoarticular

arthritis. Occult filariasis in which the classical features of the disease are absent and microfilaria can not be demonstrated in blood, can present as tropical pulmonary eosinophilia. About 40% of patients have renal involvement with proteinuria and haematuria (2, 4, 5, 14).

### Diagnosis

Diagnosis in symptomatic patients living in endemic areas is based on appropriate history and typical clinical findings. In patients above 15 years of age the appearance of lymphedema of the extremities or disease of the male genitalia is most likely due to filarial infection.

A definitive diagnosis can be made only by detection of the parasites. The standard method for diagnosing active infection is the identification of microfilariae in a blood smear by microscopic examination. The microfilariae exhibit nocturnal periodicity with surges of circulating microfilariae at night. Blood collection should be done at night to coincide with the appearance of the microfilariae. A small dose of Diethylcarbamazine (DEC) can increase microfilaraemia during the day as it causes the microfilariae to be expelled from the pulmonary vascular bed. A thick smear should be made and stained with Giemsa or Haematoxylin and Eosin. Microfilariae are sometimes detected in chylous urine, hydrocoele fluid and ascites fluid (19). An alternative to microscopic detection of microfilariae is provided by serologic techniques for the diagnosis of lymphatic filariasis. Patients with active filarial infection are found to have elevated levels of antifilarial IgG4 in the blood and these can be detected using routine assays (19).

The difficulty in detection of microfilariae led to the development of simple immunochromatographic tests. These are very sensitive, very specific and simple "card tests" to detect circulating parasite antigens without the need for laboratory facilities. They use only finger - prick blood droplets taken anytime of the day (1, 20). Adult worms are difficult to detect. Sonographic examination of the scrotum or breast using high frequency ultrasound may result in the identification of adult worms within dilated lymphatics (2, 5).

### Treatment

Diethylcarbamazine (DEC) is the drug used most widely for treatment of lymphatic filariasis. It exerts no direct lethal action on the adult worms but changes them in a manner which makes their removal by the host's immune system possible (2). It is considered safe and effective against all filarial infections. The dose is 9 - 12 mg / kg orally in three divided doses for 14 or 21 days. The full dose must be reached slowly, starting with 50 mg daily to avoid side effects. For treatment of tropical eosinophilia, a 21 day treatment regimen must be followed. This course may be repeated twice at intervals of 4 - 6 weeks. Ivermectin has also been found effective in a single oral dose of 200 - 400 µg / kg body weight. Two drug regimens have also been found effective. The combination that may be used include 400 mg albendazole with 6mg / kg DEC or 400 mg albendazole with 150 µg / kg ivermectin once a year. Symptomatic treatment such as analgesics, antipyretics and antihistaminics may be required. Surgical procedures to correct elephantiasis must be preceded by drug therapy.



In filariasis endemic areas, the primary goal of community treatment is to eliminate microfilariae from the blood of infected individuals so that transmission of the infection by the mosquito can be interrupted. Recent studies have shown that single doses of Diethylcarbamazine (DEC) have the same long - term effect in decreasing microfilaraemia as the 12 day regimens of DEC. The use of single doses of two drugs administered together (Albendazole with DEC or Ivermectin) is 99% effective in removing microfilariae from the blood (1).

### Prevention and Control

Active disease surveillance, vector control, personal protection and mass treatment of communities in endemic areas are the corner stone of lymphatic filariasis control. The success of control measures depends on the level of co - operation by the public. The importance of health education cannot be overemphasized. Vector control and personal protective measure are dealt with in detail in the chapter on Entomology.

The WHO strategy of the Global Programme to Eliminate Lymphatic Filariasis aims to stop the spread of infection and morbidity control. To interrupt transmission, districts in which lymphatic filariasis is endemic must be identified and then mass treatment programmes implemented to treat the entire at - risk population.

Mass Treatment involves once - yearly administration of single doses of two drugs given together, albendazole plus either diethylcarbamazine (DEC) or ivermectin. An alternative community - wide regimen with equal effectiveness is the use of common table / cooking salt fortified with DEC in the endemic region for a period of one year (1). This programme is in operation on a national level in India (7, 22 24).

### Summary

Lymphatic Filariasis is widely known as Elephantiasis. According to the World Health Organization as on 31 Dec 2006, 83 countries are considered endemic for filaria. The most highly - endemic countries are Bangladesh, Democratic Republic of Congo, India, Indonesia, Madagascar, Nigeria and the Philippines. One - third of the people infected with the disease live in India. Almost all the cases in India are caused by *Wuchereria bancrofti* (99.4%) while the remaining 6% are attributed to *Brugia malayi*. The three species of nematodes causing lymphatic filariasis : *Wuchereria bancrofti*, *Brugia malayi* and *Brugia timori* are threadlike in appearance. In India, the most important vector for lymphatic filariasis is *Culex quinquefasciatus*. It is the vector for *Wuchereria bancrofti*. *Mansonia annulifera* and *Mansonia uniformis* are the vectors for *Brugia malayi* in India. The prevalence of infection rises with age from 5 years to 30 years beyond which it stabilizes. Lymphatic filariasis is primarily a disease of the poor as it occurs mostly in rural areas or urban slums. The incubation period is very variable stretching from 8 to 16 months or even longer. Clinical manifestations range from those without apparent clinical disease to those with lymphedema and severe disfigurement of the limbs and genitalia. A definitive diagnosis can be made only by detection of the parasites. The standard method for diagnosing active infection is the identification of microfilariae in a blood smear by microscopic examination. Immunochromatographic tests are very sensitive, very specific

and simple “card tests” to detect circulating parasite antigens without the need for laboratory facilities. Diethylcarbamazine (DEC) is the drug used most widely for treatment of lymphatic filariasis. Other drugs used are Albendazole and Ivermectin. The use of single doses of two drugs administered together (albendazole with DEC or ivermectin) is 99% effective in removing microfilariae from the blood. Control of the disease can be achieved by active disease surveillance, vector control, personal protection and mass treatment of communities in endemic areas are the corner stone of lymphatic filariasis control. The WHO strategy of the Global Programme to Eliminate Lymphatic Filariasis aims to stop the spread of infection and morbidity control. To interrupt transmission, districts in which lymphatic filariasis is endemic must be identified and then mass treatment programmes implemented to treat the entire at - risk population.

### Study Exercises

**Long question :** Discuss the epidemiology, prevention and control of Lymphatic Filariasis.

**Short Notes :** (1) Clinical Spectrum of Filariasis (2) Treatment of Lymphatic Filariasis and mass treatment regimen.

#### MCQ

1. Most prevalent parasitic worm in India (a) *Wuchereria bancrofti* (b) *Brugia malayi* (c) *Brugia timori* (d) None of the above
2. *Brugia timori* has only been found in parts of (a) South India (b) Indonesia (c) China (d) Bangladesh
3. The most important vector for lymphatic filariasis in India (a) *Culex quinquefasciatus* (b) *Culex tritaeniorhynchus* (c) *Mansonia annulifera* (d) *Mansonia uniformis*
4. Drug most widely used for treatment of lymphatic filariasis (a) Diethylcarbamazine (DEC) (b) Ivermectin (c) Albendazole (d) None of the above
5. Dose of Diethylcarbamazine (DEC) (a) 1 - 3mg / kg orally in three divided doses (b) 3 - 6 mg / kg orally in three divided doses (c) 6 - 9 mg / kg orally in three divided doses (d) 9 - 12 mg / kg orally in three divided doses

**Answers :** (1) a; (2) b; (3) a; (4) a; (5) d.

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## 173 Leishmaniasis

*Rajesh Vaidya*

Leishmaniasis encompasses a varied collection of diseases ranging in severity from a spontaneously healing skin ulcer to overwhelming visceral disease (1). The disease is named after Leishman, who first identified the organisms in smears taken from a man who had died of "Dum Dum" fever in 1901 (2). An estimated two million cases of all forms of Leishmaniasis taken together occur worldwide every year (3, 4). The disease is caused by 21 species of the genus *Leishmania* which are pathogenic to humans and transmitted by the bite of 30 species of the phlebotomine sandfly (3, 4). There are four main types of the disease : Cutaneous, Diffuse cutaneous, Mucocutaneous and Visceral Leishmaniasis which is commonly called Kala Azar (3). *Leishmania* species are members of the family Trypanosomatidae, order Kinetoplastida. They reside as intracellular amastigotes within macrophages in mammals and as extracellular promastigotes in the gut of their insect vectors, phlebotomine sand flies (5). Leishmaniasis has also emerged as an AIDS - associated opportunistic infection (6).

### Epidemiology

**Global** : Leishmaniasis is endemic in 88 countries on five continents. More than 90% of Cutaneous Leishmaniasis cases occur in Iran, Afghanistan, Syria, Saudi Arabia, Brazil and Peru. More than 90% of Visceral Leishmaniasis cases occur in Bangladesh, Brazil, India and Sudan. The World Health Organization estimates that 350 million people are at risk of

Leishmaniasis world wide. The true incidence and prevalence are uncertain because of the large number of undiagnosed cases, the lack of screening, and underreporting (7 - 9). Every year, an estimated one and a half to two million children and adults develop symptomatic disease and the incidence of infection is substantial when sub - clinical infections are included. The number of new cases of Cutaneous Leishmaniasis each year in the world is estimated to be about 1.5 million while the number of new cases of Visceral Leishmaniasis is estimated to be about 5,00,000. An estimated 12 million people are presently infected worldwide. Leishmaniasis is associated with about 2.4 million disability - adjusted life years and around 7,00,000 deaths per year (7 - 9). Since 1993, the geographical distribution of Leishmaniasis has expanded significantly.

The disease is endemic in three countries of the WHO South East Asia Region, Bangladesh, India and Nepal. Approximately 200 million people in the Region are "at risk" from the disease. The disease is reported in 45 districts in Bangladesh, 52 in India and 12 in Nepal. Of the estimated 5,00,000 people in the world infected each year, nearly 1,00,000 are estimated to occur in the Region (10).

**India** : India is one of the world's largest foci of Visceral Leishmaniasis, accounting for 50% of the total burden of this disease. Leishmaniasis is endemic in eastern States of India. A total of 52 districts in the country are considered endemic for the disease. An estimated 165.4 million population is at risk of Kala Azar in four states. In India, about 1,00,000 cases of Visceral Leishmaniasis are estimated to occur annually. Of these, the State of Bihar accounts for more than 90 per cent of the cases. Cutaneous Leishmaniasis usually occurs in the dry, north eastern states of India, bordering Pakistan extending from

Amritsar to Kutch and Gujrat plains. Cases of Anthroponotic Cutaneous Leishmaniasis has been reported from Bikaner city (10, 11).

**Agent** : The disease is caused by 21 protozoan species of the genus *Leishmania* (order Kinetoplastida). The amastigote forms are obligate intracellular parasites while the promastigotes are extracellular in the arthropod vectors.

These human pathogens include the *Leishmania donovani* complex with three species (*Leishmania donovani*, *Leishmania infantum* and *Leishmania chagasi*). The *Leishmania mexicana* complex has three main species which are *Leishmania mexicana*, *Leishmania amazonensis* and *Leishmania venezuelensis*. The other major pathogenic species are *Leishmania tropica*, *Leishmania major* and *Leishmania aethiopica*. The different species are morphologically indistinguishable, but they can be differentiated by isoenzyme analysis, molecular methods, or monoclonal antibodies. In India, *Leishmania donovani* is the only parasite causing this disease.

The life cycle is relatively simple. Amastigotes are oval or round in shape and approximately 2 to 3  $\mu\text{m}$  in diameter. They have a large, eccentrically located nucleus, a specialized mitochondrial structure, the kinetoplast, which contains a substantial amount of extranuclear DNA and a flagellar pocket and flagellum, which lie within the confines of the cell. They multiply by simple binary division. In the gut of the sand fly, leishmania live and multiply as extracellular, flagellated promastigotes that vary morphologically from short, stumpy forms to elongated ones ranging from 10 to 15  $\mu\text{m}$  in length and 2 to 3  $\mu\text{m}$  in diameter. A single flagellum extends from the anterior pole. After development in the sand fly gut, which takes approximately 1 or 2 weeks depending on the *Leishmania* species, infectious metacyclic promastigotes migrate to the proboscis (5, 12, 13).

**Vector** : *Leishmania* species are transmitted by female sand flies of the genus *Lutzomyia* in the Americas and *Phlebotomus* in other parts of the world. Depending on the species, sand flies live in forested areas, rodent burrows, or debris in peri-domestic habitats. Sandflies breed in cracks and crevices in the soil and buildings, tree holes, caves. They are weak fliers, but they can be carried considerable distances by the wind. Sand flies probe with their proboscis to form a venous pool, from which they obtain blood by capillary action (5, 14, 15). A total of about 30 species in *Phlebotomus* genus (old world) and *Lutzomyia* genus (new world) have been identified as vectors. Sandflies are active in the evening and night-time hours. In India, *Phlebotomus argentipes* is a proven vector of Kala Azar. Cutaneous Leishmaniasis is transmitted by *Phlebotomus papatasi* and *Phlebotomus sergenti*.

**Host** : Most leishmaniasis are zoonotic and humans become infected only when accidentally exposed to the natural transmission cycle. The animal host may be wild animals, such as rodents, and domestic animals, such as dogs. However, in the anthroponotic forms humans are the sole reservoir host. Indian Kala - Azar is anthroponotic with humans being the only known reservoir of infection.

Infection can occur in all age groups and both genders. In India peak age of infection is 5 to 9 years. Males are affected

more often than females probably due to greater exposure. Population movement is important in spreading infection between endemic and non endemic regions. The disease usually strikes the poorest of the poor (10, 16, 17). It is common in various farming practices, forestry, mining and fishing who have greater risk of being bitten by sand - flies. Recovery from Kala - Azar gives a lasting immunity.

**Environment** : The disease is mostly confined to the plains. It does not occur in altitudes over 2000 feet. Prevalence usually shows a rise during and after rains. The diseases are largely confined to rural areas and those urban areas where opportunities for breeding of sand flies exist. Overcrowding, poor ventilation and accumulation of organic matter in the environment facilitates transmission. Developmental projects like forest cleaning, and cultivation projects, large water resources schemes, and colonization and resettlement programmes are bringing human beings into areas of high vector and reservoir concentration (5, 18).

**Transmission** : The disease is transmitted by the bite of infected female sandflies. Rarely other modes of transmission might result in infection. Visceral Leishmaniasis can be directly initiated by amastigotes via blood (shared needles, transfusion, transplacental spread) or organ transplantation. Cutaneous infection can develop after inadvertent needlestick injury if the needle or syringe contains infected material (6, 12 14).

**Clinical Features** : The outcome of leishmanial infection is dependent on a series of complex and only partially understood interactions between *Leishmania* species - specific virulence factors and the genetically determined cell-mediated immune responses of their mammalian hosts. The incubation in man is extremely variable. It usually ranges from 3 to 8 months but can be as short as 10 days to as long as two years.

Leishmaniasis has several diverse clinical manifestations : ulcerative skin lesions, destructive mucosal inflammation, and disseminated visceral infection (Kala Azar). Epidemiology, immunopathology, and outcome are similarly diverse, since infection occurs in multiple endemic regions, in both children and adults, and is caused by nearly two - dozen distinct *Leishmania* species. Nevertheless, all forms of this protozoal infection share three pathogenetic features : resident tissue macrophages are targeted and support intracellular parasite replication; the host immunoinflammatory response regulates expression and outcome of disease; and persistent tissue infection is characteristic (6, 12, 13). Each of the three major clinical syndromes can present with a wide spectrum of findings. Each of these syndromes is associated with more than one *Leishmania* species, and any given species is capable of producing more than one syndrome. Variations are common, particularly among people who are concurrently infected with HIV or other immunosuppressive illness (5, 12, 13).

**Cutaneous Leishmaniasis** : The typical lesion of Cutaneous Leishmaniasis (5, 12) develops at the site where promastigotes are injected by the vector. Promastigotes are taken up by mononuclear phagocytes. They transform to amastigotes and multiply within the macrophages. A papule is formed at the site of inoculation. The papule enlarges and then ulcerates. Multiple lesions may be present in the same patient. Depending

on the location, Old World Cutaneous Leishmaniasis is known locally as Oriental sore, Bouton d'Orient, Bouton de Crete, Bouton d'Alep, Bouton de Briska, Aleppo evil, Baghdad boil, and Delhi boil.

There can be marked variation in the appearance of the lesions. The classic wet lesion of *Leishmania major* and *Leishmania braziliensis* is "pizza - like" with a raised outer border, granulating base, and overlying white, purulent exudate. Infection by *Leishmania tropica* produces dry lesions in the Middle East and India. The ulcer tends to be smaller and covered with a crust. Contiguous mucosal involvement may be seen in some patients. Some leishmanial lesions are papular or nodular, without ulceration. Cutaneous lesions persist for months, and in some cases years, before they heal, leaving flat, atrophic scars as evidence of disease. Once a lesion has resolved, the person is usually left with immunity against the infecting *Leishmania* species. Cutaneous Leishmaniasis should be considered in the differential diagnosis of subacute or chronic skin lesions in people who have lived, worked, or traveled in endemic areas.

**Mucosal Leishmaniasis (Espundia)** : A small proportion of people infected with *Leishmania braziliensis* develop mucosal lesions in the nose, mouth, pharynx, or larynx months to years after resolution of the primary skin lesion. The condition is known as Espundia in Latin America. Mucosal Leishmaniasis often begins with nasal stuffiness and inflammation. Ulceration of the nasal mucosa and septum follows. The lips, cheeks, soft palate, pharynx and larynx may eventually be involved, resulting in substantial disfigurement. Mucosal involvement is also observed with other *Leishmania* species, although the pathophysiology may be somewhat different. Destructive involvement of the nose and mouth has been reported with *Leishmania tropica* in Saudi Arabia. Mucosal involvement has been reported rarely in immunocompetent people and more frequently in those who are immunosuppressed with neoplasms or AIDS. (5, 12).

**Visceral Leishmaniasis** : The majority of infections of Visceral Leishmaniasis are sub clinical. Only a minority of those infected develop full - blown Visceral Leishmaniasis, or Kala - Azar. The disease is characterized by fever, weight loss, and hepatosplenomegaly.

Malnutrition is known to suppress cell - mediated immune responses and may contribute to progression to symptomatic Visceral Leishmaniasis. The incubation period is typically weeks to several months, but it may be as short as 10 days or as long as several years. The onset of Visceral Leishmaniasis is usually insidious, but it can be abrupt, with high fever. Full - blown, progressive Visceral Leishmaniasis, or Kala - Azar, is associated with fever, abdominal enlargement, weakness, loss of appetite, and weight loss. The clinical findings are similar with disease due to *Leishmania donovani* and *Leishmania infantum* / *chagasi*. Symptoms may be present for weeks to months before patients come to medical attention in rural, endemic areas. The fever pattern may be intermittent, remittent or rarely continuous. The spleen is firm, non - tender, and over time becomes massively enlarged. There is hepatomegaly with the enlarged liver having a sharp edge and smooth consistency. Some patients in India develop hyperpigmentation leading to

the name Kala - Azar, which means "black fever" in Sanskrit. The late stages of disease are characterized by malnutrition, severe wasting, and progressive debilitation. Stunting may be seen in children. Death often occurs due to a secondary bacterial infection, such as pneumonia, septicemia, dysentery, or tuberculosis, or with measles or other viral infection.

Laboratory findings include anaemia, neutropenia, thrombocytopenia and pronounced hypergammaglobulinemia. The anaemia is usually normocytic, normochromic, unless there is concomitant iron deficiency. Leukopenia can be profound with white blood cell counts below 1000/mL. The globulin level can reach 9 or 10 g/dl.

**Post - Kala - Azar Dermal Leishmaniasis** : Some patients of Visceral Leishmaniasis in India and Africa develop skin lesions following treatment, ranging from hyperpigmented macules to frank nodules. Skin lesions typically appear in India 1 or 2 years after treatment and may persist for as long as 20 years. Persistence of lesions beyond one year is associated with high anti - leishmanial antibody titers and negative leishmanial skin test responses. Anti - leishmanial treatment is indicated in Indian post - Kala Azar dermal Leishmaniasis. In a few instances in India, Visceral Leishmaniasis has recurred in patients with post - Kala - Azar dermal Leishmaniasis. The differential diagnosis includes leprosy (5, 12, 13).

**HIV - Visceral Leishmaniasis Co - infection** : *Leishmania* with HIV co - infection has emerged as a serious new disease and is increasingly frequently being reported. Immunocompromised individuals progress to full blown Visceral Leishmaniasis far more often than immunocompetent people who get infected. AIDS and Visceral Leishmaniasis are mutually reinforcing. Visceral Leishmaniasis quickly accelerates the onset of AIDS and shortens the life expectancy of HIV - infected people. Similarly AIDS increases the risk of Visceral Leishmaniasis by 100 - 1000 times in endemic areas. This combination of HIV and Leishmaniasis produces cumulative deficiency of the immune response since *Leishmania* parasites and HIV destroy the same cells, exponentially increasing disease severity and consequences. Visceral Leishmaniasis is considered a major contributor to a fatal outcome HIV in co - infected patients. Another implication of this combination is that Leishmaniasis can be transmitted directly person to person through the sharing of needles, as is often the case among intravenous drug users (13, 19).

## Diagnosis

Cases of Leishmaniasis should be confirmed by demonstration of the parasite, which is straightforward if parasites are plentiful as in Visceral Leishmaniasis but can be difficult otherwise.

**Parasite Identification** : The diagnosis of Leishmaniasis is most often confirmed by identifying leishmania amastigotes in Wright - Giemsa - stained touch preparations or tissue sections or by isolating the parasite in culture. Amastigotes are seen in macrophages in tissue sections, but they may appear to be extracellular in touch preparations. *Leishmania* can be grown as promastigotes in NNN medium, Schneider's insect medium, and other tissue culture media. The cultures are incubated at



24 to 26°C to approximate sand fly temperatures.

**Serology** : Antileishmanial antibody titers are typically present in high titer in people with Visceral Leishmaniasis and at low titer or undetectable in those with Cutaneous Leishmaniasis. They can be measured by a number of assays. Enzyme - Linked Immunosorbent Assay (ELISA), indirect immunofluorescent tests, and agglutination assays have all been used (20).

**Skin Test** : The intradermal leishmanin (Montenegro) skin test is positive in the majority of people who have asymptomatic, self resolving *Leishmania donovani* and *Leishmania infantum*/chagasi infections and in people with Cutaneous or Mucosal Leishmaniasis. The skin test is negative in people with progressive Visceral Leishmaniasis or Diffuse Cutaneous Leishmaniasis, but it becomes positive in the majority of people who are successfully treated for Visceral Leishmaniasis.

### Treatment

The drug of choice for the treatment of Visceral Leishmaniasis is Sodium stibogluconate, a pentavalent antimonial compound except in regions that are considered Sodium stibogluconate unresponsive. The dose is 20 mg Sb/kg/day IV or IM daily for 20 - 30 days. However, resistance is on the rise and resistance levels as high as 43% have been reported from Bihar where Visceral Leishmaniasis is endemic. Patients resistant to stibogluconate should be treated with alternative agents, such as liposomal amphotericin (0.5 - 3 mg/kg) on alternate days or pentamidine (2 - 4 mg/kg) on alternate days for 15 doses. Amphotericin B deoxycholate is the drug of choice in India, whereas the lipid formulation liposomal amphotericin is used in Europe (2). The dose of Amphotericin B used in India is 1mg/kg IV infusion daily or alternate day for 15 - 20 infusions. The dose can be increased in patients with incomplete response with 30 injections. Miltefosine, the first effective oral treatment for Visceral Leishmaniasis, including for antimony - resistant infection has been approved for self - administered outpatient therapy (13, 21, 22). The drug is to be used in a dose of 100 mg daily for four weeks. Supportive treatment includes rest, high - calorie diet, blood transfusions, and treatment of secondary infections.

### Prevention and Control

Leishmaniasis can be prevented by interrupting sand fly transmission or by removing or treating reservoirs of infection. (18, 23). The short - term visitor to an endemic area should use personal protective measures to avoid sand fly bites. Sand flies tend to bite from dusk to dawn. The application of DEET (diethyltoluamide) - containing insect repellents to exposed skin and under pant and shirt cuffs, the use of fine - mesh screens or insect nets, and the application of insecticide (usually permethrin or other pyrethroids) to clothing and bed nets - decrease the risk of transmission of Leishmaniasis. Further details on vector control are given in the chapter on Entomology.

### Vaccine

There is experimental evidence to indicate that Leishmaniasis should be vaccine preventable. However, there is currently no vaccine against any form of Leishmaniasis for general human use. One major factor may be the lack of a conceived

market for human Leishmaniasis vaccines. Leishmaniasis is a considered a local/regional problem and not a global one (24). A number of candidate vaccines are undergoing clinical trials. Killed parasites as vaccines produced encouraging results in Brazil in the 1970s. Trials have tested autoclaved *Leishmania* major plus BCG versus adjuvant (BCG) alone. In Ecuador, two doses of a killed multi - leishmania species cocktail plus BCG reduced Cutaneous Leishmaniasis incidence by 73% the first year (13,25).

### Summary

Leishmaniasis encompasses a varied collection of diseases ranging in severity from a spontaneously healing skin ulcer to overwhelming visceral disease. Leishmaniasis is endemic in 88 countries on five continents. The World Health Organization estimates that 350 million people are at risk of Leishmaniasis world wide. Leishmaniasis each year in the world is estimated to be about 1.5 million while the number of new cases of Visceral Leishmaniasis is estimated to be about 5,00,000. India is one of the world's largest foci of Visceral Leishmaniasis, accounting for 50% of the total burden of this disease. The disease is caused by 21 protozoan species of the genus *Leishmania* (order Kinetoplastida). The amastigote forms are obligate intracellular parasites while the promastigotes are extracellular in the arthropod vectors. *Leishmania* species are transmitted by female sand flies of the genus *Lutzomyia* in the Americas and *Phlebotomus* in other parts of the world. In India, *Phlebotomus argentipes* is a proven vector of Kala - Azar. The disease is transmitted by the bite of infected female sandflies. The incubation in man is extremely variable. It usually ranges from 3 to 8 months but can be as short as 10 days to as long as two years. There are three main types of the disease : Cutaneous, Diffuse Mucocutaneous and Visceral Leishmaniasis which is commonly called Kala Azar. Immunocompromised individuals progress to full blown Visceral Leishmania with HIV co - infection is has emerged as a serious new disease and is increasingly frequently being reported. AIDS and Visceral Leishmaniasis are mutually reinforcing. Cases of Leishmaniasis should be confirmed by demonstration of the parasite by identifying leishmania amastigotes in Wright - Giemsa - stained touch preparations or tissue sections or by isolating the parasite in culture. The drug of choice for the treatment of Visceral Leishmaniasis is Sodium stibogluconate. However, resistance is on the rise and these patients should be treated with alternative agents, such as liposomal amphotericin (0.5 - 3 mg/kg) on alternate days or pentamidine (2 - 4 mg/kg) on alternate days for 15 doses.

### Study Exercises

**Long Question** : Discuss the epidemiology, treatment, prevention and control of Kala - Azar

**Short Notes** : (1) Life cycle of *Leishmania* parasite (2) Visceral Leishmaniasis (3) HIV - Visceral Leishmaniasis Co - infection (4) Treatment of Visceral Leishmaniasis

### MCQs

1. The disease is endemic in following three countries of the WHO South East Asia Region except (a) Bangladesh (b) India (c) Nepal (d) Sri lanka



2. The disease is reported in \_\_\_\_\_ no of districts in India  
(a) 51(b) 52(c) 53(d) 54
3. State which accounts for more than 90 per cent of the cases in India (a) Uttar Pradesh (b) Bihar (c) Assam (d) Madhya Pradesh
4. Leishmania donovani complex comprises of all except  
(a) Leishmania infantum (b) Leishmania chagasi  
(c) Leishmania venezuelensis (d) Leishmania donovani
5. Cutaneous Leishmaniasis is also known as all the following except (a) Oriental sore (b) Aleppo evil (c) Delhi boil (d) Espundia

Answers : (1) d; (2) b; (3) b; (4) c; (5) d.

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## Dengue & Dengue Haemorrhagic Fever

Rajesh Vaidya

Dengue is a vector borne viral disease which occurs in tropical and sub - tropical regions around the world, predominantly in urban and semi - urban areas. Dengue fever (DF) is the most rapidly spreading vector borne viral disease and is a major international public health concern (1, 2). The disease is caused by the four serotypes of the Dengue virus which are arboviruses of the genus *flaviviruses*. The principal vector for the disease is the mosquito *Aedes aegypti*. The disease can present in several forms, from asymptomatic illness to life threatening diseases like Dengue Haemorrhagic Fever (DHF) and Dengue Shock Syndrome (DSS).

The virus is widely distributed in the tropical and subtropical

regions of the world. The global prevalence of Dengue has grown dramatically in recent decades. The World Health Organization reports that the disease is now endemic in more than 100 countries in Africa, the Americas, the Eastern Mediterranean, South - East Asia and the Western Pacific. South - East Asia and the Western Pacific are most seriously affected. WHO currently estimates there may be 50 million cases of Dengue infection worldwide every year. 2.5 billion people live in Dengue endemic countries and are at risk of acquiring the infection (4, 5).

### Epidemiology

**Global Situation** : The geographical extent of the disease has risen significantly in the recent past. It has spread to new areas and reemerged in areas where it appeared to have been controlled. Tropical areas in South - East Asia, Africa, Western Pacific and the Mediterranean are most seriously affected. Prior to 1970 only nine countries had experienced DHF epidemic, a number that had increased by more than four times by 1995. During 1998 over 1.2 million cases with 3, 442 deaths were

reported to WHO which is the largest for any single year. WHO currently estimates there may be 50 million cases of Dengue infection worldwide every year with around 24,000 deaths (5). The rapid rise in the geographical extent of the disease has been attributed to the enhanced geographic distribution of the four Dengue viruses and of their mosquito vectors, particularly the predominantly urban *Aedes aegypti*. A rapid rise in urban population particularly urban slums has contributed to the rise in the number of cases (3, 5). The WHO expects the spread of the disease to continue because of increasing urbanisation, increasing population movement, and proliferation of man-made larval habitats of the mosquito vector.

1.3 billion people living in South - East Asia are at risk of Dengue fever. In 2003 only eight countries in South - East Asia Region reported Dengue cases. By 2006, ten out of the 11 countries which form part of the WHO South - East Asia region were reporting the disease. Bhutan reported the first Dengue outbreak in 2004. An outbreak, with a high case fatality rate (3.55%) was first reported in Timor - Leste in 2005. Nepal reported Dengue cases for the first time in Nov 2006 (6 - 8).

**Indian Situation** : Large parts of India are endemic for Dengue Fever. The disease is reported from most parts of the country except those at high altitudes. The first major outbreak in India was reported during 1963 in Kolkata. The next major outbreak of Dengue / Dengue Haemorrhagic Fever was reported in Delhi and neighboring states in 1996. Following this outbreak, the reporting of Dengue fever was made mandatory to ensure early preventive measures in case of outbreak. Out of 18 endemic states, the most affected states are Delhi, West Bengal, Kerala, Tamil Nadu, Karnataka, Maharashtra, Rajasthan, Gujarat and Haryana (9). Data for the last 10 years reveals that the largest number of cases and deaths due to Dengue/DHF were reported in 1996 while the next increase was in 2003. 12, 317 cases with 184 deaths were reported to the National Vector Borne Diseases Control Programme in India in 2006 (9). Delhi recorded several outbreaks of Dengue fever between 1967 and 2006. The outbreak in 2006 was estimated to have resulted in 10, 344 cases and 162 deaths (10, 11).

**Agent Factors** : DF / DHF is caused by Dengue virus which belongs to genus *Flavivirus* family *Flaviviridae* and includes serotypes 1, 2, 3 and 4 (Den - 1, Den - 2, Den - 3 and Den - 4). The Dengue virus is composed of single - stranded RNA. Each serotype provides specific lifetime immunity and short - term cross - immunity. All serotypes can cause severe and fatal disease. There are genetic variations within the serotypes. Some genetic variants within each serotype appear to be more virulent or have greater epidemic potential. When a person has had classic Dengue, a second infection later by another serotype increases the likelihood of suffering from DHF as explained by the immune enhancement mechanism (1, 2, 4). Infection with one serotype provides life - long homologous immunity but does not provide protection against other serotypes, and instead may exacerbate subsequent infection (4, 6, 7).

**Vector** : *Aedes aegypti* is the main vector of Dengue transmission in India. Another important vector is the *Aedes albopictus*. The mosquito is a peri - domestic and domestic breeder. Mosquito breeding can occur in any water - storage containers, such as desert coolers, flower vases, coconut shells, construction sites,

overhead uncovered or partially covered water tanks, discarded buckets, tyres, utensils and large containers used for collecting rain water which are not emptied and cleaned periodically. The mosquitoes rest indoors on various objects, in closets and other dark places. Outside, they rest where it is cool and shady. *Aedes* mosquito can fly upto a limited distance of 400 meters but can spread over vast distances mechanically in various types of vehicles used by man. *Aedes aegypti* is primarily a day time biter (4, 6, 12, 13).

**Environmental Factors** : The outbreaks of DF/DHF are most likely to occur in post - monsoon period when the breeding of the mosquitoes is highest. High temperature and high humidity during these seasons prolongs the life span of the vector. The spread of Dengue has resulted from several factors including human behaviour, climate and movement of humans. Usually urban areas, having high population density, poor sanitation and large number of desert coolers, flower vases, construction sites, overhead tanks etc which promote mosquito breeding, are at high risk. Dengue fever/DHF can also occur in rural areas where the environment is friendly for mosquito breeding like storage water for cattle feeding and drinking, cement cisterns and underground cemented water sumps (4, 6, 8).

**Transmission** : The infection is transmitted by the bite of an infected female mosquito *Aedes aegypti*. Mosquitoes acquire the virus while feeding on the blood of an infected person. After an extrinsic incubation period of 8 to 10 days, an infected mosquito can transmit the virus for the rest of its life. Trans - ovarian transmission of the Dengue virus in mosquitoes maintains the virus in nature. Humans are the main host of the virus, although studies have shown that in some parts of the world monkeys may become infected. The virus circulates in the blood of infected humans for two to seven days (4, 6, 12, 13).

### Clinical Presentation

The incubation period of Dengue fever is usually 5 - 6 days, but may vary from 3 to 10 days. Infection with Dengue virus can result in four different clinical syndromes. They are undifferentiated fever, the Classic Dengue fever, Dengue Haemorrhagic fever (DHF) and Dengue Shock syndrome (DSS) (14 - 16).

**Undifferentiated Fever** : This is the most common manifestation of Dengue infection. Almost 90% of those infected remain either asymptomatic or only mildly symptomatic. The patient has fever, headache, body ache and may develop a mild rash.

**Classic Dengue Fever** : This is characterized by abrupt onset of high fever, severe headache, severe muscle and joint pain (Break Bone Fever), rash and other haemorrhagic manifestations.

**Dengue Haemorrhagic Fever** : DHF is a potentially deadly complication that is characterized by high fever, accompanied by headache, anorexia, vomiting and abdominal pain. Petechiae on the extremities, face, and trunk are the manifestations of haemorrhage. Bleeding from nose, gums and gastrointestinal tract may be found. In moderate cases, spontaneous mucocutaneous bleeding, nasal bleeding and GI bleeding usually occurs. In severe cases, the patient's condition may suddenly deteriorate after a few days of fever. Any case with fever, or recent history of acute fever, haemorrhagic manifestations, low

platelet count (100,000/mm or less), and objective evidence of “leaky capillaries” in the form of elevated haematocrit (20% or more over baseline), low albumin, or pleural or other effusions meets the case definition for DHF.

**Dengue Shock Syndrome** : Patients may rapidly develop varying degree of circulatory disturbances and go into a critical state of shock. Patients with DHF who develop evidence of circulatory failure manifested indirectly by rapid and weak pulse, narrow pulse pressure (< 20 mm Hg) or hypotension for age, cold, clammy skin and altered mental status meet the criteria for DSS. Frank shock is direct evidence of circulatory failure. Prolonged shock is often complicated by metabolic acidosis and severe bleeding. Case fatality rates can exceed 20% in such patients. A major cause of deaths due to DHF is leakage of plasma in the pleural and abdominal cavities leading to hypovolaemic shock. Encephalitic signs associated with intracranial haemorrhage, metabolic and electrolyte disturbances, and hepatic failure may occur.

### Differential Diagnosis

Differential diagnosis must include all other arboviral fevers, measles, rubella and other systemic febrile illnesses, especially those accompanied by rash (6). The presence of marked thrombocytopenia with concurrent haemoconcentration differentiates DHF / DSS from other syndromes such as endotoxic shock from bacterial or meningococcaemia.

### Alarming Signs

- (a) Minute spots on the skin suggesting bleeding within the skin.
- (b) Nose bleeds and gum bleeds, haemetemesis.
- (c) Abdominal pain and/or passage of black tarry stool.
- (d) Refusal to food or drink.
- (e) Abnormal behaviour or drowsiness.
- (f) Difficulty in breathing or cold hands and feet, reduced amount of urine being passed.

### Diagnosis

Patients suspected to be suffering from Dengue fever must undergo repeated clinical laboratory tests : Complete Blood Counts including WBC, platelets, haematocrit, Liver function tests, and urine analysis for microscopic haematuria. These blood tests may indicate a diagnosis of Dengue fever and DHF / DSS. Thrombocytopenia (100,000 cells or less per mm) and haemoconcentration as evidenced by a greater than 20% rise in average haematocrit for age and sex are the haematological criteria for diagnosis.

Laboratory tests essential for confirmatory diagnosis of Dengue infection include isolation of the virus, demonstration of a rising titre of specific serum Dengue antibodies, and demonstration of a specific viral antigen or RNA in the tissue or serum. Virus isolation can be done by inoculation of clinical material in tissue culture, mosquitoes or suckling mice and further detection is performed using fluorescent antibody test or haemagglutination inhibition test. Viral antigen can be demonstrated by doing direct fluorescent antibody test using specific monoclonal antibodies for Dengue virus. Viral RNA or genomic sequence can also be detected in autopsy specimen, serum, CSF or culture supernatant by doing Polymerase Chain Reaction (PCR) and gene sequencing.

Serological diagnosis is based on detection of IgM antibodies. IgM antibodies against Dengue virus appear around 5 days after onset of symptoms and are detectable for one to three months after the illness. The tests employed are IgM capture ELISA test and Rapid IgM strip test. IgM capture ELISA test kit is available from NIV Pune and commercial sources and Rapid IgM Strip Test kit is available commercially.

### Treatment

The basics of management of cases of Dengue fever are fluids, rest, antipyretics (avoid aspirin and non - steroidal anti - inflammatory drugs) and close monitoring of blood pressure, haematocrit, platelet count and level of consciousness. Liberal fluids intake including home available fluids like rice water, kanji, fruit juices, plain water or ORS solution are recommended for patient with excessive sweating, nausea, vomiting or diarrhoea to prevent dehydration (1, 3). Monitoring must be continued after defervescence. If the level of hydration falls intravenous fluids, guided by serial haematocrits, blood pressure, and urine output must be given. The volume of fluid needed is similar to the treatment of diarrhoea with mild to moderate isotonic dehydration.

**Management of DHF** : Patients of DHF need regular assessment by serial haematocrit levels. Urine output should be monitored closely in areas where serial haematocrit estimation is not possible. A rise in haematocrit of 20% or more or single haematocrit value of more than 40%, platelets count of 50,000/cmm or less and spontaneous haemorrhage are all danger signs.

**Management of DSS** : DSS patients present with shock. Volume replacement is the most important treatment measure and immediate administration of intravenous fluids to expand plasma volume is essential. Close observation with good nursing care is imperative. Blood transfusion should be given in case with significant haemorrhage. Fresh frozen plasma or concentrated platelet transfusion may be given when disseminated intravascular coagulation causes massive bleeding. Readers may refer to standard texts for details on management of patients (3, 4, 14 - 17)

### Prevention and Control

**Vector Control** : Vector control and personal protective measures are the mainstay of prevention of Dengue infections. Both aspects are dealt with in detail in the chapter on Entomology.

**Surveillance** : Epidemiological surveillance of the disease as well as the vector form an important part of control measures. The disease surveillance should include fever surveillance, diagnosis based on standard case definitions, and reporting of DF/DHF cases to state health authorities. Vector surveillance includes both larval and adult vector surveillance (18). A number of indices have been described and are currently used to monitor the vector population :

**House index** : Percentage of houses positive for larvae of *Aedes aegypti*. House index of more than 10% indicates high risk of transmission

**Breteau index** : Number of positive containers for *Aedes aegypti* per 100 houses. An index of more than 50 indicates high risk of transmission while index below five indicates low risk of transmission.



**Notification** : Dengue is a cross border disease. With massive air travel, outbreaks can rapidly cross international borders. Outbreaks must, therefore, be notified at the earliest to both the national as well as international health authorities.

**Vaccine** : No effective vaccine is available for Dengue. Research into Dengue vaccines has focused on the use of live attenuated or inactivated vaccines, infectious clone derived vaccines, and nucleic acid vaccine (19).

## Summary

Dengue is a vector borne viral disease which occurs in tropical and sub - tropical regions around the world. Dengue fever is the most rapidly spreading vector borne viral disease and is a major international public health concern. WHO currently estimates there may be 50 million cases of Dengue infection worldwide every year. 2.5 billion people live in Dengue endemic countries and are at risk of acquiring the infection. Large parts of India are endemic for Dengue Fever. The first major outbreak in India was reported during 1963 in Kolkata. Indian data for the last 10 years reveals that the largest number of cases and deaths due to Dengue/DHF were reported in 1996 while the next increase was in 2003. DF / DHF is caused by Dengue virus which belongs to genus *Flavivirus* family *Flaviviridae* and includes serotypes 1, 2, 3 and 4. All serotypes can cause severe and fatal disease. *Aedes aegypti* is the main vector of Dengue transmission in India. Another important vector is the *Aedes albopictus*. The infection is transmitted by the bite of an infected female mosquito *Aedes aegypti*. The incubation period of Dengue fever is usually 5 - 6 days, but may vary from 3 to 10 days. Clinical Presentation comprises of Undifferentiated Fever, Classic Dengue Fever, Dengue Haemorrhagic Fever and Dengue Shock Syndrome. Complete Blood Counts, Liver function tests, and urine analysis for microscopic haematuria indicate a diagnosis of Dengue fever and DHF / DSS. Confirmatory diagnosis of Dengue is done by isolation of the virus, demonstration of a rising titre of specific serum Dengue antibodies, and demonstration of a specific viral antigen or RNA in the tissue or serum. The basics of management of cases of Dengue fever are fluids, rest, antipyretics. In DSS volume replacement is the most important treatment measure and immediate administration of intravenous fluids to expand plasma volume is essential. Prevention and Control comprise of Vector Control, epidemiological surveillance of the disease as well as the vector and notification at the earliest to both the national as well as international health authorities.

## Study exercises

**Long Question** : Discuss the epidemiology, treatment, prevention and control of Dengue.

**Short Notes** : (1) Spectrum of clinical presentation of Dengue (2) Enlist Alarming sign's in Dengue Fever (3) Indices of vector population

### MCQs

1. Prior to 1970 only \_\_\_\_\_ countries had experienced DHF epidemic (a) 3 (b) 5 (c) 7 (d) 9
2. In which city was the first major outbreak in India during 1963 reported ? (a) Mumbai (b) Kolkata (c) Delhi (d) Chennai

3. Dengue virus has how many serotypes (a) 2 (b) 4 (c) 6 (d) 8.
4. IgM antibodies against Dengue virus appear around \_\_\_\_\_ days after onset of symptoms (a) 3 (b) 5 (c) 7 (d) 9
5. House index of more than \_\_\_\_ % &/or Breteau index of more than \_\_\_\_ indicates high risk of transmission (a) 5 & / or 40 respectively (b) 10 &/ or 50 respectively (c) 15 &/ or 60 respectively (d) 20 &/ or 70 respectively

**Answer** : (1) d; (2) b; (3) b; (4) b; (5) b.

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Rajesh Vaidya

Chikungunya fever is an arboviral illness characterized by severe, persistent joint pains, fever and rash. The disease resembles dengue fever and is spread by the bite of infected mosquitoes. It is rarely life - threatening. However, widespread occurrence of the disease causes substantial morbidity and economic loss. Chikungunya virus disease has occurred sporadically in India and Southeast Asia for at least 200 years. Epidemics with symptoms resembling Chikungunya fever have been recorded as early as 1824 in India (1). Over the last 40 years, several widespread epidemics have occurred in many cities of India and Southeast Asia affecting thousands of people (2, 3). Occasionally, epidemics of Dengue and Chikungunya have occurred simultaneously in the same community, making clinical differentiation of the two diseases difficult. Unlike Dengue which has become endemic in many parts of Asia, Chikungunya virus disappears and reappears at irregular intervals. The name Chikungunya originates from Swahili, and means "that which bends up," which refers to the characteristic posture assumed by patients suffering severe joint pains. Chikungunya virus was first isolated during a 1952 epidemic in Tanzania (2, 3).

### Epidemiology

**Global** : The Chikungunya virus is probably maintained in nature by transmission between jungle primates (4). The disease displays a striking epidemiological profile with major epidemics appearing and disappearing cyclically, usually with an inter - epidemic period of 7 - 8 years and sometimes as long as 20 years (1). Currently, Chikungunya is a major arboviral disease in urban parts of Africa and Asia. The known geographic distribution of the virus includes large parts of Sub - Saharan Africa, Southeast Asia including Indonesia, Philippines, and India, as well as islands in the South - West Indian Ocean (2, 3). Other affected regions include Mauritius and Seychelles in the Indian Ocean. Imported cases have been reported by European countries like France, Germany, Italy, Norway and Switzerland (5 - 7).

**India** : The virus was first isolated in India from Kolkata in 1963 (8). In the mid sixties outbreaks resembling Chikungunya were reported from various parts of India including Vellore, Kolkata and parts of Maharashtra (1). The last outbreak of Chikungunya virus infection was reported in 1971. There has been no active or passive surveillance of Chikungunya and therefore, it appeared that the virus had disappeared from the country (9). Since 2005, however, there have been several reports of outbreaks from widespread parts of the country and the re - emergence of the virus has been confirmed (10 - 12). In the present outbreak, 151 districts of eight states of India have reported Chikungunya fever as of Oct 2006. The affected states are Andhra Pradesh, Andaman & Nicobar Islands, Tamil Nadu, Karnataka, Maharashtra, Gujarat, Madhya Pradesh, Kerala and Delhi. More than 1.25 million cases have been reported from the country with 7, 52, 245 cases from Karnataka and

2, 58, 998 from Maharashtra. In some areas attack rates have reached up to 45% (1).

**Agent** : The Chikungunya virus is an arbovirus belonging to the group *alphaviruses* of the family *Togaviridae*. It is believed that there are two distinct lineages of the Chikungunya virus, one containing Western African and the second comprising all Southern and East African strains. The virus originated in Africa and was subsequently introduced into Asia (12).

**Vector** : Chikungunya is transmitted by mosquitoes, including many *Aedes species* which bite during daylight hours. In some parts of the world *Culex species* are important vectors. In India, the two important vectors are *Aedes aegypti* and *Aedes albopictus*, both of which also transmit dengue virus (13).

**Transmission** : There appear to be two distinct transmission cycles for Chikungunya virus. A sylvatic cycle between wild primates and arboreal *Aedes* mosquitoes, similar to that of sylvatic Yellow fever virus in the same region has been seen in Africa. Urban Chikungunya outbreaks are associated with *Aedes aegypti* transmission in a human - mosquito - human cycle. Urban outbreaks are sporadic in occurrence but explosive in nature. Till recently it was believed that there is no direct person - to - person transmission. However, vertical maternal foetal transmission of the virus has been documented in an outbreak at La Reunion Island (14). The virus has been isolated from monkeys in Africa (15). There is a risk for travellers in areas where Chikungunya is endemic and in areas affected by epidemics (16, 17).

### Clinical Features

The Incubation period is usually 2 - 3 days with a range of 1 - 12 days (3). The onset is with fever, chills, headache, photophobia, backache, nausea, vomiting, arthralgia, and rash. The acute illness usually lasts about 3 to 5 days but can be very severe. Most patients recover completely within 5 to 7 days. More than three fourths of the patients complain of severe arthralgia. One or more joints may be involved, with swelling and redness. Another characteristic feature is the rash which is maculopapular and mainly involves the trunk. In some cases the joint pains may persist for weeks, months or even longer. Chikungunya may also be asymptomatic (2, 5, 18 - 21). Children may suffer from febrile convulsions. Infrequently, haemorrhagic manifestations (petechiae, purpura, epistaxis) also have been reported.

### Diagnosis

Any illness with the classical triad of fever, rash, and joint pains in endemic areas must give rise to suspicion of Chikungunya. The definitive diagnosis can only be reached by serology or isolation of the virus. Alphaviruses can usually be recovered from blood taken during the first few days of illness. Seroconversion can be shown in acute and convalescent serum samples drawn two weeks apart. Virus - specific IgM antibodies can be detected by capture ELISA in patients recovering from Chikungunya infection and they decline within 3 - 6 months. Haemagglutination inhibition antibodies appear as the viraemia declines. Patients usually become positive by the 5th to 7th day of illness. RT - PCR can be used for molecular diagnosis at specialized centre (12, 20).

## Differential Diagnosis

Chikungunya infection is often mistaken for dengue, which has a similar distribution in Asia and Africa. It may also be confused with West Nile virus infection.

## Treatment

Treatment is symptomatic and includes antipyretic and anti-inflammatory drugs. Aspirin should be avoided because of reports of mild haemorrhagic manifestations. Movement and mild exercise tend to improve stiffness and morning arthralgia, but heavy exercise should be avoided as it may exacerbate rheumatic symptoms. Although the joint symptoms may persist for months, Chikungunya is generally an acute, self-limited infection with no deaths reported. Patients should be nursed under mosquito nets during the viraemic stage to avoid transmission of the disease (2, 5, 21).

## Prevention and Control

There is no vaccine against this arboviral disease. No specific treatment is available. Prevention is entirely dependent upon taking steps to avoid mosquito bites and elimination of mosquito breeding sites. Control measures consist of vector control activities as outlined for dengue earlier. Details about vector control and personal protective measures are given in the Chapter on Entomology.

## Summary

Chikungunya fever is an arboviral illness characterized by severe, persistent joint pains, fever and rash. The name Chikungunya originates from Swahili, and means "that which bends up," which refers to the characteristic posture assumed by patients suffering severe joint pains. The disease appears and disappears cyclically, usually with an inter-epidemic period of 7-8 years. The known geographic distribution of the virus includes large parts of Sub-Saharan Africa, Southeast Asia including India. Chikungunya is transmitted by mosquitoes, including many *Aedes species*. In India, the two important vectors are *Aedes aegypti* and *Aedes albopictus*. Urban Chikungunya outbreaks are associated with *Aedes aegypti* transmission in a human-mosquito-human cycle. The incubation period is usually 2-3 days with a range of 1-12 days (3). The onset is with fever, chills, headache, photophobia, backache, nausea, vomiting, arthralgia, and rash. Most patients recover completely within 5 to 7 days. More than three fourths of the patients complain of severe arthralgia. Any illness with the classical triad of fever, rash, and joint pains in endemic areas must give rise to suspicion of Chikungunya. The definitive diagnosis can only be reached by serology or isolation of the virus. Treatment is symptomatic and includes antipyretic and anti-inflammatory drugs. There is no vaccine against this arboviral disease. No specific treatment is available. Prevention is entirely dependent upon taking steps to avoid mosquito bites and elimination of mosquito breeding sites.

## Study Exercises

**Long Question :** Discuss the epidemiology, treatment, prevention and control of Chikungunya.

**Short Note :** Control measures for Chikungunya.

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Japanese Encephalitis (JE) is an arboviral disease spread by Culicine mosquitoes. The disease presents periodically in epidemic form in areas such as northern India, parts of central and southern India. An overwhelming majority of the infections are asymptomatic. However, among symptomatic individuals case fatality rates may be higher than 20%. The public health importance of this vaccine preventable disease lies in the fact that most infections occur among children and that a sizeable proportion of the survivors are left with permanent neurological and/or psychiatric sequelae (1). The incidence of Japanese encephalitis has shown an increasing trend in recent times and the disease is fast becoming a major public health problem in India (2).

### Epidemiology

**Global** : Japanese encephalitis infections occur throughout the temperate and tropical zones of Asia. The annual incidence of Japanese encephalitis disease varies considerably from one country to the other as well as within affected countries, ranging from less than 10 to more than 100 per 100,000 population. Nearly 3 billion people or close to half the global population live in Japanese encephalitis endemic regions. Over 50,000 cases are reported worldwide every year with 10,000 deaths (3). The disease periodically becomes hyperendemic in areas such as northern India, parts of central and southern India, southern Nepal, and northern Vietnam (3). Other countries reporting large number of cases of Japanese encephalitis include Philippines, Thailand, Cambodia, Myanmar, and Sri Lanka. Though named Japanese encephalitis, the disease is now rare in Japan, due to extensive vaccination and adequate vector control.

**India** : In India Japanese encephalitis was first reported in 1955 from Vellore in Tamil Nadu (4). Currently this disease is reported from 26 states in India. Of these, only 15 states are reporting JE regularly. The total population at risk is estimated to be 160 million (5). A disturbing feature of Japanese encephalitis reporting in India has been the occurrence of several large outbreaks from different parts of the country. The first major outbreak of JE was reported from West Bengal in 1973 in two districts followed by another outbreak in 1976. Subsequently outbreaks have been reported from the states of Bihar, Uttar Pradesh, Assam, Manipur, Andhra Pradesh, Karnataka, Madhya Pradesh, Maharashtra, Tamil Nadu, Haryana, Kerala, West Bengal, Orissa and union territories of Goa and Pondicherry (2). In the recent past the reported annual incidence in India has ranged between 1,765 and 3,428 and deaths between 466 and 707 (6).

**Agent** : Japanese encephalitis virus belongs to the family Flaviviridae, which are single - stranded RNA viruses. Like other flaviviruses, the Japanese encephalitis virus is an enveloped, plus sense virus. It is antigenically related to several other flaviviruses including dengue virus, St. Louis encephalitis virus, Murray Valley virus and West Nile virus (2). The envelope glycoprotein of the JE virus contains specific as well as cross

- reactive, neutralizing epitopes. The virus contains several structural and non - structural polypeptides, which are encoded by a single long open reading frame (7). The virus has two sub types, *Nakayam* and *Jagar* - 01 (2). The major genotypes of this virus have different geographical distribution, but all belong to the same serotype and are similar in terms of virulence and host preference (3).

**Vector** : Anthropophilic culicine mosquitoes transfer the virus to humans from animal amplifying hosts, principally domestic pigs and wading birds. The virus is transmitted chiefly by the bites of mosquitoes of the *Culex vishnui* complex; with individual vector species differing in specific geographic areas. In India and many endemic areas in Asia, *Culex tritaeniorhyncus* is the principal vector. This species feeds outdoors beginning at dusk and during evening hours until dawn. It breeds in water pools, marshes, flooded rice fields, and small stable collections of water around cultivated fields. This vector has a wide host range, including domestic animals, birds, and humans. In temperate zones, the vectors are present in greatest numbers from June through September and are inactive during winter months (8).

**Host Factors** : Pigs and aquatic birds (mainly herons and egrets of the *Ardeidae* family) are the natural hosts for the virus. Pigs are considered amplifying hosts since they allow manifold virus multiplication without suffering from disease and maintain prolonged viraemia (6). Viraemic adult pigs remain asymptomatic, but pregnant sows may abort or deliver still births. Humans are dead end accidental hosts.

Among humans, the virus has no specific age or sex predilection. In areas where the virus has been recently introduced, all age groups are affected equally. In endemic areas, however, most people are infected below the age of 15 years. In hyper - endemic areas, half of all Japanese encephalitis cases occur before the age of four years, and almost all before 10 years of age. Only one out of 250 to 500 JE viral infections lead to symptomatic disease. Those endemic regions where childhood JE vaccination has been widely implemented have experienced a shift in the age distribution of cases towards older children and adults (3). In India, Japanese encephalitis is considered to be largely a paediatric problem. Young children below 10 years of age are more likely to die, and if they survive, are more likely to have residual neurological sequelae (2).

**Environmental Factors** : Environmental factors related to transmission of JE are related principally to temperature and humidity conditions conducive to breeding and survival of the vector. In tropical and subtropical areas, transmission intensifies in the rainy season. In temperate locations, transmission usually starts in April and may last until October. In irrigated areas, transmission may occur even in the dry season (3). Habitats supporting the transmission cycle of JE virus are principally in rural, agricultural locations. In many areas of Asia, appropriate ecologic conditions for virus transmission occur near and even within urban centres (8). In many Asian countries, major outbreaks of JE occur at intervals of 2 - 15 years (3).

### Clinical Features

The incubation period of Japanese encephalitis ranges from



4 to 14 days (3). The virus initially multiplies at the site of the bite and in the draining lymph nodes. Subsequently, viremia develops, leading to inflammatory changes in the heart, lungs, liver, and reticuloendothelial system. Most infections are cleared before the virus can invade the central nervous system (CNS). However, neurologic invasion can develop leading to involvement of large areas of the brain, including the thalamus, basal ganglia, brain stem, cerebellum, hippocampus, and cerebral cortex (9). Most infected persons develop mild symptoms or no symptoms at all. Symptoms soon after exposure appear 6 - 8 days after the bite of an infected mosquito. The disease is characterized by sudden onset of fever, chills, body ache and mental confusion. Severe cases may progress to coma. In children, gastrointestinal pain and vomiting may be the dominant initial symptoms. Irritability, vomiting and diarrhoea or an acute convulsion may be the earliest objective signs of illness in an infant or child. JE may present as a mild disease, leading to an uneventful recovery, or may rapidly progress to severe encephalitis with mental disturbances, general or focal neurological abnormalities and coma.

Out of the approximately 50,000 cases of JE that are estimated to occur each year, about 10,000 end fatally, and about 15,000 of the survivors are left with neurological and/or psychiatric sequelae, requiring rehabilitation and continued care (2, 3). Approximately 33 - 50% of patients who survive have major neurologic sequelae at one year, including seizure disorders; motor or cranial nerve paresis, or movement disorders. Nearly 75% of symptomatic patients with JE who are evaluated five years after the disease score lower than uninfected subjects on standardized tests (9).

### Diagnosis

JE is clinically indistinguishable from other forms of viral encephalitis. History of exposure to mosquitoes in an endemic area or during an epidemic may be elicited. A CBC count often shows nonspecific modest leukocytosis in the first week of illness. A mild anaemia also may be present. Some studies have reported thrombocytopenia in children with Japanese encephalitis (9). Neutrophils predominate in early CSF samples but a lymphocytic pleocytosis is typical. CSF protein is moderately elevated in about 50% of cases (2).

Confirmation of a suspected case of Japanese encephalitis is mainly based on serology using IgM - capture ELISA which detects specific IgM in the cerebrospinal fluid or in the blood of almost all patients within 7 days of onset of disease. Other methods include conventional antibody assays on paired sera for the demonstration of a significant rise in total JE - specific antibody, as well as a dot - blot IgM assay, suitable for use in the field (3).

### Case Definitions for JE Diagnosis and Reporting (6)

**Clinical Suspect** : Febrile illness of variable severity associated with neurological symptoms ranging from headache to meningitis or encephalitis. Symptoms can include headache, fever, meningeal signs, stupor, disorientation, coma, tremors, paralysis (generalized), hypertonia, loss of coordination (Patient with fever, altered sensorium lasting more than 6 hours, no skin rash & other known causes of encephalitis excluded).

**Probable** : A suspected case with presumptive laboratory results: Detection of an acute phase anti - viral antibody response through IgM in serum/ elevated and stable JE antibody titres in serum through ELISA/ HI/ Neutralizing assay.

**Confirmed** : A suspect case with confirmed laboratory result: JE IgM in CSF or 4 fold or greater rise in paired sera (acute and convalescent) through IgM/IgG ELISA, HI, Neutralization test or detection of virus, antigen or genome in tissue, blood or other body fluid by immuno - chemistry, immunofluorescence or PCR.

### Treatment

There is no specific anti - viral medicine available against JE virus. The cases are managed symptomatically. Clinical management of JE is supportive and in the acute phase is directed at maintaining fluid and electrolyte balance and control of convulsions, if present. However, treating raised intracranial pressure and convulsions have been reported to decrease the mortality and morbidity significantly (10).

### Prevention and Control

Vector control and vaccination are the two primary strategies for control of Japanese Encephalitis. In countries such as Japan and Korea the incidence of JE has decreased over several decades, primarily as a result of extensive use of JE vaccines. Improved socioeconomic conditions, changed life styles and control measures such as centralized pig production and the use of insecticides may also have contributed to this development (3). Details on vector control are available in the chapter on Entomology.

**Vaccines** : Three types of vaccines are currently in use against Japanese encephalitis. The mouse brain - derived, purified and inactivated vaccine, which is based on either the *Nakayama* or *Beijing* strains of the JE virus and is produced in several Asian countries including India. Another inactivated vaccine is the cell culture - derived, vaccine based on the viral *Beijing P - 3* strain. A live attenuated vaccine widely used in China is the cell culture - derived vaccine based on the *SA 14 - 14 - 2* strain of the JE virus (3).

The mouse brain - derived JE vaccine is used in India. It is produced by the Central Research Institute, Kasauli. Three doses are required to produce primary immunization. Two doses of 1 ml (0.5 ml for children below three years) are administered sub - cutaneously within a gap of 7 - 14 days followed by third dose any time after one month and before one year of the second dose. A booster is required after 3 years (6). Several other Asian countries have adopted a similar schedule of two primary doses four weeks apart, followed by a booster after one year. In some countries, subsequent boosters are recommended, usually at about 3 - year intervals up to the age of 10 to 15 years (3). For travellers aged more than one year visiting rural areas of endemic countries, the established practice is to administer 3 primary doses at days 0, 7 and 28 or two primary doses preferably four weeks apart.

The mouse brain - derived JE vaccine is been considered safe. Local reactions such as tenderness and swelling occur in about 20% of vaccinees. Mild systemic symptoms, including headache, myalgia, gastrointestinal symptoms and fever may



also occur. Being a killed vaccine, only contraindication to the use of this vaccine is a history of hypersensitivity reactions to a previous dose. Pregnant women should be vaccinated only when at high risk of exposure to the infection. The vaccine can be given to HIV infected individuals (3). The biggest limitation of the mouse derived killed vaccine is that rapid large scale production of the vaccine is not feasible.

The live attenuated vaccine was licensed in China in 1989. Extensive use of this and other vaccines has significantly contributed to reducing the burden of JE in China. The vaccine has recently been licensed for use in India. It is administered in two doses at an interval of one year.

**WHO Position on JE Vaccines :** The World Health Organization recommends that JE immunization should be integrated into the EPI programmes in all areas where JE constitutes a public health problem. The most effective immunization strategy in JE - endemic settings is one time catch - up campaigns including child health weeks or multi - antigen campaigns in the locally - defined primary target population, followed by incorporation of the JE vaccine into the routine immunization programme (3).

## Summary

Japanese encephalitis is an arboviral disease spread by culicine mosquitoes. The public health importance of this vaccine preventable disease lies in the fact that most infections occur among children and that a sizeable proportion of the survivors are left with permanent neurological and/or psychiatric sequelae. Nearly 3 billion people or close to half the global population live in Japanese encephalitis endemic regions. Over 50,000 cases are reported worldwide every year with 10000 deaths. In India Japanese encephalitis was first reported in 1955 from Vellore in Tamil Nadu. Currently this disease is reported from 26 states in India. Japanese encephalitis virus belongs to the family Flaviviridae, which are single - stranded RNA viruses. Anthropophilic culicine mosquitoes transfer the virus to humans from animal amplifying hosts, principally domestic pigs and wading birds. The virus is transmitted chiefly by the bites of mosquitoes of the *Culex vishnui* complex. In India and many endemic areas in Asia, *Culex tritaeniorhynchus* is the principal vector. Pigs and aquatic birds are the natural hosts for the virus. Humans are dead end accidental hosts. In hyper - endemic areas, half of all Japanese encephalitis cases occur before the age of four years, and almost all before 10 years of age. Only 1 in 250 to 500 JE viral infections result in symptomatic disease. The incubation period of Japanese encephalitis ranges from 4 - 14 days. The disease is characterized by sudden onset of fever, chills, body ache and mental confusion. Severe cases may progress to coma. JE is clinically indistinguishable from other forms of viral encephalitis. Confirmation of a suspected case of Japanese encephalitis is mainly based on serology using IgM. There is no specific anti - viral medicine available against JE virus. The cases are managed symptomatically. Vector control and vaccination are the two primary strategies for control of

Japanese Encephalitis. Three types of vaccines are currently in use against Japanese encephalitis. The mouse brain - derived, purified and inactivated vaccine, which is based on either the *Nakayama* or *Beijing* strains of the JE virus. A live attenuated vaccine widely used in China is the cell culture - derived vaccine based on the *SA 14 - 14 - 2* strain of the JE virus. The World Health Organization recommends that JE immunization should be integrated into the EPI programmes in all areas where JE constitutes a public health problem.

## Study Exercises

**Long Question :** Discuss the epidemiology, treatment, prevention and control of Japanese encephalitis.

**Short Notes :** (1) Case definitions for JE, Diagnosis and Reporting (2) Vaccines for Japanese Encephalitis

**MCQs :**

1. Currently this disease is reported from \_\_\_\_ no. of states in India (a) 23 (b) 24 (c) 25 (d) 26
2. Japanese encephalitis virus is (a) Single - stranded RNA Virus (b) Double - stranded RNA Virus (c) Single - stranded DNA Virus (d) Double - stranded DNA Virus
3. In India principal vector for JE is (a) *Culex quinquefasciatus* (b) *Culex tritaeniorhynchus* (c) *Aedes vittatus* (d) *Aedes niveus*
4. Natural host for the virus are (a) Humans (b) Cattle (c) Pigs (d) Monkeys
5. Cell culture - derived vaccine is based on the \_\_\_\_\_ strain of the JE virus (a) *SA 14 - 14 - 1* (b) *SA 15 - 15 - 1* (c) *SA 14 - 14 - 2* (d) *SA 15 - 15 - 2*

**Answers :** (1) d; (2) a; (3) b; (4) c; (5) c.

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Rickettsial diseases occur in all parts of the world and are a significant cause of morbidity and mortality (1). The occurrence of rickettsial diseases often goes unrecognized because of difficulties in arriving at a definitive diagnosis. Lately, however, Rickettsiae are being recognized as emerging or re-emerging pathogens in many places of the world making them the cause of some of the oldest and most recently recognized infectious diseases (2, 3). New genetic tools have led to the discovery of many new rickettsial diseases over the past 20 years (4). Of the 14 currently recognized rickettsioses, six have been described within the last 12 years (5). Although rickettsiae require living cells for growth, they are true bacteria as they have metabolic enzymes and cell walls, and are susceptible to antibiotics. Most rickettsial infections result in zoonotic diseases which are maintained in nature through a complex interaction between mammalian reservoirs and invertebrate factors (ticks, mites, fleas, and lice). An important feature of rickettsial infections is that some invertebrate vectors can also serve as reservoirs. Humans are usually accidental hosts and play little role in natural disease transmission.

Different authors have grouped Rickettsial diseases in several ways. Rickettsial diseases are usually divided into four groups:

Spotted fever group; Typhus group; Scrub typhus (or *Orientia* group); and others (1, 6).

### Epidemiology

**Global** : The geographic as well as temporal distribution of rickettsial diseases is largely determined by their vectors. Louse borne rickettsial diseases are reported from across the world. Common flea species like the dog, cat, and rat flea are also global in distribution. As a consequence, rickettsial diseases transmitted by them are also reported from all parts of the world. Ticks are more restricted in their distribution. Tick borne diseases are, therefore, more localized in their distribution. The geographic distribution of rickettsial agents is described in Table - 1.

**India** : Rickettsioses are reported from many parts of India. A large number of studies have documented outbreaks of rickettsial diseases, particularly Scrub typhus among Indian Armed Forces personnel from different parts of the country (7 - 13). Occurrence of Rickettsioses, including scrub typhus as well as spotted fevers have been reported from Himachal Pradesh, Maharashtra, Assam, West Bengal, Kerala and Tamil Nadu (2, 14 - 19).

**Agent** : Rickettsiae are a diverse collection of organisms with several differences. The common threads that hold the rickettsiae into a group are their epidemiology and their obligate intracellular lifestyle. The classification of rickettsia has seen a significant reorganization in the recent past particularly

Table - 1 : Epidemiologic Features of Rickettsial Diseases (20)

Disease Group	Disease	Agent	Vector	Animal Reservoir	Geographical Distribution
Typhus Group	Epidemic typhus	<i>Rickettsia prowazekii</i>	Human body louse ( <i>Pediculus humanus corporis</i> ),	Humans	Mountainous regions of Africa, Asia, and Central and South America. <i>India</i> - J&K, Himachal, Uttarakhand, W Bengal, Arunachal Pradesh.
	Murine typhus	<i>Rickettsia typhi</i>	Rat flea ( <i>Xenopsylla cheopis</i> )	Rats, mice	Worldwide
	Indian Tick Typhus	<i>Rickettsia conorii</i>	Tick ( <i>Ixodes sp</i> <i>Boophilus sp</i> <i>Haemophysalis sp</i> )	Dogs, rodents	Africa, India, Europe, East, Mediterranean, <i>India</i> - Uttaranchal
Spotted Fever Group	Rickettsial pox	<i>Rickettsia akari</i>	Mite	House mice	Russia, South Africa, Korea, Turkey, Balkan countries
	Rocky Mountain spotted fever	<i>Rickettsia rickettsii</i>	Tick	Rodents	Mexico, Central and South America
Orientia	Scrub typhus	<i>Orientia tsutsugamushi</i>	Mite ( <i>L deliense</i> )	Rodents	Asia and Australia <i>India</i> - J&K, Himachal, Uttarakhand, W Bengal, Arunachal Pradesh
Others	Q fever	<i>Coxiella burnetii</i>	Inhalation of infectious aerosols; tick	Goats, sheep, cattle, cats	Worldwide

due to technological advances in molecular genetics. The order *Rickettsiales* has two families *Rickettsiaceae* and *Anaplasmataceae*. The family *Rickettsiaceae* has two genera : *Rickettsia* and *Orientia*. The family *Anaplasmataceae* has five genera. At least 26 agents from the order *Rickettsiales* have been recognized as human pathogens (1). *Rickettsia* are small (0.3 X 2 µm) aerobic, obligate intracellular parasites. They are Pleomorphic, usually coccobacillary. They appear blue with Giemsa's stain and their growth is enhanced in the presence of sulphonamides.

**Host** : Groups at risk for exposure to agents of rickettsial diseases are travellers, wood cutters, farmers and armed forces personnel as their occupational or recreational activities bring them in contact with habitats that support the vectors or animal reservoir species associated with these pathogens (21).

**Transmission** : Rickettsiae are transmitted to humans by the bite of infected ticks and mites and by the contamination of the bite or other skin wounds with the faeces of infected lice and fleas. The rickettsiae present in the dried excreta of insects may also enter through the conjunctivae or even through inhalation. In ticks and mites transovarial and trans -stadial transmission of rickettsia frequently occurs. After entering the body rickettsia spread through the bloodstream to infect vascular endothelium in the skin, brain, lungs, heart, kidneys, liver, gastrointestinal tract and other organs.

### Clinical Features

Most rickettsial diseases are characterized by the classical triad of fever, headache, and rash. Hepatosplenomegaly and myalgia are often accompanying features. Rash is absent in Q fever and in several of the newly recognized rickettsial infections. About half the patients infected by a tick or mite bite develop a typical eschar at the bite site.

### Diagnosis

Confirmation of diagnosis is done most often by serology. Titres of specific antibodies rise to diagnostic levels usually by the second week of illness (1). Indirect Fluorescent Antibody (IFA) and ELISA tests are available for serology. The Weil - Felix test, which uses the OX and K strains of *Proteus mirabilis*, is still the most widely used diagnostic test in India. However, the test is not very sensitive. PCR is also being increasingly used to confirm the diagnosis (4).

### Treatment

Tetracyclines are the antibiotic of choice against rickettsial infections. Doxycycline is the most commonly prescribed drug. Chloramphenicol should be used for infections in pregnant women but caution should be exercised in the third trimester because of the risk of "gray baby syndrome". Chloramphenicol is not considered effective against Ehrlichioses. The clinical features, diagnosis and treatment of common rickettsial diseases is given in Table - 2.

### Prevention and Control

The essential method of prevention is avoidance of potentially vector infected areas and the use of personal protective measures. The use of insect repellents such as DEET and DEPA in combination with appropriate clothing such as long sleeves and anklets may be useful in avoiding contact with vectors.

### Scrub Typhus

Scrub typhus is caused by *Orientia tsutsugamushi* and transmitted by the bite of infected larvae of the mite *Leptotrombidium deliense*. It is a zoonoses with humans being accidental, dead end hosts. Scrub typhus was first described by Hashimoto from Japan (22). It is reported most often from Southeast Asia and Japan and is the most commonly reported

**Table 2 : Clinical Features and Treatment of Rickettsial Diseases**

Disease	Incubation period	Clinical Features	Weil Felix Reaction	Treatment
Epidemic typhus	6 - 15 days	Headache, chills, fever, prostration, confusion, photophobia, vomiting, rash (generally starting on trunk)	OX - 19	Doxycycline 100mg BD for 7 - 10 days or till person is afebrile. Chloramphenicol 60 - 75mg/kg/day in 4 divided doses for pregnant women
Murine typhus	8 - 16 days	As above, generally less severe	OX - 19	Same as above
Indian Tick Typhus	5 - 10 days	Fever, eschar, regional adenopathy, maculopapular rash on extremities	OX - 19 or OX - 2	Same as above Alternative - Ciprofloxacin
Rocky Mountain spotted fever	2 - 14 - days	Headache, fever, abdominal pain, macular rash progressing into opular or petechial (starting on extremities)	OX - 19 or OX - 2	Same as above
Scrub typhus	6 - 21 days	Fever, headache, sweating, conjunctival injection, adenopathy, eschar, rash, respiratory distress	OX - K	Doxycycline 100mg BD. Rifampicin 600 - 900mg/day, Azithromycin and Ciprofloxacin are other alternatives
Q fever	3 - 30 days	Fever, headache, chills, sweating, pneumonia, hepatitis, endocarditis	None	Doxycycline. Rifampicin, Ciprofloxacin are other alternatives

rickettsial infection in India. Globally over one billion people are at risk for scrub typhus and an estimated one million cases occur annually (22).

### Epidemiology

The disease is largely limited to Southeastern and Eastern Asia, Northern Australia, India, Pakistan, Ceylon and other islands in the region. In India, it is present in whole of the Shivalak ranges from Kashmir to Assam, Eastern and Western Ghats and the Vindhya and Satpura ranges in the central part of India. The distribution of the disease corresponds with the distribution of *Leptotrombidium deliense* and *Leptotrombidium akamushi*. The vector mite is now known to be present in diverse ecological niches such as equatorial rain forests, semi-deserts and Alpine subarctic terrains in the Himalayan regions. Endemic foci are usually associated with specific habitats such as abandoned plantations, gardens or rice fields, overgrown forest clearings, shrubby fringes of fields and forests, river banks and grassy fields. These ecological patches which attract the natural host of mite vectors are called “mite islands”. Within the mite islands there may be a limited area of intensive transmission of rickettsiae called “Typhus Island”. Outbreaks of scrub typhus have been repeatedly reported in India both among civilians and personnel of the Armed Forces (8 - 13, 16, 17, 19).

**Agent** : *Orientia tsutsugamushi* is the agent of scrub typhus in India. It differs from other rickettsiae in its antigenic structure. At least eight serotypes are recognized. Infection with one strain does not produce immunity against infection by others.

**Vector** : The infection is transmitted through the larval mites or “chiggers” belonging to the family *Trombiculidae*, genus and subgenus *Leptotrombidium*. More than 150 species have been described but only a few are known to be of importance to man. About 204 trombiculid mite species have been described from India so far. The important mite species are *Leptotrombidium deliense*, *Leptotrombidium akamushi*, *Leptotrombidium scutellare* and *Leptotrombidium pallidum*. Transovarian transmission of rickettsiae occurs in mites for several generations. Only the larval stage takes a blood meal.

**Host** : A number of small rodents particularly wild rats of subgenus *Rattus* are the natural hosts for scrub typhus (22). The rodents and acarine hosts do not succumb to the disease. Thus the field rodents and the vector mites act as a reservoir and between the two the infection perpetuates in nature. The migration of infested or infected rodents leads to establishment of new foci of disease.

**Transmission** : The infection is transmitted to man through the bite of infective mite larvae, which feeds on lymph and tissue fluid rather than blood. Rather than biting or piercing the skin, mite larvae prefer to insert their mouthparts down hair follicles or pores. A large number of the *Orientia tsutsugamushi* are present in the salivary glands of the larvae and these are injected into its host when it feeds (23). Human infection takes place when man accidentally picks up an infective larval mite while walking, sitting, or lying on the infested ground.

### Clinical Features

Scrub typhus has a broad clinical spectrum varying from mild or inapparent infection to organ failure and death. After an

incubation period ranging from 6 to 21 days (usually 10 - 12 days), patients usually present with fever and headache. Other symptoms and signs include myalgia, chills, cough, adenopathy, and diarrhoea. The patient is often labeled as “fever of unknown origin” because of the non specific symptoms. In about half the patients, a skin ulcer may develop after the onset of fever at the site of the mite bite. The ulcer is approximately 1 cm in diameter and fills with fluid, eventually rupturing and forming a black eschar. A macular rash may appear on the body on 5th to 7th day and last for a few hours to a few days. Complications such as pneumonitis, myocarditis, encephalitis and peripheral circulatory failure may occur. Deaths usually occur as a result of late presentation or a delayed diagnosis (22).

### Diagnosis

A high index of suspicion in occupational settings like the armed forces can aid timely clinical diagnosis. The diagnosis can be confirmed by Weil - Felix (WF), Fluorescent Antibody (FA), Complement Fixation (CF) or Microscopic Agglutination (MA) test. Initial laboratory diagnosis may be difficult since antibody levels may be low during early infection. Most serological tests become positive only in the second week of illness. PCR has now become one of the important diagnostic techniques for scrub typhus. A nested PCR on the eschar provides a rapid diagnostic test for scrub typhus in the early, acute stage (24). Ready to use ELISA kits are also available commercially.

Most of these tests may not be available in remote areas where most cases occur. The Weil - Felix test (WF) using *Proteus OXK* strain is still the most commonly used test, though it lacks sensitivity. Only half the patients will have positive Weil - Felix test during second week of illness. A four fold rise in titre or a single reading of at least 1:80 are considered significant (22).

### Treatment

Tetracyclines are the antibiotic of choice. The dosage is Tetracycline, 500 mg four times a day or doxycycline 200 mg once (or 100 mg BD) a day for 7 to 14 days. Alternatives include Chloramphenicol 500 mg four times a day or Rifampicin, 900 mg per day for seven days. Early treatment results in better outcomes and faster resolution (22, 23).

### Prevention and Control

Avoidance of exposure to the vector and personal protective measures are the mainstay of prevention of scrub typhus. Outdoor camp sites should be selected carefully to avoid mites. Camp sites should be cleared of vegetation and treated with insecticide (Malathion / Fenthion) before occupation. Anti rodent measures like denying shelter and food to rodents by proper storage of food, hygienic disposal of refuse and keeping the area cleared of all junk, and rubble must be followed. Application of repellants to all clothing is the most important single preventive measure (25, 26).

### Epidemic Typhus

Epidemic typhus is the classical form of rickettsial disease. About 30 million cases including three million deaths occurred in the Soviet Union & Eastern Europe during 1918 - 1922. During World War II, typhus struck heavily in concentration



camps in Eastern Europe and North America.

The disease is caused by *Rickettsia prowazekii* and transmitted by the human louse *Pediculus humanus corporis*. The infection is transmitted by the entry of the infectious faeces, the gut contents, or the body fluid of the louse through abrasion on the skin which may result from simultaneous scratching. The rickettsiae present in the dried excreta of insects may also enter through the conjunctivae or even through inhalation. Once infected, the lice remain infective throughout their remaining life.

Epidemic typhus is characterized by sub - acute onset, with fever interposed by rigors, accompanied by headache, nausea, giddiness, vomiting and flushed dry skin. On the third day, the temperature rapidly rises up to 40° C, face and eyes become suffused, headache and bodyache become severe, and the peculiar stuporose, drunken, confused and delirious state, similar to that found in enteric fever is seen. The patient has a foul smell and heavily coated tongue. The spleen is enlarged and haematuria and albuminuria occur. Blood pressure falls. Temperature remains high for 12 - 14 days. Rash occurs on 5th or 6th day. The case fatality varies widely and is influenced by the nutritional state and age of patient. In healthy, well fed young adults the case fatality is less than 5 percent. Diagnosis is confirmed by Microscopic Agglutination (MA), Complement Fixation (CF) and Fluorescent Antibody (FA) tests.

Man has no natural immunity; one clinical attack confers high immunity but not life long and a second attack may occur. All ages and sexes are susceptible. The immunity is type specific; therefore, an attack does not confer immunity against other rickettsial diseases. Cases are infectious to the louse during the last two or three days of the incubation period, and throughout the febrile period, for a total of about 12 to 13 days. Doxycycline or chloramphenicol (for pregnant women) are the drug of choice for treatment.

A high standard of personal hygiene to prevent louse infestation, avoidance of contact with those likely to be infected with the disease and infested with louse and preventive immunization are the important preventive measures. Treatment of louse infested individuals can be carried out by application of dust of 10% DDT, 1% malathion or 1% indane powder to the person as well as his clothing. Treatment can also be done with phenothrin dust 0.3 - 0.4%. Other lotions or shampoo formulations can also be applied for better results like permethrin lotion (1.0%) or deltamethrin lotion (0.03%).

A formalin inactivated epidemic typhus vaccine prepared from rickettsia grown in embryonated eggs was used to protect troops during World War II. It is given in 2 subcutaneous injections of 1 ml each at an interval of 10 to 14 days. Booster doses are recommended every 6 months. A recent advancement is the development of a vaccine consisting of live attenuated strain 'E' rickettsial organisms. It has been tried extensively and appears to be effective when tested under field conditions. It is not yet available for general use.

### Brill - Zinsser Disease

It is a recrudescence episode of epidemic typhus which occurs years after the initial attack, in persons who have recovered from the epidemic disease acquired while residing in the

endemic country (27, 28). The recurrence is presumed to be precipitated by stress or a waning immune system. The illness is similar to louse borne typhus but is usually milder. Weil - Felix reaction may be negative in very low titre.

### Endemic (Murine) Typhus

It is an acute febrile illness caused by *Rickettsia typhi* and transmitted to humans by the rat flea *Xenopsylla cheopis*. The mode of transmission is by contamination of the broken skin by rickettsia - laden faeces, and dried flea faeces gaining entry through conjunctivae or the upper respiratory tract by aerosol. Complement fixing antibodies against murine typhus have recently been detected in paired sera from local cases of fever of unknown origin by workers of NIV, Pune. Similar studies elsewhere indicate that murine typhus is endemic in practically every town of India especially where rats abound. Control measures should be directed against rodents and rat fleas. There is no specific vaccine. Epidemic typhus vaccine does not protect against murine typhus. However following attack by one disease, there is some cross - protection against the other disease.

### Q Fever

It is an acute infectious disease caused by *Coxiella burnetii*. The disease has world - wide distribution. During World War II it was a cause of major epidemics in Europe (Balkan grippé). Apart from two case reports, studies on human Q fever in India have been mainly limited to sero epidemiological surveys in several parts of the country. Isolation of and demonstration of its antibodies from human milk have also been reported.

Small mammals and possibly some birds are the permanent reservoirs of infection with some *Ixodid* and *Argasid* ticks acting as vectors. From the wild animals the infection spreads to cattle, sheep and goats. The mode of transmission for humans is by inhalation of infected dust, by handling infected materials and possibly by drinking contaminated raw milk.

The incubation period of Q fever ranges from 15 to 26 days with an average of approximately 19 days. The disease is characterized by fever, malaise, myalgia, headache, weakness, anorexia, loss of weight and interstitial pneumonitis. Case fatality is low but convalescence is prolonged. Complications such as hepatitis, endocarditis, thrombosis, haemorrhages and meningitis may follow. The diagnosis is confirmed by CF tests. Radiological findings resemble those of primary atypical pneumonia. Human cases of Q fever should be treated with tetracyclines or chloramphenicol.

The disease can be prevented by avoiding exposure to infected aerosols. Milk from infected cattle must be boiled or pasteurized. Persons at risk such as dairy workers, butchers, wool sorters, farmers, cowherds and laboratory workers can be protected by immunization with specific vaccines such as those prepared from phase I rickettsiae.

### Summary

Rickettsial diseases occur in all parts of the world and are a significant cause of morbidity and mortality. Most rickettsial infections result in zoonotic diseases. Humans are usually accidental hosts and play little role in natural disease

transmission. Rickettsial diseases are usually divided into four groups : Spotted fever group; Typhus group; Scrub typhus (or *Orientia* group); and others. The geographic as well as temporal distribution of rickettsial diseases is largely determined by their vectors. Rickettsia are small (0.3 X 2  $\mu$ m) aerobic, obligate intracellular parasites. Groups at risk for exposure to agents of rickettsial diseases are travellers, wood cutters as their occupational or recreational activities bring them in contact with habitats that support the vectors. Rickettsiae are transmitted to humans by the bite of infected ticks and mites and by the contamination of the bite or other skin wounds with the faeces of infected lice and fleas. Most rickettsial diseases are characterized by the classical triad of fever, headache, and rash. Confirmation of diagnosis is done most often by serology. The Weil - Felix test, which uses the *OX* and *K* strains of *Proteus mirabilis*, is still the most widely used diagnostic test in India. Tetracyclines are the antibiotic of choice against rickettsial infections. The essential method of prevention is avoidance of potentially vector infected areas and the use of personal protective measures.

## Study Exercises

**Long Question :** Discuss the epidemiology, treatment, prevention and control of Rickettsial diseases.

**Short Notes :** (1) Classification of Rickettsial diseases (2) Scrub Typhus (3) Epidemic Typhus

### MCQs

1. Limited area of intensive transmission of rickettsiae called as (a) Typhus Island (b) Mite islands (c) Rickettsiae Island (d) None of the above
2. Agent for Indian Tick Typhus is (a) *Rickettsia typhi* (b) *Rickettsia conorii* (c) *Rickettsia akari* (d) *Rickettsia prowazekii*
3. Most commonly reported rickettsial infection in India is (a) Scrub typhus (b) Indian Tick Typhus (c) Epidemic typhus (d) Rickettsial pox
4. Epidemic Typhus is transmitted by (a) Tick (b) Mite (c) Human louse (d) Rat flea
5. The infection is transmitted to man through the bite of which form of infective mite (a) Larvae (b) Pupa (c) Male adult (d) Female adult

Answers : (1) a; (2) b; (3) a; (4) c; (5) a.

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Yellow fever was the first viral haemorrhagic fever to be described. It is a mosquito - borne infection endemic to Africa and South America. Its presentation is widely variable ranging from a minimal flulike illness to a fulminant disease characterized by haemorrhage, hepatic failure, renal failure and death. The Yellow Fever virus is an arbovirus, of the family *Flaviviridae* (1). Despite being currently restricted to parts of Africa and South America, Yellow fever has the potential to cause large outbreaks in other areas due to the presence of suitable vectors and climatic conditions (2). Yellow fever has been cited in historic texts dating back to 400 years ago. The "yellow" in the name originates from the jaundice that occurs in seriously ill patients. Although an effective vaccine has been available for 60 years, the number of people infected over the last two decades has increased and the World Health Organization considers Yellow fever to be a serious public health issue again (3). The virus is transmitted by several species of mosquitoes. The *Aedes* is the most important vector while *Haemogogus species* are responsible for the transmission in South America. Mosquito - borne transmission of Yellow fever was first suggested by Carlos Finlay in 1881. In 1900, Walter Reed observed that the infectious agent was transmitted by means of a mosquito bite. Extensive mosquito control measures and widespread vaccination led to the elimination of Yellow fever in the early 20th century from most areas of the world except parts of Africa, South America and the Caribbean.

### Epidemiology

**Global** : Yellow fever is currently confined almost entirely to South and Central America and Africa. The virus is constantly present with low levels of infection in these areas. Periodically this viral presence amplifies into regular epidemics. Over 500 million people live in 33 endemic countries in Africa and are considered to be at risk of suffering from Yellow fever. All these countries lie within a band from 15°N to 10°S of the equator. In South America, Yellow fever is endemic in nine countries and in several Caribbean islands. The countries considered to be at high risk are Bolivia, Brazil, Colombia, Ecuador and Peru. A small number of imported cases also occur in countries free of Yellow fever. Yellow fever has never been reported from Asia. However, WHO considers this region to be at risk because the appropriate primates and vectors are present (3). The global incidence of Yellow fever fluctuates with the occurrence of large epidemics in Africa. The World Health Organization estimates that there are 2,00,000 cases of Yellow fever every year with 30,000 estimated deaths. However, due to underreporting, only a small percentage of these cases are identified (3).

**Agent** : The viral pathogen is a *Flavivirus* belonging to the family *Togaviridae*. It is a small (40 to 60 nm), single stranded positive sense, enveloped RNA virus. The envelope consists of a lipid bilayer containing an envelope glycoprotein and a matrix protein (4, 5).

**Vectors** : The virus is transmitted by several different species of the *Aedes* and *Haemogogus* (only in South America). These

mosquitoes may be domestic (breeding close to and around houses), wild (breeding in the jungle) or semi - domestic types. In South America *Haemogogus spegazzinii* is the principal vector for forest transmission. In Africa, the principal vectors for forest transmission are the *Aedes africanus* and *Aedes simpsoni*. In both the continents, the principal urban vector is the *Aedes aegypti*. Female mosquitoes become infected by feeding on an infected host usually during the first to third day of fever. The extrinsic incubation period in the mosquitoes can vary from 4 to 18 days depending on the ambient temperature (6). During subsequent blood meals, the virus is transmitted to a new vertebrate host. In addition, Yellow fever virus can be transmitted transovarially, allowing viral survival in the absence of adult mosquitoes. The principal urban vector *Aedes aegypti*, is an inefficient vector of the Yellow fever virus. However, the anthropophilic nature of the vector and the high densities of the mosquito in urban areas make it an excellent vector for human - to - human transmission (5, 7).

**Host** : Primates are the only vertebrate hosts for Yellow fever. Humans and monkeys are the principal hosts. The reservoir of urban Yellow fever is sub - clinical human cases. For rural Yellow fever the most important animal reservoir is the monkey. In endemic areas almost 30% monkeys may be infected. Monkey is the only reservoir for jungle Yellow fever (2, 5).

**Transmission** : Three transmission cycles can be distinguished in Africa - The sylvatic (in jungle areas, mainly affecting the wild monkeys), intermediate (primarily affecting both man and monkeys) and urban (mainly affecting human beings in high population density areas). In South America, only the sylvatic and urban Yellow fever cycles of transmission are seen. In all three cycles, Yellow fever virus is transmitted between primates by diurnally active tree hole-breeding mosquitoes. In all of these cycles, endemic & epidemic disease patterns can occur (4).

The normal low risk to travellers increases with travel to jungle areas in endemic countries and in or near cities during urban outbreaks. Areas where Yellow fever virus is present far exceed those officially reported. The risk of exposure to infection can be reduced by taking measures to prevent mosquito bites (4, 5, 7). The mosquito vectors of Yellow fever are mostly day biters. Although reported cases of human disease are the principal indicator of disease risk, some countries may have no reported cases, either because of a high level of vaccine coverage against Yellow fever in the population or because poor surveillance resulted in no cases being reported. However, the risk of Yellow fever may still persist as the virus, the vector or the animal reservoirs are still present (8 - 10).

**Incubation Period** : The intrinsic incubation period in human beings is between two and six days. The extrinsic incubation period in a mosquito varies from four to 18 days (average 12 days), with the temperature and humidity. Once the mosquito becomes infective, it remains so for the rest of its life (2).

**Period of Communicability** : The case is infective to the vector mosquito during the later part of the incubation period and first three clinical days. An infected individual, therefore, can spread infection for about four to six days, starting two to three days after exposure to the infection. It is to prevent the entry of such individuals in India that rigorous rules and regulations are enforced (2).



## Clinical Features

The disease presents in two phases. Some infections may be completely asymptomatic. Usually the first “acute” phase is characterized by fever, muscle pain, headache, loss of appetite, nausea and vomiting. The high fever may be paradoxically associated with a slow pulse. After three to four days most patients improve and their symptoms disappear. About 15% of patients enter a “toxic phase” within 24 hours. The patient rapidly develops jaundice and has abdominal pain with vomiting. Bleeding can occur from the mouth, nose, eyes and/or stomach. Blood may appear in the vomit and faeces. Kidney function deteriorates. About half of the patients in the “toxic phase” die within 10 - 14 days. The remaining recover without significant organ damage. Yellow fever is difficult to recognize, especially during the early stages. It can easily be confused with malaria, typhoid, rickettsial diseases, haemorrhagic viral fevers, dengue fever, leptospirosis and viral hepatitis (3).

## Diagnosis

Baseline investigations must be carried out in suspected case. Leukopenia with relative neutropenia can occur. Thrombocytopenia can occur as part of a consumptive coagulopathy. Patients are also likely to have an elevated prothrombin time and prolonged clotting times. Renal damage, if present, results in grossly elevated serum creatinine levels and markedly elevated levels of urinary protein. In severe cases liver function tests are grossly deranged. Specific laboratory diagnosis relies on serology or on detection of the virus and viral antigens. Rapid detection methods include the detection of Yellow fever antigen by monoclonal enzyme immunoassay in serum specimens & detection of viral genome sequences in tissue or blood using polymerase chain reaction (PCR). Serologic studies include the Immunoglobulin - M (IgM) antibody - capture enzyme - linked immunosorbent assay (MAC - ELISA) used to detect the specific presence of IgM for Yellow fever. IgM appears 7 - 10 days following infection. A four - fold rise in haemagglutination inhibition, complement fixation, or neutralization of antibodies in acute and convalescent phases is also diagnostic of Yellow fever. The Yellow fever virus can be isolated from viral culture with the intracerebral inoculation of suckling mice or inoculation of mosquito cell cultures (1).

## Treatment

As there is no specific treatment for Yellow fever, supportive care is critical. Dehydration and fever must be corrected with oral rehydration salts and anti - pyretics. Any superimposed bacterial infection should be treated with appropriate antibiotics. Intensive supportive care may improve the outcome for seriously ill patients.

## Prevention and Control

Vector control and vaccination are the cornerstones of Yellow fever control. Vector control is considered in detail in the Chapter on Entomology.

**Yellow Fever Vaccine** : During the 1930s, both wild - type Yellow fever virus strains, Asibi and French, were attenuated to derive live vaccines known as 17D and the French neurotropic vaccine, respectively (2). Currently, 17D is the only strain of Yellow fever virus used for vaccination. 17D vaccines are heterogenous mixtures of multiple virus subpopulations (10).

**Immune Response** : More than 95% of vaccinated people develop neutralizing antibodies within 10 to 14 days of immunization. The International Health Regulations stipulate that the vaccination certificate for Yellow fever is valid for 10 days after administration of 17D vaccine, corresponding to the time at which the majority of vaccinees are demonstrably immune. Immunity following 17D vaccination is remarkably durable and may be lifelong.

**Dose, Route of Administration and Preparations** : A 17D vaccine dose contains approximately 105 PFU in 0.5 mL and is given subcutaneously, usually in the upper arm. Because there is no preservative in the vaccine and because the vaccine rapidly loses potency after reconstitution, it must be refrigerated at the point of use and held on ice and used soon after reconstitution. Reconstituted vaccines must be discarded within 4 hours. The vaccine is supplied in single and multiple - dose containers.

**Vaccine Failure** : Rarely, healthy people fail to develop neutralizing antibodies following 17D vaccination. This is not an absolute refractoriness; people who fail to develop antibody after their first vaccination may develop antibody upon revaccination (2, 4, 7).

**Precautions and Contraindications** : Tolerance of the vaccine is generally good. Less than 5% of vaccine recipients have mild reactions, including myalgia and headache. Contraindications include true allergy to the constituents, cellular immunodeficiency and symptomatic HIV infection. Many industrialized countries administer Yellow fever vaccine to persons with symptomatic HIV infection provided that the CD4 count is at least 200 cells/mm<sup>3</sup> (11, 12). Asymptomatic HIV - positive individuals may have a reduced response to the vaccine. There is a theoretical risk of harm to the foetus if the vaccine is given during pregnancy, but this must be weighed against the risk to the mother of remaining unvaccinated and travelling to a high - risk zone. There have been recent reports of a small number of cases of serious disease, including deaths, following Yellow fever vaccination; most of these reactions occurred in elderly persons (12, 13 - 15).

The risk to unvaccinated individuals who visit countries where there may be Yellow fever transmission is far greater than the risk of a vaccine - related adverse event and it remains important for all travellers at risk to be vaccinated. Nonetheless, Yellow fever vaccination should not be prescribed for individuals who are not at risk of exposure to infection (16 - 18). Yellow fever vaccination should be encouraged as a key prevention strategy, but it is important to screen travel itineraries, particularly of older travellers and carefully evaluate the potential risk of systemic illness after Yellow fever vaccination (2, 7, 10, 11).

**Mandatory Vaccination** : Mandatory vaccination against Yellow fever is carried out to prevent the importation of Yellow fever virus into vulnerable countries. These are countries where Yellow fever does not occur but where the mosquito vector and non - human primate hosts are present. Importation of the virus by an infected traveller could potentially lead to the establishment of infection in mosquitoes and primates, with a consequent risk of infection for the local population. In such cases, vaccination is an entry requirement for all travellers arriving from countries, including airport transit, where there is a risk of Yellow fever transmission. If Yellow fever vaccination



is contraindicated for medical reasons, a medical certificate is required for exemption (19). The international Yellow fever vaccination certificate becomes valid 10 days after vaccination and remains valid for a period of 10 years. Travellers should be aware that the absence of a requirement for vaccination does not imply that there is no risk of exposure to Yellow fever in the country.

**Prevention of Entry of Disease in India :** In India, *Aedes aegypti* is wide spread and the people possess no immunity against Yellow fever. Yellow fever has not so far entered India due to the stringent regulations and their rigid enforcement. It is, however, interesting to note that Yellow fever never entered India even before these regulations were introduced. May be, this was due to the slow mode of voyage from the African coast to India. Due to faster means of travel the danger of its entry has increased. The details on International Health Regulations are given in a separate chapter.

## Summary

Yellow fever was the first viral haemorrhagic fever to be described. The “yellow” in the name originates from the jaundice that occurs in seriously ill patients. Yellow fever is currently confined almost entirely to South and Central America and Africa. All these countries lie within a band from 15°N to 10°S of the equator. WHO considers Asian region to be at risk because the appropriate primates and vectors are present. The viral pathogen is a *Flavivirus* belonging to the family *Togaviridae*. In South America *Haemogoggus spegazzinii* is the principal vector for forest transmission. In Africa, the principal vectors for forest transmission are the *Aedes africanus* and *Aedes simpsoni*. In both the continents, the principal urban vector is the *Aedes aegypti*. Humans and monkeys are the principal hosts. The reservoir of urban Yellow fever is sub-clinical human cases. For rural Yellow fever the most important animal reservoir is the monkey. Three transmission cycles can be distinguished in Africa. The sylvatic, intermediate and urban cycle. The intrinsic incubation period in human beings is between two and six days. The extrinsic incubation period in a mosquito varies from four to 18 days (average 12 days). The case is infective to the vector mosquito during the later part of the incubation period and first three clinical days. The disease presents in two phases first “acute” phase is characterized by fever, muscle pain, headache, loss of appetite, nausea and vomiting. About 15% of patients enter a “toxic phase” within 24 hours. The patient rapidly develops jaundice and has abdominal pain with vomiting. About half of the patients in the “toxic phase” die within 10 - 14 days. Complications include Kidney, liver and myocardial damage. Specific laboratory diagnosis relies on serology or on detection of the virus and viral antigens. There is no specific treatment for Yellow fever, supportive care is critical. Vector control and vaccination are the cornerstones of Yellow fever control. Currently, 17D is the only strain of Yellow fever virus used for vaccination. More than 95% of vaccinated people develop neutralizing antibodies within 10 to 14 days of immunization. The international Yellow fever vaccination certificate becomes valid 10 days after vaccination and remains valid for a period of 10 years. Mandatory vaccination against Yellow fever is carried out to prevent the importation of Yellow fever virus into vulnerable countries. These are countries where

Yellow fever does not occur but where the mosquito vector and non-human primate hosts are present.

## Study Exercises

**Long Question :** Discuss the epidemiology, treatment, prevention and control of Yellow fever.

**Short Notes :** (1) Transmission cycles of Yellow Fever (2) Yellow fever Vaccine (3) Importance of Yellow fever vaccine in International Travel.

## MCQs

1. All the following are countries considered to be at high risk for yellow fever except (a) Brazil (b) Colombia (c) Hong Kong (d) Peru
2. Principal urban vector of Yellow fever is (a) *Aedes aegypti* (b) *Aedes africanus* (c) *Aedes simpsoni* (d) *Aedes vittatus*
3. In South America \_\_\_\_\_ is the principal vector for forest transmission (a) *Aedes simpsoni* (b) *Haemogoggus spegazzinii* (c) *Aedes vittatus* (d) *Aedes niveus*
4. Strain of Yellow fever virus used for vaccination (a) 16 D (b) 17 D (c) 18 D (d) 19 D
5. The international Yellow fever vaccination certificate becomes valid \_\_\_\_\_ days after vaccination (a) 10 (b) 15 (c) 20 (d) 25

**Answers :** (1) c; (2) a (3) b; (4) b; (5) a.

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Rajesh Vaidya

The word “Jaundice” comes from old french “Jaunice” or “Yalnice”. “Icterus” is a greek word for yellow. Some brightly coloured birds belong to the family “*Icteradae*”. Pliny believed that if a jaundiced patient looked at the icterus or golden oriole, the patient recovered but the bird died. Epidemic jaundice was described by Hippocrates in 400 BC. Outbreaks among armies have been documented in Europe in the 17th and 18th centuries (1). The distinction between ‘infectious’ and ‘serum’ hepatitis was first made by Krugman (2).

The term hepatitis indicates an inflammation of the liver due to any cause. Infection by a number of viruses can cause inflammation of the liver. However, the term ‘Viral Hepatitis’ is used only for disease caused by hepatotropic viruses. There are five viruses which are taxonomically diverse but share the common characteristic of replicating primarily in the liver. These viruses are the Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Hepatitis D Virus (HDV), and Hepatitis E Virus (HEV). These five viruses are further divided into two groups. The hepatitis A and E viruses are primarily transmitted by the faeco-oral route and result in acute but self limited infection. The hepatitis B, C & D viruses are transmitted by the parenteral route and can cause both acute and chronic infection. Some newer agents have been identified as causes of viral hepatitis but they are not well characterized so far.

Other viruses like Cytomegalovirus, Epstein Barr virus, Yellow Fever virus & Rubella virus can also cause hepatitis. In immunocompromised individuals, herpes simplex virus, varicella virus and adenovirus also result in hepatic dysfunction. However, as the site of primary infection is not the liver in these cases, they are not listed as causes of viral hepatitis.

## Hepatitis A

The Hepatitis A Virus (HAV) is the commonest cause of viral hepatitis worldwide (1).

### Epidemiology

**Global** : Endemicity of HAV infection is closely related to sanitary and living condition and other indicators of development, various sero-epidemiological studies show that prevalence of anti-HAV antibodies in the general population varies from 15% to close to 100% in different parts of the world. An estimated 1.5 million clinical cases of hepatitis A occur world-wide each year (4). In areas of low endemicity such as United States, Canada, western Europe, Australia, and other developed countries, hepatitis A usually occurs as single cases (5). However HAV is also known to have potential to cause large outbreaks, one of the worst known outbreaks was seen in 1988 in Shanghai, China, when over 3,00,000 young adults became ill when shellfish contaminated with HAV were sold in the marketplace and subsequently prepared in a traditional manner at temperatures that did not kill the virus (6).

**India** : In India, limited epidemiological data are available on HAV infection. A few reports suggested that India was

hyperendemic for HAV infection with very high infection rates in the first few years of life and most of the population acquiring antibodies to HAV by 10 yrs of age. Seroprevalence was of anti-HAV was lower (54.5%) in the higher socio-economic group as compared to the lower socio-economic group (85%) (7-9). However recent studies suggest that seroprevalence of anti-HAV vary in different parts of country with some parts showing a gradual shift in the epidemiology of hepatitis A with more cases occurring in adult population (10).

**Agent** : The HAV is a member of the *Picornavirus* family. It is an icosahedral virus 27 to 32 nm in diameter. The particle is non-enveloped and has single stranded, positive sense RNA (3). Four human genotypes of the virus have been identified. However, they are closely related anti-genically and infection with one genotype results in immunity against the other strains. There is only one serotype. HAV is relatively resistant to destruction.

**Host** : HAV infection, usually, is common in children and the risk of developing symptomatic illness following HAV infection is directly correlated to age. In children below six years of age, HAV infection is usually asymptomatic, with only 10% developing jaundice. Among older children and adults, infection usually causes clinical disease, with jaundice occurring in more than 70% of cases. However any age group can be affected, if susceptible. For practical purposes, the world can be divided into areas of low, intermediate and high disease endemicity. In areas of low endemicity disease occurs mainly in adolescents and adults in high-risk groups (e.g. homosexual men, injecting-drug users), persons travelling to countries of intermediate and high HAV endemicity. In areas of intermediate endemicity person to person in the general community via faeco-oral route is predominant, most cases occur in late childhood and early adulthood. In areas of high disease endemicity lifetime risk of infection is greater than 90%, most infections occur in early childhood and are asymptomatic (4).

**Modes of Transmission** : Person-to-person transmission by the faeco-oral route is the predominant mode of HAV transmission. The other less common mode of transmission include blood-borne transmission, sexual transmission in homosexuals and in some rare cases vertical intrauterine transmission has also been demonstrated (11). Secondary attack rates are as high as 30% among household contacts.

**Incubation Period** : Incubation period ranges from 15 to 50 days with median of about 28 days(12).

**Period of Infectivity** : 2 weeks before to 1 week after onset of jaundice. Highest concentration of virus is excreted in faeces 2 weeks prior to onset of clinical illness, which rapidly declines with appearance of jaundice (13).

### Clinical Features

The clinical course of acute hepatitis A is indistinguishable from other types of acute viral hepatitis. Symptoms typically include fever, malaise, anorexia, nausea and abdominal discomfort, followed by dark urine and jaundice. The severity of disease and mortality increases in older age groups. The convalescence following hepatitis A may be slow, and is characterized by fatigue, nausea and lack of appetite. Complications of hepatitis A include relapsing hepatitis, cholestatic hepatitis and fulminant

hepatitis. Fulminant hepatitis occurs in approximately 0.01% of clinical infections and is characterized by rapid deterioration in liver function and a very high fatality rate. Chronic infection with HAV does not occur.

### Diagnosis

Since Hepatitis A is clinically indistinguishable from other forms of hepatitis, diagnosis requires serologic detection of IgM in single acute-phase serum sample. IgM anti-HAV is usually detectable from 5 days prior to the onset of symptoms and declines to undetectable levels within six months after infection. IgG anti-HAV is used to detect previous infection as it usually persists for lifelong after infection. PCR can be used to detect virus in faeces, blood etc. Other biochemical parameters include elevated levels of serum bilirubin and elevated hepatic enzymes (AST, ALT) (14).

### Treatment

Treatment primarily comprises of symptomatic management with complete bed rest and low protein diet as no specific antiviral therapy is currently available.

### Prevention and Control

As almost all HAV infections are spread by the faeco - oral route, good personal hygiene, high quality standards for public water supplies and proper disposal of sanitary waste are the mainstay of prevention and control of infective hepatitis. Some of the important measures are as follows :

- Water supply should be safeguarded against faecal contamination. Even chlorination may sometimes not kill the virus, unless water is very efficiently chlorinated and a half an hour contact period is ensured. Water should be preferably boiled during an outbreak.
- Sanitation should be kept at a very high level. Methods of proper disposal of human wastes and strict anti-fly measures should be reinforced.
- Personal hygiene must be maintained at an extremely high level. Particularly cooks and housewives must be persuaded to wash their hands with soap and water after defaecation and before handling or consuming food.
- Complete inactivation of HAV in food can be done by heating at 85°C for at least one minute.

**Active Immunization** : Several inactivated or live attenuated vaccines against hepatitis A have been developed, but only four inactivated hepatitis A vaccines are currently available internationally. All four vaccines are all highly immunogenic. Nearly 100% of adults will develop protective levels of antibody within one month after a single dose of vaccine. Similar results are obtained with children and adolescents in both developing and developed countries. These vaccines are given parenterally (IM), as a two-dose series, 6-18 months apart. The dose of vaccine, vaccination schedule, paediatric and adult formulation varies from manufacturer to manufacturer. Currently no vaccine is available for children less than 1 yr.

A combination vaccine containing inactivated hepatitis A and recombinant hepatitis B vaccines has been licensed since 1996 for use in children aged one year or older in several countries. The combination vaccine is given as a three-dose series, using a 0, 1, 6 month schedule.

WHO recommends that in highly endemic countries where HAV is almost universal before the age of 10 years and is usually a minor public health problem, large-scale immunization efforts against this disease should not be undertaken. In developed countries with low endemicity of hepatitis A and with high rates of disease in specific high-risk populations (injection-drug users, homosexual men, persons travelling to high-risk areas, and certain ethnic or religious groups), vaccination should be given to this high risk population. Recommendations for hepatitis A vaccination in outbreak situations should depend on the epidemiology of hepatitis A in the community, and the feasibility of rapidly implementing a widespread vaccination programme. Hepatitis A vaccination in small, self-contained communities has been found to be very successful in control of the outbreak (15).

**Passive Immunization** : Passive immunization with IG that contain anti-HAV are more than 85% effective in preventing symptomatic HAV infection if given before, or within two weeks of exposure. With the availability of hepatitis A vaccines, IG is primarily recommended for postexposure prophylaxis for unvaccinated persons who are exposed to HAV. A single IM dose of IG (0.02 mL/kg) should be administered as soon as possible, but not more than two weeks after the last exposure, to unvaccinated household contacts, to persons who have shared illegal drugs with a person with hepatitis A, and to children and staff exposed in day care or certain other institutional settings.

## Hepatitis E

Hepatitis E virus (HEV) was first identified in India in 1955 but it was only after development of specific serological test for acute HAV which resulted in the retrospective determination that large outbreaks of hepatitis with faeco-oral mode of transmission were not hepatitis A, but enterically transmitted Non-A Non-B virus (NANB or E-NANB). Hepatitis E was recognized as a distinct human disease in early 1990's (16).

### Epidemiology

**Global** : The highest rates of infection occur in regions where low standards of sanitation promote the transmission of the virus. Hepatitis E is endemic in many parts of the world and always where HAV infection is highly endemic. Epidemics of hepatitis E have been reported in Central and South-East Asia, North and West Africa, and in Mexico, especially where faecal contamination of drinking water is common (19).

**India** : HEV is responsible for the majority of epidemic and sporadic hepatitis in adults. Epidemics of Hepatitis E have been reported from across the country, one of the largest such epidemic occurred in Delhi during the winter of 1955-56, infecting over 30,000 persons within six weeks (17).

**Agent** : HEV is a 27-34 nm non-enveloped icosahedral virus with a single-stranded, positive-sense RNA genome. The surface of the viron shows indentation and spikes (17). In morphology it resembles Calcivirus like Norwalk virus hence was wrongly classified into the family *Caliciviridae*, but now has been reclassified to an separate genus of "Hepatitis E like viruses" (18).



**Host** : The zoonotic origin of HEV is suspected, as monkeys, rats, cattle, sheep, goats, ducks and pigs are susceptible to infection with humans being an end or inadvertent target.

The reservoir of Hepatitis E is unknown. Although asymptomatic infections occur among children, seroprevalence studies in high endemic areas have not identified high rates of infection in this age group. Various studies have shown high attack rate among young adults (20). Hepatitis E has been found to have intriguing relationship with pregnancy. Pregnant women particularly those in the second and the third trimester, are more frequently affected during HEV outbreak. In addition, among pregnant women, especially those infected in the third trimester, the disease is more severe with high mortality (20-40%) (21).

**Modes of Transmission** : HEV is transmitted via the faeco-oral route. Hepatitis E is a waterborne disease, and contaminated water or food supplies have been implicated in major outbreaks. Consumption of faecally contaminated drinking water has given rise to epidemics, and the ingestion of raw or uncooked shellfish has been the source of sporadic cases in endemic areas. Hepatitis E has been found to be transmitted from infected mothers to their babies with significant perinatal morbidity and mortality (22). However Person-to-person transmission is uncommon with low secondary attack rates ranging from 0.7 to 2.2%. There is no evidence for sexual transmission or for transmission by transfusion.

**Incubation Period and Period of Infectivity** : The incubation period following exposure to HEV ranges from 3 to 8 weeks, with a mean of 40 days. The period of communicability is unknown. There are no chronic infections reported (23).

### Clinical Features

Clinical signs and symptoms are indistinguishable from Hepatitis A. Typical signs and symptoms of hepatitis include jaundice (yellow discoloration of the skin and sclera of the eyes, dark urine and pale stools), anorexia (loss of appetite), an enlarged, tender liver (hepatomegaly), abdominal pain and tenderness, nausea and vomiting, and fever. Most persons with Hepatitis E have self limited disease except in pregnant women in whom high degree of fatality is observed. Infants acquiring infection via vertical transmission have increased risk of fulminant hepatitis (24). Chronic liver disease is not known to occur with HEV infection.

### Diagnosis

Hepatitis E are not clinically distinguishable from other types of acute viral hepatitis, diagnosis is made by blood tests which detect elevated antibody levels of specific antibodies to hepatitis E in the body or HEV RNA can be detected in faeces or serum by Reverse Transcriptase Polymerase Chain Reaction (RT-PCR).

### Treatment

HEV infections are usually self-limited and available therapy is capable of altering the course of acute infection. Hospitalization is required for fulminant hepatitis and should be considered for infected pregnant women.

### Prevention and Control

As almost all HEV infections are spread by the faeco-oral

route, good personal hygiene, high quality standards for public water supplies and proper disposal of sanitary waste is the key for prevention of HEV infection. At present, no commercially available vaccines exist for the prevention of hepatitis E. However, several studies for the development of an effective vaccine against hepatitis E are in progress.

## Hepatitis B

HBV is one of the oldest known hepatitis viruses. Even after the advent of an effective vaccine it still continues to be a major public health problem with more than 2 billion people infected worldwide.

### Epidemiology

**Global** : The prevalence of HBV infection varies greatly worldwide. There are more than 2 billion people infected worldwide, and 350 million suffering from chronic HBV infection. HBV infections result in 5,00,000 to 1.2 million deaths per year caused by chronic hepatitis, cirrhosis, and hepatocellular carcinoma. More than one-third of the population has been infected with HBV, and it is estimated that there are 80 million HBV carriers (about 6% of the world population) (27).

**India** : On meta-analysis, the point prevalence of hepatitis B was found to be 2.1 per cent with a chronic carrier rate of 1.7 per cent (28). Hepatocellular carcinoma is rare in India and constitutes only 1.6 per cent of all cancers. The estimated annual deaths attributable to hepatocellular carcinoma due to hepatitis B was found to be approximately 5000 (29). However certain studies have found higher carrier state ranging from 11% in healthcare worker to 5% in general population (30).

**Agent** : The Hepatitis B Virus (HBV) is a double-stranded, enveloped virus of the *Hepadnaviridae* family. With a genome of only 3200 base pairs, HBV is one of the smallest DNA viruses known. The complete HBV viron (Dane Particle) is 42nm in diameter and is composed of outer lipoprotein coat containing the Hepatitis B Surface Antigen (HBsAg) and 27nm nucleocapsid core, the Hepatitis B Core Antigen (HBcAg) (17). HbsAg circulates independently in the blood and has four possible subtypes (*adw*, *adr*, *ayw* and *ayr*). Antibodies to the "a" antigen confer immunity to all subtypes (25). A third antigen HBeAg is a soluble protein, which can be detected in serum of patients with acute HBV infection. It acts as a marker of viral replication.

There are eight genotypes of hepatitis B Virus (*A* to *H*). Genotypes have different geographic distributions like genotype *A* is pandemic whereas genotype *B* and *C* are present in Asia, *D* in Southern Europe and US, *E* in Africa, *F* in the US, *G* in US and France and *H* in Central and South America (26)

**Host** : There is a direct relationship between the age of the patient and the likelihood to develop symptomatic infection which includes acute (clinically apparent) hepatitis B, chronic HBV infection, cirrhosis and HCC. Acute hepatitis B occurs in approximately 1% of perinatal, 10% of early childhood (1-5 years old) and 30% of late (>5 years old) HBV infections. Fulminant hepatitis develops in 0.1-0.6% of acute hepatitis cases; mortality from fulminant hepatitis B is approximately 70%. However, there is an inverse relationship with age and probability of developing chronic infection. About 90% of infants



infected during the first year of life and 30% to 50% of children infected between 1 to 4 years of age develop chronic infection. Whereas only 2-6% of adults develop chronic infection (31).

Certain occupational categories have been identified as associated with an excess risk of hepatitis B, C & D infection. The categories include dentists, nurses, laboratory technicians and the work areas include haemodialysis units, blood banks and surgical intensive care units.

**Modes of Transmission** : Humans are the only reservoir of HBV. The virus is highly contagious and is transmitted by percutaneous and permucosal exposure to infected blood and other body fluids (i.e. semen and vaginal fluid). The virus is found in highest concentrations in blood and serous exudates followed by lower concentrations in various body secretions such as saliva, semen and vaginal fluid. Common modes of transmission include mother-to-infant, unsafe injection practices, blood transfusions and sexual contact.

**Perinatal Transmission** : Perinatal HBV transmission is one of the most efficient modes of infection. Most perinatal HBV infections occur among infants of pregnant women with chronic HBV infection. Risk of transmission from pregnant women who acquire infection during the third trimester is approximately 60%. Perinatal transmission occurs most often at the time of birth, with in utero transmission rarely accounting for infections transmitted from mother to infant. Although HBV can be detected in breast milk, there is no evidence that HBV is transmitted by breast-feeding (32-33).

**Sexual Transmission** : Presence of HBV in semen and vaginal fluid favours transmission of virus by sexual contact, which is one of the common modes of acquiring the infection. Both heterosexual and homosexual intercourse may transmit HBV. The sexually promiscuous, particularly male homosexuals, are at very high risk of infection with hepatitis B.

**Percutaneous Transmission** : The risk of acquiring HBV infection through needle stick injury exposure to HBsAg positive blood is approximately 30-60%. This poses a significant risk to health care workers and IV drug abusers.

In highly endemic areas (>8% of the population HBsAg-positive), HBV is most commonly spread from mother to child at birth, or from person to person in early childhood. In countries with low HBV endemicity (<2% of the population HBsAg-positive), sexual transmission and the use of contaminated needles, especially among injecting drug users, are the major routes of infection (34).

**Incubation Period and Period of Infectivity** : The incubation period ranges from 30 to 180 days with median of 75 days. Period of Infectivity may extend from appearance of HBV in blood (30-60 days following infection) to several months or until disappearance of HBsAg and appearance of surface antibody.

### Clinical Features

As mentioned earlier, the chances of development of symptomatic illness is directly related to age. In patients who develop symptomatic infection, the clinical onset of hepatitis B is usually insidious, with malaise, weakness, and anorexia being the most common findings. In 5-10% of patients, a serum

sickness-like syndrome may develop during the prodromal phase that is characterized by arthralgias or arthritis, rash, and angioedema. In patients with icteric hepatitis (30% or more of infected adults), jaundice usually develops within 1-2 weeks after onset of illness, dark urine and clay-colored stools may appear 1-5 days before the onset of clinical jaundice (25). Liver enzyme elevations usually occur prior to onset of jaundice. In most cases it is a self limiting disease and clinical signs and symptoms of acute hepatitis B usually resolve within 1-3 months.

### Diagnosis

Acute hepatitis is indistinguishable from other hepatitis by biochemical parameters which include elevated levels of serum bilirubin and elevated hepatic enzymes (AST, ALT). Diagnosis can be made on the basis of serological antigen and antibody markers of HBV infection. HBsAg, IgM anti-HBc, and HBeAg can all be detected in serum as early as 1-2 months after exposure to HBV, but IgM anti-HBc is the only reliable marker of acute infection, as the others can also be detected in persons with chronic HBV infection. IgM anti-HBc usually becomes undetectable within 6-9 months after acute infection, and HBsAg and HBeAg are usually cleared within six months following onset of illness in those who recover from the acute infection. Anti-HBs and anti-HBe develop during the convalescent phase, with anti-HBs being a protective antibody that neutralizes the virus. Presence of anti-HBs following acute infection indicates recovery and immunity from reinfection. And anti-HBs can also be detected in persons who have received hepatitis B vaccine. Detection of anti-HBs is not routinely performed during diagnostic testing of persons with clinical illness but may be used in certain instances to determine a person's immune status following vaccination. In persons who develop chronic HBV infection, HBsAg and total anti-HBc remain detectable, generally for life. Although all persons with detectable HBsAg should be considered infectious, but its presence along with HBeAg and HBV DNA, is more indicative of infectivity (35). In addition Polymerase Chain Reaction (PCR) can be used to detect HBV DNA.

### Treatment

In most cases treatment is supportive as the infection is self limiting. Patient is advised to avoid most drugs and bed rest till jaundice is completely resolved. Patients with fulminant viral hepatitis require ICU care with absolute bed rest, low protein diet, enemas to cleanse the bowel and oral neomycin (1 - 1.5g every six hours). Patients with chronic active Hepatitis B may be given specific anti viral therapy in the form of:

- (a) Interferon  $\alpha$ : 5 million units / day or 10 million units thrice a week for 16 weeks OR
- (b) Lamivudine: 100 mg OD orally for one year OR
- (c) Adefovir: 10 mg OD orally for 48 weeks

### Prevention and Control

General prophylactic measures for HBV prevention include the following:

- Safe sexual practices
- Use of Condoms
- Safe hygiene practices (not sharing shaving blades)

- Safe blood transfusion and injections
- Health care personnel to practice proper “Universal safety precautions” and correct disinfection procedures
- Biomedical waste management as per laid down guidelines

**Active Immunization** : More than three decades of experience have shown that hepatitis B vaccination is safe and cost effective way of preventing HBV infection. Currently Two types of hepatitis B vaccines are available: plasma derived vaccines and recombinant vaccines are available world wide. The two vaccines show no differences in terms of reactogenicity, efficacy or duration of protection. Plasma-derived vaccines are prepared from purified HBsAg obtained from the plasma of persons with chronic HBV infection and inactivated using formalin. Aluminium phosphate or aluminium hydroxide is added to the vaccine as adjuvant and for multi-dose vials; thiomersal is used as a preservative. The recombinant hepatitis B vaccines (RDNA - Yeast derived vaccine) use HBsAg synthesized in yeast or mammalian cells.

**Doses and Schedule** : The recommended dose varies by product and with the age of the recipient. In most cases, infants and adolescents receive 50% of the adult dose. The vaccine is administered by intramuscular injection in the anterolateral aspect of the thigh (infants and children aged <2 years) or in the deltoid muscle (older children and adults). Administration in the buttock is not recommended. In case of adults schedule is 0, 1 & 6 months. In case of infants and children there are multiple options for incorporating the hepatitis B vaccine into national immunization programmes (36). The choice of schedule depends on the local epidemiological situation and programmatic considerations. The minimum recommended interval between the doses is four weeks.

**Immunogenicity and clinical efficacy** : The protective efficacy of hepatitis B vaccination is directly related to the induction of anti-HBs antibodies. An antibody titre of >10 mIU per ml measured 1-3 months after the administration of the last dose of the primary vaccination series is considered a reliable marker of immediate and long-term protection against infection. The complete vaccine series induces protective antibody levels in >95% of infants, children and young adults. After the age of 40 years, protection following the primary vaccination series drops below 90%. However despite the loss of anti-HBs over time, booster doses are not recommended (37,38).

**Passive Immunization** : Post exposure prophylaxis using HBIG is indicated in the following situation :

- For newborn infants whose mothers are HBsAg-positive
- Following percutaneous or mucous membrane exposure to HBsAg-positive blood or body fluids
- Following sexual exposure to an HBsAg-positive person
- To protect patients from recurrent HBV infection following liver transplantation

HBIG as early as possible (ideally with 6 to 48 hrs). Immunoglobulin (16 % solution) should be given at 0.02 to 0.12 ml per kg of body weight intramuscularly in two doses 30 days apart. As a rule, HBIG should be used as an adjunct to hepatitis B vaccine.

**WHO position on hepatitis B vaccine** : WHO has called for all countries to add hepatitis B vaccine into their national immunization programmes in 1991. As of March 2004, more than 160 countries had followed the WHO recommendation and had added hepatitis B vaccine as an integral part of their national infant immunization programmes. The need for catch-up vaccination of older age groups, including adolescents and adults, is determined by the baseline epidemiology of HBV infection in the country. In countries of high endemicity, large-scale routine vaccination of infants rapidly reduces infection and transmission of HBV. In this situation, catchup vaccination of older children and adults has relatively little impact because most of them will have already been infected. In countries of intermediate or low hepatitis B endemicity, catch-up strategies targeted at adolescents could be considered as a supplement to routine infant vaccination. Possible additional target groups for catch-up vaccination include persons with risk factors for acquiring HBV infection, such as health care workers who may be exposed to blood or blood products, dialysis patients, persons interned in prisons, injecting drug users, household and sexual contacts of persons with chronic HBV infection, and persons with multiple sexual partners. Catch-up vaccination should be considered only if the continuity of the infant vaccination programme can be ensured (34).

## Hepatitis C

Hepatitis C is a viral infection of the liver which was initially referred to as parenterally transmitted “non A, non B hepatitis” until identification of the causative agent in 1989. HCV is one of the major cause of acute hepatitis and chronic liver disease, including cirrhosis and liver cancer and despite extensive global efforts there is still no vaccine available to prevent HCV.

### Epidemiology

**Global** : It is estimated that about 180 million people or 3% of the world’s population, are infected with hepatitis C virus (HCV), 130 million of whom are chronic HCV carriers at risk of developing liver cirrhosis and/or liver cancer. It is estimated that three to four million persons are newly infected each year, 70% of whom will develop chronic hepatitis (40).

**India** : Hepatitis C virus (HCV) which accounts for one-fourth of all cases of chronic liver disease in India. It is estimated that there are 12.5 million HCV carriers in our country (41). Seroprevalance studies among blood donors in India, have shown a rate varying from 0.48% in Vellore (42) to 1.85% in New Delhi (43).

**Agent** : HCV is an enveloped virus with an icosahedral capsid that contains a 9.6 kb-long, single-stranded, positive sense genomic RNA. It has been classified into genus *Hepacivirus* in the family *Flaviviridae*. The single translated polypeptide contains structural proteins including the core and two envelope proteins and three nonstructural proteins. Two regions of one of the envelope proteins called the hypervariable regions have extremely high rate of mutation. It is postulated that this rapid evolution of genetic variation facilitates viral persistence in most infected persons. There are 6 HCV genotypes and more than 100 subtypes (39).

**Host** : Since HBV is transmitted parenterally, certain group of people can be classified as high risk. This includes recipients of blood transfusions, healthcare and laboratory personnel, homosexuals, prostitutes, percutaneous drug abusers, infants of HCV carrier mothers.

**Modes of Transmission** : HCV is transmitted by percutaneous or mucosal exposure to infectious blood and blood-derived body fluids. The primary route of transmission is percutaneous exposure to blood. Sexual and perinatal transmission of HCV infection appears to be inefficient, occurring at a frequency lower than that observed for HBV and HIV infection (44).

**Percutaneous Transmission**: Injection drug use is a major source of HCV transmission in developed countries. Drug users who have injected even once or twice in the past should be considered at high risk of infection, since HCV infection is acquired more rapidly among IDUs than either HBV or HIV infection (45). Transfusion of blood or plasma-derived products and transplantation of solid organs from HCV infection donors are highly effective routes for transmitting HCV infection. Nosocomial transmission of HCV infection due to poor infection control practices and aseptic techniques is a common means of transmission in developing countries.

Other modes of transmission such as social, cultural, and behavioural practices using percutaneous procedures (e.g. ear and body piercing, circumcision, tattooing) can occur if inadequately sterilized equipment is used. HCV is not spread by sneezing, hugging, coughing, food or water, sharing eating utensils, or casual contact.

**Incubation Period** : The incubation period of HCV infection before the onset of clinical symptoms ranges from 15 to 150 days.

### Clinical Features

Most persons (60-80%) with newly acquired HCV infection are asymptomatic and only 15-30% become jaundiced. The clinical illness in persons with acute hepatitis C is similar to that observed in hepatitis of other viral etiologies and the diagnosis of hepatitis C can only be made with appropriate serologic testing. The most outstanding feature of HCV infection is that about 80% of newly infected patients progress to develop chronic infection. Cirrhosis develops in about 10% to 20% of persons with chronic infection, and liver cancer develops in 1% to 5% of persons with chronic infection over a period of 20 to 30 years. Most patients suffering from liver cancer who do not have hepatitis B virus infection have evidence of HCV infection. The mechanisms by which HCV infection leads to liver cancer are still unclear (46).

### Diagnosis

Diagnostic tests for HCV are used to prevent infection through screening of donor blood and plasma, to establish the clinical diagnosis and to make better decisions regarding medical management of a patient. Diagnostic tests commercially available today are based on Enzyme Immunosorbent Assays (EIA) for the detection of HCV-specific antibodies. EIAs can detect more than 95% of chronically infected patients but can detect only 50% to 70% of acute infections. This limitation of diagnosis of recent HCV infection is due to the lack of a

sensitive and specific immunoassay, such as IgM anti-HCV. A Recombinant Immunoblot Assay (RIBA) that identifies antibodies which react with individual HCV antigens is often used as a supplemental test for confirmation of a positive EIA result. PCR can be utilized for confirmation of serological results as well as for assessing the effectiveness of antiviral therapy. A positive result indicates the presence of active infection and a potential for spread of the infection and/or the development of chronic liver disease.

### Treatment

Treatment of acute hepatitis is essentially symptomatic and similar to other forms of viral hepatitis. For chronic hepatitis C, antiviral drugs such as interferon taken alone or in combination with ribavirin, can be used. Treatment with interferon alone is effective in about 10% to 20% of patients. Interferon combined with ribavirin is effective in about 30% to 50% of patients. Ribavirin does not appear to be effective when used alone (47).

### Prevention and Control

There is no vaccine against HCV. Research is in progress but due to high mutability of the HCV genome, possibility of development of vaccine in the foreseeable future seems remote. Hence in the absence of a vaccine, all precautions to prevent infection must be taken including :

- Screening and testing of blood and organ donors.
- Virus inactivation of plasma-derived products.
- Implementation and maintenance of infection control practices in health care settings, including appropriate sterilization of medical and dental equipment.
- Promotion of behaviour change among the general public and health care workers to reduce overuse of injections and to use safe injection practices; and risk reduction counselling for persons with high-risk drug and sexual practices (47).

## Hepatitis D

HDV is a defective single-stranded RNA virus that requires the helper function of HBV to replicate. HDV infection can be acquired either as a co-infection with HBV or as a Superinfection of persons with chronic HBV infection.

### Epidemiology

**Global** : In general, the global pattern of HDV infection corresponds to the prevalence of chronic HBV infection; however, several distinct features of the distribution of HDV infection have been identified. The highest prevalences of HDV infection are found in the Amazon basin, parts of Africa, and Romania where 20% of persons with chronic HBV infection and up to 90% of people with HBV-related chronic liver disease have HDV infection. Other countries, including northern Italy, Spain, Turkey, and Egypt, have a moderate prevalence of HDV infection among asymptomatic HBV carriers (10%-19%) and among patients with chronic HBV-related liver disease (30%-50%). In most of Southeast Asia and China, where the prevalence of chronic HBV infection is very high but HDV infection is uncommon (49).

**India** : The anti-HDV positivity in acute viral hepatitis patients has been reported to vary from 10.7 to as high as >30 per



in various studies conducted across the country. In chronic hepatitis and cirrhosis groups, anti-HDV antibodies have been found to range from 8-21% and 15-19% patients respectively (50).

**Agent :** The hepatitis delta virus (HDV) is a 1.7kb RNA virus particle containing a circular, single-stranded RNA genome. HDV encodes a single protein, the delta antigen, which is encapsulated with HBsAg, encoded by the hepatitis B virus (HBV). HDV is classified as a satellite virus or subviral agent because it requires HBsAg as a surface protein to replicate (48).

**Host :** Certain group of people are found to be at high risk of contracting HDV infection these are as follows :

- Intravenous drug users using HDV-contaminated injection needles.
- Promiscuous homosexual and heterosexual groups (although HDV infections are less frequent than HBV or HIV infections).
- People exposed to unscreened blood or blood products such as haemophiliacs, persons with clotting factor disorders.

**Modes of Transmission :** Transmission is similar to that of HBV:

- Bloodborne and sexual.
- Percutaneous (injecting drug use, haemophiliacs).
- Per mucosal (sexual).
- Rare perinatal.

**Incubation Period :** The incubation is period similar to HBV infection 30 to 180 days.

### Clinical Features

An HDV infection absolutely requires an associated HBV infection. The outcome of disease largely depends on whether the two viruses infect simultaneously (*co-infection*), or whether the newly HDV-infected person is a chronically infected HBV carrier (*Superinfection*).

**Co-infection :** HBV and HDV (simultaneous infection with the two viruses) results in both acute type B and acute type D hepatitis. The incubation period depends on the HBV titre of the infecting inoculum. Depending on the relative titres of HBV and HDV, a single bout or two bouts of hepatitis may be seen. Co-infections of HBV and HDV are usually acute, self-limited infections. The chronic form of hepatitis D is seen in less than 5% of HBV - HDV coinfecting patient (51).

**Superinfection :** HBV and HDV (HDV infection of a chronically infected HBV carrier) causes a generally severe acute hepatitis with short incubation time that leads to chronic type D hepatitis in up to 80% of cases. Superinfection is associated with fulminant acute hepatitis and severe chronic active hepatitis, often progressive to cirrhosis (52).

Acute hepatitis D occurs after an incubation period of 3 - 7 weeks, and a pre-icteric phase begins with symptoms of fatigue, lethargy, anorexia and nausea, lasting usually 3 to 7 days. The appearance of jaundice is typical at the onset of the icteric phase. Fatigue and nausea persist, clay-colored stools and dark urine appear, and serum bilirubin levels become abnormal. In patients with acute hepatitis, self-limiting infection, convalescence begins with the disappearance of clinical symptoms. Fulminant viral hepatitis is rare, but still

about 10 times more common in hepatitis D than in other types of viral hepatitis.

About 60 to 70% of patients with chronic hepatitis D develop cirrhosis. Progression to cirrhosis usually takes 5 - 10 yrs, but it can appear 2 years after onset of infection. A high proportion of these patients die of hepatic failure.

### Diagnosis

The diagnosis of acute hepatitis D is made by serologic tests for detecting anti HDV. One of the major drawbacks is that commercially available Radioimmunoassay (RIA) or Enzyme Immunoassay (EIA) kits can only detect Total anti-HDV and may result in under diagnosis of HDV. HD-ag detection in serum is only available in research laboratories and not very sensitive. Hence method of choice for the diagnosis of ongoing HDV infection if available, should be RT-PCR, which can detect 10 to 100 copies of the HDV genome in infected serum (53).

### Treatment

Currently there is no effective antiviral therapy available for treatment of acute or chronic type D hepatitis. In some cases giving massive doses of  $\alpha$ -interferon (9 million units three times a week for 12 months or 5 million units daily for up to 12 months) have yielded remissions, but most of the patients have remained unaffected.

### Prevention and Control

Since HDV is dependent on HBV for replication, HBV-HDV coinfection can be prevented with either pre- or postexposure prophylaxis for HBV. However, no products exist to prevent HDV superinfection of persons with chronic HBV infection. Thus, prevention of HDV superinfection depends primarily on education to reduce risk behaviours.

## Hepatitis G

In 1995, a new virus that causes hepatitis was cloned. The 3 viruses identified were GBV-A, GBV-B, GBV-C. They were together named HGV. Of the three, the third, GBV-C appears to affect man and seems to produce a long standing disease. This hepatitis G virus (HGV) or the GB virus C (GBV-C), is a 30-60 nm. Enveloped, single stranded RNA virus which belongs to the *flavivirus* family. HGV is distinct from hepatitis C virus but has a similar genomic organization. The virus has a global distribution and is reported to be present in 1-3% in volunteer blood donors (54). In India, no formal information is available on the prevalence of HGV in acute viral hepatitis however various studies have reported hepatitis G virus infection in acute viral hepatitis with rates varying from 0 to 34.0%.

Incubation period ranges from 30-120 days. HGV can be transmitted by blood transfusion, sexual contact or vertical transmission from mother to child. It is often detected in patients who received multiple blood transfusion or in hemodialysis patients and intravenous drug users. The virus has a global distribution and is reported to be present in 1-3% in volunteer blood donors. HGV co-infection is observed in 6% of chronic HBV infections and in 10% of chronic HCV infections. HGV has been shown to produce a persistent infection in a high proportion of persons with or without acute hepatitis or hepatitis -related chronic liver disease (55). Since hepatitis G



is a blood-borne infection, prevention relies on avoiding any possible contact with contaminated blood. Drug users should not share needles, syringes, or other equipment. Till date there is no vaccine or treatment of HGV, however it has shown high sensitivity to interferon but most cases relapsed after completion of treatment.

## Summary

Viral hepatitis is defined as an infection of the liver caused by hepatotropic virus and is clinically characterized by an acute or sub acute febrile illness associated with nausea, anorexia, abdominal discomfort, dark colored urine, light colored stools and appearance of jaundice in sclera or skin. The known hepatotropic viruses commonly include hepatitis viruses A, B, C, D, E and G. Infections with hepatitis viruses, especially hepatitis virus B and C, have been associated with a wide variety of extra hepatic manifestations. Whether hepatitis G virus (HGV) is pathogenic in humans remains unclear. HAV has a world wide distribution. The risk of infection is inversely proportional to levels of sanitation and personal hygiene. In developing countries with poor environmental hygienic conditions, nearly all children are infected with HAV before the age of 9. HBV also has world wide distribution where 66 percent of the world's population is living in areas where there are high levels of infection. More than 2 billion people in the world had been found to have HDV prevalence rates ranging from 17-90%. Sexual and perinatal transmissions are also described. HEV is transmitted via the faeco-oral route. HEV appears to be endemic in some parts of the lesser-developed countries. Sporadic infections are observed in persons travelling from western countries to these regions. HGV can be transmitted by blood transfusion. HGV co-infection is observed in 6% of chronic HBV infections and in 10% of chronic HCV infections. However, whether HGV is actually pathogenic in humans remains unclear. Maximum infectivity for hepatitis A & E is during the later half of incubation period continuing through early acute phase of infection during the first 1-2 weeks or longer. In hepatitis B, C & D blood remains infective many weeks before the onset of symptoms, through the acute clinical course of the disease and during the chronic carrier state. As almost all HAV & HEV infections are spread by the faeco - oral route, good personal hygiene, high quality standards for public water supplies and proper disposal of sanitary waste are the mainstay of prevention and control of infective hepatitis. Preventive measures for HBV & HCV infection include active and passive immunization & universal precautions in all health care settings.

## Study Exercises

**Long Question :** Discuss the epidemiology, treatment, prevention and control of Viral Hepatitis

**Short Notes :** (1) Difference between Hepatitis A & B (2) Active and Passive Immunization against Hepatitis A & B

### Fill in the blanks

- (1) HBV also has world wide distribution where \_\_\_\_\_ of the world's population is living in areas where there are high levels of infection.
- (2) HDV prevalence rates ranging from \_\_\_\_\_
- (3) 350 million are chronic carriers of the virus, which is

harboured in the \_\_\_\_\_

- (4) The virus causes 60-80 per cent of all primary liver cancer, which is one of the three common causes of cancer related death in \_\_\_\_\_
- (5) HCV is a \_\_\_\_\_ with a diameter of 55 nm. It has \_\_\_\_\_ serotype and multiple genotypes.
- (6) \_\_\_\_\_ is the reservoir for all the viruses.
- (7) Acute hepatitis occurs in approximately \_\_\_\_\_ of perinatal, \_\_\_\_\_ of early childhood and about \_\_\_\_\_ in those above 5 years of age.
- (8) Maximum infectivity for hepatitis A & E is during the \_\_\_\_\_ half of incubation period continuing through early acute phase of infection during the first 1-2 weeks or longer.
- (9) Contacts of HAV may be given normal human immunoglobulin (16 % solution) at \_\_\_\_\_ ml per kg of body weight intramuscularly as soon as possible after exposure to prevent or attenuate clinical illness.
- (10) Yeast derived vaccine is as effective in protection but more cost effective than the above vaccine. The schedule is \_\_\_\_\_ months. Protection is up to \_\_\_\_\_ years.
- (11) Needles and syringes used for routine immunization must be autoclaved for twenty minutes or boiled for \_\_\_\_\_ min.

**Answers :** (1) 66%; (2) 17-90%; (3) liver; (4) East and SEAR, the Pacific Basin and Sub-Saharan Africa; (5) Flavivirus; one (6) Man; (7) 1%, 10%, 30% (8) later; (9) 0.02 to 0.12; (10) 0, 1 & 6, 15; (11) 30

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Rajesh Vaidya

The word "Anthrax" originates from Greek for black or coal because of the black eschar which is characteristic of the cutaneous form of Anthrax infection. It is principally a disease of herbivores but has the potential to infect all mammals and even some birds (1). Anthrax is caused by infection with the bacterium, *Bacillus anthracis*. The spores of the bacteria can survive in the environment for years or decades (2). The disease is endemic in all parts of the world but human cases are not common. Human infection results from direct or indirect exposure to infected animals or occupational exposure to infected or contaminated animal products. Anthrax has been in the news because of the fact that it is a suitable agent for germ warfare and its use as a weapon of bioterrorism in the United States of America (3). Other names for anthrax include "malignant pustule" and "Wool sorter's disease".

### Epidemiology

Anthrax incidence among humans is dependent on the level of exposure to affected animals. Anthrax continues to be endemic in many parts of the world. The WHO also reports that the disease is enzootic in most parts of Asia and Africa and sporadic outbreaks among herbivorous animals are reported from other parts of the world (4).

Accurate figures on human anthrax in India are not available. However sporadic outbreaks continue to occur. The three southern states of Tamil Nadu, Andhra Pradesh and Karnataka have recorded at least 200 cases of human anthrax since the 1950s. In the recent past, the National Institute of Communicable Diseases has investigated two outbreaks of human anthrax one in Mysore and the other in Midnapore (5). Animal anthrax remains endemic in India because inadequate vaccination.

**Agent :** *Bacillus anthracis* is a large, spore - forming, gram - positive bacillus with a diameter of 1.5  $\mu\text{m}$  and a length of 5  $\mu\text{m}$ . It can easily be cultured on sheep blood agar growing typically "medusa head" colonies. Anthrax can be differentiated from other gram - positive bacilli as it is non motile and non haemolytic and typically sensitive to penicillin. The virulence of the organism depends on the bacterial capsule and the toxin complex. The capsule is a poly - D - glutamic acid that protects it against lysis and phagocytosis. There are three anthrax toxins: the Edema Factor (EF), the Lethal Factor (LF) and a protective antigen (2). Only one strain is known.

Under unfavourable conditions which are not conducive to growth and multiplication of the bacilli, they form spores. Sporulation requires the presence of free oxygen. The spores are resistant to drying, heat, ultraviolet light, radiation, and most disinfectants. The spores can survive for many years in the soil. Spores are the predominant form in the environment and it is through the uptake of spores that anthrax is contracted.

**Environment :** There is clear evidence that anthrax is a seasonal disease. The occurrence of anthrax among animals in any one place is related to temperature and rains. However, the conditions which predispose to outbreaks differ widely from

location to location (4).

**Transmission :** Anthrax is a zoonosis. Though the bulk of infections occur in herbivores, carnivores are not immune to the disease. Cases among scavengers and other carnivores have been reported with infection occurring due to eating infected carcasses. The precise manner in which grazing animals become infected is not known. It is speculated that infection of the herbivorous animals occurs due to ingestion of the spores while grazing accompanied by minor trauma in the oral mucosa or other parts of the gastrointestinal tract due to chewing rough vegetation.

Human infections occur as a result of contact with diseased animals or animal products. The modes of transmission include direct inoculation of spores through breaks in the skin, inhalation of spores and ingestion of contaminated meat. Human-to-human transmission and laboratory acquired anthrax are extremely rare (6).

### Clinical Features

Anthrax can present in three different forms depending on the route through which the infection was acquired. Cutaneous anthrax occurs when the spores enter through a skin lesion, gastrointestinal tract anthrax is contracted from ingestion of contaminated food, and pulmonary (inhalation) anthrax from breathing in airborne anthrax spores. Another form is Anthrax meningitis.

**Cutaneous Anthrax :** This is the commonest form of presentation accounting for over 95% of all cases. The incubation period can be as short as 9 hours to as long as two weeks, but usually ranges from two to six days. Over a period of approximately ten days the cutaneous lesion which occurs at the site of entry of the spores, goes through the stages of a papule, ring of vesicles, ulceration and formation of a typical black eschar. The cutaneous lesion is non purulent and is typically painless. After ten days the eschar begins to resolve. The resolution of the eschar occurs over six weeks and is not hastened by treatment. Cutaneous anthrax is self limiting and in over 90% of cases resolution of the eschar takes place without complications. However, a small proportion of cases, if untreated, develop systemic anthrax (4, 6).

**Pulmonary Anthrax :** Inhalational anthrax usually occurring after the inhalation of spores from contaminated animal hides or products. Historical evidence indicates the role of individual susceptibility to infection as only a few cases on inhalational anthrax occurred among workers exposed occupationally to high concentration of viable anthrax spores (6). The onset of illness is usually non specific with fever, chills, non-productive cough, myalgia and malaise. After one to three days, the disease suddenly becomes hyperacute with dyspnoea, strident cough, cyanosis and disorientation culminating in death. Death may occur within hours of onset of symptoms. Case fatality rate can be over 80% even with aggressive antimicrobial therapy (4, 6, 7).

**Gastro - intestinal Anthrax :** Gastrointestinal anthrax can present in two clinical forms following ingestion of *Bacillus anthracis* in contaminated food. The incubation period ranges from two to five days following consumption of contaminated meat (8). Intestinal anthrax usually presents with nausea,



vomiting, fever, abdominal pain, haematemesis, diarrhoea and ascites. Overt gastrointestinal tract anthrax cases are often fatal, because they may remain unrecognized until it is too late for effective treatment. Oropharyngeal anthrax is characterized by sore throat, dysphagia, fever, regional lymphadenopathy in the neck and toxæmia. These cases are usually milder than the classic gastrointestinal disease and carry a more favourable prognosis.

**Anthrax Meningitis** : Haematogenous spread of the pathogen can take place from any form of anthrax. Meningitis due to anthrax is a serious development which carries close to 100% mortality. The patient shows clinical signs of meningitis. The meningitis of anthrax is haemorrhagic (9).

### Diagnosis

Cutaneous anthrax has the characteristic painless, blackened, necrotic eschar in the late stages of the infection. The early forms of the cutaneous lesion need to be differentiated from other papular lesions that present with lymphadenopathy. A high index of suspicion is required for a clinical diagnosis of gastrointestinal and inhalational anthrax. History of possible occupational exposure or consumption of contaminated meat must be sought.

Confirmation of diagnosis can be done by serology or bacteriological tests. Specific Enzyme - Linked Immunosorbent Assays (ELISAs) are available for anthrax antibodies. Detection indicates past infection or vaccination while a four fold rise in titre indicates recent infection (10, 11). Indirect Hemagglutination tests have also been developed (12, 13).

Blood cultures can also be used to confirm diagnosis. Bacilli can also be cultured from ascitic fluid, pleural fluid, and CSF. In cases of systemic anthrax infection blood cultures are almost always positive but patients often die before blood cultures are obtained. Cultures from skin lesions are not useful diagnostically (14).

Newer molecular techniques including the Polymerase Chain Reaction (PCR) are now available for diagnosis of Anthrax. These rapid methods may be useful because early diagnosis is crucial (15, 16).

### Treatment

Prompt and timely antibiotic therapy is essential results in complete recovery of cases of anthrax. *Bacillus anthracis* is highly sensitive to penicillin which is the antibiotic of choice. The pathogen is also sensitive to several other antibiotics including Chloramphenicol, Tetracyclines, Fluoroquinolones and Erythromycin. In most cases particularly inhalational and gastrointestinal anthrax, antibiotics must initially be administered intravenously.

During the bioterrorism attacks of 2001 in the United States, it was found that using two or more antibiotics intravenously improved survival (9). CDC protocols issued after the bioterrorism attacks recommend Ciprofloxacin 400mg BD or Doxycycline 100mg BD for a total of 60 days. The dose of Ciprofloxacin for children is 10 - 15 mg/Kg BD for 60 days (17). The treatment remains the same for pregnant women and immunocompromised individuals.

### Prevention and Control

Control of the disease in animals is the key to prevention of anthrax in humans. Vaccination of susceptible animals, correct disposal of carcasses of anthrax cases and proper disinfection, decontamination and disposal of contaminated materials will prevent exposure of humans to anthrax spores. In addition vaccination of persons at risk and chemoprophylaxis of those exposed can also be used for prevention.

Annual immunization of livestock herds is required to be carried out in endemic areas. Decontamination and disinfection of materials and surfaces suspected to be harbouring spores is difficult because the spores are highly resistant to common measures. Autoclaving, dry heat, formaldehyde, ethylene oxide, gamma irradiation and sodium hypochlorite solution can all be used for disinfection. Carcasses of suspected anthrax cases can be disposed by incineration or deep burial. Details pertaining to decontamination and disposal of contaminated material are given in reference 4.

**Vaccination** : Vaccination among humans should be restricted to those at risk, particularly those at occupational risk. Live spore vaccines are used in China and Russia. In Britain and the United States bacteria free aluminium hydroxide precipitated vaccine is licensed. A complex primary schedule of six vaccinations over an 18 month period is required followed by annual boosters. Newer vaccines including a plasmid DNA vaccine and vaccines for intranasal use are under development (2, 4, 9).

**Chemoprophylaxis** : The United States Army recommends Ciprofloxacin or Doxycycline for four weeks for unimmunized individuals. A longer duration of chemoprophylaxis is required for complete clearance of spores from the lungs (18).

### Summary

The word 'Anthrax' originates from Greek for black or coal because of the black eschar which is characteristic of the cutaneous form of Anthrax infection. Anthrax continues to be endemic in many parts of the world. Accurate figures on human anthrax in India are not available. The three southern states of Tamil Nadu, Andhra Pradesh and Karnataka have recorded at least 200 cases of human anthrax since the 1950s. *Bacillus anthracis* is a large, spore - forming, gram - positive bacillus with a diameter of 1.5  $\mu$ m and a length of 5  $\mu$ m. There are three anthrax toxins : the Edema Factor (EF), the Lethal Factor (LF) and a protective antigen. Only one strain is known. Spores are the predominant form in the environment and it is through the uptake of spores that anthrax is contracted. Human infections occur as a result of contact with diseased animals or animal products. The modes of transmission include direct Inoculation of spores through breaks in the skin, inhalation of spores and ingestion of contaminated meat. Anthrax can present in three different Cutaneous, Pulmonary and Gastrointestinal Anthrax. Confirmation of diagnosis can be done by serology or bacteriological tests or blood culture. Prompt and timely antibiotic therapy is essential which results in complete recovery of cases of anthrax. Penicillin is the antibiotic of choice. Control of the disease in animals is the key to prevention of anthrax in humans. Vaccination of susceptible animals, correct disposal of carcasses of anthrax cases and proper disinfection,



decontamination and disposal of contaminated materials will prevent exposure of humans to anthrax spores. Vaccination among humans should be restricted to those at risk, particularly those at occupational risk. Chemoprophylaxis recommended in the United States Army is Ciprofloxacin or Doxycycline for four weeks for unimmunized individuals.

## Study Exercises

**Long Question :** Discuss the epidemiology, treatment, prevention and control of Anthrax.

**Short Notes :** (1) Spectrum of clinical presentation of Anthrax (2) Prevention and control of Anthrax.

### MCQs

1. All are properties of *Bacillus anthracis* except (a) Gram - positive (b) Spore - forming (c) Non motile (d) Haemolytic
2. All are anthrax toxins Except (a) Edema Factor (EF) (b) Swelling Factor (SF) (c) Lethal Factor (LF) (d) Protective antigen
3. *Bacillus anthracis* is known to have how many strains (a) 1 (EF) (b) 2 (c) 3 (d) 4
4. Antibiotic of choice in treatment of Anthrax (a) Penicillin (b) Ciprofloxacin (c) Tetracyclines (d) Chloramphenicol
5. Commonest clinical form of presentation of Anthrax is (a) Pulmonary Anthrax (b) Gastrointestinal Anthrax (c) Cutaneous Anthrax (d) Anthrax Meningitis

**Answers :** (1) d; (2) b; (3)a; (4) a; (5) c.

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Tetanus is the only non communicable disease that is vaccine preventable (1). It is an infectious disease caused by infection with *Clostridium tetani*. Under favourable anaerobic conditions, the pathogen produces tetanospasmin, which is a potent neurotoxin. This toxin blocks inhibitory neurotransmitters in the central nervous system and causes the muscular stiffness and spasms typical of generalized tetanus (2). Despite a marked decrease in the occurrence of disease following the introduction of vaccination, the disease continues to be a important public health problem in many parts of the world, particularly in developing countries. Infection occurs through

spores of *Clostridium tetani* which are universally present in the soil. The disease can occur at any age but is particularly common and serious in newborn babies in the form of neonatal tetanus (3). Tetanus among adolescents and young adults usually occurs as result of infection through skin injuries.

### Epidemiology

The widespread use of a safe and effective vaccine has made the disease rare in the developed world. In developing countries, however, tetanus remains a major public health problem. The WHO estimated that the total number of tetanus deaths worldwide in 2002 was 213,000, of which neonatal tetanus was estimated to cause about 180,000 deaths and maternal tetanus about as 15,000 - 30,000 deaths (4). The global incidence of tetanus is estimated to be one million cases annually or 10 per 100,000 population. Mortality rates can be as high as 28 per 100,000 in developing countries as compared to less than 0.1

per 100,000 in North America (5).

A large majority of tetanus cases are birth - associated and occur in developing countries among newborn babies or in mothers following unclean deliveries and poor postnatal hygiene (4). Neonatal tetanus accounts for more than half of all tetanus cases in developing countries. The WHO aims to eliminate maternal and neonatal tetanus; MNT defined as less than one neonatal tetanus case per 1000 live births at district level per year. 47 countries have not been able to eliminate MNT as of December 2007 (6). In South East Asia, India, Bangladesh, Myanmar and Indonesia are yet to eliminate MNT.

Neonatal tetanus is one of the most under reported notifiable diseases. In 1995, over 5,500 cases of tetanus were reported from Uttar Pradesh, Madhya Pradesh, Rajasthan, Orissa, Bihar and Assam.

**Agent :** *Clostridium tetani* are gram positive bacilli that are obligate anaerobes. The organisms are sluggishly motile in fresh cultures. On maturity they lose their flagellae and develop a terminal spore which gives the characteristic drumstick appearance. The vegetative forms produce two exotoxins, tetanolysin and tetanospasmin (also called Tetanus Toxin). The role of tetanolysin in the pathogenesis of tetanus is unknown. Tetanospasmin is a neurotoxin and causes the clinical manifestations of tetanus. It diffuses from the wounds to local muscles and can also spread systemically through the blood and lymphatics. Weight for weight, tetanospasmin is one of the most potent toxins known. The estimated human lethal dose is less than 2.5 ng per kg (2).

Tetanus spores are extremely stable and can germinate into vegetative forms even after years. They are highly resistant to heat and most chemical disinfectants including ethanol, phenol, and formalin. They can be destroyed by iodine, glutaraldehyde, and hydrogen peroxide. Autoclaving at 121°C under 15 psi pressure also destroys the spores (1, 5). Tetanus spores are widely distributed in nature. They are found in the soil, human and animal faeces, and even on human skin.

**Host :** Tetanus can occur at any age. In developed countries tetanus is now largely a disease of the elderly. In the United States, the risk of tetanus increases with age (7). In developing countries, however, a large proportion occur among newborn babies or in mothers following unclean deliveries and poor postnatal hygiene. Tetanus in children and adults following injuries also constitutes a considerable public health problem. Neonatal tetanus in India is reported more in male children. This male preponderance may reflect a male bias for health care seeking rather than an actual male predilection (8). In India, neonatal tetanus shows distinct seasonal variation with the largest number of cases being reported during the monsoons and post - monsoon period.

**Transmission :** The ubiquitous nature of tetanus spores makes it possible for them to enter the body through any form of injury. Neonatal tetanus results from unclean deliveries and the application of contaminated material on the umbilical stump. In children and adults tetanus can result from both acute wounds and chronic infections. Puncture and deep wounds are more likely to result in tetanus rather than superficial abrasions.

## Clinical Features

The incubation from the entry of spores to the onset of clinical manifestations can vary from 3 to 21 days, but is usually between six and eight days. Usually, the further the injury site is from the central nervous system, the longer the incubation period. The severity of disease is inversely related to the duration of the incubation period. The shorter the incubation period, the higher the chance of death. In neonatal tetanus, the average incubation period is about 7 days with a range of 4 - 14 days (1, 9). Tetanus can be classified into four forms based on clinical presentation.

**Generalized Tetanus :** This is the most common form of presentation. The earliest sign of the disease is usually a spasm of the jaw muscles (lockjaw) and a grimace like appearance of the face (*Risus Sardonicus*). As the symptoms progress, there is spasm of the muscles of the abdomen, neck, back and thorax. In severe cases tonic seizures can occur. A characteristic feature is that the patient does not lose consciousness during the spasms. The spasms can be triggered by external stimuli. Patients may also have elevated temperature, sweating, hypertension and tachycardia. Spasms may continue for over three weeks and complete recovery may take months.

**Localized Tetanus :** This is a less common form of the disease. There is stiffness and rigidity of the muscles around the site of infection. Recovery is usually spontaneous. Only about 1% of cases are fatal. However, at times, localized rigidity may be a prodrome of generalized tetanus.

**Cephalic Tetanus :** This is a rare form of the localized disease and is generally associated with lesions on the head or face. Involvement of cranial nerves is a characteristic feature of this form of tetanus.

**Neonatal Tetanus :** This is the form of generalized tetanus occurring in neonates. Generalized weakness followed by an inability to suckle are the common manifestations. WHO considers any neonate with normal ability to suck and cry during the first 2 days of life and who, between 3 and 28 days of age, cannot suck normally and becomes stiff or has spasms (i.e. jerking of the muscles) as a confirmed case of neonatal tetanus (6).

## Diagnosis

Diagnosis of tetanus is usually based on history and clinical signs and symptoms rather than laboratory findings. A bedside diagnostic test called the 'Spatula Test' with very high specificity and sensitivity has been proposed from India (10). Isolation of *Clostridium tetani* from can neither confirm nor exclude the diagnosis. The pathogen is often isolated from wounds among patients who do not have the disease and even carefully performed anaerobic cultures are negative even from contaminated wounds. The only condition which mimics tetanus closely is strychnine poisoning. Serology also has little value as antibody levels even in the protective range do not rule out disease (1, 5).

## Treatment

Local wound management, supportive therapy particularly airway maintenance and passive immunization are the main

requirements of management of cases of tetanus. All wounds should be cleaned and adequate debridement carried out. The course of the disease, however, is not altered by wound debridement. *Clostridium tetani* is sensitive to several antibiotics including Penicillin, Tetracycline and Metronidazole. Antibiotics may eliminate the organism and consequently prevent further production of toxin. Airway maintenance may require an endotracheal tube or even a tracheostomy. Sedation is the mainstay of symptomatic treatment. Intravenous Diazepam or Lorazepam may be required for control of the spasms.

**Immunization** : Passive immunization with Human Tetanus Immunoglobulin (HTIG) is required to neutralize unbound tetanus toxin. Doses ranging from 500 units to 3000 - 6000 units have been recommended by various experts (11). Intrathecal HTIG was earlier used for neonatal tetanus, but has now been shown to be ineffective. As the amount of tetanus toxin released during infection is inadequate to produce an effective immune response, all patients of tetanus should also be given active immunization.

### Prevention and Control

Active immunization against tetanus is the cornerstone of prevention and control of tetanus. Mass education campaigns and training of birth attendants to ensure hygienic and safe deliveries are also important measures for prevention of neonatal tetanus.

**Active Immunization** : Tetanus toxin is inactivated by formaldehyde to form tetanus toxoid. The toxoid has been used as a Monovalent Vaccine (TT) to immunize adults, or as a component of combined Diphtheria - Tetanus - Pertussis (DTP) vaccine or Diphtheria - Tetanus (DT) vaccine for immunization of children. Several other combinations like combined Tetanus diphtheria (Td) vaccine for adults and a Tetanus - diphtheria - acellular Pertussis (Tdap) combination are also available. Adsorption of tetanus toxoid onto aluminium salts increases its antigenicity (2). Tetanus toxoid can withstand exposure to temperatures of around 20°C for months and storage at 37°C for a few weeks without significant loss of potency. The vaccine should be stored at 2 - 8°C. Vaccines that have been frozen should not be used (4).

WHO recommends a childhood tetanus immunization schedule of five doses. In India, the primary series of three doses of DTP are given at six, ten and fourteen weeks followed by a booster between 16 and 24 months of age. Another booster of the DT vaccine is given at the school going age, while boosters of TT are given at 10 years and 16 years of age.

Pregnant women with an inadequate or unknown immunization history should always receive 2 doses of tetanus toxoid - containing vaccine : the first dose as early as possible during pregnancy and the second dose at least 4 weeks later (4).

In cases of injury a dose of tetanus toxoid vaccine may be given depending on the severity of the injury and on the reliability of the history of previous tetanus vaccinations. The vaccine should be given if the last dose was administered more than 10 years ago (or 5 years in the case of severe injuries) (4).

## Summary

Tetanus is the only non communicable disease that is vaccine preventable. Despite a marked decrease in the occurrence of disease following the introduction of vaccination, the disease continues to be an important public health problem in many parts of the world, particularly in developing countries. The WHO estimated that the total number tetanus deaths worldwide in 2002 were 213,000. The global incidence of tetanus is estimated to be one million cases annually or 10 per 100,000 population. The WHO aims to eliminate maternal and neonatal tetanus; MNT defined as less than one neonatal tetanus case per 1000 live births at district level per year. In South East Asia, India, Bangladesh, Myanmar and Indonesia are yet to eliminate MNT. *Clostridium tetani* are gram positive bacilli that are obligate anaerobes. The vegetative forms produce two exotoxins, tetanolysin and tetanospasmin. The ubiquitous nature of tetanus spores makes it possible for them to enter the body through any form of injury. The incubation from the entry of spores to the onset of clinical manifestations can vary from 3 to 21 days, but is usually between six and eight days. The severity of disease is inversely related to the duration of the incubation period. The shorter the incubation period, the higher the chance of death. Tetanus can be classified into four forms based on clinical presentation they are Generalized Tetanus, Localized Tetanus, Cephalic Tetanus and Neonatal Tetanus. Diagnosis of tetanus is usually based on history and clinical signs and symptoms rather than laboratory findings. A bedside diagnostic test called the 'Spatula Test' has a very high specificity and sensitivity. Local wound management, supportive therapy particularly airway maintenance and passive immunization are the main requirements of management of cases of tetanus. Passive immunization with Human Tetanus Immunoglobulin (HTIG) is required to neutralize unbound tetanus toxin. Active immunization against tetanus is the cornerstone of prevention and control of tetanus.

## Study Exercises

**Long Question** : Discuss the epidemiology, treatment, prevention and control of Tetanus.

**Short Notes** : (1) Forms of clinical presentation of Tetanus  
(2) Active Immunization against Tetanus

### MCQs

- The global incidence of tetanus is estimated to be (a) 1 per 100,000 population (b) 10 per 100,000 population (c) 100 per 100,000 population (d) None of the above
- In South East Asia, following country has eliminated Maternal and Neonatal Tetanus (a) India (b) Bangladesh (c) Myanmar (d) None of the above
- In neonatal tetanus, the average incubation period is about (a) 4 days (b) 7 days (c) 11 days (d) 15 days
- This is the most common form of clinical presentation of tetanus (a) Localized Tetanus (b) Generalized Tetanus (c) Cephalic Tetanus (d) Neonatal Tetanus
- The only condition which mimics tetanus closely is (a) Strychnine poisoning (b) Botulism Poisoning (c) Rabies (d) None of the above

**Answers** : (1) b; (2) d; (3) b; (4) b; (5) a.



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## Plague

Rajesh Vaidya

Plague is one of the oldest diseases known to man (1). It is primarily a zoonotic disease that exists in nature between small mammals, usually wild rodents, and the fleas that they harbour (2). Plague is endemic in many parts of the world and exists in many small natural foci. It is widely distributed in the tropics and subtropics and in warmer areas of temperate countries. The causative bacteria, *Yersinia pestis* can also infect humans. It is transmitted between animals and humans by the bite of infected fleas, direct contact, inhalation and rarely, ingestion of infective materials. Untreated plague can be a very serious disease with case fatality rates between 30% and 60% (3). Recent outbreaks have shown that plague may recur in areas that have long remained silent (1).

Plague has been known as a dreaded killer from times immemorial. The first pandemic, also called the *Justinian plague* took place in the sixth century and is reputed to have killed nearly a hundred million victims. The second plague pandemic is known as the "Black Death" of the fourteenth century which caused 50 million deaths. A quarter of the population of Europe is said to have been wiped out by this pandemic. The third pandemic began in Hong Kong in 1894. Within 10 years this pandemic had spread to all the continents. This pandemic resulted in 13 million deaths in India (1, 4). During the third pandemic, the causal agent, *Yersinia pestis* was discovered in 1894.

### Epidemiology

**Global** : The number of cases of human plague reported to the World Health Organization has remained stable in the recent past. The WHO believes that the number of cases officially notified is considerably lower than the actual number (5). Plague exists in natural enzootic cycles involving wild rodents and their fleas in several parts of the world. These natural cycles are usually hidden with no transmission to humans.

Epidemics of plague occasionally occur when the disease spreads from wild rodents to rats that live in close proximity of human habitation.

Between 1989 and 2003, a total of 15 year period, 38, 310 cases with 2845 deaths were recorded in 25 countries. In these 15 years the highest number of human plague cases was reported in 1991 and the lowest number 1989. Eight countries reported human plague almost every year. These countries were the Democratic Republic of the Congo, Madagascar and the United Republic of Tanzania in Africa; Peru and the United States in the Americas, and China, Mongolia and Viet Nam in Asia. An increase in the incidence of human plague has become apparent since the early 1990s, particularly in Africa. Three geographical areas experienced outbreaks of human plague after silent periods of about 30 - 50 years : India in 1994, Indonesia in 1997 and Algeria in 2003 (5 - 7). The total number of human plague cases reported to WHO in 2002 was 1925, of which 177 were fatal. In 2003, nine countries reported 2,118 cases and 182 deaths. 98.7% of those cases and 98. 9% of those deaths were reported from Africa. Today the distribution of plague coincides with the geographical distribution of its natural foci (3, 5).

**India** : India suffered very large number of deaths during the third Plague pandemic. Plague outbreaks continued to occur, but with decreasing frequency during the first half of the 20th century. This is often attributed to the collateral benefit from the extensive insecticide spraying done as a part of the National Malaria Programme. India remained plague free for almost 30 years after the last human case was reported from Karnataka in 1966.

In August - October 1994 human plague was reported in India. During this outbreak, 876 cases with 54 deaths were characterized as presumptive plague. Most cases were reported from Maharashtra (596), 151 from Gujarat, 68 from Delhi, 50 from Karnataka, 12 from Madhya Pradesh, and 10 from Uttar Pradesh. Almost all the deaths were reported from Gujarat. Several reasons have been put forth to explain this outbreak. Rat - fall was first reported from Mamla village in the Beed district of Maharashtra on 5 August 1994. This was followed



by reports of flea nuisance. Three weeks later, suspected cases of bubonic plague were reported from Mamla village followed by reports from other villages in Beed and other districts. Beed has had sylvatic plague in the past. Ecological changes created by the earthquake in September 1993 and large scale storage of foodgrains probably contributed to a gradual growth of the rat population. The resurgence of plague in Surat, Gujarat, was related to a record high rainfall during the September monsoon. Floods in the Tapi river resulted in inundation of large areas. Many rodents were found dead when the water floods receded. Based on the clinical picture and the plague outbreak in neighbouring Maharashtra the outbreak in Surat was declared as pneumonic plague on 21 September 1994 (1, 8 - 12). In February 2002, an outbreak of pneumonic plague (16 cases, 4 deaths) occurred in Hat Koti village, Shimla district, Himachal Pradesh. The outbreak is believed to have started after a person acquired the infection in the forest, which then spread to others through person - to - person contact (5). Since 2002 there has been no confirmed case of plague in India.

**Agent:** *Yersinia pestis* is a gram - negative coccobacillus. *Yersinia* was formerly classified in the family *Pasteurellaceae*, but has been now reclassified as members of the *Enterobacteriaceae* family. Though there are 11 species in the genus *Yersinia*, only three are considered important human pathogens. The bacteria is small (1.0 to 2.0  $\mu\text{m}$  x 0.5  $\mu\text{m}$ ), pleomorphic and is seen as single cells or short chains in direct smears. They are nonmotile, nonsporulating, non - lactose fermenting facultative anaerobes (13 - 15).

**Vector:** *Yersinia pestis* is most commonly transmitted between animal reservoirs and to humans through the bites of infected fleas. There are more than 1, 500 flea species, of which about 30 are known to be vectors for *Yersinia pestis*. The major flea vectors include the following (15) :

- (a) *Xenopsylla cheopis* (the oriental rat flea; nearly worldwide in moderate climates)
- (b) *Oropsylla montanus* (United States)
- (c) *Nosopsyllus fasciatus* (nearly worldwide in temperate climates)
- (d) *Xenopsylla brasiliensis* (Africa, India, South America)
- (e) *Xenopsylla astia* (Indonesia and Southeast Asia)
- (f) *Xenopsylla vexabilis* (Pacific Islands)

To be an efficient plague vector, the flea must be able to ingest the *Yersinia pestis* with its blood meal. It must also live long enough for the pathogen to multiply in sufficiently large numbers. It must be able to transfer the pathogen to an animal or human host in sufficient concentrations to cause an infection. *Xenopsylla cheopis* is the most important vector of plague. A high incidence of plague infected *Xenopsylla cheopis* in a given focus, greatly increases the risk of transmission to humans (1). *Pulex irritans*, the human flea may be responsible for human to human transmission of Plague (1, 16).

**Host Factors:** More than 200 mammalian species have been known to be naturally infected with *Yersinia pestis*. However, plague is primarily a disease of rodents. The infection is maintained in natural foci of the disease in wild rodent colonies through transmission between rodents. The animal hosts of plague are classified as enzootic (maintenance) hosts

and epizootic (amplification) hosts (1). Enzootic hosts are characterized by relatively mild illness, and low mortality rates. Voles and mice have been suggested as maintenance hosts. Epizootic rodents are associated with susceptibility and high mortality. Highly susceptible or epizootic plague hosts include various species of mice, rats, voles, gerbils, ground squirrels and marmots. Rats have historically been a primary carrier of plague (1, 15, 17 - 20).

**Transmission:** The most common mode of transmission of *Yersinia pestis* to humans is by the bite of infectious fleas. Other, less common modes of transmission include direct contact with infectious body fluids or tissues while handling an infected animal or inhaling infectious respiratory droplets (13). The mode of entry of the organism has marked clinical significance.

### Clinical Features

Infection by *Yersinia pestis* causes a severe febrile illness characterized by headache, myalgia, malaise, shaking chills, prostration and gastrointestinal symptoms. The three commonest clinical presentations of plague are bubonic, septicemic and pneumonic (1, 13, 15). Less common forms of plague include pharyngeal and meningial plague.

**Bubonic Plague:** For bubonic plague the mode of entry of the organism is by a flea bite. The infection spreads via the lymphatics to the regional lymph nodes causing inflammation and swelling in one or several nodes forming the classic buboes. Buboes may occur in any regional lymph node sites including inguinal, axillary and supraclavicular. After an incubation period of two to six days, a patient experiences sudden onset of illness characterized by headache, chills, fever, malaise and pain in the affected regional lymph nodes. Progression of symptoms is usually rapid with the regional lymphadenitis becoming tender and painful. With specific treatment in uncomplicated cases, fever and general clinical symptoms usually resolve over three to five days.

**Septicemic Plague:** Septicemic plague occurs when *Yersinia pestis* invades and continues to multiply in the bloodstream. It can occur secondarily to bubonic plague or can develop without detectable lymphadenopathy. The host response may result in a wide spectrum of pathological events including disseminated intravascular coagulopathy, multiple organ failure and adult respiratory distress syndrome. Complications include plague pneumonia, plague meningitis and hepatic or splenic abscesses.

**Pneumonic Plague:** Pneumonic plague is the least common but most dangerous and fatal form of the disease. It can develop as a secondary complication of septicemic plague or result from inhalation of infectious droplets. The incubation period is usually varies from one to three days. There is sudden onset of chills, fever, headache, body pains, weakness and chest discomfort. This progresses rapidly to severe pneumonia accompanied by high fever, dyspnea, and often haemoptysis. If specific antibiotic therapy is not begun within 18 - 24 hours of onset, the patient is unlikely to survive. Pneumonic plague must be considered highly contagious, although person - to - person transmission is most likely in cold humid environments coupled with overcrowding. As the transmission occurs through

infected droplets (and not airborne droplet nuclei), person - to - person transmission requires close contact.

### Differential Diagnosis

Differential diagnosis of bubonic plague includes bacterial lymphadenitis, infectious mononucleosis, lymphatic filariasis, tick typhus, tularemia and other causes of acute lymphadenopathy. Involvement of intra - abdominal lymph nodes may mimic appendicitis or acute cholecystitis. Pneumonic plague may be confused with other causes of acute, severe community - acquired pneumonia, such as pneumococcal, streptococcal or *Haemophilus influenzae* pneumonia (1).

### Diagnosis

Plague is diagnosed clinically based on exposure history and the symptoms of the patient. Presence of the classical buboes leads to suspicion of plague. Septicaemic plague resembles other gram - negative septicemias and is, therefore more difficult to diagnose on clinical grounds. Pneumonic plague can similarly be mistaken for other pneumonias. If possible, samples for confirmation of plague should be taken before treatment is begun. However, treatment should not be delayed by waiting for the laboratory results (15). Collection and transport of specimens is dealt with in detail in a separate chapter.

Routine blood tests show Leucocytosis with a predominance of neutrophils. Total WBC counts may be as high as 25,000/ml. The degree of leucocytosis is proportional to the severity of illness. Peripheral blood smear may show toxic granulations. Thrombocytopenia is common (21). The laboratory diagnosis of plague is based on bacteriological and/or serological evidence. Diagnostic specimens for smear and culture include whole blood, sputum, aspirates from suspected buboes, pharyngeal swabs and cerebrospinal from suspected plague meningitis cases (1). Smears stained with Gram, Giemsa, Wright, or Wayson stain can provide supportive but not confirmatory evidence of a plague infection in the form of bipolar staining Gram - negative bacilli.

The diagnosis of plague is confirmed by the culture of *Yersinia pestis* from body fluids or tissues. *Yersinia pestis* grows on solid media as grey - white, translucent colonies, usually too small to be seen as individual colonies at 24 hours. After incubation at 37°C for 48 hours, colonies are about 1 - 2mm in diameter. After 48 - 72 hours of incubation colonies are raised and have an irregular appearance. Cultures are definitely identified as *Yersinia pestis* by specific phage lysis (1, 22). Plague can be also be confirmed serologically by a four - fold or greater change in titre to the *Yersinia pestis* F1 antigen by passive haemagglutination testing of paired serum specimens. The specificity of a positive passive haemagglutination test can be confirmed by the F1 antigen haemagglutination - inhibition test. Some patients of plague seroconvert as early as five days after onset of symptoms, most seroconvert between one and two weeks after onset, while a few seroconvert three weeks or more after onset. Less than 5% do not seroconvert. After seroconversion, positive serological titres usually diminish gradually over months to years. Enzyme - Linked ImmunoSorbent Assays (ELISAs) for detecting IgM and IgG antibodies may also be used for diagnosis. Detection of the F1 antigen in tissues or fluids by direct fluorescent antibody testing

provides presumptive evidence of plague (1, 15). In the recent past rapid diagnosis of plague has become available using the F1 antigen diagnostic assays based on dipsticks. These tests make a bedside diagnosis available within 15 minutes using bubo aspirate, serum and urine specimens (23).

### Treatment

When a diagnosis of human plague is suspected, appropriate specimens for diagnosis should be taken immediately and the patient should be started on specific antibiotic treatment without waiting for laboratory confirmation. All patients suspected of having bubonic plague should be placed in isolation until 2 days after starting antibiotic treatment. Suspect plague patients with evidence of pneumonia should be placed in isolation and managed under respiratory droplet precautions.

Streptomycin is the drug of choice. The dose of streptomycin is 30 mg/Kg/day (Not more than of 2 g/day) in divided doses given intramuscularly. Streptomycin must be given for a full course of 10 days or until 3 days after the temperature has returned to normal. Chloramphenicol is a suitable alternative. The dose of chloramphenicol is 50 mg/Kg/day administered in divided doses either parenterally or orally for 10 days. Tetracyclines are effective in the primary treatment of patients with uncomplicated plague. An oral loading dose of 15 mg/Kg tetracycline (not to exceed 1 g total) should be followed by 25 - 50 mg/Kg/day (up to a total of 2 g/day) for 10 days. Tetracyclines may also be used adjunctively with other antibiotics. Fluoroquinolones, such as ciprofloxacin are also effective (1, 15, 21).

### Prophylaxis

Close contacts of cases with pneumonic plague, or persons suspected to have had direct contact with body fluids or tissues of a *Yersinia pestis* - infected mammal, or exposed during a laboratory accident to known infectious materials should receive prophylactic antibiotics if the exposure was in the previous six days. Tetracycline and chloramphenicol are the antibiotics of choice for prophylaxis (1).

### Prevention and Control

Control of transmission is directed at controlling the rodent reservoirs and flea vectors of the disease. Trying to eliminate fleas and wild rodents from the natural environment in plague - infected areas are impractical. However, controlling rodents and their fleas around places where they are in close proximity of human beings is very important. Environmental sanitation and public health education are effective means of achieving these ends. Rodent and flea control measures are discussed in detail in the relevant Chapters in the section on Entomology.

**Surveillance** : An effective surveillance system to provide early warning can abort epidemics. Effective plague prevention and control programmes require up - to - date information on the incidence and distribution of the disease. The surveillance programme must be designed to collect, analyse, and interpret clinical, epidemiological, and epizootiological data on plague. Surveillance should identify cases and epizootics as quickly as possible so that steps can be taken to control disease spread (1). Surveillance must include reporting of human cases, ecological and environmental observations, and surveillance of rodent populations. Readers may refer to the WHO Plague Manual

(1) for details on human and rodent surveillance including precautions to be observed by health care workers.

**Flea Indices :** The most basic information obtained from flea and rodent surveys is the number of fleas of different species found on various species of hosts. This raw data can be used to calculate various indices. The important flea indices in use are (1) :

$$\text{Total Flea index} = \frac{\text{Total number of fleas collected (regardless of species)}}{\text{Total number of host species examined}}$$

$$\text{Specific Flea Index} = \frac{\text{Number of fleas of species 'A' collected from host species}}{\text{Number of individuals of host species examined}}$$

(Multiplication of this index by 100 gives the percentage index).

$$\text{Percentage of hosts infested} = \frac{\text{Number of host species infested with flea species}}{\text{Total number of host species examined}} \times 100$$

$$\text{Burrow (or nest or house) index} = \frac{\text{Number of Flea species collected from burrows (or nest or house) of host species}}{\text{Total number of burrows (or nest or house) of host species examined}}$$

The specific flea index is the most widely used of the above indices. It has been reported that a specific flea index of greater than 1 for *Xenopsylla cheopis* on rats represents a potentially dangerous situation with respect to increased plague risk for humans.

**Vaccination :** Plague vaccines were widely used in the past but have not proven effective in the control of plague. Both live attenuated and formalin - killed *Yersinia pestis* vaccines have been developed. The vaccines are variably immunogenic and moderately to highly reactogenic. They do not protect against primary pneumonic plague. Vaccination is of little use during human plague outbreaks, since a month or more is required to develop a protective immune response. Vaccines are, therefore, not recommended for immediate protection in outbreak situations. Vaccination is only recommended as a prophylactic measure for high - risk groups like laboratory personnel who are constantly exposed to the risk of contamination (1,16,24).

The killed or inactivated plague vaccine is prepared from *Yersinia pestis* organisms grown in artificial media and then inactivated in formaldehyde. It is administered intramuscularly as a series of three primary doses. The initial dose of 1 ml is followed 1 to 3 months later by a 0.2 ml dose. A third primary injection of 0.2 ml is given 5 to 6 months after the second. Two booster doses of 0.2 ml are administered at 6 - month intervals, and additional boosters may be given every 1 to 2 years (15). Adverse reactions following injection of the first dose of plague vaccine generally are mild, but the frequency and severity of such events can increase with repeated doses. Live *Yersinia*

*pestis* vaccines composed of presumably avirulent strains also have been developed. However, none of these vaccines is commercially available, and their safety and efficacy have not been adequately tested (13, 25).

## Summary

Plague is one of the oldest diseases known to man. The first plague epidemic has been described in the Bible as the outbreak among the Philistines in 1320 BC. The causal agent, *Yersinia pestis* was discovered in 1894. Plague exists in natural enzootic cycles involving wild rodents and their fleas in several parts of the world. These natural cycles are usually hidden with no transmission to humans. Between 1989 and 2003, a total of 15 year period, 38, 310 cases with 2845 deaths were recorded in 25 countries including India. *Yersinia pestis* is nonmotile, nonsporulating, non - lactose fermenting, gram - negative coccobacillus. *Yersinia pestis* is most commonly transmitted between animal reservoirs and to humans through the bites of infected fleas. There are more than 1, 500 flea species, of which about 30 are known to be vectors for *Yersinia pestis*. Plague is primarily a disease of rodents. The infection is maintained in natural foci of the disease in wild rodent colonies through transmission between rodents. The most common mode of transmission of *Yersinia pestis* to humans is by the bite of infectious fleas. The three commonest clinical presentations of plague are bubonic, septicemic and pneumonic. Plague is diagnosed clinically based on exposure history and the symptoms of the patient. The laboratory diagnosis of plague is based on bacteriological and/or serological evidence. Smears stained with Gram stain can provide supportive but not confirmatory evidence in the form of bipolar staining Gram - negative bacilli. The diagnosis of plague is confirmed by the culture of *Yersinia pestis* from body fluids or tissues. In the recent past rapid diagnosis of plague has become available using the F1 antigen diagnostic assays based on dipsticks. These tests make a bedside diagnosis available within 15 minutes using bubo aspirate, serum and urine specimens. All patients suspected of having bubonic plague should be placed in isolation until 2 days after starting antibiotic treatment. Streptomycin is the drug of choice. The dose of streptomycin is 30 mg/Kg/day (Not more than of 2 g/day) in divided doses given intramuscularly. Close contacts of cases with pneumonic plague should receive prophylactic antibiotics if the exposure was in the previous six days. Tetracycline and chloramphenicol are the antibiotics of choice for prophylaxis. Control of transmission is directed at controlling the rodent reservoirs and flea vectors of the disease. An effective surveillance system to provide early warning can abort epidemics. The surveillance programme must be designed to collect, analyse, and interpret clinical, epidemiological, and epizootiological data on plague. Plague vaccines were widely used in the past but have not proven effective in the control of plague. Vaccines are, therefore, not recommended for immediate protection in outbreak situations.

## Study Exercises

**Long Question :** Discuss the epidemiology, treatment, prevention and control of Plague

**Short Notes :** (1) Spectrum of clinical presentations of plague  
(2) Characteristics of efficient plague vector (3) Flea Indices



### MCQs

1. *Yersinia pestis* was first discovered in (a) 1893 (b) 1894 (c) 1895 (d) 1896
2. Number of species in the genus *Yersinia* considered important human pathogens (a) 1 (b) 3 (c) 5 (d) 7
3. Human flea responsible for human to human transmission of Plague (a) *Pulex irritans* (b) *Oropsylla montanus* (c) *Nosopsyllus fasciatus* (d) *Xenopsylla vexabilis*
4. Epizootic hosts are all except (a) Amplification hosts (b) Maintenance hosts (c) Highly susceptible (d) Have high mortality
5. \_\_\_\_\_ Plague is the least common but most dangerous (a) Septicaemic plague (b) Bubonic plague (c) Pneumonic plague (d) None of the above
6. Drug of choice for treatment of plague (a) Tetracyclines (b) Chloramphenicol (c) Ciprofloxacin (d) Streptomycin
7. Antibiotics of choice for prophylaxis (a) Tetracyclines (b) Rifampicin (c) Ciprofloxacin (d) Streptomycin
8. Specific flea index of greater than \_\_\_\_\_ for *Xenopsylla cheopis* on rats represents a potentially dangerous situation (a) 1 (b) 2 (c) 3 (d) 4

**Answers :** (1) b; (2) b; (3) a; (4) b; (5) c; (6) d; (7) a; (8) a.

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The word 'Rabies' has its origin in Sanskrit, "*rabhas*" means "to do violence". The Greek word for rabies, "*lyssa*" derives from the root "*lud*" which means "violent". Rabies is an acute viral disease, which causes encephalomyelitis in virtually all the warm blooded animals, including man. The causative agent is found in domestic and wild animals and is transmitted to

other animals and humans through close contact with their saliva (bites, scratches, licks on broken skin, and mucus membranes).

### Epidemiology

**Magnitude of the problem** : Rabies is enzootic in animal in more than 100 countries with a population of over 3.3 billion. Approximately 55,000 people die from rabies each year, the vast majority of these deaths occurring in Asia and Africa. In Africa, there are estimated at 24,000 (or 4 per 1,00,000 population) deaths annually. More than 10 million people, mostly in Asia, receive post exposure vaccination against rabies every



year (1). In India alone, 20,000 deaths are estimated to occur annually, i.e. 2 per 1,00,000 population. Almost 1.8 million people annually receive post exposure - prophylaxis against rabies. With the exception of Andaman & Nicobar islands and Lakshadweep islands, human cases of rabies are reported from all over the country round the year (2).

**Agent** : The Rabies viruses belong to the genus *Lyssavirus* of the *Rhabdoviridae* family. Currently, this genus comprises seven genotypes, type 1 of which represents the classic rabies virus. This RNA virus is bullet shaped round at one end and flat at the other measuring 100 - 300 nm in length and 75 nm in diameter. The virus is covered with a lipid envelope having spike like projections.

The rabies virus is highly resistant to cold, and dryness. The virus is highly thermolabile with a half life of approximately 4 hours at 40°C and 35 seconds at 60°C. In brain tissue, it can survive up to 1 - 2 weeks at room temperature (1). The rabies virus remains stable for several days at 0 - 4°C, indefinitely at (-) 70°C and when freeze dried. The virus cannot withstand pH less than 4 or more than 10. It is also susceptible to the action of oxidizing agents, most organic solvents, surface acting agents and quaternary ammonium compounds. Proteolytic enzymes and UV rays rapidly inactivate the rabies virus. Soaps and detergents are effective against rabies virus because of their lipid eliminating property, which destroy the outer covering of the virus (3, 4).

**Host factors** : Although all age groups are susceptible, rabies is most common in children aged below 15 years, with 30 - 50% of post - exposure prophylaxis given to children aged 5 - 14 years, the majority being male (3).

**Transmission** : Human infection usually occurs following a transdermal bite or scratch by an infected animal. Transmission may also occur when infectious material, usually saliva, comes into direct contact with the victim's mucosa or with fresh skin lesions. The virus cannot cross intact skin. Very rarely, rabies may occur through inhalation of virus - containing aerosol or via infected organ transplants. In developing countries, dog bites account for over 90% of cases. Wild animals like jackals, fox, or hyena may also be a source of infection. In developed countries, rabies due to domestic animal bites is rare. Most cases are due to contact with wild animals such as raccoons or skunks. Bat rabies is reported from Latin American countries like Brazil, Venezuela and Mexico, Southern United States and parts of Europe including Germany, Denmark, and Holland.

Incubation periods for Rabies have been reported from as short as four days to as long as 19 years. The usual duration is between 20 to 90 days. 95% cases have incubation period less than one year. The duration of the incubation period may depend on the severity of bite, quantity of virus inoculated, innervation of the bitten area and distance from CNS (3).

### Pathogenesis

On entering the human body, the virus then either replicates in non - nervous tissues or directly enters peripheral nerves and travels by retrograde axoplasmic flow to the central nervous system (CNS). The estimated speed of virus migration is 15 - 100 mm per day. The virus then moves from the CNS via anterograde axoplasmic flow within peripheral nerves, leading

to infection of some of the adjacent non - nervous tissues like secretory tissues of salivary glands. The virus is widely disseminated throughout the body at the time of clinical onset (4).

### Clinical Features

Prodromal symptoms of rabies are non specific and may last for 2 to 10 days. Malaise, headache, anorexia may be present along with fever, cough, chills, and sore throat. Some patients may have gastro - intestinal symptoms like abdominal pain, nausea and diarrhoea (3). The first rabies specific symptom is pain or paraesthesia referred to the site of exposure which is present in about 50% of cases. Major clinical signs are related to the virus - induced encephalomyeloradiculitis. The acute neurological period shows objective signs of CNS involvement. Two major clinical presentations are observed : furious and paralytic forms that cannot be correlated with any specific anatomical localization of rabies virus in the CNS. In furious rabies there is hyperactivity, disorientation, and hallucinations. The patient may have periods of agitation alternating with periods of calm. Attempts at drinking result in spasm of pharynx, larynx, and diaphragm. Similar effects may occur even on seeing water or blowing air on the face (Aerophobia). Eventually there may be abrupt death or paralysis develops. Paralytic rabies is present in about 20% of cases from onset. The paralysis is maximal in bitten extremity, diffuse or symmetric. The final stage of coma almost always begins within 10 days. Death may occur due to respiratory arrest soon after onset of coma. In cases the patient survives for a few days complications like raised ICT, cardiac arrhythmias, hypotension, and renal failure may be seen. Rabies is invariably fatal (3).

### Diagnosis

A diagnosis of rabies can be made on clinical grounds if reliable history of exposure is available or specific signs like hydrophobia or aerophobia are present. There are no laboratory tests to diagnose the infection before onset of clinical disease. Fluorescent Antibody detection in skin biopsy (from neck) can be done for confirmation of diagnosis. Post mortem tests include demonstration of 'Negri Bodies' and isolation of virus. It is important to distinguish rabies from treatable conditions to ensure protection of health care workers, prevent rabies hysteria / psychosis. It is also essential to distinguish rabies from post vaccinal encephalomyelitis caused by the nerve tissue vaccine (5, 6, 7).

### Treatment

Rabies is invariably fatal once symptoms develop. Treatment discussed later in the chapter focuses on animal exposures where rabies transmission is a possibility.

### Prevention and Control

The essential measures required for the control of rabies are eliminating the diseases in domestic animals like dogs and immunoprophylaxis for humans.

### Rabies Vaccines

**Nerve Tissue Vaccine (NTV)** : More than 100 years ago, Louis Pasteur and his colleagues developed the first crude rabies vaccine for post - exposure prophylaxis based on attenuated virus in desiccated nerve tissue. Although continuously

improved over the years, inactivated NTVs produced in the brains of sheep or goats (Semple) or suckling mice (Fuenzalida) are associated with neurological adverse reactions. In about 0.3 - 0.8 individuals per 1000 vaccinees, contaminating neuroproteins present in the vaccine cause severe allergic encephalomyelitis. India and Nepal have successfully phased out production and use of NTVs (1, 3).

**Cell Culture Vaccines (CCV)** : CCVs consist of virus that has been inactivated following propagation in cell cultures the human diploid cell vaccine was introduced in 1967. The more recently developed, and less expensive, purified chick embryo cell vaccine and purified Vero cell - based vaccines have characteristics comparable to the human diploid cell vaccines. CCVs are based on fixed viruses of genotype 1.

Factors that should be taken into consideration when deciding whether or not to initiate post exposure prophylaxis include the likelihood of the concerned animal being rabid, category of exposure (I - III), clinical features of the animal, as well as its availability for observation and laboratory testing. In most situations in developing countries, the vaccination status of the offending animal should not be taken into consideration to withhold prophylaxis (1, 3).

**Rabies Immunoglobulin (RIG)** : Rabies immunoglobulin of both equine (ERIG) and human (HRIG) is available. RIG should be administered in all category III exposures and in category II exposures involving immunodeficient individuals. Given its relatively slow clearance, Human Rabies Immunoglobulin (HRIG) is the preferred product, particularly in cases of multiple severe exposures. Where HRIG is not available or affordable, purified Equine Immunoglobulin (ERIG) is used. Most of the new ERIG preparations are potent, highly purified, safe and considerably less expensive than HRIG. The dose for HRIG is 20 IU/kg body weight, and for ERIG is 40 IU/kg body weight. As much of the recommended dose of passive immunization products as is anatomically feasible should be infiltrated into and around the wounds. The remainder should be administered by deep intramuscular injection at an injection site distant from the vaccine injection site. In case of multiple wounds, the RIG should be diluted with normal saline to make sufficient volume to ensure infiltration at all wound sites. RIG for passive immunization should not be injected later than seven days after the initiation of post - exposure vaccination. Several studies of patients with HIV/AIDS have reported that those with very low CD4 counts will mount a significantly lower or no detectable neutralizing antibody response to rabies. In such patients local infiltration of a passive immunization product are of utmost importance (1, 3).

### Vaccination

Rabies vaccines are required to be used in three situations : Post exposure prophylaxis, pre exposure prophylaxis, and vaccination in those previously vaccinated.

#### Post Exposure Prophylaxis

**Intramuscular administration** : The post exposure vaccination schedule is based on IM doses of 1 ml or 0.5 ml, depending on the manufacturer. The recommended regimen consists of either a 5 - dose or a 4 - dose schedule.

(a) *The 5 - dose regimen (Essen regimen)* : Prescribes 1 dose

injected into the deltoid muscle (or anterolateral thigh in children aged <2 years) on each of days 0, 3, 7, 14 and 28.

(b) *The 4 - dose regimen ("2 - 1 - 1" or Zagreb regimen)* : Prescribes 2 doses on day 0 (1 in each of the 2 deltoid/thigh sites) followed by 1 dose on each of days 7 and 21.

**Intradermal Administration** : The high cost of CCVs by the volume required for the standard IM route is prohibitive for widespread use in many areas where dog rabies is endemic. For some CCVs, equal immunogenicity has been demonstrated by ID using at least 60% less vaccine than by IM vaccination. Since 1991, WHO has recommended the ID route of administration for rabies pre - and post - exposure prophylaxis. Either the 8 - site or the 2 - site regimen should be used, as recommended by the respective vaccine manufacturer (8, 9).

(a) *The 8 - site ID regimen* : Prescribes on day 0, injections of 0.1 ml given at 8 sites (1 in each upper arm, 1 in each lateral thigh, 1 on each side of the suprascapular region, and 1 on each side of the lower quadrant region of the abdomen) ; on day 7, 1 injection in each upper arm and each lateral thigh; and on each of days 30 and 90, 1 injection in one upper arm. The dose on day 90 may be replaced by 2 ID injections on day 30.

(b) *The 2 - site ID regimen* : Prescribes 1 injection of 0.1 ml at 2 sites on days 0, 3, 7 and 28.

**Previously Vaccinated Individuals** : For rabies - exposed patients who have previously undergone complete pre - exposure vaccination or post - exposure prophylaxis with a CCV, 2 IM or ID doses of such a vaccine administered on days 0 and 3 are sufficient. RIG is not necessary in such cases. The same rules apply to people vaccinated against rabies who have demonstrated VNA titres of at least 0.5 IU/ml.

**Post - exposure prophylaxis of HIV - infected persons and HIV/AIDS patients** : Several studies of patients with HIV/AIDS have reported that those with very low CD4 counts will mount a significantly lower or no detectable neutralizing antibody response to rabies. In such patients and those in whom the presence of immunological memory is no longer assured as a result of other causes, proper and thorough wound treatment as described above and antisepsis accompanied by local infiltration of a passive immunization product are of utmost importance. Immunocompromised patients with category II exposures should receive rabies immunoglobulin in addition to a full post - exposure vaccination series as listed above. An infectious disease specialist with expert knowledge of rabies prevention should be consulted.

#### Pre Exposure Vaccination

Pre exposure vaccination should be offered to :

- People at high risk of exposure such as those working in rabies diagnostic or research laboratories
- Veterinarians, animal handlers (including bat handlers), animal rehabilitators and wildlife officers
- People (especially children) living in or traveling to high - risk areas

**Intramuscular Administration** : Pre - exposure rabies vaccination requires IM doses of 1 ml or 0.5 ml, depending on the vaccine type, given on days 0, 7 and 28 (day 28 preferable,

but administration may be advanced towards day 21 if time is limited). For adults, the vaccine should always be administered in the deltoid area of the arm; for children aged <2 years, the anterolateral area of the thigh is recommended. Rabies vaccine should not be administered in the gluteal area, where the induction of an adequate immune response may be less reliable.

**Intradermal Administration** : ID administration of 0.1 ml volumes on days 0, 7, and 28 (day 28 preferable, but administration may be advanced towards day 21 if time is limited) is an acceptable alternative to the standard IM route. However, ID administration is technically more demanding and requires appropriate staff training and qualified supervision.

**Booster Injections** : Periodic booster injections are recommended only for people whose occupation puts them at continuous or frequent risk of rabies exposure. In such cases, a booster dose should be given at intervals ideally dictated by regular testing for antirabies antibodies (1, 3).

**Control of Rabies in Dogs** : Canine rabies can be eliminated, as has been demonstrated in North America and Western Europe. However, canine rabies is still widespread, occurring in over 80 countries and territories, which are predominantly in the developing world. In more than 99% of all human rabies cases, the virus is transmitted from dogs. Effective animal vaccines that provide a considerable duration of immunity have been developed and mass parenteral vaccination programmes remain the mainstay of canine rabies control. Dog destruction alone is not effective in rabies control. Canine rabies control programmes should incorporate three basic elements of epidemiological surveillance, mass vaccination, and dog population control. Rabies should be a notifiable disease. Mass

canine vaccination campaigns have been the most effective measure for controlling canine rabies. At least 70% of the dog population in each community should be vaccinated in areas where canine rabies is endemic. Oral vaccination of dogs offers a new approach that may significantly improve dog vaccination coverage (especially of free - roaming and poorly supervised dogs) when applied either exclusively or in combination with parenteral vaccination. There is no evidence that removal of dogs alone has ever had a significant impact on dog population densities or the spread of rabies. However, the targeted and humane removal of unvaccinated, ownerless dogs may be effective when used as a supplementary measure to mass vaccination (10, 11, 12).

#### Post Exposure Treatment

**Local** : Elimination of rabies virus at the site of the infection by chemical or physical means is an effective mechanism of protection. It is, therefore, important to have prompt local treatment of all bite wounds and scratches that might be contaminated with rabies virus. Recommended first - aid procedures include immediate and thorough flushing and washing of the wound for a minimum of 15 minutes with soap and water, detergent or povidone iodine. If soap or an antiviral agent is not available, the wound should be thoroughly and extensively washed with water. People who live in rabies - infected areas should be educated in simple local wound treatment and warned not to use procedures that may further contaminate the wounds. Most severe bite wounds are best treated by daily dressing followed by secondary suturing where necessary. If suturing after wound cleansing cannot be avoided, the wound should first be infiltrated with passive rabies immunization products and suturing delayed for several hours. This will allow diffusion of the antibody to occur through the

**Table - 1 : Type of contact, exposure and recommended post - exposure prophylaxis**

Category	Type of contact with a suspect or confirmed rabid domestic or wild animal, or animal unavailable for testing <sup>(a)</sup>	Type of exposure	Recommended post-exposure prophylaxis
I	<ul style="list-style-type: none"> <li>Touching or feeding of animals</li> <li>Licks on intact skin</li> </ul>	None	<ul style="list-style-type: none"> <li>None, if reliable case history is available</li> </ul>
II	<ul style="list-style-type: none"> <li>Nibbling of uncovered skin</li> <li>Minor scratches or abrasions without bleeding</li> </ul>	Minor	<ul style="list-style-type: none"> <li>Administer vaccine Immediately <sup>(b)</sup></li> <li>Stop treatment if animal remains healthy throughout an observation period of 10 days <sup>(c)</sup> or if animal is proven to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques</li> </ul>
III	<ul style="list-style-type: none"> <li>Single or multiple transdermal bites or scratches, licks on broken skin</li> <li>Contamination of mucous membrane with saliva (i.e. licks)</li> <li>Exposure to bats <sup>(d)</sup></li> </ul>	Severe	<ul style="list-style-type: none"> <li>Immunoglobulin and vaccine immediately</li> <li>Stop treatment is animal remains healthy throughout an observation period of 10 days or if animal is found to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques</li> </ul>

(a) Exposure to rodents, rabbits and hares seldom, if ever, requires specific anti-rabies post-exposure prophylaxis.

(b) If an apparently healthy dog or cat in or from a low-risk area is placed under observation, the situation may warrant delaying initiation of treatment.

(c) This observation period applies only to dogs and cats. Except in the case of threatened or endangered species, other domestic and wild animals suspected as rabid should be humanely killed and their tissues examined for the presence of rabies antigen using appropriate laboratory techniques.

(d) Post-exposure prophylaxis should be considered when contact between a human and a bat has occurred unless the exposed person can rule out a bite or scratch, or exposure to a mucous membrane.



tissues before suturing is performed.

**Other treatments** : Such as the administration of antibiotics and tetanus prophylaxis, should be applied as appropriate for other bite wounds.

#### Post Exposure Prophylaxis

Table - 1 should serve as a guide for post - exposure prophylaxis. In cases where exposure is questionable or a patient has a concurrent medical condition that may complicate post exposure prophylaxis, an expert in the administration of rabies prophylaxis should be consulted.

### Summary

The word 'Rabies' has its origin in Sanskrit, "*rabhas*" means "to do violence". Rabies is an acute viral disease, which causes encephalomyelitis in virtually all the warm blooded animals, including man. Approximately 55,000 people die from rabies each year, the vast majority of these deaths occurring in Asia and Africa. In India alone, 20,000 deaths are estimated to occur annually. The Rabies viruses belong to the genus *Lyssavirus* of the *Rhabdoviridae* family. This RNA virus is bullet shaped round at one end and flat at the other measuring 100 - 300nm in length and 75 nm in diameter. Human infection usually occurs following a transdermal bite or scratch by an infected animal. The virus cannot cross intact skin. Incubation periods for Rabies have been reported from as short as four days to as long as 19 years. The usual duration is between 20 to 90 days. The duration of the incubation period may depend on the severity of bite, quantity of virus inoculated, innervation of the bitten area, and distance from CNS. The first rabies specific symptom is pain or paraesthesia referred to site of exposure which is present in about 50% of cases. Acute neurological period shows objective signs of CNS involvement. Two major clinical presentations are observed : furious and paralytic forms that cannot be correlated with any specific anatomical localization of rabies virus in the CNS. The final stage of Coma almost always begins within 10 days. Death may occur due to respiratory arrest soon after onset of Coma. Rabies is invariably fatal. A diagnosis of rabies can be made on clinical grounds. There are no laboratory tests to diagnose the infection before onset of clinical disease. Fluorescent Antibody detection in skin biopsy (From neck) can be done for confirmation of diagnosis. The essential measures required for the control of rabies are eliminating the diseases in domestic animals like dogs and immunoprophylaxis for humans. Rabies Vaccines (Nerve Tissue Vaccine (NTV), Cell Culture Vaccines (CCV) ) are required to be used in three situations : Post exposure prophylaxis, pre exposure prophylaxis, and vaccination in those previously vaccinated. Since 1991, WHO has recommended the ID route of administration for rabies pre - and post - exposure prophylaxis. Rabies Immunoglobulin of both Equine (ERIG) and Human (HRIG) is also available. Effective animal vaccines that provide a considerable duration of immunity have been developed and mass parenteral vaccination programmes remain the mainstay of canine rabies control. Dog destruction alone is not effective in rabies control. Canine rabies control programmes should incorporate three basic elements of epidemiological surveillance, mass vaccination, and dog population control.

### Study Exercises

**Long Questions** : (1) Discuss the epidemiology, treatment, prevention and control of Rabies (2) Describe in detail the measures to be taken in post exposure treatment.

**Short Notes** : (1) Intradermal regimen in Post Exposure Prophylaxis (2) Zagreb regimen (3) Pre Exposure Vaccination (4) Rabies Immunoglobulin (RIG) (5) Control of Rabies in Dogs.

#### MCQs

1. Rabies is found in all parts of India except (a) Maharashtra (b) Gujarat (c) Andaman & Nicobar Islands (d) Uttar Pradesh
2. Rabies virus is (a) Bullet shaped (b) Diamond shaped (c) Cone shaped (d) Round shaped
3. Fluorescent Antibody detection test in diagnosis of rabies is done in (a) Blood (b) Urine (c) Skin Biopsy (d) Saliva
4. The dose for Human Rabies Immunoglobulin (HRIG) is (a) 10 IU/Kg body weight (b) 20 IU/Kg body weight (c) 30 IU/Kg body weight (d) 40 IU/Kg body weight
5. The 2 - site ID regimen prescribes 1 injection of 0.1 ml at 2 sites on days (a) 0, 1, 3 and 7 (b) 0, 3, 7 and 28 (c) 0, 3, 9 and 21 (d) 0, 3, 7 and 21

**Answers** : (1) c; (2) a; (3) a; (4) b; (5) b.

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Rajesh Vaidya

Leptospirosis is a zoonosis spread throughout the world. Often under reported, the disease is now a prominent re-emerging infection and surveillance data suggests that it may be the most common zoonosis in the world (1). It is primarily an infection in rodents and several other wild and domesticated animals. Leptospirosis occurs worldwide but is most common in tropical and subtropical areas with high rainfall. The disease is found wherever humans come into contact with the urine of infected animals. Occupational exposure probably accounts for 30 - 50% of human cases (1 - 3). Most human infections are asymptomatic and the disease presentation can vary from extremely mild illness to fatal illness (4). The severe form of the disease was first described by Adolf Weil as a disease entity in four men who had fever, haemorrhage and severe jaundice in 1886 in Heidelberg (5). His name is still attached to a serious form of Leptospirosis called Weil's disease. Inada and Ido identified the causal organism in 1916 in Japan.

### Epidemiology

**Global** : Leptospirosis is endemic throughout the world. However, the incidence of the disease is significantly higher in tropical countries as compared to temperate regions. This is attributed to both the favourable climatic conditions in tropical countries as well as the fact that the tropics have a greater proportion of developing countries which provide greater opportunities for exposure of the human population to infected animals. The peak incidence of the disease is in summer or fall in temperate regions, and during rainy seasons in warm - climate regions (6). The number of human cases worldwide is not known precisely. The World Health Organization estimates that incidence ranges from approximately 0.1 - 1 per 1,00,000 per year in temperate climates to 10 - 100 per 1,00,000 in the humid tropics. During outbreaks and in high - exposure risk groups, disease incidence may reach over 100 per 1,00,000 (7). Increased awareness of the disease has led to increased recognition (8).

**India** : Though Leptospirosis is widespread in India, the true extent of the disease is not known because no large scale serological surveys have been carried out. However, a number of studies have reported outbreaks in different parts of the country since 1930 (9, 10). Several epidemics of Leptospirosis have occurred in Andaman and Nicobar islands and in southern and western parts of India during the past century. For the past 10 years, the city of Mumbai has been witnessing a seasonal increase in the number of cases of Leptospirosis. Large outbreaks have occurred following the monsoon flooding in the city. A post - cyclone outbreak was reported in Orissa, India in 1999.

**Agent** : *Leptospira icterohaemorrhagiae* is the causal organism for Leptospirosis. It is a slender, closely wound, very actively motile spirochete varying in length from 6 $\mu$  to 20 $\mu$ . Before 1989, the genus *Leptospira* was divided into two species.

*Leptospira interrogans* which were the pathogenic strains and *Leptospira biflexa* which were the saprophytic strains in the environment. Over 12 species with over 250 serologic variants (Serovars) of the pathogen have been identified. Serovars that are antigenically related have traditionally been grouped into serogroups. The serogroups are useful for epidemiological understanding.

**Host** : A wide variety of animal species, primarily mammals, serve as the animal hosts for the pathogen and are the primary sources for human infection. Small mammal species, notably feral and peridomestic rodents (rats, mice) and insectivores (shrews and hedgehogs) are the most important hosts for maintaining the infection in nature. Domestic animals like cattle, pigs, dogs, sheep and even larger mammals like horses and buffaloes can be infected. Reptiles and amphibians have also been detected to carry *Leptospire*s.

Humans are a "dead end" for *Leptospire*s as they do not form an infection reservoir. Adult males are most affected due to occupational exposure. Occupations such as livestock farmers, sewer workers and abattoir workers are most affected. The names for some forms of Leptospirosis like rice field fever, cane cutter's disease, swine herd's disease, dairy farm fever, mud fever reflect transmission conditions. Some recreational activities like swimming in natural waters may also result in exposure. Children may acquire infection from dogs. People living in cities may also be exposed to animal hosts notably rats. Outbreaks of Leptospirosis have been reported following natural disasters such as flooding and hurricanes.

**Environment** : The pathogenic organisms can survive for weeks in soil and water contaminated with urine and faeces of reservoir animals. Poor housing, improper sewage disposal and unsafe water supply increase the risk of transmission. Warm, humid conditions are ideal for survival of the *Leptospire*s and consequently the disease shows a seasonal variation in India.

**Transmission** : The *Leptospire*s have the ability to penetrate mucosa but not intact skin. However they can enter the body through broken skin and some researchers have suggested that they can penetrate through waterlogged skin. Human leptospiral infections result primarily from either direct contact with urine or tissue of infected animals or indirect contact through soil, water or vegetation that is contaminated with animal urine. They may occasionally enter the human body via the inhalation of droplets of urine or via drinking - water. They can be transmitted from human to human by sexual intercourse, transplacentally from the mother to the fetus and via breast milk to a child. The urine from a patient suffering from Leptospirosis should be considered infectious (7).

### Pathogenesis

On entering the human body, the organisms are carried by blood to all parts of the body. The leptospiremia can spread to any part of the body but particularly affects the liver and kidney. It causes a systemic vasculitis which allows entry of the spirochetes into different organs and tissues which accounts the broad spectrum of clinical presentation. Despite the possibility of severe complications, the disease is mostly self - limited and nonfatal.

## Clinical Features

The incubation period is usually between 5 - 14 days but can range from 2 to 30 days. The clinical presentation of the disease can be extremely variable. Most cases present with symptoms of sudden headaches, fevers, nausea and bodyache. 90% of cases have an acute febrile illness with a biphasic course, non - specific signs and symptoms and an excellent prognosis. The first stage is called the septicemic or leptospiremic stage. During this stage, which lasts about 4 - 7 days, the patient develops a nonspecific illness characterized by fever, chills, weakness, and body ache. These symptoms abate during a one to three day period. The fever subsides and the patient may become completely symptom free. The return of fever heralds the onset of the second stage. This stage is called the immune or leptospiruric stage. Disease referable to specific organs is seen. These organs include the meninges, liver, eyes, and kidney. About three fourths of patients complain of headache. Less than 10% of patients suffer from Icteric Leptospirosis or Weil's disease. The presentation includes fever, jaundice, renal failure and haemorrhage. Other organ systems (pulmonary, cardiac, central nervous) also are involved frequently. Weil's disease carries a mortality rate of 5 to 30% (4, 6, 7).

## Diagnosis

As the manifestations of Leptospirosis are non specific, laboratory investigations are essential to confirm the diagnosis. Routine blood and biochemical tests also reveal abnormalities that do not confirm the diagnosis. Patients will have raised ESR. Blood counts reveal thrombocytopenia and leucocytosis while biochemical assays may show hyperbilirubinaemia, elevated serum creatinine, elevated creatinine kinase and elevated serum amylase.

Direct visualization, culture and serology have all been used to confirm the diagnosis of Leptospirosis. Samples for culture from blood, CSF or peritoneal fluid should be collected before antibiotic treatment has been started. Cultures take very long as initial growth is very slow, and hence are not a practical means of confirming the diagnosis. The most reliable serological test is the Microscopic Agglutination Test (MAT). A four fold rise in the MAT titre or a single titre of at least 1 : 800 are diagnostic. Other tests include an indirect haemagglutination test and ELISA for specific IgM antibodies. Rapid commercial tests for leptospiral antibodies have recently become available. PCR may be used for molecular diagnosis for epidemiological studies.

## Differential Diagnosis

The diseases which should be considered in the differential diagnosis of Leptospirosis are : Influenza; Dengue and Dengue haemorrhagic fever; Yellow fever and other viral haemorrhagic fevers; Rickettsiosis; Borreliosis; Brucellosis; Malaria; Pyelonephritis; Aseptic Meningitis; Chemical poisoning; Food poisoning; Typhoid fever and other enteric fevers; Viral Hepatitis (7).

## Treatment

The spirochetes are sensitive to several antibiotics. There is no need to wait for the confirmation of diagnosis before starting antibiotic treatment. Severe cases of Leptospirosis should be treated with high doses of intravenous penicillin. Less severe

cases can be treated with oral antibiotics such as amoxycillin, ampicillin, doxycycline or erythromycin. Third - generation cephalosporins, such as ceftriaxone and cefotaxime, and quinolone antibiotics also appear to be effective. Aggressive supportive care with strict attention to fluid and electrolyte balance is essential. Peritoneal or haemodialysis is indicated in renal failure (2, 3, 7). Doxycycline 200mg orally once a week has been used for chemoprophylaxis. The drug should be given for a few weeks at a time.

## Prevention and Control

The control of Leptospirosis in reservoir animals is impossible because of their sheer variety and numbers. Prevention of human cases may be achieved by use of personal protective measures, avoidance of high risk exposure, immunization and chemoprophylaxis. Some degree of reservoir control can be achieved by rodent control and by reducing infection in domestic animals such as dogs or livestock by immunization. Risk of infection is minimized by avoiding contact with animal urine, infected animals or an infected environment. Protective clothing should be worn and wounds covered with waterproof dressings to reduce the chance of infection if occupational or recreational exposure is likely. In case of an outbreak, persons exposed to animal urine (wading through flood waters etc.) may be given doxycycline chemoprophylaxis.

Killed vaccine is available against Leptospirosis. Due to the large number of serovariants, the effectiveness of the vaccine is limited. Protective antibodies are produced only against the serovars present in the particular vaccine used.

## Summary

Leptospirosis is a zoonosis and surveillance data suggests that it may be the most common zoonosis in the world. It is primarily an infection in rodents and several other wild and domesticated animals. The World Health Organization estimates that incidences range from approximately 0.1 - 1 per 1,00,000 per year in temperate climates to 10 - 100 per 1,00,000 in the humid tropics. *Leptospira icterohaemorrhagiae* is the causal organism for Leptospirosis. It is a slender, closely wound, very actively motile spirochete. A wide variety of animal species, primarily small mammal species, notably feral and peridomestic rodents (rats, mice) and insectivores (shrews and hedgehogs) are the most important hosts for maintaining the infection in nature. Humans are a "dead end" for Leptospirae as they do not form an infection reservoir. Occupations such as livestock farmers, sewer workers and abattoir workers are most affected. The Leptospirae have the ability to penetrate mucosa but not intact skin. Human leptospiral infections result primarily from either direct contact with urine or tissue of infected animals or indirect contact through soil, water or vegetation that is contaminated with animal urine. The incubation period is usually between 5 - 14 days but can range from 2 to 30 days. 90% of cases have an acute febrile illness with a biphasic course, non - specific signs and symptoms and an excellent prognosis. Less than 10% of patients suffer from Icteric Leptospirosis or Weil's disease. The presentation includes fever, jaundice, renal failure and haemorrhage. Weil's disease carries a mortality rate of 5 to 30%. Confirm diagnosis can be achieved by direct visualization, culture and serology. Rapid commercial tests for

leptospiral antibodies have recently become available. PCR may be used for molecular diagnosis for epidemiological studies. Severe cases of Leptospirosis should be treated with high doses of intravenous penicillin. Less severe cases can be treated with oral antibiotics such as amoxycillin, ampicillin, doxycycline or erythromycin. Prevention of human cases may be achieved by use of personal protective measures, avoidance of high risk exposure, immunization and chemoprophylaxis. Some degree of reservoir control can be achieved by rodent control and by reducing infection in domestic animals such as dogs or livestock by immunization. Doxycycline 200mg orally once a week has been used for chemoprophylaxis. Killed vaccine is available against Leptospirosis but due to the large number of serovariants, the effectiveness of the vaccine is limited.

## Study Exercises

**Long Question :** Discuss the epidemiology, treatment, prevention and control of Leptospirosis.

**Short Notes :** Clinical Features of Leptospirosis

### MCQs

- Weil's disease was first described by Adolf Weil in (a) 1884 (b) 1885 (c) 1886 (d) 1887
- Drug used in chemoprophylaxis of Leptospirosis (a) Ciprofloxacin (b) Septran (c) Doxycycline (d) Rifampicin
- Inada and Ido identified the causal organism of Leptospirosis in (a) America (b) Japan (c) S. Korea (d) China

- Humans are (a) Dead end host for Leptospire (b) Intermediate host for Leptospire (c) Amplifying host for Leptospire (d) None of the above.

**Answers :** (1) c; (2) c; (3) b; (4) a.

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## Brucellosis

Rajesh Vaidya

Brucellosis is a zoonotic infection of domesticated and wild animals, caused by organisms of the genus *Brucella*. It is transmitted from animals to humans by ingestion of infected food products, direct contact with an infected animal, or inhalation of aerosols. It is known by several names like Malta Fever and Undulant Fever. In 1954, *Brucella* was the first bacteria to be weaponised as biological warfare agent because aerosols are a remarkably efficient method of disease transmission. However, its relatively long and variable incubation period and the fact that many infections are asymptomatic, has made it a less desirable agent for biological warfare. Four species of *Brucella* are known to cause human disease. They are *Brucella melitensis*, *Brucella abortus*, *Brucella suis* and *Brucella canis*.

Descriptions of the disease date back to Hippocrates. Brucellosis in humans has a strong association with military medicine (1).

The disease was first described in 1751 by Cleghorn, a British army surgeon stationed on the island of Minorca (2). In 1861, Marston described the clinical characteristics of the disease (3). In 1887, a British army doctor David Bruce, isolated the causative organism from the spleens of five fatal cases (4). The species was named *Brucella* after him. The term Undulant Fever was given by ML Hughes (5). Bang identified *Brucella abortus* as a cause of abortion in cattle in 1895 (6).

### Epidemiology

**Global :** Brucellosis is a worldwide zoonosis. The highest incidence is seen in areas where cattle or other animal rearing is carried out. High rates of disease are observed in the Middle East, Mediterranean region, China, India, Peru and Mexico. Abortus fever occurs sporadically in all parts of the world including India. No epidemics have been reported from any part of the world but upsurge of the sporadic cases occurs in various parts from time to time. With the advent of animal vaccines and improvements in hygiene in animal rearing, the disease has declined in developed countries. However, the global burden of human brucellosis remains large. It is estimated to cause more than 5,00,000 infections per year worldwide. The number



of reported infections is much lower because the diagnosis is often not confirmed.

**India** : In India, cattle in Maharashtra, Karnataka, Madhya Pradesh, Tamil Nadu and Orissa have been found infected. Very few surveys have been made. A few surveys in dairy farms show low incidence.

**Agent** : Brucellae are small, nonmotile, nonsporing, nontoxogenic, nonfermenting, aerobic, Gram-negative coccobacilli. The outer cell membrane is similar to that of other Gram - negative bacilli with a dominant lipopolysaccharide (LPS) component and three main groups of proteins. Brucella species do not harbor plasmids naturally although they are known to readily accept broad - host - range plasmids (6, 7, 8). Brucella colonies become visible on suitable solid media in 2 - 3 days (9, 10). Among the four species that cause disease in humans, *Brucella melitensis* is the most virulent and causes the most severe and acute cases. *Brucella suis* infection causes a prolonged course of illness and may be associated with suppurative destructive lesions. Mild-to-moderate sporadic disease, rarely associated with complications is the characteristic of *Brucella abortus*. Infection with *Brucella canis* results in a disease course that is similar to *Brucella abortus* infection. The onset of disease is insidious, marked by frequent relapses and does not commonly cause chronic disease.

**Host** : Each Brucella species has a specific animal reservoir. The infection in the animal hosts result in chronic disease that persists for life. The organisms tend to localize in the reproductive organs of the animals, causing sterility and abortions. They are shed in large numbers in the urine, milk and placental fluid of the infected animals. This localization is responsible for the efficient spread of infection to workers who come in contact with these liquids. The specific animal reservoirs for the various Brucella species are shown in Table - 1. Human brucellosis is predominantly a disease of adult males. Farmers, shepherds, butchers, abattoirs workers, veterinarians and laboratory workers are particularly at special risk because of occupational exposure.

**Table - 1 : Animal Reservoirs of Brucella (11)**

Organism	Animal reservoir	Geographic distribution
<i>B melitensis</i>	Goats, sheep & camels	Mediterranean, Asia & Latin America
<i>B abortus</i>	Cattle, buffalo & camels	Worldwide (Eliminated in Japan, Israel & several European nations)
<i>B suis</i>	Domestic & feral swine	South America, Asia & mid - western United States
<i>B canis</i>	Canines	Cosmopolitan

**Environment** : The organism can survive for weeks under favourable conditions. High humidity, overcrowding of herds and poor hygienic conditions of milk and meat production are favourable for the transmission of infection.

**Transmission** : Animals shed large amounts of Brucella organisms during septic abortion, at the time of slaughter

and in their milk. The incidence of human disease is closely linked to the prevalence of infection in sheep, goats and cattle and to practices that allow exposure of humans to potentially infected animals or their products. Brucellae can gain entry into humans through breaks in the skin, mucous membranes, conjunctiva, respiratory and gastrointestinal tracts. Ingestion of the organisms with milk or other contaminated animal products or by contact with contaminated fingers is the most common route of infection. Inhalation of aerosols containing the bacteria, or aerosol contamination of the conjunctivae, is another route. Percutaneous infection through skin abrasions or by accidental inoculation is a rare mode of transmission of infection.

### Pathogenesis

On entry into the human host, Brucellae are rapidly phagocytosed by polymorphonuclear leukocytes. Brucellae possess the ability to survive and multiply within the phagocytic cells. Soon after infection, the organisms become localized in the organs of the reticulo - endothelial system such as the spleen and lymph nodes. In animals the organisms also localize in the reproductive organs. Large granulomas serve as a source for persistent bacteraemia. The specific host defences against brucellae are similar to those against other intracellular bacteria and are both humoral and cell - mediated. Macrophages process brucellar antigen and present this to T lymphocytes which produce lymphokines. T cell - derived lymphokines are also involved in attracting cells to the foci of infection. This leads to granuloma formation.

### Clinical Features

The incubation period is extremely variable. Symptoms usually begin insidiously within two to four weeks but may start after as long as 6 months or more. The presentation of brucellosis is characteristically variable. Symptoms of brucellosis are protean in nature. The onset is usually insidious but rarely may be abrupt. Subclinical infections are common. The symptoms are non-specific. Patients develop fever, malaise, headache, loss of appetite. Bodyache may be unusually severe. Sweating, including malodorous sweat and fatigue are common. The leukocyte count may be normal or reduced, with a relative lymphocytosis. Splenomegaly may often be the only clinical finding.

If the disease is not treated, the symptoms may continue for 2 to 4 weeks and a characteristic undulant pattern of fever can be discerned. Many patients will then recover spontaneously but others may suffer a series of exacerbations. Most affected persons recover entirely within 3 to 12 months but some will develop complications marked by involvement of various organs and a few may enter an ill - defined chronic syndrome. Complications include arthritis, often sacroilitis and spondylitis, central nervous system effects including meningitis, uveitis and occasionally, epididymo - orchitis. In contrast to animals, abortion is not a feature of brucellosis in pregnant women (6). Depression, out of proportion to the symptoms has often been reported.

### Diagnosis

Cases of Brucellosis are often not diagnosed because of the non specific presentation of the disease. A high index of suspicion



and a detailed history of possible exposure, either occupational or during travel or of ingestion of contaminated foods are essential. However, at times patients can present several years after initial exposure making diagnosis difficult.

Definitive diagnosis is made by isolation of the organism. Blood culture is the method of choice but specimens need to be obtained early in the disease and cultures may need to be incubated for up to four weeks. Despite these precautions, failure to grow the organism is common, especially in cases of *Brucella abortus* infection. Culture from bone marrow and from presenting foci may be successful. Presumptive identification of cultures can be made from morphology and slide agglutination with specific antiserum. Serology is the most commonly used method for confirming the diagnosis. However interpretation of the results should be done carefully. The tube agglutination test, which tests for anti-O-polysaccharide antibody is considered the best. A titer of 1 : 160 or higher of specific IgG and IgM is considered diagnostic. Most patients already have high titers at the time of clinical presentation, so a 4 - fold rise in titer may not occur. The diagnosis of the chronic Brucellosis Syndrome, without specific localization is difficult. If the cultures are negative and the results of serology are equivocal a confident diagnosis may not be possible.

### Treatment

The organism is susceptible to a variety of antibiotics. Doxycycline is usually drug of choice. Other antibiotics that may be used are Rifampicin, Gentamycin and Streptomycin. The use of a single drug has been found to have a high relapse rate, so combined regimens should be used whenever possible. A 6 week regimen of doxycycline 200 mg/day administered orally, with the addition of streptomycin 1 g/day administered intramuscularly for the first 2 to 3 weeks is effective therapy for adults with most forms of Brucellosis. The WHO recommended treatment regime is a combination of both rifampicin 600 to 900 mg/day and doxycycline 200 mg/day given orally for six weeks (6). Some workers have reported that treatment with a combination of streptomycin and doxycycline may result in less frequent relapse than treatment with the combination of rifampin and doxycycline. Endocarditis needs longer duration of treatment. Doxycycline along with a combination of two more drugs for six weeks may be required. Central nervous system disease also needs prolonged treatment with drug combinations like rifampicin.

### Prevention & Control

**Animals** : Eradication of the infection from animal reservoirs is the most important means for preventing human brucellosis. Eradication of brucellosis from domestic animals dramatically reduces the threat to humans and has been successful in several countries. Vaccination of animals and improving the hygiene of slaughter houses can markedly reduce the disease in animals. Animal vaccines are available against several strains of *Brucella*. Detection of infected herds and individual animals and their elimination are also important control measures.

**Humans** : A live vaccine is available only against a particular strain of *Brucella abortus* (Strain 19 BA). Early diagnosis and treatment of cases is important. Protection of dairy products and pasteurization or boiling of milk is also required for control

of transmission. Personal protective measures in the form of wearing impermeable clothing, rubber boots, gloves and face masks, care during handling of carcasses and safe laboratory procedures also help in control.

### Summary

Brucellosis is a zoonotic infection of domesticated and wild animals, caused by organisms of the genus *Brucella*. Four species of *Brucella* are known to cause human disease. They are *Brucella melitensis*, *Brucella abortus*, *Brucella suis* and *Brucella canis*. *Brucella melitensis* is the most virulent and causes the most severe and acute cases. Brucellosis is a worldwide zoonosis, it is estimated to cause more than 5,00,000 infections per year worldwide. Brucellae are small, nonmotile, nonsporing, nontoxigenic, nonfermenting, aerobic, Gram-negative coccobacilli. Each *Brucella* species has a specific animal reservoir and the organisms tend to localize in the reproductive organs of these animals, causing sterility and abortions. They are shed in large numbers in the urine, milk and placental fluid of the infected animals. Farmers, shepherds, butchers, abattoir workers, veterinarians and laboratory workers are particularly at special risk. Brucellae can gain entry into humans through breaks in the skin, mucous membranes or ingestion of the organisms with milk or animal products. The incubation period is extremely variable ranging from two to four weeks but may sometimes be as long as 6 months or more. The symptoms are non specific. Patients develop fever, malaise, headache, loss of appetite. Splenomegaly may often be the only clinical finding. Definitive diagnosis is made by isolation of the organism. Blood culture is the method of choice. The WHO recommended treatment regime is a combination of both rifampicin 600 to 900 mg/day & doxycycline 200 mg/day given orally for six weeks. Vaccination of animals and improving the hygiene of slaughter houses can markedly reduce the disease in animals and thus in man. A live vaccine is available only against a particular strain of *Brucella abortus* (Strain 19 BA). Personal protective measures in the form of wearing impermeable clothing, rubber boots, gloves and face masks, care during handling of carcasses and safe laboratory procedures also help in control.

### Study Exercises

**Long Question** : Discuss the epidemiology, treatment and control of *Brucella* infection in man.

**Short Notes** : (1) Enlist different species of *Brucella* known to cause human disease and also mention animal reservoir of each species (2) Control of *Brucella* in both human beings and animals.

### MCQs

1. Brucellae are all except (a) Motile (b) Nonsporing (c) Nontoxogenic (d) Nonfermenting
2. Animal Reservoirs of *Brucella suis* is (a) Buffalo (b) Camels (c) Feral swine (d) Goats
3. Brucellae causes abortion in (a) Animals only (b) Human beings only (c) Both Animals & Human beings (d) None of the above
4. Drug of choice in treatment Brucella is (a) Streptomycin (b) Rifampicin (c) Gentamycin (d) Doxycycline

Answers : (1) a; (2) c; (3) a; (4) d.

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## Mechanism of Air - borne Infections

Rajesh Vaidya

The central aspect of the spread of infectious disease is the transmission of infection, or the various mechanisms by which disease agents reach and infect the human host. This involves escape of the agent from the source, conveyance to the susceptible host, and entry into that host. Transmission may be direct or indirect. A basic classification is shown in Table 1.

**Table 1 : Modes of Transmission**

Direct	Indirect
Direct Contact	Airborne
Droplet Infection	Vehicle Borne
	Vector Borne

### Air - Borne Transmission

All through history man and his ancestors have sought refuge from the elements by taking shelter within caves, tents and wooden structures. Little aware that the common protection they obtained also fostered the exchange and proliferation of airborne pathogens, which would in the coming years form of one of the most dreaded group of organisms.

Airborne infection is defined as "A mechanism of transmission of an infectious agent by particles, dust, or droplet nuclei suspended in the air." Two types of particles are implicated in

the airborne form of spread of infectious agents :

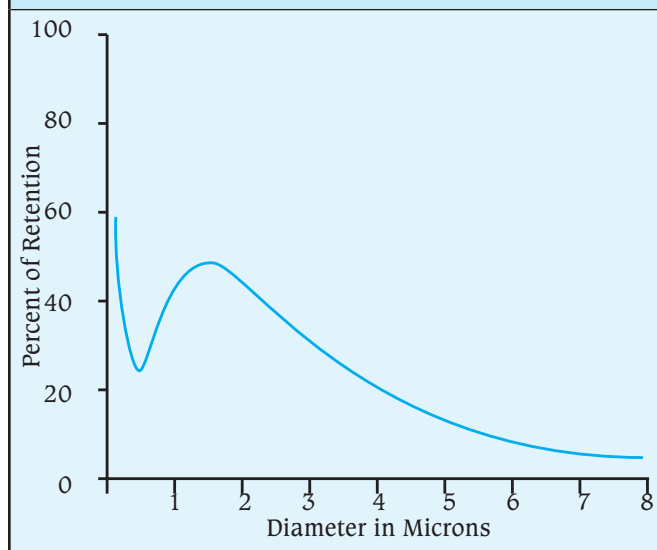
(a) Droplet nuclei (b) Dust

**Droplet Nuclei** : Droplet nuclei are tiny particles (1-10 microns) that represent the dried residue of droplets. Smaller particles that are less than 3 to 5 microns in diameter may contain one or two micro - organisms which fail to settle due of gravity and remain suspended in the atmosphere for long periods of time. These infectious aerosols are small enough to bypass host defences in the upper respiratory tract and airways. More particles are deposited in small bronchioles and alveoli as particle size decreases below 5 micron. Typical pulmonary infections acquired due inhalation of infectious aerosols include Tuberculosis, Influenza, Legionellosis, Histoplasmosis, Q fever etc. Fig - 1 shows the relationship between particle size and retention in the alveoli. These droplet nuclei may be formed by evaporation of droplets that have been coughed or sneezed into the air, aerolization of infective material in the course of laboratory procedures, and processes for rendering animals in slaughter houses.

### General Prevention and Control Measures

**Ventilation** : Since organisms transmissible through the air can be widely dispersed, specific air ventilation is required to manage their dispersion thus control outbreaks of airborne infections. If resources are available then (especially in healthcare facilities) techniques such as the use of monitored negative airflow ventilation with at least six air changes per hour and filtration of direct exhaust to the outside should be used. In routine areas of work and stay adequacy of ventilation at all times is ensured by provision of at least two windows per room with an area of about 10 percent of the floor space and arranged so as to provide cross ventilation.

**Fig. - 1 : Relationship between Particle Size and Retention in Alveoli**



**Avoid Overcrowding** : Other important measure, for preventing airborne infections is prevention of overcrowding. The minimum floor area should be 6 m<sup>2</sup> per person. Beds must be spaced with an interval of at least two meters between the centres of the

two adjacent beds.

**Respiratory Protection Devices** : Surgical masks that cover the mouth and nose should be worn by healthcare staff in hospitals and by the patient themselves also. N95 respirator / surgical mask are currently recommended.

## Summary

Airborne infection is defined as “A mechanism of transmission of an infectious agent by particles, dust, or droplet nuclei suspended in the air.” Droplet nuclei are tiny particles (1 - 10 microns) that represent the dried residue of droplets. Typical pulmonary infections acquired due to inhalation of infectious aerosols include Tuberculosis, Influenza, Legionellosis, Histoplasmosis, Q fever etc. Prevention and control measures involve ventilation, avoiding overcrowding and respiratory protection devices.

## Study Exercises

**Short Notes** : (1) Modes of transmission (2) Droplet Nuclei (3) Prevention and Control Measures for Air Borne transmission

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## 187 Measles

*Rajesh Vaidya*

Measles, an acute viral exanthematous fever is a leading cause of childhood deaths in developing countries. Measles is one of the most contagious diseases known. Almost all non - immune children contract this respiratory disease if exposed to the virus. It is a human disease not known to occur in animals. Before the development of safe and effective vaccines measles was responsible for approximately six million deaths of infants and children globally every year. As measles vaccination has become more and more widespread, there has been a marked decline in measles particularly in developed countries. Despite these advances, however, an estimated 20 million cases of measles resulted in 242,000 deaths in 2006 (1). The overwhelming majority of measles deaths occur in poor countries.

## Epidemiology

**Global** : Measles is one of the most important infectious diseases of humans. It has been responsible for millions of deaths since its emergence over five thousand years ago (2). Measles is reported from all countries without exception. Prior to the introduction of a safe and effective vaccine measles epidemics would occur every two to five years resulting in an estimated five to eight million deaths every year (2, 3). The introduction and widespread use of the vaccine has brought about a marked decline in measles occurrence and mortality. In 2000, measles was estimated to have killed over 750,000 children. This has been brought down to an estimated 279,006 reported cases and 242,000 measles deaths in 2006. The largest proportional reduction in deaths due to measles has occurred in the African Region accounting for 70% of the global reduction in measles mortality (4). Despite this remarkable reduction in measles mortality, most deaths occur among infants and young children living in Africa and South East Asia. Measles is the leading cause of vaccine - preventable deaths during childhood.

98% of deaths due to measles occur in developing countries. Case - fatality rates in these countries are normally in the range 1 to 5% but may reach as high as 10 to 30% in populations with high levels of malnutrition and poor access to health care (5).

**India** : Despite the fact that reliable epidemiological data is relatively limited, measles is clearly important cause of sickness and death in India. Before the introduction of measles vaccine as part of the National Immunization Schedule in 1985, an estimated 100,000 cases of measles occurred each year in the country with outbreaks at an interval of about 3 years. After the introduction of measles vaccination, the number of cases has decreased and the interval between outbreaks has also increased to about 5 years. The number of reported cases of measles in India has declined from 162,560 in 1989 to 51,546 in 2004. The problem with this data is the gross under - reporting of measles as shown by the fact that many Indian states did not report any case of measles for 3 years (2001 - 2003). As a result the estimated measles incidence varies from 0 to 142.7 per 100,000 population (6). States with low immunization coverage report the least number of cases indicating a non functional surveillance system in these States (6).

**Agent** : The measles virus is a member of the genus *Morbillivirus* from the family paramyxoviridae. The virus is a non segmented, enveloped, negative sense single stranded RNA virus. Measles virus particles are pleomorphic spheres with diameter ranging from 100 nm to 250 nm. It is made up of six structural proteins. The measles virus is easily destroyed by drying, exposure to sunlight and acids. It can, however, remain viable in droplets for several hours (7). Humans are the only natural hosts for the virus. However, non - human primates can be infected with the measles virus and develop an illness similar, but milder to measles in humans (2, 3). There is only one serotype.

**Host** : Susceptibility to infection is universal in those not exposed irrespective of age. However, most infections occur in the age group six months to three years in developing countries. In India, more than 50% of cases were reported in children less than five years of age. The disease takes a more serious form in adults. While the virus exhibits no gender predilection, mortality following acute measles has been observed to be higher in females at all ages (8). Immunity lasts lifelong after natural infection. Nutritional status has an important bearing on the severity of disease. Measles is very severe in malnourished with higher mortality. It can precipitate Kwashiorkor in borderline cases. Persons with malnutrition, especially vitamin A deficiency, or with severe immunological disorders such as advanced HIV infection are at increased risk of developing severe or even fatal measles.

**Environment** : In India, the peak incidence of measles is in winter and early spring. In temperate countries most cases occur in winter months. Overcrowding favours transmission.

**Transmission** : Measles is one of the most contagious diseases known with secondary attack rates close to 90%. The mode of transmission is person to person by direct contact. Transmission is through droplets or airborne spread of secretions from the respiratory tract of measles cases. Articles freshly soiled by discharges are also infective. The period of communicability is from one to two days before prodrome to four days after

appearance of rash. Communicability rapidly reduces after appearance of rash (9).

### Clinical Features

The incubation period ranges from 8 to 13 days from exposure to fever and is usually 14 days from exposure to appearance of rash. The first sign of infection is high fever.

The fever lasts one to seven days. During the initial stage the patient may develop cough, coryza and conjunctivitis. Koplik's spots, which are considered pathognomonic for measles, appears towards the end of the prodrome. They are small white spots on a red background inside the cheeks. The measles rash usually appears 2 to 4 days after prodromal symptoms. It first appears on the face and upper neck. Over a period of about three days, the rash spreads, to the trunk and extremities. The rash lasts for five to six days and then fades in the order of appearance. Patients normally improve by the third day of rash, and uncomplicated cases recover completely within 7 to 10 days of the onset of disease.

### Complications

Measles is often an unpleasant mild or moderately severe illness. However, the disease can take a severe form particularly in poorly nourished young children, those with Vitamin A deficiency, and immunocompromised individuals. Children usually do not die directly of measles, but from its complications. Complications are more common in children under the age of five years or adults over the age of 20 years.

The commonest complications of measles result from involvement of the respiratory tract or the Central Nervous System (CNS). The most serious complications include blindness, encephalitis, severe diarrhoea possibly leading to dehydration, ear infections including otitis media, and severe respiratory infections such as pneumonia, which is the most common cause of death associated with measles. Measles encephalitis, which is considered an autoimmune disorder, occurs once in about 1000 cases. The case fatality rate in developing countries is generally in the range of 1 to 5%, but may be as high as 25% in populations with high levels of malnutrition and poor access to health care. Subacute Sclerosing Panencephalitis (SSPE) occurs at an average of seven years after initial infection.

### Special Situations

The presentation of measles can vary from the typical in some situations. The increased severity of measles among the immunocompromised has already been described. Measles during pregnancy is associated with spontaneous abortion and premature delivery. The disease has a more severe presentation during pregnancy but is not known to cause congenital abnormalities. Children born to mothers with measles may suffer from severe measles (10). It has been speculated that depression of cell mediated immunity as a result of infection with the measles virus may aggravate tuberculosis. It may, therefore, be advisable to delay measles vaccination in persons with tuberculosis until after initiation of chemotherapy for tuberculosis (3).

### Diagnosis

History of contact with a case and the typical rash provide adequate clues for a clinical diagnosis of measles in endemic



areas. Laboratory confirmation, if required can be through reliable serological tests. IgM antibodies become detectable within 72 hrs and then fall to undetectable after 1 to 2 months. A four fold rise in measles antibody titer in acute or convalescent serum is considered diagnostic for measles. IgG antibodies appear shortly after onset of rash, peak in 2 to 4 weeks and last for the lifetime. Viral particles can be demonstrated using a sensitive RT - PCR.

### Treatment

Most patients of measles need no specific treatment. However, severe cases and those with complications should be provided supportive therapy. General nutritional support and treatment of dehydration with oral rehydration solution may be indicated. Antibiotics may also be required for treatment of eye and ear infections as well as pneumonia. However, prophylactic antibiotics are not recommended. Some studies have demonstrated some clinical benefit of the antiviral drug Ribavirin (11). The severity of measles in children can be decreased by oral vitamin A administration (12). All children in developing countries diagnosed with measles should receive two doses of vitamin A supplements given 24 hours apart. This can help prevent eye damage and blindness. Vitamin A supplementation has been shown to reduce the number of deaths from measles by 50%. Supplementary dosage is : Infants 6 - 11 months - 1,00,000 IU; Children 12 months and over - 2,00,000 IU.

### Prevention and Control

Active immunization is the primary method of measles prevention. Passive immunization may be resorted to in special circumstances. General measures have little role in the prevention of measles and are included largely for the sake of completion.

**General Measures** : Outbreaks of measles must be reported to local health authorities. Respiratory isolation may be indicated. Exclusion from school is required for one week from appearance of rash to avoid contact with susceptibles. In hospital strict isolation of cases is essential. Articles soiled by secretions or fluids from vesicles to be incinerated or treated with disinfectants.

**Active Immunization** : A live attenuated vaccine against measles has been available since 1966. A number of strains like the Edmonston B strain, Schwarz strain and Moraten strain are used in vaccine manufacture. The vaccine is extremely effective and safe.

The age of administration and schedule for the vaccine depends on the risk of contacting measles and the ability of the vaccinee to respond to the vaccine. Programme considerations also determine the number of doses recommended. In India, a single dose of 0.5 ml SC is given at nine months of age. In developed countries two doses are given. The first dose at 12 to 15 months followed by a second dose at 4 to 5 years of age.

Measles vaccination is contraindicated for immunocompromised individuals and during pregnancy. Persons with a history of an anaphylactic reaction to neomycin, gelatin or other components of the vaccine should not be vaccinated. While the vaccine should not be administered if there is high fever

or serious diseases, mild illness is not a contraindication for vaccination.

The WHO position on the vaccine is that immunization against measles is recommended for all susceptible children and adults for whom measles vaccination is not contraindicated (12). Asymptomatic HIV infection is an indication, not a contraindication, for measles vaccination. HIV-infected infants should be given the measles vaccine at 6 months of age, followed by an additional dose at 9 months unless they are severely immunocompromised.

**Passive Immunization** : Passive immunization involves the administration of normal human immunoglobulin at a dose : 0.25 ml per Kg body weight. The immunoglobulin should ideally be administered within six days of exposure. Passive immunization is indicated for vulnerable susceptible household contacts like immunocompromised children. HIV infected children must also receive passive immunization, even if they have been vaccinated (13, 14).

### Summary

Measles is one of the most important infectious diseases of humans. It has been responsible for millions of deaths since its emergence over five thousand years ago. It is a human disease not known to occur in animals. An estimated 20 million cases of measles resulted in 2,42,000 deaths in 2006. Measles is the leading cause of vaccine - preventable deaths during childhood. 98% of deaths due to measles occur in developing countries. The measles virus is a member of the genus *Morbillivirus* from the family paramyxoviridae. The virus is a non segmented, enveloped, negative sense single stranded RNA virus. There is only one serotype. Susceptibility to infection is universal in those not exposed irrespective of age. Immunity lasts lifelong after natural infection. In India the peak incidence of measles is in winter and early spring. The period of communicability is from one to two days before prodrome to four days after appearance of rash. The incubation Period ranges from 8 to 13 days from exposure to fever and is usually 14 days from exposure to appearance of rash. The measles rash usually appears 2 to 4 days after prodromal symptoms. Patients normally improve by the third day of rash, and uncomplicated cases recover completely within 7 to 10 days of the onset of disease. Most serious complications include blindness, encephalitis, severe diarrhoea, Otitis Media, and severe respiratory infections. History of contact with a case and the typical rash provide adequate clues for a clinical diagnosis of measles. Most patients of measles need no specific treatment. Active immunization is the primary method of measles prevention. A live attenuated vaccine against measles has been available since 1966. In India, a single dose of 0.5 ml SC is given at nine months of age. In developed countries two doses are given. The first dose at 12 to 15 months followed by a second dose at 4 to 5 years of age.

### Study Exercises

**Long Question** : Discuss the epidemiology, treatment, prevention and control of Measles.

**Short Note** : (1) Complications of Measles (2) Measles vaccination

### MCQs

1. Most common cause of death associated with measles is (a) Measles encephalitis (b) Pneumonia (c) Subacute Sclerosing Panencephalitis (d) Severe diarrhoea.
2. Measles virus is (a) Single - stranded RNA Virus (b) Double - stranded RNA Virus (c) Single - stranded DNA Virus (d) Double - stranded DNA Virus.
3. Immunity lasts for \_\_\_\_\_ after natural infection (a) 5 Yrs (b) 10 Yrs (c) Lifelong (d) None of the above.
4. A live attenuated vaccine against measles has been available since (a) 1964 (b) 1965 (c) 1966 (d) 1967.
5. The dose of human immunoglobulin for Passive immunization against measles is (a) 0.25 ml per Kg body weight (b) 0.50 ml per Kg body weight (c) 0.75 ml per Kg body weight (d) 1.00 ml per Kg body weight.

**Answers :** (1) b; (2) a; (3) c; (4) c; (5) a.

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## Rubella

Rajesh Vaidya

Rubella, also called German measles or "three day measles", is viral fever, which occurs worldwide and is normally a mild childhood disease. However, infection during early pregnancy may cause fetal death or the congenital rubella syndrome.

### Epidemiology

Rubella has a worldwide distribution. Data from developing countries is sparse. Before the advent of widespread vaccination in developed countries epidemics of rubella occurred every 6 - 9 years and large scale epidemics at intervals of 30 years (1). The World Health Organization (WHO) estimates that more than 1,00,000 cases of congenital rubella syndrome occur each year in developing countries alone (2). Before the introduction of rubella vaccine the incidence of congenital rubella syndrome varied from 0.1 - 0.2 per 1,000 live births. Epidemic rates varied from 1 - 4 per 1,000 live births. In many developed and some developing countries, widespread rubella vaccination during the past decade has markedly reduced rubella and CRS.

A number of serological surveys particularly among women of child bearing age (15-45 years) have been carried out in India to determine the extent of infection. A large study carried out

by the National Institute of Communicable Diseases (NICD) covering a period of 15 years reported that immunity status of women of childbearing age was as low as 49% in 1988. Over the 15 year period it rose to 87% in 2002. The study concluded that approximately 10 to 15 % of women reached childbearing age without developing immunity against rubella virus and were at high risk of contracting infection during pregnancy (3). A more recent study carried out in Tamil Nadu in 2004 reported that 82.2 per cent children in between 1 - 5 years and 13.5 per cent of girls in the 10 - 16 years age groups were seronegative for rubella (4).

**Agent :** The rubella virus is an enveloped, single - stranded RNA virus of the genus *Rubivirus* from the family *Togaviridae*. Roughly spherical, the virus has a diameter of 60 nm. Humans are the only known reservoir (5). A delicate virus, rubella is easily inactivated by lipid solvents, formalin, ultraviolet light, and extremes of pH and heat (1).

**Host :** In the pre - vaccine era, the peak age of incidence was in the 5 - 9 years age group. With widespread childhood vaccination in the developed countries, the frequency of rubella has increased in the older age groups.

**Environment :** The disease exhibits a seasonal pattern. In temperate countries seasonal peaks of the disease are seen in late winter and spring, though infection remains endemic through the year.

**Transmission** : Rubella virus is transmitted by the respiratory route. The virus is spread by droplets shed from respiratory secretions of infected persons. The virus is highly communicable but less so than measles and varicella. As the disease has a large proportion of sub-clinical cases, they become important factors in disease transmission. Cases are infective from 10 days before to 15 days after onset of rash. Infants with congenital rubella continue to excrete the virus for several months despite high titers of neutralizing antibodies. Natural infection confers lifelong immunity.

### Clinical Features

**Postnatal Rubella** : The incubation period ranges from 12 to 23 days, with an average of 18 days. Viraemia occurs about a week after exposure and leads to viral spread to different organs. A large proportion of cases of postnatal rubella are subclinical. Children suffer from a milder form of the disease as compared to adults. Adults may have prodromal features of fever, malaise and anorexia. Generalized lymphadenopathy and a maculopapular rash are major clinical manifestations. The rash lasts 3 - 5 days. It usually first appears on the face and moves down the body. Complications of rubella are not as common as those following measles. Arthritis or arthralgia can occur in adults, being more common in females. Haemorrhagic manifestations, thrombocytopenia and encephalitis have been reported but are extremely rare complications.

**Congenital Rubella** : The effects of the rubella virus on the developing foetus are essentially a function of the duration of pregnancy at the time of infection. The risk of congenital defects gradually drops from as high as 65 - 85% in the first two months of pregnancy, to 30 - 35% in the third month, to 10% in the fourth month. The effects of congenital rubella may be temporary (low birth weight), permanent (deafness) and developmental (myopia). The effects of congenital rubella are often not apparent at birth but may be revealed later. More than 50% of infants born with Congenital Rubella Syndrome (CRS) appear normal at birth.

### Diagnosis

The mild presentation of the disease makes clinical diagnosis difficult. For postnatal rubella, confirmation of diagnosis can be done serologically. ELISA tests for IgG and IgM antibodies are available. Presence of rubella IgM or demonstration of a significant rise in rubella IgG from paired acute and convalescent sera provide evidence of ongoing or recent rubella infection. For congenital rubella, the diagnosis can be confirmed by RT-PCR or viral isolation from amniotic fluid.

### Treatment

Given the mild nature of postnatal rubella, no specific treatment is required. Patients with complications, commonly arthritis require symptomatic treatment.

### Prevention

A live attenuated vaccine against rubella has been available since 1966. There are a number of rubella vaccines available, either as single antigen vaccines or combined with either Measles vaccine (MR), Mumps vaccine or Measles and Mumps vaccine (MMR). Most of the currently - licensed vaccines are

based on the live, attenuated RA 27/3 strain of rubella virus. Rubella vaccine is usually administered at age 12 - 15 months. The vaccine has proven to be safe and effective. Seroconversion rates are as high as 95%. The vaccine should not be administered during pregnancy. However, accidental vaccination during pregnancy does not produce any ill effects (6).

**WHO Position** : The primary purpose of rubella vaccination is to prevent the occurrence of congenital rubella infection. Resource constraints may be an important factor in deciding the mode of use of the rubella vaccine. WHO recommends that countries wishing to prevent CRS should immunize adolescent girls and/or women of childbearing age. The most rapid impact would be achieved by mass campaigns for women of childbearing age (and men preferably). For increased impact even men should be vaccinated (2). The most commonly available rubella vaccine in India is the MMR (Measles, Mumps, and Rubella) vaccine. This vaccine is administered 0.5ml subcutaneously between 15 and 18 months of age.

### Summary

Rubella, also called German measles has a worldwide distribution. In many developed and some developing countries, widespread rubella vaccination during the past decade has markedly reduced rubella and CRS. The rubella virus is an enveloped, single-stranded RNA virus of the genus *Rubivirus* from the family *Togaviridae*. The disease exhibits a seasonal pattern. In temperate countries seasonal peaks of the disease are seen in late winter and spring. The virus is spread by droplets shed from respiratory secretions of infected persons. Cases are infective from 10 days before to 15 days after onset of rash. Clinically rubella manifest in two forms. In Postnatal Rubella the incubation period ranges from 12 to 23 days and large proportion of cases are subclinical. Generalized lymphadenopathy and a maculopapular rash are major clinical manifestations. Confirmation of diagnosis can be done serologically. In Congenital Rubella, the effects of the virus on the developing foetus are essentially a function of the duration of pregnancy at the time of infection. The risk of congenital defects gradually drops with progress of pregnancy. The effects of congenital rubella may be temporary (low birth weight), permanent (deafness) and developmental (myopia). The diagnosis can be confirmed by RT-PCR or viral isolation from amniotic fluid. No specific treatment is required in both forms of rubella. A live attenuated vaccine against rubella has been available since 1966. Most of the currently - licensed vaccines are based on the live, attenuated RA 27/3 strain of rubella virus. Rubella vaccine is usually administered at age 12 - 15 months. The most commonly available rubella vaccine in India is the MMR (Measles, Mumps, and Rubella) vaccine, administered subcutaneously 0.5ml between 15 and 18 months of age.

### Study Exercises

**Long Question** : Discuss the epidemiology, treatment, prevention and control of Rubella

**Short Notes** : (1) Clinical manifestations of Rubella (2) Rubella vaccine



### MCQs

1. The rubella virus is from \_\_\_\_\_ family  
(a) Herpesviridae (b) Togaviridae (c) Flaviviridae  
(d) Paramyxoviridae.
2. Rubella virus has a diameter of (a) 50 nm (b) 60 nm (c) 70 nm (d) 80 nm.
3. Rubella cases are infective from \_\_\_\_\_ days before to \_\_\_\_\_ days after onset of rash respectively (a) 2 & 4 (b) 8 & 10 (c) 10 & 15 (d) 20 & 15
4. Average incubation period of Rubella is (a) 16 days (b) 18 days (c) 20 days (d) 22 days
5. Rubella vaccine in India as MMR is given at (a) 6th month (b) 9th month (c) 15 - 18th month (d) 20 - 24th month

**Answers :** (1) b; (2) b; (3) c; (4) b; (5) c.

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## Chicken Pox and Herpes Zoster

Rajesh Vaidya

Chickenpox and Herpes zoster are distinct diseases but both are caused by the *Varicella zoster* virus. Chickenpox is an acute, highly contagious which occurs mostly in children. Herpes zoster on the other hand affects mostly the elderly and immunocompromised persons. Chickenpox has a worldwide distribution. It results from primary infection by the *Varicella zoster* virus. Like other Herpes viruses the *Varicella zoster* virus is capable of remaining latent in the neural ganglia. Reactivation of the latent virus causes Herpes zoster. While chickenpox is considered a benign disease in most settings, it extracts a high price in terms of absenteeism from school, parental leave and medical costs (1, 2).

### Epidemiology

Varicella infection occurs world wide. As the virus is highly contagious, disease rates in temperate countries prior to the introduction of widespread vaccination approached the annual birth rate (3). In temperate countries more than 95% of adults have antibodies against the virus (2). Childhood infection rates are somewhat lower in tropical countries but adult infection rates are higher. Chickenpox occurs in both endemic and epidemic forms in India. There has been a significant decline in the incidence and mortality due to chickenpox in countries with widespread paediatric immunization.

**Agent :** The *Varicella zoster* virus is a double - stranded DNA virus of the Herpesviridae family (Human  $\alpha$  herpes virus 3). It is an enveloped virus 150 to 200 nm in size. Humans are the only known hosts of the virus. Only one serotype is known.

**Host :** Chicken pox is primarily a disease of childhood particularly in temperate countries where 90% of cases occur before 13 years of age (4, 5). In tropical countries, it is more a disease of young adults. The virus exhibits no gender or ethnic group predilection. Natural infection confers lifelong immunity. However, the virus can remain latent in sensory root ganglia. Any reduction in cell mediated immunity can result in reactivation of the virus which causes Herpes zoster. The disease occurs with greater severity among adults, newborn infants, immunocompromised children and pregnant women (6). Mortality rates in normal young children are estimated to be less than 2 per 100,000. Mortality risk for adults is 15 times higher (3).

**Environment :** The disease epidemiology varies with ambient temperatures. In temperate countries the disease exhibits distinct seasonal variation with peak incidence in winter and spring (7).

**Transmission :** The source of infection is almost always a case of chickenpox as subclinical cases are rare (less than 5%). Transmission is through direct contact or air borne spread of infected droplets or droplet nuclei. The vesicle fluid is infective. The portal of entry for the virus is the upper respiratory tract. Patients are infective from one to two days before onset of rash to five days after first appearance of rash. Dry scabs are not infective. The virus is extremely contagious. Secondary attack rates are typically over 90% among susceptible household contacts (8). The virus can cross the placental barrier. Maternal infection in first trimester can give rise to congenital varicella syndrome. Maternal infection just prior to delivery may result in neonatal varicella which carries high mortality.

### Clinical Features

The incubation period ranges from one to three weeks, usually 13 to 17 days. It is shortened in the immunocompromised, and prolonged if Varicella Zoster Immune Globulin (VZIG) has been



taken (9). The pre eruptive stage of the disease is characterized by mild to moderate fever, malaise and shivering. This stage usually lasts a day or two but may be longer in adults. The rash which is the hallmark of the disease is distributed centrifugally. It first appears on trunk and face. The rash consisting of maculo - papules, vesicles, and scabs shows rapid evolution and pleomorphism. Early in the disease all stages of the rash can be seen. The rash appears in crops with each exacerbation of fever resulting in a fresh crop of rash. Healing starts within 4 - 5 days and the crusts fall off completely within one to two weeks. Immunocompromised children have a greater number of lesions which take longer to heal.

**Complications :** Chickenpox is usually a mild self limiting disease. However, complications can occur even in otherwise normal children. Secondary bacterial infection of the lesions is the commonest complication with Staphylococci and Streptococci being the most common pathogens. Rare complications include neurologic complications (Meningo encephalitis) and Reye's syndrome which occurs almost exclusively among children who have been given aspirin during the acute phase. In adults, primary varicella pneumonia or haemorrhagic complications may occur.

Maternal infection during the first trimester of pregnancy could result in the congenital varicella syndrome which is characterized by cicatricial skin scarring, hypoplasia of an extremity, mental retardation and low birth weight. Neonatal varicella occurs as a consequence of maternal infection in late pregnancy. The risk is highest in case of maternal disease five days prior to two days after delivery. These children may remain asymptomatic, or they may develop Herpes zoster at a young age without previous history of primary chickenpox infection.

### Diagnosis

The diagnosis of chickenpox is usually based on history of exposure and clinical features such as the characteristic rash. Laboratory confirmation of diagnosis is usually not required except in cases of atypical disease presentation. A Tzanck smear of vesicular fluid, demonstrates multinucleated giant cells and epithelial cells with eosinophilic intranuclear inclusion bodies. The disease can be confirmed by serology but tests usually take very long for diagnosis. Both IgM and IgG tests are available. IgM antibody testing is not considered useful as the tests are neither highly sensitive nor specific. Rising IgG titre from paired acute and convalescent sera are considered evidence of acute infection. Detection of virus, viral antigen or protein can also be done using electron microscopy or PCR. Direct Fluorescent Antibody (DFA) tests give rapid reliable results.

### Herpes Zoster

Between 10% and 20% of cases of chicken pox develop by Herpes zoster later in life. The disease is characterized by vesicular eruptions which are typically unilateral and follow a dermatomal distribution. The most commonly involved dermatomes are thoracic and lumbar (3). Most cases of Herpes zoster occur after the age of 50 years or among immunocompromised persons. It is a relatively common complication in HIV - positive persons occurring in 8 - 11% of patients. The disease may rarely result in permanent neurological damage in the form of cranial nerve palsies or visual impairment following Herpes

zoster ophthalmia. Nearly 15% of zoster patients have pain or paraesthesia in the affected dermatome for several weeks and sometimes permanently (postherpetic neuralgia) (10). Disseminated, Herpes zoster may occur in patients suffering from malignancies, AIDS or other immunocompromised states. Transmission of *Varicella zoster* virus from Herpes zoster patients may cause chickenpox in non - immune contacts (1).

### Treatment

No antiviral therapy recommended for routine use in uncomplicated varicella. Though the Food and Drug Administration (FDA) approved the use of oral acyclovir for the treatment of varicella in otherwise healthy children in 1992, the American Academy of Paediatric Committee on Infectious Diseases published a statement in 1993 stating that it did not consider administration of acyclovir to healthy children to have clinical benefit sufficient to justify its routine administration (11 - 14). In adults acyclovir is effective in reducing the duration and severity of illness, if the drug is administered within 24 hours of onset of rash (15, 16).

Antiviral therapy is indicated among the immunocompromised. These patients should be administered oral and intravenous acyclovir within 24 hrs of onset of rash. Famciclovir and valacyclovir have better bioavailability. Sorivudine (nucleoside analog) can be used in patients who report late. Foscarnet can be used in patients with acyclovir resistant *Varicella zoster* virus. For patients of Herpes zoster, acyclovir and famciclovir, have been approved by FDA for treating. Treatment reduces the severity of pain and hastens the healing of cutaneous lesions.

### Prevention and Control

Chickenpox may be prevented or modified by varicella - zoster immune globulin or treated with antiviral drugs. However, Varicella - zoster immune globulin and antiviral drugs are very expensive. Active immunization appears to be the only measure which can control the dissemination of varicella in a susceptible community. The control of chicken pox can be achieved only by widespread vaccination.

**Active Immunization :** A live attenuated vaccine based on the OKA strain has been available since 1974. The vaccine is considered safe and effective. A single dose achieves over 95% seroconversion. The vaccine must be given after one year of age. The dose for children from one year to below 13 years is 0.5 ml SC single dose. For those above 13 years of age two doses must be given, 4 - 8 weeks apart. The vaccine is well tolerated and side effects are rare. Contraindications and precautions include pregnancy, allergy to neomycin, immunodeficient state, malignancy, steroids administration and recent administration of blood, plasma, or immune globulin.

**WHO Position :** The World Health Organization (WHO) recognizes that in most developing countries other vaccine - preventable diseases cause greater morbidity and mortality. As a consequence, varicella vaccine is not a high priority for routine introduction into national immunization programmes. The WHO recommends that routine childhood immunization against varicella may be considered in countries where this disease is a relatively important public health and socioeconomic problem, where the vaccine is affordable, and where high (85% - 90%) and sustained vaccine coverage can be achieved (1).

**Passive Immunization** : Passive immunization against the *Varicella zoster* virus is available in the form of *Varicella zoster* Immune Globulin (VZIG). It is recommended for used in high risk groups including immunocompromised individuals, susceptible pregnant women, and new born infants. In case of exposure it should be administered as soon as possible after exposure (Within 96 h) at the dose of 125 IU per 10 Kg body weight IM injection.

**Control Measures** : As the disease is highly contagious prevention of transmission is not very effective. Outbreaks of chickenpox must be notified. Cases need to be isolated till all the lesions have crusted (Six days). Concurrent disinfection of articles soiled from discharges from the nose, throat, and from lesions should be done.

## Summary

Chickenpox and Herpes zoster are distinct diseases but both are caused by the *Varicella zoster* virus. As the virus is highly contagious, disease rates in temperate countries prior to the introduction of widespread vaccination approached the annual birth rate. Chickenpox occurs in both endemic and epidemic forms in India. The *Varicella zoster* virus is a double - stranded DNA virus of the Herpesviridae family. Chicken pox is primarily a disease of childhood particularly in temperate countries where 90% of cases occur before 13 years of age. The source of infection is almost always a case of chickenpox. Transmission is through direct contact or air borne spread of infected droplets or droplet nuclei. Secondary attack rates are typically over 90% among susceptible household contacts. The incubation period ranges from one to three weeks, usually 13 to 17 days. The pre eruptive stage of the disease is characterized by mild to moderate fever, malaise and shivering. The rash consisting of maculo - papules, vesicles, and scabs shows rapid evolution and pleomorphism. Healing starts within 4 - 5 days and the crusts fall off completely within one to two weeks. The diagnosis of chickenpox is usually based on history of exposure and clinical features such as the characteristic rash. Laboratory confirmation of diagnosis is usually not required. No antiviral therapy recommended for routine use in uncomplicated varicella. In adults acyclovir is effective in reducing the duration and severity of illness if the drug is administered within 24 hours of onset of rash. Antiviral therapy is indicated among the immunocompromised. Between 10% and 20% of cases of chicken pox develop Herpes zoster later in life. The disease is characterized by vesicular eruptions which are typically unilateral and follow a dermatomal distribution. It is a relatively common complication in HIV - positive persons occurring in 8-11% of patients. A live attenuated vaccine based on the OKA strain has been available since 1974. A single dose achieves over 95% seroconversion. The World Health Organization (WHO) recognizes that in most developing countries other vaccine - preventable diseases cause greater morbidity and mortality. As a consequence, varicella vaccine is not a high priority for routine introduction into national immunization programmes.

## Study Exercises

**Long Question** : Discuss the epidemiology, treatment, prevention and control of Chickenpox

**Short Notes** : (1) Characteristics of Chickenpox rash (2) Herpes zoster

### MCQs

1. Chickenpox occurs in \_\_\_\_\_ forms in India (a) Endemic forms (b) Epidemic forms (c) Both endemic and epidemic (d) None of the above.
2. The *Varicella zoster* virus is a (a) Single - stranded RNA Virus (b) Double - stranded RNA Virus (c) Single - stranded DNA Virus (d) Double - stranded DNA Virus.
3. Mortality rates in normal young children are estimated to be (a) less than 1 per 100,000 (b) less than 2 per 100,000 (c) less than 3 per 100,000 (d) less than 4 per 100,000.
4. The diagnosis of chickenpox is usually based on (a) Smear of vesicular fluid examination (b) Serology (c) Blood test (d) History of exposure and clinical features.
5. Disseminated Herpes zoster may occur in patients suffering from (a) Malignancies (b) AIDS (c) Immunocompromised states (d) All of the above.

**Answers** : (1) c; (2) d; (3) b; (4) d; (5) d.

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Smallpox an acute contagious disease caused by *variola* virus is the only disease to have been eradicated by medical science (1). Smallpox is believed to have originated over 3,000 years ago and was one of the most devastating diseases known to humanity. Epidemics of smallpox had inflicted mankind throughout history, and as recently as 1967, some 10 - 15 million cases were still occurring annually in more than 30 endemic countries (2). No treatment for the disease was ever devised. Despite its eradication over 30 years ago smallpox still evokes fear and dread. A part of this fear stems from the potential use of the smallpox virus as a biological weapon.

### Eradication

The story of the eradication of smallpox has been lucidly written by Fenner and Hendersen (2). The demonstration in 1798 by Edward Jenner that pus from a cowpox pustule could protect against smallpox brought the first hope that the disease could be controlled. Over a 150 years after the introduction of the vaccine an estimated 50 million cases of smallpox were still occurring in the world each year. When mass vaccination became widespread, the number of cases dropped to around 10 - 15 million by 1967. In 1967 WHO launched an intensified plan to eradicate smallpox (1).

The last known naturally occurring case of smallpox occurred in Somalia on 26 Oct 1977. Subsequently, two cases due to accidental laboratory infections were reported from England in 1978 (3, 4). A little over two year later smallpox officially was declared eradicated by the World Health Organization in 1980. In 1976, there were 76 laboratories through out the world that officially kept stocks of Smallpox virus. By 1980, the number was reduced to six laboratories. In 1983, the number was down to two; the US Laboratory in Atlanta, Georgia, and the Research Centre of Virology, Koltsovo, Russia, both WHO collaborating centers (5).

The two strategies used for the eradication of smallpox were mass vaccination and surveillance containment of the disease. The development of a stable freeze dried vaccine and the use of the bifurcated needle greatly facilitated mass immunization. However, high levels of immunization alone were not enough to eradicate smallpox. The surveillance - containment strategy was an essential accompaniment to mass vaccination for smallpox eradication to be achieved. Eradication was also facilitated by some epidemiological features of smallpox. The disease has no known animal reservoir. There is no long - term carrier state. Recovery from infection provides stable life long immunity. Detection of cases of smallpox was relatively simple because the rash was so characteristic and occurred on the visible parts of the body. An extremely effective and stable vaccine which provides long term immunity was available.

### The Disease

Smallpox is caused by the *variola* virus which is a member of the orthopoxvirus family. Other members of the genus include

cowpox and monkeypox. Transmission of smallpox occurs from person to person by infected aerosols droplets. The disease can also be transmitted by contaminated clothes and bedding. The disease has no animal reservoir. The incubation period of smallpox ranges from 7 - 17 days. Individuals are not infective to other during the incubation period.

The onset of symptoms is sudden with fever, malaise, headache, and body ache. Abdominal pain and vomiting may occur. About three days after the onset of fever, the characteristic rash appears, first on the face, hands and forearms and then after a few days progressing to the trunk. The centrifugal distribution of lesions, more prominent on the face and extremities than on the trunk, is a distinctive diagnostic feature of smallpox. Lesions progress from macules to papules to vesicles to pustules. All lesions in a given area progress together through these stages. 8 to 14 days after the onset of symptoms, the pustules form scabs which leave depressed depigmented scars upon healing. The disease can present in either of two main forms : *variola major* and *variola minor*. The disease followed a milder course in *variola minor*, which had a case - fatality rate of less than 1 per cent. The fatality rate of *variola major* was around 30%. Rare forms of smallpox are haemorrhagic and malignant smallpox both of which carry almost 100% mortality (1).

### Is Smallpox a Threat Today?

In 1979, WHO recommended that vaccination against smallpox be stopped in all countries. By 1986, routine vaccination had ceased in all countries. The eradication of smallpox was defined by successive WHO expert groups (WHO Scientific Group on Smallpox Eradication, 1968; WHO Expert Committee on Smallpox Eradication, 1972) as "the elimination of clinical illness caused by *variola* virus". An important corollary of this definition was that it did not involve the extinction of *variola* virus. However, there have been no cases of smallpox from any source for over thirty years. Fears of conversion of animal viruses like monkeypox to the smallpox virus have been discounted. Currently, the only credible sources of the virus are the stocks held in the two WHO Collaborating Centres in the United States and Russia. Therefore, other than the use of the virus as a biological weapon, there appears to be little reason to fear the return of smallpox.

### Summary

Smallpox is the only disease to have been eradicated by medical science. Over a 150 years after the introduction of the vaccine an estimated 50 million cases of smallpox were still occurring in the world each year. Hence in 1967 WHO launched an intensified plan to eradicate smallpox. The two strategies used for the eradication of smallpox were mass vaccination and surveillance containment of the disease. Finally smallpox was officially declared eradicated by the World Health Organization in 1980. Smallpox is caused by the *variola* virus which is a member of the orthopoxvirus family. Transmission of smallpox occurs from person to person by infected aerosols droplets. The incubation period of smallpox ranges from 7 - 17 days. The onset of symptoms is sudden with fever, malaise, headache and body ache. Three days after the onset of fever, the characteristic rash appears. Lesions progress from macules to papules to



vesicles to pustules 8 to 14 days after the onset of symptoms, the pustules form scabs which leave depressed depigmented scars upon healing.

## Study Exercises

**Short Note :** Eradication of Small pox

### MCQs

1. The last known naturally occurring case of smallpox occurred in (a) Somalia (b) Nigeria (c) Uganda (d) Libya.
2. Smallpox officially was declared eradicated by the World Health Organization in (a) 1978 (b) 1979 (c) 1980 (d) 1981.
3. Characteristic rash of smallpox appears \_\_\_\_ days after the onset of fever (a) 2 days (b) 3 days (c) 4 days (d) 5 days.

**Answers :** (1) a; (2) c; (3) b.

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## Diphtheria

Rajesh Vaidya

Diphtheria has been one of the most feared childhood diseases as, prior to the advent of treatment and vaccination, it carried a very high case fatality rate and occurred in devastating outbreaks (1). The word “diphtheria” originates from Greek “leather” which describes the pharyngeal membrane which is pathognomonic for diphtheria. The disease results from infection with toxigenic strains of *Corynebacterium diphtheriae*. The diphtheria bacillus was first described by Klebs in 1883 and was first cultured by Loeffler in a culture medium of his own design in 1884. It is, therefore, known as the “Klebs - Loeffler” bacillus.

### Epidemiology

**Global :** During the course of the twentieth century diphtheria has moved from being a dreaded childhood killer to a relatively rare disease in large parts of the world. In the United States diphtheria has dropped from 147,000 cases reported in 1920 to an average of two cases every year between 1990 and 2003 (2). In developing countries also, the inclusion of diphtheria vaccination in childhood programmes saw a steady decline in the incidence of the disease. The World Health Organization (WHO) estimates that one million cases of diphtheria including 50,000 - 60,000 deaths occurred each year in developing countries before diphtheria toxoid became easily accessible in the 1980s (1). Despite widespread immunization, diphtheria remains endemic in several parts of the developing world including Africa, India, Bangladesh, Vietnam and Brazil (3-5). 80 - 90% of the global burden of diphtheria cases still comes from developing countries (6). However, over the last decade and a half, the infection has re - emerged in some parts of

the developed world. An ongoing epidemic in the states of the former Soviet Union which began during the 1990s has brought diphtheria back into the list of important public health problems (2). This diphtheria epidemic had caused more than 157,000 cases and 5000 deaths by 1999. A total of 12,735 cases of diphtheria were reported to WHO in 2005 (7).

**India :** The inclusion of vaccination against diphtheria in the National Immunization Schedule has brought about a marked reduction in the incidence of diphtheria in India. Only 1326 cases of diphtheria were reported in India in 1997. This may represent gross underreporting. Over the last decade the number of reported cases has declined from 5,125 in year 2000 to 3,354 in year 2007 with a peak of 10,231 in year 2005 (8). The disease remains endemic in many parts of the country with the highest number of cases being reported from Andhra Pradesh (9, 10). Sporadic outbreaks have repeatedly been reported from in and around Delhi (11).

**Agent :** *Corynebacterium diphtheriae* are nonmotile, nonsporulating, unencapsulated gram positive bacilli (12). The word “Coryne” originates from Greek meaning “club” and refers to the club shaped appearance of the bacillus. The species is subdivided into four biotypes : *gravis*, *mitis*, *belfanti* and *intermedius* (1). This division is based on colony characteristics, haemolytic activity, and fermentation reactions. The most important factor determining virulence of *Corynebacterium diphtheriae* is the exotoxin. The production of exotoxin depends on a lysogenic  $\beta$  phage. Diphtheria exotoxin causes both local and systemic cell destruction. In addition to the exotoxin, cell - wall components such as the O and K antigens are important in the pathogenesis of the disease.

**Host :** Before vaccination became widespread, diphtheria was essentially a disease of children. Even today, in endemic countries, the highest incidence rates for diphtheria are in preschool children and school age children. Childhood immunization programmes have altered the age distribution



of cases. Over 60% of cases and more than three fourths of deaths due to diphtheria in an epidemic that began in 1990 in the Newly Independent States of the former Soviet Union occurred among adults (13, 14). In developed countries, where the incidence of diphtheria has declined markedly, the disease now occurs predominantly in unimmunized adults, homosexual men, intravenous drug abusers, and minority racial groups (3). Studies in India have also demonstrated a rise in proportion of cases of diphtheria over five years of age (15).

**Environment :** The incidence of diphtheria shows a seasonal variation. In temperate countries most of the cases occur during the winter. In tropical areas, this distinction is blurred with transmission taking place throughout the year (1).

**Transmission :** The primary modes of transmission are airborne respiratory droplets and direct contact with respiratory secretions or exudates from skin lesions. Transmission can occur through fomites. Contaminated milk has also been implicated in transmission. Humans are the only known reservoir of the disease. Infection can spread from both cases and carriers.

### Clinical Features

The incubation period for diphtheria ranges from one to five days. In most cases, transmission of infection to susceptible individuals results in short term pharyngeal carriage rather than in disease. Presentation of diphtheria depends on the portal of entry which may be the respiratory tract or the skin. *Corynebacterium diphtheriae* is not very invasive and usually remains confined to the respiratory mucosa and the skin. Systemic spread of the organism is not common.

**Respiratory Tract :** Infection can result in an asymptomatic carrier state, particularly in regions where the disease is endemic. The common sites within the respiratory tract are anterior nasal infection, faucial infection, and laryngeal or tracheobronchial infection.

**Anterior Nasal :** The patient is febrile and has serous or seropurulent nasal discharge. Symptoms are usually mild and toxin effects are uncommon.

**Faucial Infection :** This is the commonest site for respiratory diphtheria. The patient has fever, malaise and sore throat. The characteristic feature is the development of a membrane on one or both sides. The membrane may be confined to the tonsils or extend over a larger area including the uvula, soft palate, oro - pharynx and naso - pharynx. The extent of the membrane corresponds with the severity of the symptoms. The membrane is white in colour to begin with, but rapidly changes to a grey colour. Attempts to remove the membrane result in bleeding. Cases with severe disease develop marked local edema resulting in a "bull neck" appearance and respiratory stridor.

**Laryngeal or tracheobronchial infection :** This is the most severe type of respiratory infection. It usually results from a downward spread of pharyngeal infection. Patients present with cough, hoarseness of voice, respiratory stridor and may even have dyspnoea.

**Cutaneous Diphtheria :** Cutaneous diphtheria is characterized by a chronic non - healing ulcer covered by a dirty gray membrane. The ulcers are usually indolent, non - progressive and superficial. Erythema, tenderness, and pain may be present.

Cutaneous diphtheria can co - exist with other skin infections. These lesions are far more common in tropical countries and may constitute an important reservoir of infection. Infection at other sites is uncommon but otitis externa, purulent or ulcerative conjunctivitis, purulent or ulcerative vulvovaginitis and even pyogenic arthritis are known.

### Complications

Death from diphtheria results as a consequence of severe respiratory disease resulting in airway obstruction or from systemic complications due to diphtheria toxin. The extent of toxin absorption depends largely on the extent of the mucosal lesions. The WHO - defined clinical conditions associated with increasing risk of toxin - induced systemic disease are the catarrhal form (erythema of pharynx, no membranes); the follicular form (patches of exudates over pharynx and the tonsils); the spreading form (membranes covering the tonsils and posterior pharynx); and the combined form (more than one anatomical site involved, for example throat and skin). Diphtheria toxin is toxic to all body tissues but the most important complications result from its effects on the heart and the nervous system.

**Cardiac Toxicity :** The probability of developing cardiac dysfunction is directly correlated with severity of local disease. Myocarditis can begin anytime from the first to the sixth week of clinical illness. The complication is seen in 10 to 25% of patients and carries 50 to 60% mortality. Presentation of myocarditis can extend from heart blocks to congestive failure and circulatory collapse.

**Neurologic Toxicity :** Peripheral or cranial neuritis can develop one to eight weeks after onset of clinical illness. The occurrence of Neurologic toxicity also correlates well with the severity of local disease. Local paralysis of the soft palate and the posterior pharyngeal wall are the most common presentations. Peripheral neuritis occurs more rarely and takes longer to present. Patients who survive recover completely.

### Diagnosis

Prompt treatment greatly improves the prognosis in cases of diphtheria. A high index of suspicion can help in early clinical diagnosis. The presence of hoarseness and stridor along with the characteristic membrane in patients with febrile pharyngitis are adequate to make a diagnosis. Confirmation can be done by culturing smears from the membrane on Loeffler's or tellurite media. Culture specimens should ideally be taken before administration of antibiotics. A PCR test is now available for confirming diphtheria.

### Treatment

Diphtheria antitoxin is the cornerstone of definitive treatment. Institution of definitive treatment should not wait for bacteriological confirmation of diagnosis as the antitoxin can neutralize the toxin only before it enters the cells. As the antitoxin is equine in origin and can result in severe anaphylaxis, hypersensitivity testing must be done before use. The dose depends on the duration of and severity of disease. Doses ranging from 20,000 units to 100,000 units have been recommended. Both intravenous (for severe cases) and intramuscular (for moderate cases) routes of administration

are recommended.

Antibiotics are administered to cases of diphtheria for terminating toxin production by eliminating the organism and preventing transmission of disease. A number of antibiotics can be used against *Corynebacterium diphtheriae* including penicillin, erythromycin, azithromycin, tetracycline and rifampicin. Procaine penicillin can be given intramuscularly in the dose of 300,000 units for children below 10 Kg weight and 600,000 units for children weight more than 10 Kg twice daily till the patient is able to swallow comfortably. The dose for erythromycin is 125 mg to 500 mg four times a day for 14 days. Supportive treatment is required particularly in severe cases. Management of complications including airway obstruction must be done energetically. Natural infection does not always confer immunity against the toxin. Patients must, therefore, be given active immunization during convalescence.

### Contacts

Household and other close contacts of diphtheria cases should be investigated with culture from nasal swabs. Prophylactic antibiotics, either penicillin or erythromycin should be given for seven days irrespective of immunization status. Contacts with positive cultures should receive active immunization against the disease and repeat cultures two weeks after the course of antibiotics.

### Prevention and Control

Active immunization against diphtheria is the mainstay of disease prevention. Diphtheria vaccines are based on diphtheria toxoid, which is a modified bacterial toxin that induces protective antitoxin. The vaccine is available almost always combine with Tetanus toxoid (DT) or tetanus toxoid and Pertussis vaccine (DPT).

The potency of diphtheria toxoid is expressed as flocculation units (Lf) whereas toxoid potency is measured in international units (IU). According to WHO requirements, the potency of diphtheria vaccine used for the immunization of children shall not be less than 30 IU per single human dose. Vaccines of lower potency are used for immunization of children aged above 7 years and adults. This reduction of diphtheria toxoid potency minimizes reactogenicity at the injection site but is still sufficient to provoke an antibody response in older children and adults.

The recommended schedule for childhood immunization in India is three doses of DPT given 0.5 ml intramuscularly (IM) at six, ten and fourteen weeks of age. This primary series is followed by another 0.5 ml IM between 16 and 24 months of age. A booster of DT is given at four to six years of age. For previously unimmunized children aged between one and seven years, WHO recommends two doses of DPT two months apart followed by a third dose after 6 to 12 months. For older children and adolescents a similar schedule should be followed using the DT vaccine.

Vaccines containing diphtheria toxoid should be stored 2 to 8 °C. Vaccines that have been accidentally frozen should not be used. Diphtheria toxoid is one of the safest vaccines available. Severe reactions are extremely rare.

## Summary

The word “diphtheria” originates from Greek “leather” which describes the pharyngeal membrane which is pathognomonic for diphtheria. The diphtheria bacillus was first described by Klebs in 1883 and was first cultured by Loeffler in a culture medium of his own design in 1884. A total of 12, 735 cases of diphtheria were reported to WHO in 2005. The inclusion of vaccination against diphtheria in the National Immunization Schedule has brought about a marked reduction in the incidence of diphtheria in India with only 3354 cases in 2007. *Corynebacterium diphtheriae* are nonmotile, nonsporulating, unencapsulated gram positive bacilli. The species is subdivided into four biotypes : *gravis*, *mitis*, *belfanti* and *intermedius*. The most important factor determining virulence of *Corynebacterium diphtheriae* is the exotoxin. The primary modes of transmission are airborne respiratory droplets and direct contact with respiratory secretions or exudates from skin lesions. The incubation period for diphtheria ranges from one to five days. The common sites within the respiratory tract are anterior nasal infection, faucial infection, and laryngeal or tracheobronchial infection. Death from diphtheria results as a consequence of severe respiratory disease resulting in airway obstruction or from systemic complications due to diphtheria toxin. Confirmation of diagnosis can be done by culturing smears from the membrane on Loeffler's or tellurite media. Diphtheria antitoxin is the cornerstone of definitive treatment. Antibiotics are administered to cases of diphtheria for terminating toxin production by eliminating the organism and preventing transmission of disease. Household and other close contacts of diphtheria cases should be given prophylactic antibiotics, either penicillin or erythromycin for seven days irrespective of immunization status. Active immunization against diphtheria is the mainstay of disease prevention. In India, three doses of DPT 0.5 ml intramuscularly (IM) are given at six, ten and fourteen weeks of age.

## Study Exercises

**Long Question :** Discuss the epidemiology, treatment, prevention and control of Diphtheria

**Short Notes :** (1) Clinical manifestations of Diphtheria  
(2) Diphtheria Vaccine

### MCQs

1. The diphtheria bacillus was first described by (a) Klebs (b) Loeffler (c) Robert Koch (d) None of the above.
2. The most important factor determining virulence of *Corynebacterium diphtheriae* is (a) Exotoxin (b) Edotoxin (c) O antigens (d) K antigens.
3. This is the commonest site for respiratory diphtheria is (a) Anterior Nasal (b) Faucial Infection (c) Laryngeal or tracheobronchial infection (d) None of the above.
4. This is the most severe type of respiratory infection (a) Anterior Nasal (b) Faucial Infection (c) Laryngeal or tracheobronchial infection (d) None of the above.
5. All are characteristics of *Corynebacterium diphtheriae* except (a) Nonmotile (b) Nonsporulating (c) Encapsulated (d) Gram positive bacilli.

**Answers :** (1) a; (2) a; (3) b; (4) c; (5) c.

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## Mumps

*Rajesh Vaidya*

The name comes from the British word “to mump”, that is grimace or grin. This results from the appearance of the patient as a result of parotid gland swelling. Mumps is a viral infection primarily affecting the salivary glands. In most instances mumps is a mild childhood disease. However, the mumps virus may also affect adults, among whom complications such as meningitis and orchitis are relatively common. Encephalitis and permanent neurological sequelae are rare complications of mumps.

### Epidemiology

Mumps is endemic worldwide. Before the 1960s, mumps was a common infectious disease in all parts of the world, with annual incidences usually ranging from approximately 0.1% to 1%, and up to 6% in certain populations. Currently, in most parts of the world, the annual incidence of mumps is in the range of 100 to 1000 per 100,000 population. In areas without childhood vaccination against mumps, epidemics occur every two to five years (3).

**Agent :** The mumps virus belongs to the genus rubulavirus and is a part of the paramyxoviridae family. It is an enveloped, non - segmented, negative - sense RNA virus with helical symmetry. It has two major surface glycoproteins : the haemagglutinin - neuraminidase and the fusion protein. Mumps virus is sensitive to heat and ultraviolet light. Only one serotype is known (2).

**Host Factors :** Humans are the only natural hosts. The disease is rare in children younger than one year of age. Peak incidence

is found among children five to nine years of age (3). However, with increasing vaccination, cases are increasingly being reported among young adults. Natural infection usually results in life long immunity.

**Environment :** In hot climates the disease is endemic throughout the year, whereas in temperate climates incidence peaks in winter and spring (3).

**Transmission :** Humans are the only known natural host for mumps virus. The virus is spread via direct contact or by airborne droplets from the upper respiratory tract and requires more intimate contact for transmission than measles or chicken pox. Rarely, transmission can be fomite borne through articles freshly contaminated with saliva. Overcrowding resulting in close contact such as school classrooms, cinema halls, army barracks facilitates transmission. Persons with mumps are infective from about 2 days before the onset of swelling of the salivary glands up to 9 days after the onset of swelling.

**Pathogenesis :** The primary site of viral replication is the upper respiratory tract or the gastrointestinal tract. The virus spreads rapidly to the local lymphoid tissue and a primary viraemia ensues following which the virus spreads to distant sites in the body. The parotid gland is most commonly involved. However the testis, epididymis, pancreas, ovary and CNS may also be involved. A few days after the onset of illness, virus can again be isolated from the blood, indicating that virus multiplication in target organs leads to a secondary viraemia. The virus is excreted in the urine in infectious form during the two weeks following the onset of clinical illness.

### Clinical Features

The incubation time averages 16 to 18 days with a range of 2 to 4 weeks (3). With an overall mortality of only 1 per 10,000 cases, mumps is generally a mild, self limiting disease (3). A



prodromal illness of headache, malaise, myalgia and low grade fever occurs for one or two days before the onset of parotid enlargement. Cases of classic mumps develop enlargement of one parotid gland, followed a few days later by enlargement of the contralateral gland. The patient complains of pain and tenderness in the area of the gland. The sub - mandibular and sublingual glands may occasionally be involved. Parotid swelling develops in 95% of those with clinical illness. Upto 30% of patients may have no or very mild symptoms (sub - clinical cases). Most infections in children below two years of age are subclinical. In a small proportion of patients, the symptoms may resemble mild URTI. The parotid swelling starts to subside after 4 to 7 days and complete recovery usually takes another three days.

### Complications

Although the disease is usually mild, up to 10% of patients can develop aseptic meningitis. Encephalitis which can result in death or disability is a less common complication. Permanent deafness, orchitis, and pancreatitis are other untoward effects of mumps. Epididymo - orchitis occurs in about 25% of postpubertal men who contract mumps (4). Testicular atrophy occurs in about one - third of patients with mumps orchitis, but sterility is rare. Mumps orchitis appears to be a risk factor for testicular cancer, though not a major one (5).

Oophoritis can occur in postpubertal women. Among women who acquire mumps during the first 12 weeks of pregnancy, more than a quarter suffer spontaneous abortion. Maternal mumps is not associated with congenital anomalies (6 - 9). Aseptic meningitis occurs in 10% of patients with mumps but as many as 50% show abnormalities in the CSF. Encephalitis is a rare complication of mumps. The incidence of encephalitis is around 1 in 6000 cases of mumps. Deafness is a well - recognized complication of mumps. The incidence of hearing loss is estimated to be in the region of 1 per 15,000 cases. The exact incidence of pancreatitis is hard to determine but is thought to be as high as 4%. There is evidence suggesting that mumps virus can infect human pancreatic beta cells, and may trigger the onset of insulin - dependent diabetes mellitus in some individuals. Arthralgia affecting a large joint may develop 2 weeks after parotitis. Myocarditis can usually only be found on ECG examination in 10 - 15% of patients.

### Diagnosis

Cases are commonly diagnosed based on history and clinical presentation; laboratory tests are unnecessary. For specific diagnosis, it is possible to isolate the virus from throat swabs, saliva, urine, and CSF. An assay for the detection of mumps - specific immunoglobulin M antibodies in serum and oral fluid specimens is commercially available. Diagnosis can also be made by significant rise between acute and convalescent phase titers in serum mumps IgG antibody level using any standard serologic assay or positive serologic test for mumps IgM antibody. Interpretation of titer rise may have limitations because of mumps cross - reaction with parainfluenza viruses (1, 2). The presence of mumps virus in a cell culture may be detected by the Haemadsorption Inhibition (HAI) test (3).

### Management

Mumps is a mild, self limited disease. No specific anti - viral

therapy is indicated. Treatment is conservative. Analgesics may be given for severe headaches or discomfort due to parotitis. In orchitis, stronger analgesics may be needed. Bed rest is recommended for a faster recovery.

### Prevention

Deaths due to mumps are rare. However, the fact that in unvaccinated communities almost every person may get infected and infections are associated with a number of complications imposes a substantial economic burden on society (3). Effective vaccines against mumps and high vaccination coverage reduce the incidence of mumps to insignificant levels. The first vaccine developed against mumps was a killed vaccine which was used in the United States between 1950 and 1978. This vaccine offered low efficacy and short term effectiveness. Since then, live attenuated mumps virus vaccines have been developed based on several different strains. The common ones are the Jeryl - Lynn strains, RIT 4385 strains, Leningrad - 3 strains, L - Zagreb strains, Urabe strains & the Rubini strains (3). The recommended use is the form of a single dose schedule, given at age 12 - 18 months. This is because persistent maternal antibody to mumps virus from previous infection or vaccination interferes with the response to mumps vaccines in young infants. Mumps vaccines are available as monovalent, bivalent Measles - Mumps (MM) and trivalent Measles - Mumps - Rubella (MMR) vaccines. Most of these vaccines contain more than 1,000 cell - CCID50 of attenuated mumps virus per dose. The trivalent MMR vaccine is given as 0.5 ml subcutaneously in the outer aspect of upper arm between 12 to 15 months of age. In India, the MMR vaccine is manufactured by the Serum Institute of India. The strains used are L - Zagreb for mumps, Edmonston Zagreb for measles and Plotkins RA 27/3 for rubella. Being live vaccines, these have exacting storage requirements. They should be protected from heat and light both before and after reconstitution. Reconstituted vaccine must be discarded if not used within 6 hours.

There are very few contraindications to mumps vaccination. Like all other live vaccines the mumps vaccine should not be administered to immunocompromised individuals. MMR vaccine can be given to individuals infected with Human Immunodeficiency Virus (HIV) and who are not severely immunocompromised. Though the vaccine has no known teratogenic effects, the mumps vaccine should not be administered to pregnant women and pregnancy should be avoided for three months after vaccination. The mumps vaccine has proven to be extremely safe, adverse effects are rare and mild. The most common adverse reactions following mumps vaccination are parotitis and low - grade fever. Aseptic meningitis following vaccination has been reported at widely varying frequencies. Vaccine - associated meningitis usually resolves spontaneously in less than a week without any sequelae. Orchitis and sensory - neural deafness have been reported following mumps vaccination. Immunoglobulin has not been demonstrated to be of established value in post exposure prophylaxis and is not recommended.

### Control

The World Health Organization (WHO) indicates that mumps can be controlled through high routine coverage with mumps



vaccine administered at age 12 - 18 months. Coverage rates below 70% - 80% may result in an epidemiological shift, as reduced (but not interrupted) circulation of mumps virus in the community may result in an increased number of cases in adults without immunity from natural infection. It considers the addition of mumps vaccine to the measles and rubella vaccination programmes using the MMR combined vaccine as logistically sound, encourages the use of MMR combination where affordable and where vaccine supply is sufficient. The WHO recommends that introduction of mumps vaccine into national childhood immunization programmes should be considered only in countries that have or are establishing adequate vaccination programmes for measles elimination and control of the congenital rubella syndrome (3).

## Summary

Mumps is a viral infection primarily affecting the salivary glands. Mumps is endemic worldwide. The annual incidence of mumps is in the range of 100 to 1000 per 100,000 population. The mumps virus belongs to the genus rubulavirus and is a part of the paramyxoviridae family. Humans are the only natural hosts. Peak incidence is found among children five to nine years of age. The virus is spread via direct contact or by airborne droplets from the upper respiratory tract. Persons with mumps are infective from about 2 days before the onset of swelling of the salivary glands up to 9 days after the onset of swelling.

The incubation time averages 16 to 18 days with a range of 2 to 4 weeks. A prodromal illness of headache, malaise, myalgia and low grade fever occurs for one or two days before the onset of parotid enlargement. The parotid swelling starts to subside after 4 to 7 days and complete recovery usually takes another three days. Complications include aseptic meningitis, encephalitis, Permanent deafness, orchitis and pancreatitis. Cases are commonly diagnosed based on history and clinical presentation and laboratory tests are unnecessary. Mumps is a mild, self limited disease. No specific anti - viral therapy is indicated. Treatment is conservative. Analgesics may be given for severe headaches or discomfort due to parotitis. Mumps vaccines are available as monovalent, bivalent Measles - Mumps (MM) and trivalent Measles - Mumps - Rubella (MMR) vaccines. The trivalent MMR vaccine is given as 0.5 ml subcutaneously in the outer aspect of upper arm between 12 to 15 months of

age. The WHO recommends that introduction of mumps vaccine into national childhood immunization programmes should be considered only in countries that have or are establishing adequate vaccination programmes for measles elimination and control of the congenital rubella syndrome.

## Study Exercises

**Long Question :** Discuss the epidemiology, treatment, prevention and control of Mumps.

**Short Notes :** (1) Complications of Mumps (2) Vaccination against Mumps

### MCQs

1. The mumps virus belongs to \_\_\_\_\_ family  
(a) Myxoviridae (b) Paramyxoviridae (c) Flaviviridae (d) Rhabdoviridae.
2. Mumps virus how many known serotype ? (a) 1 (b) 2 (c) 3 (d) 4
3. Average Incubation time of Mumps is ? (a) 10 - 12 (b) 13 - 15 (c) 16 - 18 (d) 19 - 21
4. In India, the MMR vaccine uses which strain for mumps  
(a) Rubini strain (b) Urabe strain (c) L - Zagreb strain (d) Jeryl - Lynn strain.

**Answers :** (1) b; (2) a; (3) c; (4) c.

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Meningitis, or inflammation of the meninges, can be caused by several different bacterial pathogens. By far, the most important of these pathogens is *Neisseria meningitides* because of its potential to cause epidemics (1).

### Epidemiology

Meningococcal meningitis occurs worldwide in both endemic and epidemic forms. It is estimated to be responsible for over 500,000 cases and about 135,000 deaths annually (2). First isolated in 1887, *Neisseria meningitides* is an exclusive human pathogen with the mucosal surfaces of the human nasopharynx being its natural habitat and reservoir (3). In most cases colonization of the human nasopharynx is asymptomatic. However, blood stream invasion by *Neisseria meningitides* can lead to meningitis and septicaemia with serious consequences. Even with adequate chemotherapy, meningococcal meningitis has a fatality rate of about 10% and about 15% of the survivors have residual Central Nervous System (CNS) damage (4).

Worldwide serogroups A, B and C account for most cases of meningococcal disease. The predominant serogroups in Asia and Africa are A and C while serogroups B and C are responsible for the majority of cases in Europe and the Americas. Recent outbreaks among Haj pilgrims have been attributed to serogroup W135. Epidemic rates of meningococcal disease varies from <1 - 3/100,000 in many developed nations to 10 - 25/100,000 in some developing countries.

The highest level of meningococcal disease occurs in the 'African meningitis belt', which stretches across sub-Saharan Africa from Senegal in the west, to Ethiopia in the east. During epidemics this region has a disease incidence rate of >1,000 cases per 10,000 population. The largest recorded outbreak of meningococcal disease in history occurred in Africa in 1996 where 250,000 cases including 25,000 deaths were reported to the WHO. Major epidemics of meningococcal meningitis have been reported from Asia over the past 35 years. China, Vietnam, Mongolia, Bhutan, and Nepal have all reported large outbreaks with Serogroup B being implicated most often.

Isolated cases of meningococcal meningitis have been reported from many Indian states including Haryana, Uttar Pradesh, Rajasthan, Sikkim, Gujarat, Jammu & Kashmir, West Bengal, Chandigarh, Kerala and Orissa. Serogroup A has been associated with all the repeated outbreaks of meningitis, although serogroup B and C have been detected in a few sporadic cases. Several outbreaks of meningococcal meningitis have been reported from Delhi in 1966, 1985 and 2005.

It is estimated to be responsible for over 500,000 cases and about 135,000 deaths annually (2). First isolated in 1887, *Neisseria meningitides* is an exclusive human pathogen with the mucosal surfaces of the human nasopharynx being its natural habitat and reservoir (3). In most cases colonization of the human nasopharynx is asymptomatic. However, blood stream invasion by *Neisseria meningitides* can lead to

meningitis and septicaemia with serious consequences. Even with adequate chemotherapy, meningococcal meningitis has a fatality rate of about 10% and about 15% of the survivors have residual Central Nervous System (CNS) damage (4).

**Agent** : *Neisseria meningitides* are bean shaped gram negative, aerobic diplococci. The bacteria are surrounded by an outer membrane of lipids, membrane proteins and lipopolysaccharides. Pathogenic meningococci are enveloped by a polysaccharide capsule (5). The capsular polysaccharide provides the basis for their classification into serogroups (6). They differ in their agglutination reactions to sera directed against polysaccharide antigens. At least 13 serogroups have been described : A, B, C, D, E, H, I, K, L, W - 135, X, Y and Z. Almost all meningococcal infections are caused by five serogroups A, B, C, 29E or W - 135 (7).

**Host** : Maternal antibodies offer protection against invasive disease till the age of six months. Susceptibility peaks at age 6 - 12 months and decreases again after colonization of closely related nonpathogenic bacteria. Subsequent colonization with *Neisseria meningitides* induces antibodies to the infecting strain, thus reinforcing natural immunity. Invasive disease occurs if no protective bactericidal antibodies are mounted against the infecting strain (7). Those infected with the Human Immunodeficiency Virus are probably also at increased risk for sporadic meningococcal disease (8).

Incidence rates are highest between the age of six months and two years (8). The disease is rarely reported in individuals over 50 years of age. There appears to be no gender predilection, though males account for slightly more than half the reported cases (7). Smoking, both active and passive, antecedent upper respiratory tract infection, underlying chronic illnesses are all associated with increased risk of meningococcal disease (8). Low socioeconomic status with its attendant attributes of poor housing, overcrowding, and inadequate ventilation have been consistently found to be associated with higher risk for meningococcal disease.

**Environment** : Individuals acquire the infection if they are exposed to virulent bacteria and have no protective bactericidal antibodies. Smoking and concurrent viral infection of the upper respiratory tract diminish the integrity of the respiratory mucosa and increase the likelihood of invasive disease. Crowded living conditions also facilitate disease spread, since individuals from different areas have different strains of meningococci. The risk of invasive disease is higher in the first few days after exposure to a new strain.

**Transmission** : The main modes of transmission are direct contact and respiratory droplets. Respiratory droplets produced by coughing and sneezing can be transmitted to non immune hosts within a distance of one meter. Close contact like kissing, living in close quarters (like military dormitories) and sharing of utensils enhance the risk of transmission (1).

The average incubation period is 3 - 4 days with a range of 2 to 10 days (1). This is also the period of communicability. The bacteria are rapidly eliminated from the nasopharynx after starting antibiotics, usually within 24 hours. Humans are the only reservoir. Both cases and carriers serve as the source of infection. 5 - 10% adults are asymptomatic nasopharyngeal

carriers during inter - epidemic periods. This figure can, however, rise to 60 - 80% in closed populations like military recruits in camps (7).

**Pathophysiology** : For invasive disease to occur, a susceptible host must be exposed to a pathogenic strain, be colonized by the pathogenic strain on the naso - oropharyngeal mucosa followed by invasion by the bacteria. Invasion can be subdivided into mucosal penetration followed by invasion of blood stream and finally, invasion of meninges (8). Meningococci overcome host defenses and attach to the microvillous surface of nonciliated columnar mucosal cells of the nasopharynx, where they multiply. In a small proportion of those infected, *Neisseria meningitidis* penetrates the mucosa and gains access to the bloodstream, causing systemic disease (6). Systemic disease appears with the development of meningococemia and usually precedes meningitis by 24 to 48 hours. This can lead to systemic infection in the form of bacteremia, involvement of the meninges or severe systemic infection with circulatory collapse and disseminated intravascular coagulation. Meningococemia leads to diffuse vascular injury (7).

### Clinical Features

The most common symptoms are acute onset of intense headache, high fever, nausea, vomiting, sensitivity to light (photophobia), and stiff neck. These symptoms can develop over several hours, or they may take 1 - 2 days. Most adult patients have an altered mental state with clinical signs of nuchal rigidity. Less commonly reported symptoms include stupor or coma, which carries a poorer prognosis. A more severe form of meningococcal disease is meningococcal septicaemia which is characterized by a haemorrhagic rash which usually indicates disease progression and rapid circulatory collapse.

In Infants and young children bacterial meningitis usually presents as a subacute infection that progresses over several days. There is a slower onset of signs and symptoms with nonspecific symptoms and neck stiffness may be absent. Irritability and projectile vomiting may be the presenting features in this age group. Seizures occur in 40% of children with meningitis. The Waterhouse - Friderichsen syndrome may develop in 10 - 20% of children with meningococcal infection. This syndrome is characterized by large petechial haemorrhages in the skin & mucous membranes, fever, septic shock & DIC (7). Even when the disease is diagnosed early and adequate therapy instituted, 5% to 10% of patients die, typically within 24 - 48 hours of onset of symptoms. Bacterial meningitis may result in brain damage, hearing loss or learning disability in 10 to 20% of survivors (1).

### Diagnosis

The diagnosis of meningococcal meningitis is suspected by the clinical presentation and a lumbar puncture showing a purulent spinal fluid. Typical CSF abnormalities in meningitis include the increased pressure (>180 mm water), WBC counts between 10 and 10,000 cells/ $\mu$ L, (predominantly neutrophils), decreased glucose concentration (<45 mg/dL) and increased protein concentration (>45 mg/dL) (7). Bacteriological diagnosis in patients with meningococcal disease can be done by Gram staining, direct antigen detection using latex agglutination, or culture. Blood cultures may not be always revealing and only

CSF samples are generally positive.

Gram staining of cerebrospinal fluid is still considered an important method for rapid detection of *Neisseria meningitidis*. Commercially available kits to detect polysaccharide antigen in cerebrospinal fluid, have been used to enhance the laboratory diagnosis. These methods are rapid and specific and can provide a serogroup - specific diagnosis, but false negative results are common.

### Management

Meningococcal disease is potentially fatal and should always be viewed as a medical emergency. Management of meningococcal disease requires early recognition of the disease, prompt initial parenteral antibiotic therapy and close monitoring with frequent repeated prognostic evaluations. Admission to a hospital centre is essential. Isolation of the patient is not necessary. Antimicrobial therapy must be commenced as soon as possible after the lumbar puncture has been carried out. Several antibiotics can be used for treatment including penicillin, ampicillin, chloramphenicol and ceftriaxone (1). A single intramuscular dose of an oily suspension of chloramphenicol has been shown to be as effective as a five - day course of crystalline penicillin in the treatment of meningococcal meningitis. During epidemics, this may offer a practical alternative to penicillin or ceftriaxone which require multiple injections.

The adult dose of penicillin is 4 million units IV four times a day. The paediatric dose is 250,000 Units/Kg/day given intravenously in divided doses. For Ceftriaxone, the adult dose is four gram IV per day divided into two doses. Paediatric dose is 50 mg/Kg IV divided into two doses (not to exceed 4 g/d). The use of corticosteroids has not been shown to be effective for meningococcal meningitis and its use remains controversial.

### Prevention and Control

**Chemoprophylaxis** : Chemoprophylaxis is the preferred means of prevention of disease among close contacts of sporadic cases. Household contacts, contacts at day care centres and anyone else directly exposed to an infected patient's oral secretions should be administered chemoprophylaxis as soon as possible (ideally within 24 hours). Chemoprophylaxis has probably limited or no benefit if given more than 14 days after the onset of disease. Antibiotics that can be used for chemoprophylaxis are rifampin, ciprofloxacin, ceftriaxone, minocycline, ofloxacin, and spiramycin. Ciprofloxacin single oral dose of 500 mg, rifampicin 600 mg 12 hourly for two days, or ceftriaxone 250 mg IM single dose are the options for adults. Rifampicin should be avoided during pregnancy. The choices for children include rifampicin 10 mg/Kg 12 hourly for two days (5mg/Kg for infants) or injection ceftriaxone 125 mg IM single dose.

Chemoprophylaxis is not recommended during epidemics because of multiple sources of exposure and prolonged risk of exposure. Logistic problems and high cost also make this an impractical alternative for mass use. It is not an effective means of interrupting transmission during an epidemic. Chemoprophylaxis may prevent secondary cases among close contacts, but since secondary cases comprise less than 2% of all meningococcal disease, chemoprophylaxis is of little value for the control of most endemic and epidemic disease. As



almost 15% of children and young adults carry meningococci in the nasopharynx, control of meningococcal disease based on chemotherapeutic elimination of nasopharyngeal carriage is practically impossible except in small communities. Immunization using safe and effective vaccines is the only rational approach to the control of meningococcal disease.

**Meningococcal Vaccines** : Invasive disease occurs only in patients without specific bactericidal or opsonizing antibodies and therefore, can be prevented by inducing these antibodies. Of the five common serotypes responsible for more than 90% of meningococcal disease, vaccines are available for group A, C, Y and W - 135. At present two types of meningococcal vaccines are licensed; meningococcal polysaccharide vaccines (bivalent and quadrivalent) and meningococcal conjugated polysaccharide vaccine.

**Polysaccharide Vaccines** : Bivalent polysaccharide vaccines provide protection against serogroups A and C, while the quadrivalent polysaccharide vaccines provide protection against serogroups A, C, Y and W - 135. The vaccines are purified, heat - stable, lyophilized capsular polysaccharides from meningococci of the respective serogroups. The recommended single dose of the reconstituted vaccine contains 50 µg of each of the individual polysaccharides. The dose for primary vaccination for both adults and children older than two years is a single 0.5 - ml subcutaneous injection. The vaccine can be administered at the same time as other vaccines but should be given at a different anatomic site. The antibody responses to each of the four polysaccharides in the quadrivalent vaccine are serogroup - specific and independent. Protective levels of antibody are usually achieved within 7 - 10 days of vaccination. These unconjugated polysaccharide vaccines confer protection in complement deficient persons also. The serogroup A and C vaccines have good immunogenicity, with clinical efficacy rates of 85% to 100% among children five years of age or older and adults. Serogroup Y and W - 135 polysaccharides are safe and immunogenic in older children and adults. Vaccination does not reduce the transfer of bacteria to non - vaccinated persons and carrier status is unaffected. Vaccination has been highly effective in the control of community outbreaks and epidemics in military centers (8).

The vaccine is extremely safe. Adverse effects are mild, the most frequent reaction being pain and redness at the site of injection, lasting for a couple of days. Severe reactions to polysaccharide meningococcal vaccine are uncommon. The major drawback of the presently available vaccines is the absence of activity against group B meningococci (8).

**Conjugated polysaccharide vaccine** : A quadrivalent A, C, Y and W - 135 conjugate vaccine has been licensed since January 2005. This vaccine contains 4 µg each of A, C, Y and W - 135 polysaccharide conjugated to 48 µg of diphtheria toxoid. The meningococcal conjugate vaccines induce a T - cell - dependent response, resulting in an improved immune response in infants, priming immunologic memory and leading to a booster response to subsequent doses. These vaccines provide long - lasting immunity even when given as a series in infancy and thus induce herd immunity through protection from nasopharyngeal carriage. Nasopharyngeal carriage rates may also be decreased by use of the conjugate vaccine, reducing

bacterial transmission. The conjugated polysaccharide vaccine is contraindicated in patients with a known hypersensitivity to any component of the vaccine, including diphtheria toxoid and in patients with a history of a severe reaction to any other vaccine containing similar components

#### **Recommendations for use of meningococcal vaccine:**

Routine childhood vaccination with the meningococcal polysaccharide vaccine is not recommended because of its relative ineffectiveness in young children below two years of age. Large scale coverage with current vaccines does not provide sufficient "herd immunity". Consequently, WHO does not currently recommend meningococcal polysaccharide vaccine as part of routine infant immunization. Routine vaccination with the vaccine is recommended for certain high - risk groups, including persons who have terminal complement component deficiencies and those who have anatomic or functional asplenia. Laboratory personnel and healthcare workers who are exposed routinely to *Neisseria meningitidis* in solutions that may be aerosolized should also be considered for vaccination.

Vaccination with a single dose of polysaccharide vaccine is recommended for travellers above 18 months of age going to an area experiencing an epidemic of meningococcal disease or to areas with a high rate of endemic meningococcal disease. Since the epidemic of meningococcal disease that occurred in 1987 during the Hajj in Mecca, proof of vaccination against meningococcus has been required for the pilgrims to the Hajj or Umra, at their entry in Saudi Arabia. More information concerning geographic areas for which vaccination can be obtained from internet (<http://www.cdc.gov/travel/>).

Revaccination may be indicated for persons at high risk for infection (living in endemic areas) particularly for children who were first vaccinated when they were less than four years of age; such children should be considered for revaccination after 2 - 3 years if they remain at high risk.

#### **Summary**

Meningitis can be caused by several different bacterial pathogens, but most important of these pathogens is *Neisseria meningitidis* because of its potential to cause epidemics. It is estimated to be responsible for over 500,000 cases and about 135,000 deaths annually. Meningococcal meningitis has a fatality rate of about 10% and about 15% of the survivors have residual central nervous system (CNS) damage. *Neisseria meningitidis* are bean shaped, gram negative, aerobic diplococci and at least 13 serogroups have been described: A, B, C, D, E, H, I, K, L, W - 135, X, Y and Z. Almost all meningococcal infections are caused by five serogroups A, B, C, 29E or W - 135. Maternal antibodies known to offer protection against invasive disease till the age of six months. Incidence rates are highest between the age of six months and two years. Worldwide serogroups A, B and C account for most cases of meningococcal disease. The highest level of meningococcal disease occurs in the 'African meningitis belt'. The main modes of transmission are direct contact and respiratory droplets. The average incubation period is 3 - 4 days with a range of 2 to 10 days. Humans are the only reservoir and 5 - 10% adults are asymptomatic nasopharyngeal carriers during inter -



epidemic periods. The diagnosis of meningococcal meningitis is suspected by the clinical presentation and a lumbar puncture showing a purulent spinal fluid. CSF examination shows finding similar to bacterial meningitis. Bacteriological diagnosis is by Gram staining, direct antigen detection using latex agglutination, or culture. Management of meningococcal disease requires early recognition of the disease, prompt initial parenteral antibiotic therapy and close monitoring with frequent repeated prognostic evaluations. Currently, penicillin is the drug of choice for the treatment of meningococcal meningitis and septicemia. Chemoprophylaxis is the preferred means of prevention of disease among close contacts of sporadic cases. Antibiotics that can be used for chemoprophylaxis are rifampin, ciprofloxacin, ceftriaxone, minocycline, ofloxacin and spiramycin. Chemoprophylaxis is not recommended during epidemics because of multiple sources of exposure and prolonged risk of exposure. Immunization using safe and effective vaccines is the only rational approach to the control of meningococcal disease. Vaccines are available for group A, C, Y and W - 135. At present two types of meningococcal vaccines are licensed; meningococcal polysaccharide vaccines (bivalent and quadrivalent) and meningococcal conjugated polysaccharide vaccine.

## Study Exercises

**Long Question :** Discuss the epidemiology, treatment, prevention and control of meningococcal meningitis.

**Short Notes :** (1) African Meningitis Belt (2) Meningococcal Vaccines (3) Chemoprophylaxis against meningococcal disease.

### MCQs

- How many serogroups of *Neisseria meningitidis* have been described? a) 13 b) 14 c) 15 d) 16?
- The predominant serogroups in Asia and Africa are a) A and B b) B and C c) A and C d) B and 135.
- Recent outbreaks among Haj pilgrims have been attributed to serogroup a) A b) B c) C d) W135.
- The average incubation period is a) 1 - 2 days b) 3 - 4 days c) 5 - 7 days d) 7 - 10 days.
- Typical CSF abnormalities include all except a) Increased pressure b) Decreased glucose concentration c) Predominantly neutrophils d) Decreased protein concentration.
- Drug of choice for the treatment of meningococcal meningitis and septicemia is a) Ampicillin b) Penicillin c) Chloramphenicol d) Cefotaxime

**Answers :** (1)a; (2) c; (3) d; (4) b; (5) d; (6)b.

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## Further Suggested Reading

- Control and prevention of serogroup C meningococcal disease : evaluation and management of suspected outbreaks : recommendations of the Advisory Committee on Immunization Practices (ACIP). Morb Mortal Wkly Rep 1997; 46 : 13 - 21.
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Tuberculosis (TB) is one the biggest public health challenges facing the world today. It is one of the oldest diseases known to mankind. Its causative organism *Mycobacterium tuberculosis* was one of the first bacterial pathogens to be identified. The etiopathogenesis of the disease is clearly understood. A vaccine against Tuberculosis has been available for close a century. Effective treatment against the disease has been available for

over sixty years. Yet the disease is close to its highest levels ever and the World Health Organization declared TB as a global public health emergency in 1993. It remains a potentially fatal disease which is transmitted by droplet nuclei after close contact with a person who has infectious disease. Treatment requires prolonged multidrug therapy which increases the potential risk of nonadherence by patients. Tuberculosis is a true indicator for social development. An overwhelming majority of cases and practically all deaths due to Tuberculosis take place in developing countries (1 - 4). Tuberculosis is currently second only to AIDS as an infectious cause of death worldwide. The World Health Organization estimates that the disease killed 1.7

million people in 2006 (1). The silver lining is that the number of new cases per capita appears to have been falling globally since 2003 (1).

The organism can infect practically any organ of the body. However, pulmonary tuberculosis accounts for over eighty per cent of the total cases suffering from tuberculosis. The other common forms of tuberculosis are meningeal, bone and joint, renal, genital, abdominal or mesenteric and tubercular lymphadenopathy (1, 2). Tuberculosis is the commonest opportunistic infection in patients suffering from AIDS in large parts of the world. The association with HIV infection has refocused global attention on tuberculosis.

### History

Tuberculosis has been known by a number of names through history. The ancient Greeks called it phthisis (to waste). The swollen glands of the neck due to tuberculosis were called scrofula. TB of the skin was known as lupus vulgaris. TB of the bone is known as Pott's disease with characteristic vertebral fusion and deformity of the spine. The most familiar term for TB was consumption, which means to consume or wear away. Among all these names, perhaps the most fitting is 'Captain of the Men of Death'.

*Mycobacterium tuberculosis* has been present in the human population since antiquity. There is evidence of the disease in fragments of the spinal column from Egyptian mummies from 2400 B.C. which show definite pathological signs of tubercular decay (5). Around 460 B.C., Hippocrates identified phthisis as the most widespread disease of the times, and noted that it was almost always fatal. Sylvius was the first to identify actual tubercles in the lungs and other areas of consumptive patients in 1679. He also described their progression to abscesses and cavities. In 1882, Robert Koch discovered a staining technique that enabled him to see *Mycobacterium tuberculosis* (6).

### Epidemiology

**Global** : Tuberculosis has been controlled almost completely in the developed world. Almost all the cases and practically all deaths due to tuberculosis take place in developing countries. Though the absolute numbers of cases and deaths are the largest in Asia, the rates of disease and deaths are the highest in Africa.

The latest WHO report on tuberculosis states that the disease is a major cause of illness and death worldwide, especially in Asia and Africa. A total of 9.2 million new cases (139 per 1,00,000 population) and 1.7 million deaths from TB occurred in 2006, of which 0.7 million cases and 0.2 million deaths were in HIV - positive people. 44% of the new cases were smear positive (1). The increase in the number of cases as compared to the previous year (2005) is attributed to population growth. India, China, Indonesia, South Africa and Nigeria rank first to fifth respectively in terms of absolute numbers of cases. The African Region has the highest incidence rate per capita (363 per 1,00,000 population).

The 2007 estimate is that 8.8 million new TB cases occurred of which 7.4 million occurred in Asia and Sub - Saharan Africa with 1.6 million deaths (7). In 1993, tuberculosis was declared a global public health emergency (2, 8). In Aug 2005

the WHO declared a tuberculosis emergency in Africa (9). One - third of the world's population is already infected with TB. Over the centuries, TB has taken over 1 billion lives. Deaths due to tuberculosis comprise 25% of all avoidable deaths in developing countries. 95% of TB cases and 98% of TB deaths are in developing countries. 75% of TB cases in developing countries are in the economically productive age group of 15 - 50 years (1).

The largest number of cases occurs in South East Asia which accounts for 34% of incident cases globally. In 2007 there were an estimated 5.7 million cases in the region. Every year, 3 million people develop active TB in the region and more than 50,000 die. 80% of the patients are in the age group 15 - 54 years. Bangladesh, India, Indonesia, Myanmar and Thailand account for 95% cases (7). However, the estimated incidence per capita in Sub - Saharan Africa is nearly twice that of South East Asia at 350 cases per 1,00,000 population (2). As with cases of disease, the highest number of estimated deaths due to tuberculosis is in the South - East Asian Region, but the highest mortality per capita is in the African Region, where HIV has led to rapid increases in the incidence of TB and increases the likelihood of dying from TB (1, 2, 7).

Despite these high numbers of cases and deaths the WHO believes that the global incidence of TB per capita peaked around 2003 and appears to have stabilized or begun to decline. Incidence per 1,00,000 population is falling in almost all parts of the world except Eastern Europe where it is stable. The downward trend is most pronounced in Latin America and the Caribbean (3.4% per year, 2001 - 2006). However, the slow decline in incidence is more than offset by the global population growth. This resulted in an increase in the number of new cases from 9.1 million in 2005 to 9.2 million in 2006. While there has been a tremendous decrease in tuberculosis cases in developed countries in the last forty years, there has been an increase in the absolute number of tuberculosis cases in developing countries (1). It is estimated that between 2002 and 2020, approximately 1 billion people will be newly infected, over 150 million will get sick, and 36 million will die of TB, if control is not further strengthened (2).

**India** : Tuberculosis is the biggest public health problem in the country. With 1.8 million cases occurring annually, India accounts for a fifth of the world's new TB cases and 2/3rd of the cases in South - East Asia. This makes India the highest TB burden country in the world. It has been estimated that for the year 2000 there were about 3.8 million bacteriologically positive TB cases in the country (10). Overall prevalence of infection in India is estimated to be 30% while the annual incidence of infection is estimated to be 1 - 2 %. The prevalence of disease is thought to be 4 per 1000 and the incidence of disease 1.5 per 1000. The prevalence of infection has been found to be increasing with age. The peak age for males is 45 - 54 years and that for females is 35 years. No rural-urban differences in the rate have been found.

Tuberculosis kills more adults than any other infectious disease in India. Because it affects adults, tuberculosis causes enormous social and economic disruption. Prior to 2000, the annual number of deaths due to tuberculosis was estimated to be 5,00,000. This has been revised downwards to 3,70,000

as per WHO estimates in 2004 (mortality rate 30 per 1,00,000 persons). More than 80% of the burden of tuberculosis is due to premature death, as measured in terms of Disability Adjusted Life Years (DALYs) lost. In India, over 70% of the cases occur in the economically productive age group (15 - 54 years). TB causes huge economic loss with about 17 crore workdays lost due to the disease. The annual economic cost of tuberculosis to the Indian economy is at least US\$ 3 billion (more than Rs 13,000 crore) (10). The burden of TB is enormous but is hidden by stigma. TB kills more women in India than any other infectious disease. Women with tuberculosis are often severely stigmatized (11, 12).

**Agent** : Human tuberculosis is caused by *Mycobacterium tuberculosis* which belongs to the genus *Mycobacterium*, family Mycobacteriaceae and Order Actinomycetales. *Mycobacterium tuberculosis* is Gram positive, non - motile, non - sporing, pleomorphic rod. The bacilli are obligate aerobes growing most successfully in tissues having the highest partial pressure of oxygen, such as lung apices. They are facultative intracellular pathogens, slow - growing with a generation time of 12 to 18 hours. Hence, lesions typically evolve in a sub - acute to chronic course. They are classified as Acid - Fast Bacilli (AFB) because they retain the carbol - fuchsin red dye after washing with acid, alcohol, or both (3, 4). *Mycobacterium bovis* is the etiologic agent of TB in cows and rarely in humans. Both cows and humans can serve as reservoirs. Humans can also be infected by the consumption of unpasteurized milk. *Mycobacterium africanum* can be a rare cause of tuberculosis. Other human pathogens belonging to the genus *Mycobacterium* include *Mycobacterium avium* which causes a TB - like disease especially prevalent in AIDS patients and *Mycobacterium leprae*, the causative agent of leprosy.

**Host** : Tuberculosis can occur at any age. In India disease prevalence is more in the older age groups. It occurs in both the sexes and it is not a hereditary disease. Man has no inherited immunity against tuberculosis. It is now known that both delayed hypersensitivity and acquired resistance to tuberculosis are cell mediated immune responses. Persons who are undernourished and suffering from silicosis, diabetes, myxoedema, HIV infection or under immuno - suppressive drugs are more susceptible (3, 4). Tuberculosis has often been described as a barometer of social welfare. It strikes poor people and those who do not have access to health care. The highest burden of tuberculosis is in the most impoverished countries. Poor housing and overcrowding are closely associated with transmission of infection.

**Transmission** : The source of infection is an open (sputum positive) case of pulmonary tuberculosis. *Mycobacterium tuberculosis* is spread by airborne particles, known as droplet nuclei that can be generated when persons with pulmonary or laryngeal tuberculosis sneeze, cough, speak, or sing. It has been estimated that a cough can generate 3000 droplet nuclei. The same number is generated by a person talking for five minutes (13). Persons who share the same airspace with persons with infectious tuberculosis disease are at greatest risk for infection. Infection occurs when a susceptible person inhales droplet nuclei containing tubercle bacilli and these bacilli become established in the alveoli of the lungs and spread

throughout the body. Prolonged household contact with an open case may lead to infection. Fomites do not play any role in transmission of the disease. Ingestion of unpasteurized milk or dairy products may lead to infection by *Mycobacterium bovis*. Direct inoculation through the skin can also lead to infection. However both these modes of transmission probably cause a very small number of cases (3, 7).

**Pathogenesis** : Primary infection occurs on first exposure to tubercle bacilli. Inhaled droplet nuclei are so small that they avoid the mucous - ciliary defences of the bronchi and lodge in the terminal alveoli of the lungs. Infection begins with multiplication of tubercle bacilli in the lungs. This is the *Ghon focus*. Lymphatics drain the bacilli to the hilar lymph nodes. The Ghon focus and related hilar lymphadenopathy form the primary complex. Bacilli may spread in the blood from the primary complex throughout the body. The immune response (delayed hypersensitivity and cellular immunity) develops about 4 - 6 weeks after the primary infection. The size of the infecting dose of bacilli and the strength of the immune response determine the course following primary infection. In most cases, the immune response stops the multiplication of bacilli. However, a few dormant bacilli may persist. A positive tuberculin skin test would be the only evidence of infection. The immune response in a few cases is not strong enough to prevent multiplication of bacilli and disease occurs within a few months (14).

**Post Primary Tuberculosis** : Post - primary TB occurs after a latent period of months or years after primary infection. It may occur either by reactivation or by reinfection. Reactivation means that dormant bacilli persisting in tissues for months or years after primary infection start to multiply. This may be in response to a trigger, such as weakening of the immune system by HIV infection. Reinfection means a repeat infection in a person who has already previously had a primary infection. Post - primary TB usually affects the lungs but can involve any part of the body. The characteristic features of post - primary PTB are extensive lung destruction with cavitation, positive sputum smear, and upper lobe involvement with usually no intrathoracic lymphadenopathy (14). Extra - pulmonary TB can affect the lymph nodes, pleura, bones and joints, the genitourinary tract, the nervous system (meningitis), intestines etc. If untreated, TB leads to death within 2 - 3 years in at least half the patients (15).

### Management of Tuberculosis

The source of infection for tuberculosis is almost always a sputum smear positive case of pulmonary tuberculosis. As a consequence, the focus of any public health specialist is concentrated on the management of cases of pulmonary Tuberculosis so that the source of infection can be eliminated from the community. The following description on the management of tuberculosis is, therefore, restricted largely to pulmonary tuberculosis and carries a strong public health bias. In our country, the diagnosis and treatment of cases of tuberculosis is carried out in accordance with the guidelines issued by the Revised National Tuberculosis Control Programme. The following have been extracted from the Technical and Operational Guidelines for Tuberculosis Control issued by Central TB Division, Directorate General of Health Services,



Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi in October 2005 (15).

## Diagnosis

**Identification of Tuberculosis Suspects** : Most patients with TB visit health facilities promptly after symptoms occur. Hence, every adult patient with respiratory symptoms attending the health facility must be asked about symptoms suggestive of tuberculosis. The most common symptom of pulmonary TB is a persistent cough for 2 weeks or more, usually with expectoration. It may be accompanied by one or more of the following symptoms such as weight loss, chest pain, tiredness, shortness of breath, fever, particularly with rise of temperature in the evening. In some cases there will be blood in the sputum, loss of appetite and night sweats. About 2 - 3% of new adult outpatients in a general health facility are expected to have cough for 2 weeks or more and on an average 10% of the suspects are expected to have sputum positive pulmonary TB.

**Case Finding tools** : The main tools for diagnosing pulmonary TB are sputum smear microscopy, chest X - ray, culture of *Mycobacterium tuberculosis* bacilli. Diagnostic algorithms are as given in Fig. - 1a & b.

**Sputum Smear Microscopy** : This is the primary tool for diagnosing TB as it is easy to perform at the peripheral laboratories, not expensive and specific with low inter and intra reader variation. It is simple and requires minimum training and can be used for diagnosis, monitoring and defining cure. Therefore, this is the key diagnostic tool used for case detection in RNTCP. If good diagnostic practices are followed, it is expected that at least 50% of the new pulmonary TB patients diagnosed will be smear - positive.

**Chest X - Ray** : X - ray as a diagnostic tool is sensitive but less specific with large inter and intra reader variations. No shadow is typical of TB. 10 - 15% culture - positive cases remain undiagnosed and 40% patients diagnosed as having TB by X - ray alone may not have active TB disease. It is supportive to microscopy.

**Culture** : Culture of bacilli *Mycobacterium tuberculosis* is very sensitive and specific but is expensive as it requires a specialized laboratory set - up and results are available only after several weeks. If available, culture of tubercle bacilli may be helpful, although in sputum - negative cases a clinical decision to treat for TB based on X - ray findings and lack of response to broad - spectrum antibiotics would be more practical and also ensure prompt treatment. Culture and sensitivity testing is valuable for diagnosis and management of drug resistant tuberculosis, besides epidemiological surveillance and planning.

**Tuberculin Test** : Tuberculin test may be useful as an additional tool for diagnosing paediatric TB, in whom a positive test is more likely to reflect recent infection with TB and indicates a much higher risk of developing disease. However, the tuberculin test has no role in diagnosing adult pulmonary TB disease in India.

**Diagnosis by Sputum Microscopy** : Microscopic examination of sputum is, as a rule, the only way by which the diagnosis of pulmonary TB can be confirmed. Whenever TB is suspected, at least 2 specimens of sputum should be collected over 2 consecutive days and examined by microscopy. Only one

laboratory form needs to be filled for all the three specimens of the patient. The smears are fixed by drying or heating and stained with the Ziehl - Neelsen (ZN) stain & examined under the oil immersion lens of a microscope. The interpretation of the slides is as given in Table - 1.

Table - 1 : Reporting of Smears			
Examination finding	Result Recorded	Grading	No. of fields examined
>10 AFB per oil immersion field	Positive	3+	20
1 - 10 AFB per oil immersion field	Positive	2+	50
10 - 99 AFB per 100 oil immersion fields	Positive	1+	100
1 - 9 AFB per 100 oil immersion fields	Positive	Scanty	100
No AFB in 100 oil immersion fields	Negative	Negative	100

**Classification of Tuberculosis cases** : The treatment of tuberculosis under the RNTCP is standardized into different categories. It is important to classify a patient into the correct category so that he may receive the correct combination of drugs and duration of treatment. Classification of pulmonary cases should be based on at least 2 sputum smear examinations. Sputum should also be examined for cases of suspected extra - pulmonary TB if pulmonary symptoms are present.

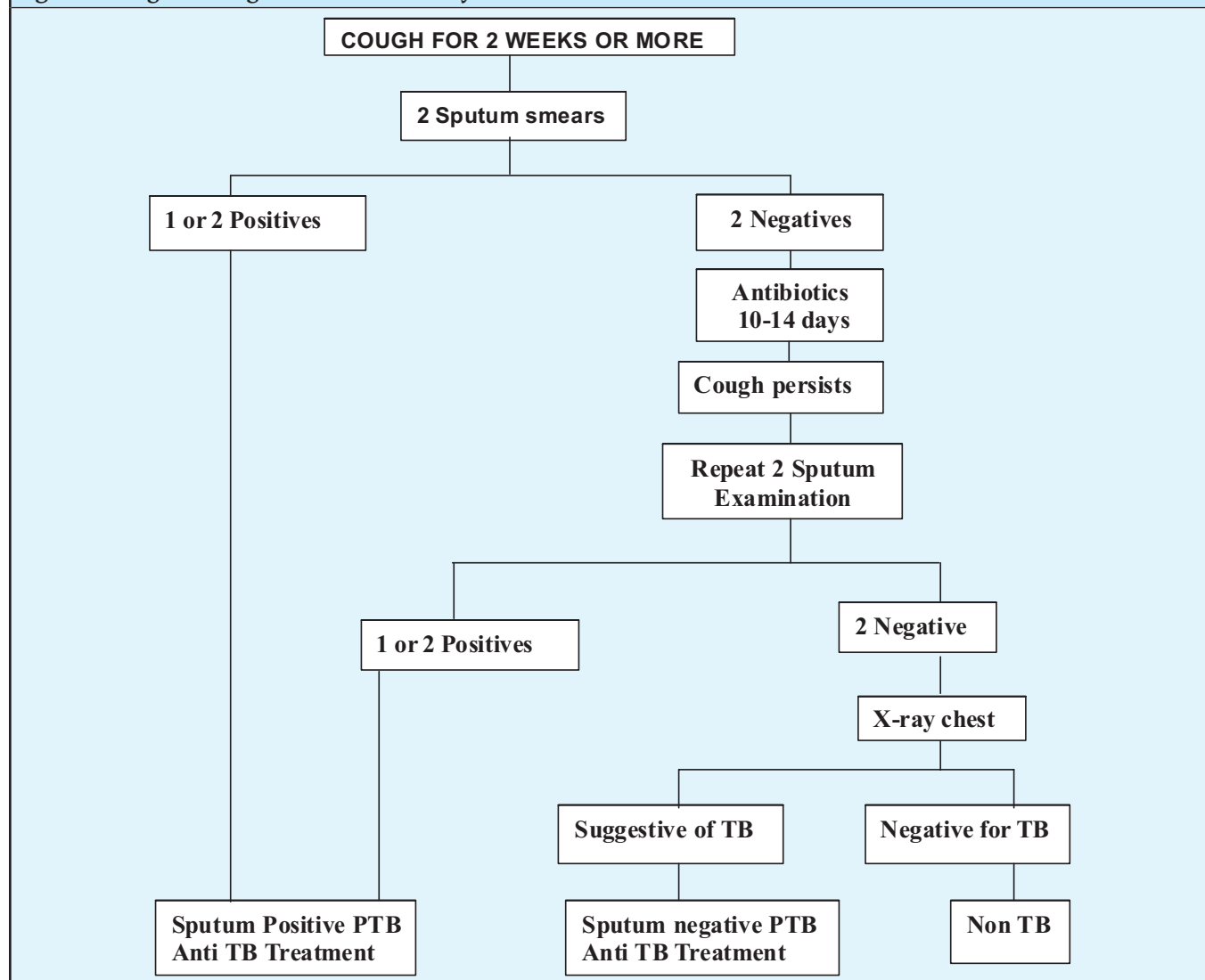
**Smear - positive patient** : A patient with at least 2 initial sputum smear examinations (direct smear microscopy) positive for Acid - Fast Bacilli (AFB) **OR** A patient with one sputum examination positive for AFB and radiographic abnormalities consistent with active pulmonary TB as determined by the treating Medical Officer (MO) **OR** A patient with one sputum specimen positive for AFB and culture positive for *Mycobacterium tuberculosis*.

**Smear - negative patient** : A patient having symptoms suggestive of TB with at least 2 sputum examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO, followed by a decision to treat the patient with a full course of anti - TB therapy **OR** A patient whose diagnosis is based on culture positive for *Mycobacterium tuberculosis* but sputum smear examinations negative for AFB.

**Extra-pulmonary Tuberculosis** : Extra-pulmonary Tuberculosis (EPTB) is tuberculosis of organs other than the lungs, such as the pleura (pleurisy), lymph nodes, intestines, genito - urinary tract, skin, joints and bones, and meninges of the brain. Diagnosis should be based on one culture - positive specimen from an extra - pulmonary site, or histological or radiological, or strong clinical evidence consistent with active extra - pulmonary TB followed by the treating MO's decision to treat with a full course of anti - TB therapy. Pleurisy is classified as extra - pulmonary TB. A patient diagnosed with both sputum smear positive pulmonary TB and extra pulmonary TB should be classified as a case of pulmonary TB.



**Fig - 1a : Diagnostic Algorithm for Pulmonary TB**



**Diagnostic Algorithm of RNTCP** : Patients with at least two positive smear results are diagnosed by the physician as a case of smear positive TB. They are further classified as new or old cases based on their treatment history, and appropriate therapy is prescribed.

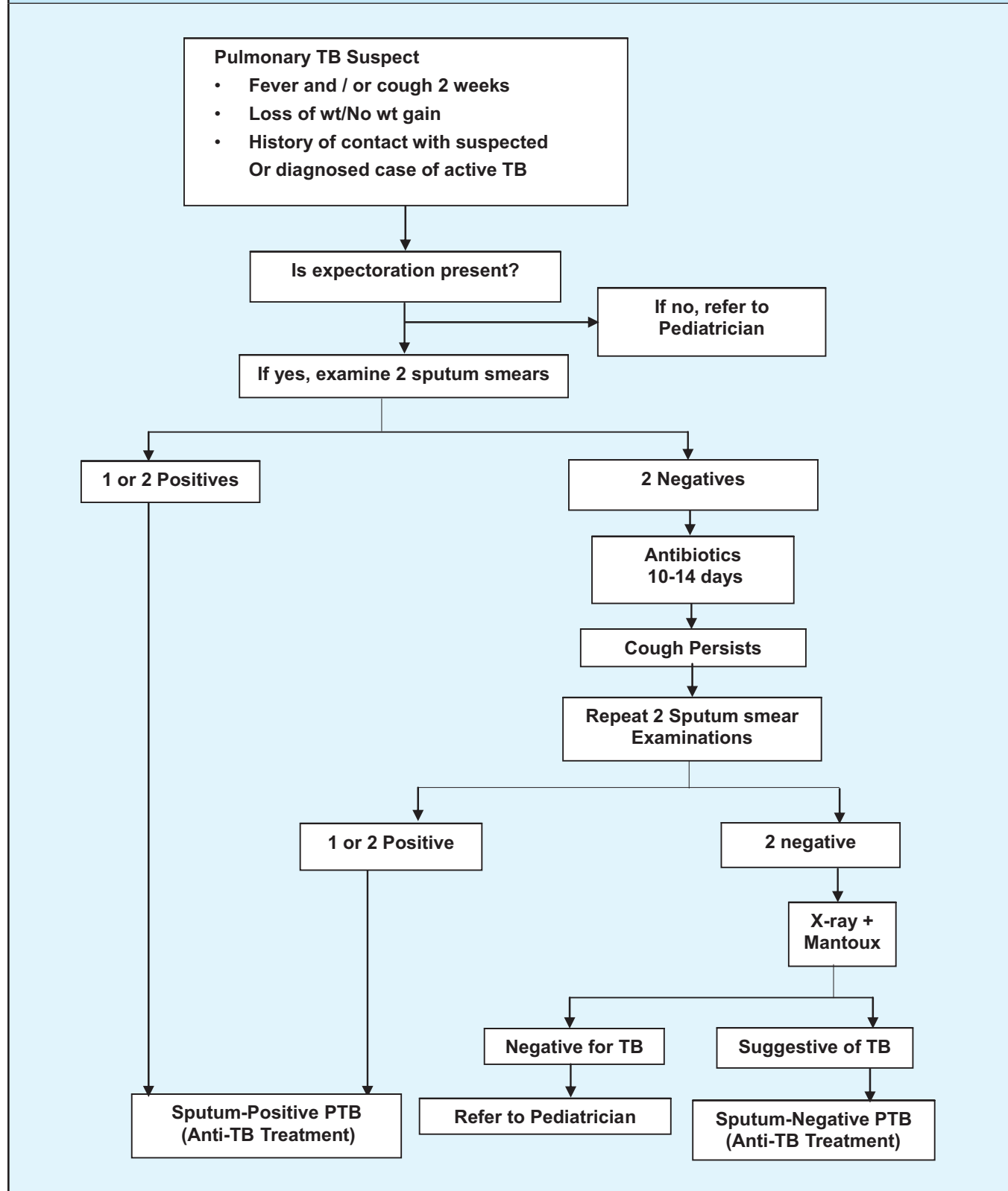
For patients with only one sputum positive result on smear examination, chest X - ray is taken. If findings of the X - ray are consistent with pulmonary tuberculosis patient is diagnosed by the physician as a case of sputum positive pulmonary TB.

Patients in whom all 2 samples are negative on sputum smear examination are prescribed symptomatic treatment and broad spectrum antibiotics (such as cotrimoxazole, doxycycline, and amoxycillin) for 10 - 14 days. In such cases antibiotics such as fluoroquinolones (ciprofloxacin, ofloxacin etc.), rifampicin or streptomycin, which are active against tuberculosis, are not to be used. Most patients are likely to improve with antibiotics if they are not suffering from TB. If the symptoms persist after

a course of broad spectrum antibiotics, repeat sputum smear examination (2 samples) must be done for such patients.

If two or more smears are positive, the patient is diagnosed as having smear positive pulmonary TB. If only one sputum sample is positive, chest X - ray is taken. If findings of the X - ray are consistent with pulmonary tuberculosis, patient is diagnosed by the physician as a case of sputum positive pulmonary TB. If the results for all the three sputum samples of repeat examination are found negative then a chest X - Ray is taken. If findings of the X - ray are consistent with pulmonary tuberculosis, patient is diagnosed by the physician as a case of sputum negative pulmonary TB. The Diagnostic Algorithms are given in Fig - 1a & b. Patients with EPTB who also have cough of any duration, should have 2 sputum samples examined. If the smear result is positive, the patient is classified as pulmonary TB and his/her treatment regimen will be that of a case of smear positive pulmonary TB.

**Fig - 1b : Diagnostic Algorithm for Paediatric Pulmonary TB**



## Treatment

Under the RNTCP, the objectives of tuberculosis treatment are to decrease mortality and morbidity by ensuring cure, minimizing relapses and preventing development of drug resistance; to decrease infections and break the chain of transmission of infection; and to achieve the above whilst minimizing side effects due to drugs. These objectives are achieved in RNTCP through intermittent (thrice weekly) treatment regimens given under direct observation for both pulmonary and extra - pulmonary tuberculosis patients. Treatment regimens for tuberculosis have emerged as a result of controlled clinical trials in India and other parts of the world. It has been proven that thrice - a - week (intermittent) treatment is as effective as daily treatment and produces lesser side effects.

RNTCP provides standardized anti - TB treatment in three categories. Once the patient has been diagnosed as having TB, may be pulmonary or extra - pulmonary, his treatment regimen is decided based on the results of sputum Smear examination, history of previous anti - TB treatment, disease classification (pulmonary/ extra - pulmonary), and severity of illness.

**Treatment Regimes** : Standardized treatment is given to patients based on their treatment category. The details of treatment are given in Table - 2. The most important drugs used in the treatment of TB are Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), Streptomycin (S) and Ethambutol (E). The dosage of the drugs is shown in Table - 3. Drugs are supplied in Patient - Wise Boxes (PWB) containing the full course of

treatment, and packaged in blister packs. The PWB have a colour code indicating the category (Red for CAT I, Blue for CAT II and Green for CAT III). In each PWB, there are two pouches one for intensive phase (A) and one for continuation phase (B). For the intensive phase, each blister pack contains medicines for one dose. For the continuation phase, each blister pack contains one week's supply of medication. The drugs for extension of the intensive phase (prolongation pouches) are supplied separately. For adults, drugs will be given in the recommended number of pills/capsules irrespective of body weight. However, for patients weighing more than 60 kilograms, an additional capsule of rifampicin 150 mg will be added to the treatment regimen. Patients who are more than 50 years old receive streptomycin 500mg and patients who weigh less than 30 Kg receive drugs as per body weight. For children, the drugs will be given according to body weight. Patient wise boxes for children have been developed.

Table - 3 : Dosage of Drugs	
Medication	Dose (thrice a week)
Isoniazid	600mg
Rifampicin	450mg
Pyrazinamide	1500mg
Ethambutol	1200mg
Streptomycin	0.75 g

Table - 2 : Treatment

Category of Treatment	Type of Patient	Regimen*
Category I	New sputum smear - positive	$2H_3R_3Z_3E_3 / 4H_3R_3$
	Seriously ill** new sputum smear - negative	
	Seriously ill** new extra - pulmonary	
Category II	Sputum smear - positive Relapse	$2H_3R_3Z_3E_3S_3 / 1H_3R_3Z_3E_3 / 5H_3R_3E_3$
	Sputum smear - positive Failure	
	Sputum smear - positive treatment after Default	
	Others***	
Category III	New Sputum smear - negative, not seriously ill	$2H_3R_3Z_3 /$
	New Extra - pulmonary, not seriously ill	$4H_3R_3$

- \* The number before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week.
- The dosage strengths are as follows : H : Isoniazid (600 mg), R : Rifampicin (450 mg), Z : Pyrazinamide (1500 mg), E : Ethambutol (1200 mg), S : Streptomycin (750 mg). Patients who weigh 60 kg or more receive additional Rifampicin 150 mg. Patients who are more than 50 years old receive Streptomycin 500 mg. Patients who weigh less than 30 kg, receive drugs as per body weight.
- Patients in Categories I & II who have a positive sputum smear at the end of the initial intensive phase receive an additional month of intensive phase treatment.
- \*\* Seriously ill also includes, any patient, pulmonary or extra - pulmonary who is HIV positive & declares his serostatus to the categorizing/treating medical officer. For the purpose of categorization, HIV testing should not be done.
- \*\*\* In rare & exceptional cases, patients who are sputum smear - negative or who have extra - pulmonary disease can have Relapse or Failure. This diagnosis in all such cases should always be made by an MO & should be supported by culture or histological evidence of current, active TB. In these cases, patient should be categorized as 'Others' & given Category II treatment.

**Management of Paediatric Tuberculosis under RNTCP :** Childhood TB is a reflection of the prevalence of sputum smear - positive Pulmonary Tuberculosis (PTB) and the extent of transmission of TB infection in the community. Children are likely to suffer from more serious forms of TB and are more likely to die if not treated properly. Reliable data on disease incidence and prevalence is however not available due to the difficulties in diagnosis of paediatric TB under field conditions. TB should be suspected among children presenting with fever and / or cough for more than 3 weeks, with or without weight loss or no weight gain; and history of contact with a suspected or diagnosed case of active TB disease within the last 2 years. Diagnosis should be based on a combination of clinical presentation, sputum examination wherever possible, Chest X ray (PA view), Mantoux test (1 TU PPD RT23 with Tween 80, positive if induration >10mm after 48 - 72 hours) and history of contact. Diagnosis should be made by a Medical Officer and the existing RNTCP case definitions be used for all cases diagnosed. Children showing neurological symptoms like irritability, refusal to feed, headache, vomiting or altered sensorium may be suspected to have TB meningitis. Use of currently available scoring systems is not recommended for the diagnosis of TB among children. Where diagnostic difficulties are faced, the child should be referred to a paediatrician for further management. DOTS is the recommended strategy for treatment of TB and all paediatric TB patients should be registered under RNTCP. Intermittent short course chemotherapy given under direct observation should be used in children, as in adults. Recent infection with tubercle bacilli is one of the risk factors for disease development. The younger the child, the higher is the risk of breakdown of infection into disease. Therefore, household contacts of smear - positive TB cases, especially those below 6 years of age, must be screened for symptoms of tuberculosis. In case of symptoms being present, the diagnostic algorithm for paediatric TB should be followed and the child should be given a full course of anti TB treatment if he / she is diagnosed as a TB case. For asymptomatic children under 6 years, chemoprophylaxis with isoniazid (5 mg per kg body wt) should be administered daily for a period of six months. This is regardless of the BCG vaccination status.

**Management of Extra - Pulmonary Tuberculosis :** Extra - Pulmonary TB (EPTB) comprises about 10% to 15% of all new TB cases in our country. Among them, 75% have lymph node or pleural TB. A person with extra - pulmonary TB may have symptoms related to the organs affected, such as, swelling of lymph nodes, occasionally with discharge of pus; pain and swelling of the joints; headache, fever, stiffness of the neck and mental confusion when the brain or meninges are involved. In addition, the following general symptoms like weight loss, fever, particularly with rise of temperature in the evening and night sweats may be present. Patients with suspected EPTB should be referred to a competent medical practitioner for expert opinion. Diagnosis of such patients may be made by using appropriate diagnostic procedures (such as FNAC/Biopsy/culture from the site of disease) as well as clinical methods. Patients with EPTB who also have cough of any duration, should have 3 sputum samples examined. If the smear result is positive, the patient is classified as pulmonary TB. Intermittent short course

chemotherapy regimens of 6 - 9 months are recommended internationally for all forms of extra - pulmonary TB. In cases of Tubercular Meningitis (TBM), initial hospitalization is recommended. In TBM, ethambutol should be replaced by streptomycin in the intensive phase and continuation phase of the treatment is for 6 - 7 months. Adjunctive steroids may be useful in pericardial & meningeal TB.

**Management of Patients with HIV Infection and Tuberculosis:** People co-infected with HIV and TB have a higher risk of developing TB disease. Irrespective of HIV status RNTCP diagnostic algorithm should be followed for all TB suspects. Anti - TB treatment is the same for HIV - infected persons as it is for HIV negative TB patients. Hence they should be treated with RNTCP regimens. All new TB cases known to be HIV positive are classified as seriously ill and treated with Category I regimen. The re - treatment cases are to be treated with Category II regimen. It is important to maintain confidentiality regarding HIV status of individuals including TB suspects and patients, in order to prevent stigmatization and discrimination. TB patients should be encouraged to voluntarily share their HIV status with the treating physician for the purpose of taking clinical decisions like categorization for treatment of TB, treatment of other opportunistic infections and provision of ART. The HIV - positive status should not be disclosed by the treating physician to any other staff involved in RNTCP. In addition, the HIV - positive status should not be mentioned in any RNTCP records. TB patients who have other HIV - associated opportunistic infections, or report risk behaviour for HIV, should be offered referral to the nearest Voluntary Counselling and Testing Centre (VCTC) for voluntary counselling and HIV testing. Routine HIV testing of all TB suspects/patients is not the national policy.

**Drug Resistance :** Drug resistance is more common among patients who show poor compliance, develop TB disease again, after having taken anti tubercular treatment in the past, or come from areas where drug - resistant TB is common.

**Multidrug Resistant (MDR) Tuberculosis :** Multidrug Resistant TB describes strains of tuberculosis that are resistant to at least the two main first - line TB drugs - isoniazid and rifampicin. Two thirds of all cases of MDR are found in China, India and the Russian Federation. In 2007, the estimated number of cases of MDR - TB were 4, 24,000 and the estimated number of deaths due to MDR - TB were 1,16,000 (17). In India MDR - TB estimates are placed at less than 3.5% of new cases and 12% of retreatment cases. RNTCP advocates using a standardised treatment regimen comprising of six drugs (kanamycin, ofloxacin, ethionamide, pyrazinamide, ethambutol and cycloserine) during 6 - 9 months of the Intensive Phase and 4 drugs (ofloxacin, ethionamide, ethambutol and cycloserine) during the 18 months of the Continuation Phase for cases of MDR - TB.

**Extensively Drug Resistant Tuberculosis :** Extensive Drug Resistant is MDR - TB that is also resistant to three or more of the six classes of second - line drugs. In 2007 the estimated number of cases were 27,000 and the estimated number of deaths due to XDR TB were 16,000. 28 countries have published cases of XDR - TB and/or reported cases to WHO.



## Prevention and Control of Tuberculosis

Early diagnosis and treatment, particularly of sputum smear positive cases is the cornerstone of tuberculosis control. The Revised National Tuberculosis Control Programme has focused on achieving high cure rates. The protective efficacy of BCG has ranged between 0 to 80% in different studies. Details on the vaccine are given in the chapter on Immunization. Further details on the Revised National Tuberculosis Control programme are given in the chapter on National Health Programmes.

*The Stop TB Strategy has six major components* : DOTS expansion and enhancement; addressing TB/HIV, MDR - TB and other challenges; contributing to health system strengthening; engaging all care providers; empowering patients and communities; and enabling and promoting research (1). It is evident that new tools are urgently needed to improve treatment, detection and prevention of TB. The Stop TB Partnership of WHO has created three specific research working groups devoted to new drugs, diagnosis, and vaccine development, respectively. The need for new rapid and inexpensive diagnostics for diagnosing Tuberculosis and drug resistance is obvious. An effective Tuberculosis vaccine is another urgent need because the BCG vaccine has demonstrated efficacy only in certain populations and only against some forms of the disease.

## Summary

Tuberculosis (TB) is one the biggest public health challenges facing the world today. It is one of the oldest diseases known to mankind. *Mycobacterium tuberculosis* was one of the first bacterial pathogens to be identified by Robert Koch who in 1882 discovered a staining technique that enabled him to see *Mycobacterium tuberculosis*. Tuberculosis is currently second only to AIDS as an infectious cause of death worldwide. Almost all the cases and practically all deaths due to Tuberculosis take place in developing countries. A total of 9.2 million new cases (139 per 1,00,000 population) and 1.7 million deaths. India, China, Indonesia, South Africa and Nigeria rank first to fifth respectively in terms of absolute numbers of cases. India accounts for a fifth of the world's new TB cases and 2/3rd of the cases in South - East Asia. The prevalence of disease is thought to be 4 per 1000 and the incidence of disease 1.5 per 1000. Human Tuberculosis is caused by *Mycobacterium tuberculosis* which is Gram positive, non - motile, non - sporing, pleomorphic rod. They are facultative intracellular pathogens, slow - growing with a generation time of 12 to 18 hours. Tuberculosis can occur at any age. In India disease prevalence is more in the older age groups. Persons who are undernourished and suffering from silicosis, diabetes, myxoedema, HIV infection or under immuno - suppressive drugs are more susceptible. The source of infection is an open (sputum positive) case of pulmonary Tuberculosis. *Mycobacterium tuberculosis* is spread by airborne particles, known as droplet nuclei. Pulmonary TB affects the lung and Extra - pulmonary TB can affect the lymph nodes, pleura, bones and joints, the genito - urinary tract, the nervous system (meningitis), intestines etc. The most common symptom of pulmonary TB is a persistent cough for 3 weeks or more. The main tools for diagnosing pulmonary TB are sputum smear microscopy, chest X - ray, and culture of *Mycobacterium tuberculosis* bacilli. Sputum Smear Microscopy is the primary

tool for diagnosing TB under RNTCP. Classification of pulmonary cases should be based on at least 3 sputum smear examinations and are classified as Smear - positive patient, Smear - negative patient and Extra - pulmonary Tuberculosis. RNTCP provides standardized anti - TB treatment in three categories. People co - infected with HIV and TB have a higher risk of developing TB disease. Anti - TB treatment is the same for HIV - infected persons as it is for HIV negative TB patients. Multidrug Resistant TB describes strains of Tuberculosis that are resistant to at least the two main first - line TB drugs - isoniazid and rifampicin. Extensive Drug Resistant is MDR - TB that is also resistant to three or more of the six classes of second - line drugs.

## Study Exercises

**Long Questions** : (1) Discuss the epidemiology, treatment, prevention and control of Tuberculosis (2) Describe the Diagnosis and treatment of TB under RNTCP.

**Short Notes** : (1) Sputum Microscopy (2) Classification of TB patient based on sputum examination and treatment history (3) Diagnostic Algorithm of RNTCP (4) Treatment Regimens under RNTCP (5) Management of Patients with HIV Infection and Tuberculosis (6) MDR TB.

## MCQs

- Which disease is known as 'Captain of the Men of Death'?  
(a) Tuberculosis (b) AIDS (c) Plague (d) Cholera.
- Pulmonary Tuberculosis accounts for over \_\_\_\_\_ per cent of the total cases (a) 50% (b) 60% (c) 70% (d) 80%.
- Commonest opportunistic infection in patients suffering from AIDS (a) Candidiasis (b) Pulmonary Tuberculosis (c) Herpes (d) Scabies.
- The \_\_\_\_\_ Region has the highest incidence rate per capita (363 per 1,00,000 population) (a) Asian (b) American (c) Indian (d) African.
- \_\_\_\_\_ is the highest TB burden country in the world (a) Nigeria (b) South Africa (c) India (d) Bangladesh.
- It is estimated that a cough can generate \_\_\_\_\_ (a) 1000 droplet nuclei (b) 2000 droplet nuclei (c) 3000 droplet nuclei (d) 4000 droplet nuclei.
- Under RNTCP in reporting of Sputum Smears, 1 - 10 AFB per oil immersion field is graded as (a) 1+ (b) 2+ (c) 3+ (d) 4+.
- Category III continuation phase comprises of (a) 4  $H_3 R_3$  (b) 5  $H_3 R_3 E_3$  (c) 1  $H_3 R_3 Z_3 E_3$  (d) None of the above.
- All new TB cases known to be HIV positive are treated with (a) Category I regimen (b) Category II regimen (c) Category III regimen (d) None of the above.
- Multidrug Resistant (MDR) Tuberculosis treatment involves all drugs expect (a) Kanamycin (b) Pyrazinamide (c) Rifampicin (d) Ethambutol.

**Answers** : (1) a; (2) d; (3) b; (4) d; (5) c; (6) c; (7) b; (8) a; (9) a; (10) c.

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## 195 Avian Influenza

Rajesh Vaidya

Avian influenza is an infectious disease of birds caused by type A strains of the influenza virus. The disease, which was first identified in Italy more than 100 years ago, occurs worldwide. All birds are thought to be susceptible to infection with avian influenza, though some species are more resistant to infection than others. Migratory waterfowl - most notably wild ducks - are the natural reservoir of avian influenza viruses. Avian influenza viruses do not normally infect species other than birds and pigs. Of the 15 avian influenza virus subtypes, H5N1 is of particular concern for several reasons. H5N1 mutates rapidly and has a documented propensity to acquire genes from viruses infecting other animal species (1, 2).

### Epidemiology

**Global Situation - Current Outbreak** : Some time prior to 1997, the H5N1 strain of avian influenza virus began circulating in the poultry populations of parts of Asia, quietly establishing itself. The virus first erupted in its highly pathogenic form in 1997, but did not appear again. Then, towards the end of 2003, H5N1 suddenly became highly and widely visible. Infection by the H5N1 strain has now been documented in either domestic poultry or migratory birds in over twenty countries spread across Asia and Europe. Over a 140 million birds have been destroyed worldwide in efforts to control the spread of this virus (3). The ability of the H5N1 strain to cause severe disease in humans has now been documented on at least two occasions. The first documented infection of humans with an avian influenza virus occurred in Hong Kong in 1997, when the H5N1 strain caused severe respiratory disease in 18 humans, of whom 6 died (4). In its second documented outbreak, since December 2003, the H5N1 strain has infected at least 387 people and killed 245 in 15 countries, mostly in South East Asia (5).

**Lessons from History** : An influenza pandemic is a rare but recurrent event. Three pandemics occurred in the previous century : "Spanish influenza" in 1918, "Asian influenza" in 1957, and "Hong Kong influenza" in 1968. The 1918 pandemic killed an estimated 40 - 50 million people worldwide. That pandemic, which was exceptional, is considered one of the deadliest disease events in human history. Subsequent pandemics were much milder, with an estimated 2 million deaths in 1957 and 1 million deaths in 1968. Experts agree that another influenza pandemic is inevitable and possibly imminent. Striking similarities exist between the 1918 virus and the H5N1 strain. The 1918 pandemic is believed by many experts to have begun following adaptive mutation of an avian virus which acquired, following stepwise changes during subsequent human infections, the adaptations needed to sustain efficient human - to - human transmission. Recent publications have suggested other similarities between H5N1 and the 1918 virus in the severity of disease, its concentration in the young & healthy and the occurrence of primary viral pneumonia in the absence of secondary bacterial infection (6, 7).

**Host Factors** : The categories of persons considered to be at the greatest risk if acquiring infection are workers handling poultry in farms, markets and involved in culling activity, veterinary workers and health workers are at higher risk of acquiring the infection. Even the family members of these workers are at higher risk. Any type of Influenza tends to be more serious in children, elderly persons above 65 years of age and the chronically sick persons.

### Transmission

#### Avian Transmission

**Transmission among birds** : Infected birds shed the virus in oculo - nasal discharges and faeces, and contaminated drinking water is commonly implicated as the source of infection among birds. Once introduced into a flock, infected birds, contaminated equipment, insects, rodents, and personnel have

all been implicated in the spread of the virus. When birds are in close proximity and air movement is conducive, airborne transmission can occur (7).

**Avian to Human Transmission** : Direct contact with infected poultry, or surfaces and objects contaminated by their faeces, is presently considered the main route of human infection. To date, most human cases have occurred in rural or peri-urban areas where many households keep small poultry flocks, which often roam freely, sometimes entering homes or sharing outdoor areas where children play. Moreover, because many households in Asia depend on poultry for income and food, many families sell or slaughter and consume birds when signs of illness appear in a flock, and this practice has proved difficult to change. Exposure is considered most likely during slaughter, defeathering, butchering, and preparation of poultry for cooking. There is no evidence that properly cooked poultry or eggs can be a source of infection (7).

**Human to Human Transmission** : There is no definite evidence of human to human transmission in the current episode. A new virus adapted for efficient human - to - human transmission would spread very rapidly. The respiratory tract is the most likely route of entry.

**International Spread** : The disease can spread from country to country through international trade in live poultry. Migratory birds, including wild waterfowl, sea birds, and shore birds, can carry the virus for long distances and have, in the past, been implicated in the international spread of highly pathogenic avian influenza. Migratory waterfowl - most notably wild ducks - are the natural reservoir of bird flu viruses, and these birds are also the most resistant to infection. They can carry the virus over great distances, and excrete it in their droppings, yet develop only mild and short-lived illness.

### Clinical Features

The incubation time for influenza ranges from 1 - 5 days with an average of 2 days. In most cases, virus is found in specimens from the respiratory tract from 1 - 2 days before to 4 - 5 days after onset of disease, corresponding to the period of communicability. There is no chronic carrier state, but in young children viral shedding tends to last longer than in adults. Clinical onset is characterized by abrupt fever, headache, malaise and myalgias. Systemic symptoms usually last for 3 days. Sore throat, rhinitis and non-productive cough may continue for several days after the systemic symptoms have ceased. Influenza may be misdiagnosed clinically, several infectious agents including respiratory syncytial virus may cause outbreaks of influenza-like disease, illustrating the importance of laboratory based confirmation of the clinical diagnosis (9).

The incubation period of influenza A (H5N1) is currently uncertain. Based on limited experience from 6 cases in Vietnam, the median time between exposure and onset of illness is 3 days (range 2 - 4 days). Cases have been characterized by high fever (above 38°C), cough and shortness of breath. Lower respiratory symptoms or signs developed early and include dyspnoea and auscultatory signs. Clinically apparent pneumonia with chest X-ray changes was seen in all patients, although the X-ray changes were nonspecific and included diffuse, multifocal or

patchy infiltrates, interstitial infiltrates, and segmental or lobular consolidation with air bronchograms. The illness rapidly progressed to respiratory distress and subsequent respiratory failure within 1 week of the onset of symptoms. Most cases have died in spite of ventilatory support. Common laboratory findings were lymphopenia and slightly or moderately raised alanine aminotransferase and aspartate transaminase (10).

### Diagnosis

The optimal specimen for influenza A virus detection is a nasopharyngeal aspirate obtained within 3 days of the onset of symptoms, although nasopharyngeal swabs and other specimens can also be used (11). Assays available for the diagnosis of influenza A virus infections include :

**(a) Rapid antigen detection** : Results can be obtained in 15 - 30 minutes.

**(i) Near - patient tests for influenza** : These tests are commercially available.

**(ii) Immunofluorescence assay** : This test is a widely used, sensitive method for diagnosis of Influenza A, B virus infections and other clinically important respiratory viruses.

**(iii) Enzyme immunoassay** : For Influenza A Nucleoprotein (NP).

**(b) Virus Culture** : Provides results in 2 - 10 days. Both shell vial and standard cell-culture methods may be used to detect clinically important respiratory viruses. Positive influenza cultures may or may not exhibit cytopathic effects but virus identification by immunofluorescence of cell cultures or Haemagglutination - Inhibition (HI) assay of cell culture medium (supernatant) is required.

**(c) Polymerase Chain Reaction and Realtime PCR Assays**: Primer sets specific for the Haemagglutinin (HA) gene of currently circulating influenza A/H1, A/H3 and B viruses are becoming more widely used. Results can be available within a few hours from either clinical swabs or infected cell cultures.

Any specimen with a positive result using the above approaches for influenza A virus and suspected of avian influenza infection should be further tested and verified by a designated WHO H5 Reference Laboratory. Laboratories that lack the capacity to perform specific influenza A subtype identification procedures are requested to forward specimens or virus isolates to a National Influenza Centre or to a WHO H5 Reference Laboratory for further identification or characterization.

### Treatment

Two drugs (in the neuraminidase inhibitors class), Oseltamivir (commercially known as Tamiflu) and Zanamivir (commercially known as Relenza) can reduce the severity and duration of illness caused by seasonal influenza. The efficacy of the neuraminidase inhibitors depends on their administration within 48 hours after symptom onset. For cases of human infection with H5N1, the drugs may improve prospects of survival, if administered early, but clinical data are limited. The H5N1 virus is expected to be susceptible to the neuraminidase inhibitors. An older class of antiviral drugs, the M2 inhibitors amantadine and rimantadine, could potentially be used against pandemic influenza, but resistance to these drugs can develop rapidly and this could significantly limit their effectiveness



against pandemic influenza. Some currently circulating H5N1 strains are fully resistant to these M2 inhibitors. However, should a new virus emerge through reassortment, the M2 inhibitors might be effective.

### Prevention and Control

Vaccination and the use of antiviral drugs are two of the most important response measures for reducing morbidity and mortality during a pandemic. On present trends, neither of these interventions will be available in adequate quantities or equitably distributed at the start of a pandemic and for many months thereafter. In such a situation surveillance to provide early warning and health education to reduce human exposure are the most important control measures.

**Surveillance** : Surveillance (13) is the cornerstone of pandemic preparedness and response. The following events need to be reported to local, state or national health authorities on priority:

- (a) Individuals with, and clusters of, acute respiratory illness on or during admission.
- (b) Unexplained deaths due to acute respiratory illness in the community.
- (c) Unexplained deaths due to acute respiratory illness in health care facilities.
- (d) Monitoring sales of antiviral drugs for influenza A viral infection, antimicrobials commonly used for the treatment of acute respiratory infections, decongestant drugs or antitussive drugs.

For countries and territories where influenza A/H5 viruses have not been identified as a cause of illness in human or animal populations since 1 October 2003, the WHO recommends that the decision on whether to test for influenza A/H5 viruses should be the result of a risk assessment that considers both geographical proximity to countries or territories where HPAI outbreaks are reported in animal populations and the following case - based factors :

- (a) Clinical presentation, including death due to unexplained acute respiratory illness
- (b) Occupational exposure : At-risk occupations such as a domestic fowl or swine farm worker, domestic fowl processing plant worker, domestic fowl culler (catching, bagging, or transporting birds, disposing of dead birds), worker in live animal market, chef working with live or recently killed domestic fowl, dealer or trader in pet birds, worker in a laboratory where specimens are tested for influenza A/H5 viruses, health care worker.
- (c) Living in an area in which there are rumours of deaths of domestic fowl ; (Domestic fowl are birds that are commonly reared for their flesh, eggs, or feathers and are kept in a yard or similar enclosure, including chickens, ducks, geese, turkeys, guinea - fowl).
- (d) History of travel, during the 7 days before the onset of symptoms, to a country or territory with reported HPAI outbreaks due to influenza A (H5N1) in the animal populations AND one or more of the following :
  - Contact (within 1 metre) with live or dead domestic fowl, wild birds, or swine in any setting;
  - Exposure to settings in which domestic fowl or swine were

or had been confined in the previous 6 weeks;

- Contact (within touching or speaking distance) with a confirmed human case of influenza A/H5 infection;
- Contact (within touching or speaking distance) with a person with an unexplained acute respiratory illness that later resulted in death;
- Positive laboratory result for influenza A.

**Vaccination** : Vaccines are universally regarded as the most important medical intervention for preventing influenza and reducing its health consequences during a pandemic. In the past, however, vaccines have never been available early enough and in sufficient quantities to have an impact on morbidity and mortality during a pandemic. Past problems, related to the special nature of pandemic vaccines and the inadequacy of manufacturing capacity, have endured. Several companies are trying to make an effective vaccine against H5N1. While initial testing of an avian flu vaccine shows promise and trials should be completed by the end of 2005, questions remain about the vaccine's ability to protect large numbers of people. Potential problems include a high initial dose, the requirement of two doses, and requirement of about six weeks for effective immunity to develop. Another major concern is the inability to produce adequate number of doses, once the vaccine is approved (14 - 15).

**Chemoprophylaxis** : The current recommendation for chemoprophylaxis against H5N1 influenza is one oseltamivir phosphate 75 mg tablet each day for at least 7 days beginning as soon as possible after exposure. Antiviral prophylaxis should begin immediately or at least within 2 days of exposure and may continue for up to 6 weeks (15).

**Non Medical Measures** : In developing countries, non - medical interventions may be the main line of defence throughout the first wave of a pandemic. Health education to inform the general public especially small poultry farmers is essential to reduce exposure risk. Stringent sanitary measures and appropriate bio - security practices should be applied, including the control of human traffic and introduction of birds of unknown disease status into the flock. Carcasses of suspected and confirmed poultry case of Influenza should preferably be incinerated or buried deep using lime and soil in the ratio of 1 : 3. The H5N1 avian influenza virus is not transmitted to humans through properly cooked food. The virus is sensitive to heat. Normal temperatures used for cooking (so that food reaches 70°C in all parts) will kill the virus. To date, no evidence indicates that any person has become infected with the H5N1 virus following the consumption of properly cooked poultry or poultry products, even in cases where the food item contained the virus prior to cooking. Poultry and poultry products from areas free of the disease can be prepared and consumed as usual, with no fear of acquiring infection with the H5N1 virus. As a standard precaution, WHO recommends that poultry and poultry products should always be prepared following good hygienic practices, and that poultry meat should be properly cooked.

### Summary

Avian influenza is an infectious disease of birds caused by type A strains of the influenza virus. Avian influenza viruses do not normally infect species other than birds and pigs. Of



the 15 avian influenza virus subtypes, H5N1 is of particular concern for several reasons. H5N1 mutates rapidly and has a documented propensity to acquire genes from viruses infecting other animal species. The first documented infection of humans with an avian influenza virus occurred in Hong Kong in 1997, when the H5N1 strain caused severe respiratory disease in 18 humans, of whom 6 died. Persons considered to be at the greatest risk if acquiring infection are workers handling poultry in farms, markets & involved in culling activity, veterinary workers. Direct contact with infected poultry, or surfaces and objects contaminated by their faeces, is presently considered the main route of human infection. There is no evidence that properly cooked poultry or eggs can be a source of infection. There is no definite evidence of human to human transmission. The incubation time for influenza ranges from 1 - 5 days with an average of 2 days. Clinical onset is characterized by abrupt fever, headache, malaise and myalgias. Systemic symptoms usually last for 3 days. Influenza A (H5N1) cases have been characterized by high fever, cough shortness of breath and lower respiratory symptoms. The illness rapidly progresses to respiratory distress and subsequent respiratory failure within 1 week of the onset of symptoms. The optimal specimen for influenza A virus detection is a nasopharyngeal aspirate obtained within 3 days of the onset of symptoms. Tests available for the diagnosis of influenza A virus infections include Rapid antigen detection, Virus Culture, Polymerase Chain Reaction and Real - time PCR Assays. Treatment comprises of two drugs oseltamivir (Tamiflu) and zanamivir (Relenza). Surveillance is the cornerstone of pandemic preparedness and response. Vaccination and the use of antiviral drugs are two of the most important response measures for reducing morbidity and mortality during a pandemic if available in adequate quantities. Vaccines are universally regarded as the most important medical intervention for preventing influenza and reducing its health consequences during a pandemic. Potential problems include a high initial dose, the requirement of two doses, and requirement of about six weeks for effective immunity to develop. Another major concern is the inability to produce adequate number of doses. Chemoprophylaxis against H5N1 influenza is one oseltamivir phosphate 75 mg tablet each day for at least 7 days beginning as soon as possible after exposure. In developing countries, non - medical interventions such as health education, stringent sanitary measures and appropriate bio - security practices may be the main line of defence.

## Study Exercises

**Long Question :** Discuss the prevention and control measures during influenza A/H5 viruses outbreak.

**Short Notes :** (1) Dynamics of Avian Influenza Transmission. (2) Surveillance of Influenza A/H5 infection (3) Non medical measures in combating Avian Influenza spread.

## MCQs

1. The first documented infection of humans with an avian influenza virus occurred in (a) Vietnam (b) China (c) Hong Kong (d) Bangladesh
2. Spanish influenza pandemic occurred in the year (a) 1918 (b) 1957 (c) 1968 (d) 1970.
3. The optimal specimen for influenza A virus detection is (a) Blood (b) Urine (c) Stool (d) Nasopharyngeal aspirate.
4. Recommended drug for chemoprophylaxis against H5N1 influenza is (a) Zanamivir (b) Oseltamivir (c) Amantadine (d) Rimantadine
5. Non - medical interventions for defence against influenza pandemic are all except (a) Health education (b) Stringent sanitary measures (c) Vaccination (d) Appropriate bio - security practices.

**Answers :** (1) c; (2) a; (3) d; (4) b; (5) c.

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Rajesh Vaidya

Severe Acute Respiratory Syndrome (SARS) is a new disease which came into notice when a patient was admitted in Hanoi (Vietnam) on 26th Feb 2003 with respiratory illness. Seven health workers who cared for this patient also became ill on 5th March 2003. Since then, the cases have been reported from 29 countries. International travel has facilitated its spread rapidly among six continents. Later on, it was found that the disease initially emerged in China (Guangdong province) in November 2002 from where it spread to other countries (1 - 4).

### Epidemiology

**Global** : The evidence suggests that a newly discovered variant of Corona virus (SARS corona virus) is accountable for this syndrome. Most SARS cases till date have occurred in previously healthy young adults. A few suspected cases have been reported among children. WHO estimates that case fatality ratio ranges from 0% to 50% depending on the age group affected, with an overall estimate of about 15% (1 - 4). As on 15th May 2003, a cumulative total of 7548 probable cases and 573 deaths due to SARS have been reported from 29 countries. The affected areas were : the People's Republic of China (PRC), particularly the Hong Kong Special Administrative Region and the Beijing Municipality, Guangdong, Inner Mongolia, Shanxi, Tianjin, Taiwan Province (China), Toronto (Canada), Singapore (Singapore), India and Manila (Philippines). As of now, China has reported more cases than the rest of the world combined (1 - 7). Currently, there is no known SARS transmission anywhere in the world. The most recent human cases of SARS - CoV infection were reported in China in April 2004 in an outbreak resulting from laboratory - acquired infections. CDC and its partners, including the World Health Organization, continue to monitor the SARS situation globally (1 - 4).

**India** : As on 14th May, 2003, three probable cases of SARS have been reported from India, one each in West Bengal, Karnataka and Gujarat (1 - 2).

**Agent** : SARS corona virus is an enveloped RNA virus. The SARS virus has fulfilled the Koch's postulates, and it has been successfully cultivated in vitro (In VERO cell line) as well as in vivo (Experimental infection has been established in monkeys). The genome of the SARS corona virus is somewhat similar to that of other corona viruses, however the detailed sequence data confirm that this SARS corona virus is a previously unrecognized corona virus. The recent studies carried out in the WHO network laboratories have shown that the SARS virus can survive after drying on plastic surfaces for upto 48 hours. The virus can survive in faeces for at least 2 days and in urine for up to 24 hours (1, 2, 5 - 9).

**Transmission** : SARS virus appears to spread most commonly by close person - to - person contact involving exposure to infectious droplets, and possibly by direct contact with infected body fluids. It is also possible that SARS is transmitting through other unidentified routes. Persons having close contact

with the cases, especially the health care workers and family members are at higher risk.

### Clinical Features

The incubation period is usually 2 - 7 days but may extend upto 10 days (1, 2). The illness begins with sudden onset of fever, sometimes associated with chills and rigors and sometimes accompanied by other symptoms e.g. headache, malaise and myalgia. Some people also experience mild respiratory symptoms at the onset. Typically, rash and neurologic findings are absent. Many patients have reported diarrhoea, especially in Hong Kong. After 3 - 7 days a lower respiratory phase begins with the onset of a dry, non - productive cough or dyspnoea that may be accompanied by or progress to hypoxemia. In 10% to 20% of cases, disease may become severe enough to require intubation and mechanical ventilation. The main symptoms of SARS are high fever (more than 38°C or 100.4°F), dry cough, or difficulty in breathing. Changes in X - ray indicative of pneumonia also occur (1, 2, 8 - 10).

### Diagnosis

As SARS is currently a diagnosis of exclusion, the status of a reported case may change over time (11 - 14). A case should be excluded if an alternative diagnosis can fully explain the illness after considering the possibility of co - infection. Cases that meet the surveillance case definition for SARS should not be discarded on the basis of a negative laboratory test. A patient should always be managed as clinically appropriate, regardless of their case status. A variety of laboratory tests have been developed and are being validated for diagnosis of SARS. These include :

#### Virus Detection Test

**Molecular Test (PCR)** : PCR can detect very minute quantities of the genetic material of the SARS virus in various clinical specimens in the early phase of the disease.

**Cell culture** : Virus in clinical specimens from SARS patients can also be detected by infecting certain cell lines (VERO cell lines). Once isolated, the virus must be identified as SARS virus with further tests. Cell culture is the only test to indicate the infectivity of a SARS case.

#### Antibody Detection Test

**ELISA test** detects antibodies in the serum of SARS patients reliably as from day 21 after the onset of clinical symptoms and signs.

**Immunofluorescence Assays (IFA)** detect antibodies in serum of SARS patients 10 days after the onset of illness.

**Neutralization Test (NT)** : This test assesses and quantifies, by means of titration, the ability of patients' sera to neutralize the infectivity of SARS - Co V on cell culture.

The test which has been most widely used so far is PCR test which is supposed to have a high specificity but low sensitivity. The clinical samples from suspect/ probable SARS cases should only be subjected to laboratory tests. Testing of samples from asymptomatic contacts is not recommended.

### Treatment

As of now, there is no vaccine or specific treatment available for SARS. However, good supportive treatment has been found

effective in many cases (1, 2, 9 - 12). Ribavirin and steroids have shown to be useful in treating critically ill patients. Ribavirin may be given 8mg/kg every 8 hours intravenously or 1.2g every 12 hours orally, with an oral loading dose of 4g for those with normal renal functions. Administer for 7 - 14 days depending upon the response. Give hydrocortisone 2mg/kg every six hours or 4 mg/kg every 8 hours intravenously. Tail off over one week when there is clinical improvement. For severe and rapidly deteriorating cases give methyl prednisolone 10mg / kg every 24 hours intravenously for two days, and then continue with hydrocortisone as above. Antibiotics treatment (coverage for typical and atypical agents for 7 - 14 days using drugs such as levofloxacin and macrolides) is advocated to prevent superadded infection.

Investigation to exclude other causes of pneumonia should be carried out. Patients who require mechanical ventilation generally fulfill the diagnostic criteria for ARDS with diffuse infiltrates on chest radiography and hypoxaemia without evidence of left ventricular failure. All suspect or probable cases of SARS must be treated in isolation with barrier nursing and universal precautions should be taken by the health care workers to prevent the further spread of disease. All the States/UTs have identified the hospitals where cases of SARS should be referred for treatment. List of such hospitals may be obtained from the respective State Health Authorities. Nebulization should not be done. If patient is on a ventilator, close system suctioning catheter and bacterial filter on expiratory and inspiratory limbs of ventilator circuit should be used.

Following discharge from the hospital, convalescent cases should remain at home for 10 days and keep minimum contact with others. Further confinement may be recommended after clinical assessment. Nevertheless, cases must contact their hospitals from where they were discharged if their condition deteriorates and symptoms reappear at any time.

### Prevention and Control

Isolation of suspect and probable cases of SARS and universal precautions taken by the healthcare workers and others who are likely to come in contact with SARS cases would prevent the further spread of disease. WHO recommends that international travellers departing from the places on the affected areas list should be screened for possible SARS at the point of departure. Travellers with one or more symptoms of SARS and having a history of exposure or who appear acutely ill should be assessed by a clinician and may be advised to postpone their trip until they feel better. Under the International Health Regulations all aircraft pilots and masters of ships are required to provide a General Declaration on Health to the Airport/Port authorities and APHOS/PHOs wherein any sickness on board is declared. This needs to be further strengthened by sensitizing all concerned to remain vigilant. Unless absolutely necessary, people should not visit hospitals where the SARS cases have been isolated to avoid any contact with them. Similarly avoid going to the crowded areas, otherwise keep your stay as short as possible.

All persons who come in contact with the suspect and probable cases of SARS should contact the local health authorities if they develop symptoms of SARS within 10 days of exposure.

Temperature should be recorded daily as this is the first symptom which is likely to appear. Contact cases should restrict their movement and remain voluntarily confined to their homes.

All persons disembarking in India are required to fill up a proforma. Any person meeting the criteria of suspect/ probable SARS should be referred to the hospitals identified by Central/ State Governments for further investigations and treatment in isolation. The cases should also be reported to Director, NICD, Delhi, respective State Health Authorities and Director, EMR. Healthy passengers are advised to contact local health authorities if they develop symptoms of SARS in the next 10 days.

**Disinfection** : In - patient rooms housing SARS patients should be cleaned and disinfected daily and at the time of patient transfer or discharge. Daily cleaning and disinfection should include horizontal surfaces (e.g. over - bed table, night stand), surfaces that are frequently touched by patients and healthcare personnel (e.g. bed rails, phone), and lavatory facilities. Terminal cleaning and disinfection following transfer or discharge should include the type of surfaces described above plus obviously soiled vertical surfaces, frequently touched surfaces (e.g. light cords and switches, door knobs), and durable patient equipment (e.g. bed, night stand, over - bed table, wheel chair, commode etc.). Curtain dividers should also be changed and laundered as appropriate for the curtain fabric. Patient care equipments such as mechanical ventilators, pulse oximeters, blood pressure cuff, should be cleaned and disinfected in accordance with current recommendations and manufacturer's instructions.

Cubicles or rooms in OPD areas where patients with suspected SARS are evaluated should be cleaned and disinfected before another patient is seen or cared for in that environment. Areas that should be specifically targeted for cleaning include the examination table and horizontal surfaces that may have been touched by the patient or healthcare providers. Solutions used for cleaning and disinfection should be discarded after use. Thoroughly rinse and clean housekeeping equipment after use in a SARS room or area and allow the equipment to dry. Launder reusable mop heads and cleaning clothes according to current practice.

### Summary

Severe Acute Respiratory Syndrome (SARS) is a new disease which came into notice in Feb. 2003. As on 15th May 2003, a cumulative total of 7548 probable cases and 573 deaths due to SARS have been reported from 29 countries. China has reported more cases than the rest of the world combined. Currently, there is no known SARS transmission anywhere in the world. SARS corona virus is an enveloped RNA virus. SARS virus appears to spread most commonly by close person - to - person contact involving exposure to infectious droplets, and possibly by direct contact with infected body fluids. The incubation period is usually 2 - 7 days but may extend upto 10 days. The illness begins with sudden onset of fever and associated symptoms, after 3 - 7 days a lower respiratory phase begins with the onset of a dry, non - productive cough or dyspnoea. In 10% to 20% of cases, disease may become severe enough



to require intubation and mechanical ventilation. SARS is currently a diagnosis of exclusion. A variety of laboratory tests have been developed and are being validated for diagnosis of SARS. These are PCR, Cell culture, Antibody Detection Test (ELISA, Immunofluorescence assays and Neutralization test). The clinical samples from suspect/ probable SARS cases should only be subjected to laboratory tests. Testing of samples from asymptomatic contacts is not recommended. As of now, there is no vaccine or specific treatment available for SARS. Ribavarin and steroids have shown to be useful in treating critically ill patients. All suspect or probable cases of SARS must be treated in isolation with barrier nursing and universal precautions should be taken by the health care workers to prevent the further spread of disease. All persons who come in contact with the suspect and probable cases of SARS should contact the local health authorities if they develop symptoms of SARS within 10 days of exposure. Disinfection procedures should be strictly followed in all health care centres for SARS.

### Study Exercises

**Long Question :** Discuss the epidemiology, treatment, prevention and control of SARS

**Short Notes :** (1) Recommendation for International Travel during SARS epidemic (2) Disinfection in SARS care centre

#### MCQs

- Country which has reported maximum no. of cases of SARS (a) Canada (b) Singapore (c) Hong Kong (d) China.
- All of the following states in India reported probable cases of SARS in 2003 except (a) West Bengal (b) Karnataka (c) Andhra Pradesh (d) Gujarat.
- SARS corona virus is (a) Enveloped RNA virus (b) Non - enveloped RNA virus (c) Enveloped DNA virus (d) Non - enveloped DNA virus.
- SARS virus can survive after drying on plastic surfaces for upto (a) 24 hours (b) 48 hours (c) 72 hours (d) 96 hours.

- Immunofluorescence Assays (IFA) detect antibodies in serum of SARS patients \_\_\_\_ days after the onset of illness (a) 5 (b) 10 (c) 15 (d) 20.

**Answers :** (1) d; (2) c; (3) a; (4) b; (5) b.

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#### Definition

Gastroenteritis (also known as gastric flu or stomach flu), caused due to infections by a wide variety of micro - organisms including bacteria, virus, protozoa and helminthes or due to toxins produced by them, is an inflammation of gastrointestinal tract, involves both the stomach and small intestine and is characterized by the presence of vomiting and diarrhoea, the

latter being prominent in cases of bacterial origin.

#### Magnitude of the problem

Acute gastroenteritis is a major cause of morbidity and mortality, especially in children under five. World wide more than a billion cases of gastroenteritis, majority being from developing world, are reported every year. Due to the improved management skills especially the introduction of oral re - hydration therapy and improved sanitation, decadal trend, in the past three decades has shown a steady decline. The mortality rate, estimated as 4.8 million deaths per year prior to 1980, declined to 3.3 million deaths per year during 1980 - 1990 and to 2.6 million deaths per year during 1990 - 2000. In



the year 2001, 1.8 million deaths worldwide were estimated to be because of gastrointestinal infections and these accounted for 3.2% of overall casualties. In India, during the year 2005, about 1.07 million cases of acute diarrhoea with 2040 deaths were reported; though the actual incidence may be manifold.

### Epidemiological determinants

**Agent factors** : A number of infectious agents including virus, bacteria, protozoa and intestinal worms, have been incriminated in the causation of gastroenteritis. Depending on the presence of blood in stool, these agents can be classified as follows :

#### (a) Causes of acute gastroenteritis without blood in stool

(i) **Viruses** : Rotavirus, Astrovirus, Norwalk group of virus, Enteric adenovirus

(ii) **Bacteria** : Early stages of *Shigella*, *C. jejuni*, *Salmonella* spp infection, Enterotoxigenic *E. coli* (ETEC), Enteropathogenic *E. coli* (EPEC), Enterococcal *E. coli* (EAVC), *Staph aureus*, *V. Cholera*, *Clostridium perfringens*, *C. difficile*, *Bacillus cereus* and *B. subtilis*

(iii) **Protozoa** : Giardiasis, Cryptosporidiosis, Cyclospora cayetenensis

(iv) **Helminths** : Strongyloidiasis

#### (b) Causes of acute gastroenteritis with blood in stool

(i) **Bacteria** : Shigellosis, Enterohaemorrhagic *E.coli*, *Campylobacter jejuni*, *Salmonella* spp, *Yersinia enterocolitis*

(ii) **Protozoa** : *Entamoeba histolytica*, *Balantidium coli* enterocolitis

(iii) **Helminths** : Massive trichuris infection, *Schistosoma mansoni*, *S. japonicum*

**Reservoir and source of infection** : Man is the principal reservoir of the infections. Mild cases which clinically recover in a few days without going to hospital, constitute one of the chief means by which the reservoir is maintained. Contaminated food or water serves as the principal source of infection.

The causative agents are significantly different from each other as far as the mode of transmission and virulence is concerned. While some like *Vibrio* and *S. typhi* are spread by water, others like *Staph. aureus* and *C. perfringens* are spread by food. Some like *salmonella* non - typhi, which multiply in food and *V. cholerae* have the potential of causing outbreaks, others like *C. jejuni* and *E. histolytica* produce sporadic diseases. Patients with acute amoebic dysentery pose only limited danger to others because of the fragility of trophozoites. Asymptomatic or mild cases excreting cystic forms of *E. histolytica* on the other hand are important reservoir of infection.

**Host factors** : Man has no natural immunity against these organisms. Both sexes are equally susceptible. Children and the aged suffer more. Transient immunity develops against the specific strain of some of the organisms like *Shigella*. However, immunity to re - infection has not been clearly demonstrated. Host differences such as race and age have been described as affecting susceptibility of individuals to infection. Intestinal motility plays an important role in providing protection against the infection. Increased gut motility associated with diarrhoea is a highly effective defence mechanism. Oral antibiotic therapy makes the host susceptible to gastrointestinal pathogens.

Diarrhoeal diseases are most common during the first two years of life. Incidence is highest at the time of weaning i.e. between 6 - 11 months. This pattern reflects the combined effects of declining levels of maternally - acquired antibodies, the lack of active immunity in the infant, the introduction of food that may be contaminated with faecal bacteria, and direct contact with human or animal faeces when the infant starts to crawl. Most enteric infections, mainly beyond 2 years of age, are asymptomatic owing to the development of active immunity. Persons with asymptomatic infections play an important role in the spread of many enteric pathogens, especially as they are unaware of their infection, take no special hygienic precautions and move normally from place to place. Under nutrition, recent measles and immunosuppression are associated with increased incidence, severity or duration of diarrhoea.

**Environmental factors** : Gastrointestinal infections are strongly linked to environmental factors. Non - availability, inadequacy or lack of access to clean drinking water, inadequate disposal of faecal waste and poor hygiene and sanitation increases the likelihood of these diseases. Travellers travelling from developed countries to developing countries usually fall prey to these conditions and develop traveller's diarrhoea.

Diarrhoeal diseases follow a distinct seasonal pattern. In tropical areas, rotavirus diarrhoea tends to occur throughout the year, increasing in frequency during the drier, cool months, whereas bacterial diarrhoeas tend to peak during the warmer, rainy season.

**Mode of Transmission** : Infection by all organisms of this group of diseases is invariably by ingestion in food or drink i.e. faeco - oral route. Person to person transmission plays an important role in transmission. Individuals primarily responsible for transmission are those with poor personal hygiene and who fail to cleanse contaminated hands and carry organisms under their fingernails after defaecation. Contaminated water is believed to play a major role in the transmission of amoebiasis. The organisms of bacillary dysentery do not thrive in water and are readily killed by chlorination but amoebic cysts are not killed by chlorine in amounts normally added for water disinfection. Water can be rendered free from cyst only by sand filtration. Milk and food are contaminated by infected water or by the hands of a carrier or case or more likely by flies & cockroaches which act as vehicles. Contamination of crockery, cutlery, kitchen utensils by food handlers or by dust containing cysts in case of *Entamoeba histolytica* is a possibility. Vegetables from fields irrigated with polluted water especially those cultivated with raw sewage as practiced in improper sewage farming are liable to carry infection.

**Incubation period and Period of communicability** : The incubation period varies from few hours as in case of bacillary dysentery to 2 to 4 weeks, but can be prolonged to several months, as in case of amoebic dysentery. Incubation period of some of the common causative organisms are shown in Table-1.

Diarrhoea and bacillary dysentery cases are most infective during the course of clinical illness and a short period thereafter. A case of amoebic dysentery is infective mostly during the non - clinical period between the remissions of clinical attack, because it is the cystic stage of amoeba which is infective and

not the vegetative form.

**Table-1 : Incubation Period of common enteric pathogens**

Causative organisms	Incubation period
<i>C. perfringens</i> , <i>B. cereus</i> (type I & II), <i>B. subtilis</i>	4 - 24 h
<i>S. enteritidis</i> , <i>S. typhimurium</i>	12 - 24 h
<i>Rotavirus</i> , Norwalk gp of virus, <i>V. cholerae</i> , <i>Shigella spp.</i>	1 - 3 days
<i>E. coli</i> (EHEC)	3 - 4 days
<i>E. histolytica</i>	2 - 4 weeks

### Clinical Features

Acute gastroenteritis usually presents with diarrhoea, vomiting or occasionally both, abruptly in an otherwise healthy individual. The frequency and consistency of the stool depends on the causative organism and the dose of inoculum and varies from person to person and from day to day.

Conventionally diarrhoea is the passage of 3 or more loose or liquid stools per day, or more frequently than is normal for the individual. Acute diarrhoea is an attack of sudden onset which usually lasts for 3 - 7 days, but may last up to 10 - 14 days. Diarrhoea that starts as an acute episode and lasts for more than 2 weeks is considered persistent or chronic. This definition excludes specific conditions like celiac disease, tropical sprue, or other congenital, biochemical or metabolic disorders. Diarrhoea that is often associated with blood in the faeces is known as dysentery (formerly known as the bloody flux or simply flux). It is, usually, more severe and more likely to result in death than other forms of acute diarrhoea.

Pathophysiologically, diarrhoeal diseases are mainly of 2 types: secretory non - invasive diarrhoea, such as cholera, due to impairment of water absorption mechanisms in the small bowel and inducing watery stools and dehydration; and enteroinvasive diarrhoea, due to alteration of the colonic mucosa, inducing dysentery. Most cases of infectious diarrhoea are acute. Some pathogens, mainly parasites, can induce chronic diarrhoea.

Usually acute gastroenteritis is not associated with constitutional symptoms. But abdominal cramps may be present in some cases especially with dysentery. Fever may be occasionally present especially in salmonella and shigella infections. In some cases, due to excessive loss of fluid, features of dehydration like thirst, restless or irritable behaviour, dry mucosa, decreased skin turgor and sunken eyes, may be present. In severe cases sensorium may be obtunded and the patient may develop hypovolemic shock. Death may follow swiftly, if rehydration is not started immediately.

### Laboratory diagnosis

Most uncomplicated cases of acute gastroenteritis can be managed successfully without resorting to any lab investigation. In hospital settings, microscopy and stool cultures may be done for the diagnosis of the causative organisms but, in majority of the cases, patients recover before the culture report is available. In complicated cases, blood sugar and electrolytes

may be required for the management.

### Acute Viral Gastroenteritis

Acute viral gastroenteritis is caused by two distinct groups of viruses - the rotavirus and the enteric calicivirus such as Norwalk virus. The rotaviruses primarily infect children while enteric calicivirus affects both children as well as adults. In general these viral enteropathogens affect duodenum and upper jejunum, causing non - inflammatory diarrhoea.

Rotavirus infection occurs worldwide and by the age of three years almost all children suffer from rotavirus infection at least once. The median of peak age of infection in developing countries was found to be between six months to one year while the same for developed countries was over eleven months. World over, rotavirus is estimated to cause 20% of childhood deaths. Rotavirus is a member of Reoviridae family. Several distinct groups (groups A, B, C etc) of rotavirus have been identified so far, but the most common among humans is group A. Children less than 3 years of age are most commonly infected. Both sexes are affected equally. One episode of rotavirus diarrhoea confers good protection against subsequent infection, which are decreasingly less severe with each fresh episode. Protection of neonates against rotavirus infection appears to be due to trans - placental transfer of maternal antibody and due to antibodies present in the breast milk.

The clinical manifestations of rotavirus infection range from sub - clinical infection to fatal dehydrating illness through mild to severe diarrhoea. Vomiting is an early feature and fever is common. Diarrhoea is usually watery and large in volume. Colicky abdominal pain, ill defined tenderness and exaggerated bowel sounds are common. Severe dehydration is not unusual.

Rotavirus infection frequently occurs in conjunction with respiratory tract symptoms. It may rarely be associated with Reye's syndrome, hemolytic uremic syndrome, Henoch Schonlein purpura and polio - like paralysis and encephalitis. It may be severe or even fatal in immuno - compromised children.

Since the virus is shed in large amounts in stool, detection with the help of ELISA and Polymerase Chain Reaction (PCR) is possible, if facilities are available.

A live attenuated oral vaccine effective in reducing the severity of the disease, was developed and marketed but was subsequently withdrawn following reports of intussusception.

### Management

Majority of the cases of acute gastroenteritis recover with re - hydration only and do not require anti - biotic therapy. Oral Rehydration Solution (ORS), introduced by WHO, is the single most important measure in the management of acute diarrhoea due to all aetiologies, in all age groups, and in all countries. The composition of reduced osmolarity ORS, as suggested by WHO, is as follows : Sodium Chloride - 2.6 g, Glucose (anhydrous) - 13.5 g, Potassium Chloride - 1.5 g, Trisodium citrate dehydrate - 2.9 g (Total weight of a packet = 20.5 g).

Packets of oral re - hydration mixture are freely available. The contents of the packet are dissolved in 1 litre of drinking water. The prepared solution should be used within 24 h. It should

not be boiled or sterilized otherwise. It alone can correct mild to moderate dehydration. The inclusion of tri - sodium citrate in place of sodium bicarbonate has made the product more stable. Besides, it also results in less stool output especially in high output diarrhoea (e.g. cholera), probably because of a direct effect of trisodium citrate in increasing intestinal absorption of sodium and water.

If these mixtures of salts are not available, simple mixture - Salt and Sugar Solution (SSS) - consisting of table salt 5 gm and sugar 20 gm dissolved in 1 litre of drinking water may safely be used. The child can also be given Home Available Fluids (HAF) like yoghurt drink, lemon drink, rice or pulse based drinks, vegetable soup, green coconut water or plain clean water. The general rule is that patients should be given as much ORS solution as they want, and that signs of dehydration should be checked until they subside. If the child's weight is known, the amount of ORS solutions required for re - hydration during the first four hours may be calculated by setting the deficit at approx 75 ml/kg body weight. Intravenous infusion is usually required only for the initial re - hydration of severely dehydrated patients who are in shock or unable to drink.

Judicious use of antibiotics in selected cases may reduce the severity and duration of the illness. Empirical treatment with quinolone (such as ciprofloxacin) in doses of 500 mg twice a day for 3 to 5 days may be considered in moderate to severe cases. For suspected cases of amoebiasis and giardiasis, treatment with metronidazole (250 mg 6 hrly for 7 days) may be considered.

The guidelines for assessment of dehydration in a patient of

acute gastroenteritis are given in Table - 2.

The guidelines for assessment of fluid deficit in each type of dehydration are given in Table - 3.

The guidelines for fluid replacement, when some dehydration is present, is given in Table - 4.

**Note :** Use the patient's age only when you do not know the weight. The approximate amount of ORS required (in ml) can also be calculated by multiplying the patient's weight in kg by 75.

- If the patient wants more ORS than shown, give more.
- Encourage the mother to continue breastfeeding her child.
- For infants under 6 months who are not breastfed, if using the old WHO ORS solution containing 90 mmol/L of sodium, also give 100 - 200ml clean water during this period. However, if using the new reduced (low) osmolarity ORS solution containing 75mmol/L of sodium, this is not necessary.
- During the initial stages of therapy, while still dehydrated, adults can consume up to 750 ml per hour, if necessary, and children up to 20 ml per kg body weight per hour.

Guidelines for replacement of fluid in case of severe dehydration are given in Table - 5.

Reassess the patient every 1 - 2 hours. If state of hydration is not improving, give IV fluids more rapidly.

### Prevention and control

Constant maintenance of a high standard of waste disposal and environmental sanitation; personal hygiene including food hygiene and habits; wholesome water and milk supply; extermination of flies, and health education are the measures to be relied upon for preventing the infection in community.

**Table - 2 : Assessment of diarrhoea patients for dehydration**

Sign	Normal (No dehydration)	Some dehydration (any two of the following)	Severe dehydration (any two of the following)
Patient's condition	Conscious, alert, well looking	Restless irritable	Lethargic, unconscious
Eyes	Normal	Sunken	Sunken
Thirst	None	Thirst ++ Drinks eagerly	Drinks poorly, unable to drink
Skin pinch	Goes back immediately	Goes back slowly	Goes back very slowly

Source : IMNCI booklet, Ministry of H& FW, Govt of India (2005)

**Table 3 : Assessment of fluid deficit in dehydration**

Assessment	Fluid deficit as % of body weight	Fluid deficit in ml/kg body weight
No signs of dehydration	<5%	<50 ml/kg
Some dehydration	5 - 10%	50 - 100 ml/kg
Severe dehydration	>10%	>100 ml/kg

**Table 4 : Approximate amount of ORS to be given in the first four hours of treatment when SOME DEHYDRATION is present**

Age	Weight (kg)	ORS (ml)
Less than 4 months	Less than 5	200 - 400
4 - 11 months	5 - 8	400 - 600
1 - 2 years	8 - 11	600 - 800
2 - 4 years	11 - 16	800 - 1200
5 - 14 years	16 - 30	1200 - 2200
More than 14 years	More than 30	2200 - 4000

Source : WHO guidelines in Oxford handbook of Tropical Medicine

**Table 5 : Approximate amount of IV infusion of Ringer Lactate to be given when SEVERE DEHYDRATION is present**

Age	First give	Then give
Less than 12 months	30 ml/ kg in 1 hour	70 ml/ kg in 5 hour
More than 12 months	30 ml/ kg in 30 min	70 ml/ kg in 2.5 hour

Source : WHO guidelines in Oxford handbook of Tropical Medicine



The following measures should be taken for controlling an outbreak :

**(a) Isolation** : All serious cases should be admitted to hospital and isolated during acute illness with rigid personal precautions by attendants. Fluid and electrolyte replacement is important along with specific drugs. This will break the chain of transmission.

**(b) Rehydration** : All cases must be given reduced osmolarity ORS liberally. Those requiring parenteral rehydration should be treated in a health care facility.

**(c) Breastfeeding** : Because of its protective qualities, breastfeeding must be continued for sick children.

**(d) Safe drinking water** : Water supplies should be scrutinized and adequately chlorinated.

**(e) Food safety** : Food hygiene should be made stricter. Adequate storage facility for storage of food (both cooked and uncooked) and adequate water for cleaning and cooking must be provided. All crockery and cutlery must be adequately cleaned before use. Milk should be boiled and the food habits of personnel should be improved. WHO guidelines for food safety, as given in Box-1

<b>Box - 1: WHO Golden rules for food safety</b>	
1.	<b><i>Cook raw foods thoroughly</i></b> : Thorough cooking will kill the pathogens, which means the temperature of all parts of the food must reach at least 70 °C. Uncooked fruits or vegetables should not be eaten, unless they can be peeled. If milk has not been pasteurized, it should be boiled before use.
2.	<b><i>Eat cooked food immediately</i></b> : When cooked foods cool to room temperature, bacteria begin to grow. The longer the wait, the greater the risk. To be on the safe side, eat cooked foods as soon as they come off the heat.
3.	<b><i>Prepare food for only one meal</i></b> : Foods should be prepared freshly and for one meal only, as far as possible. If foods have to be prepared in advance, or if there are leftovers, they should be stored cold, i.e. below 5 °C (in a refrigerator or in a cold box), or hot, i.e. above 60 °C. This rule is vitally important when it is planned to store food for more than 4-5 hours. Cooked foods that have been stored must be thoroughly reheated before eating, i.e. all parts reheated to at least 70 °C. Thorough reheating of foods is essential if refrigerators have ceased to operate for some hours due to power cuts.
4.	<b><i>Avoid contact between raw foods and cooked foods</i></b> : Safely cooked food can become contaminated through even the slightest contact with raw food. This cross-contamination can be direct, e.g. when raw fish comes into contact with cooked foods. It can also be indirect. For example, preparing raw fish and then using the same unwashed cutting surface and knife to slice cooked food should be avoided, or all the potential risks of illness that were present before cooking may be reintroduced. Cross-contamination may also occur in a freezer when the power has been off for some time and this should be checked for. The juice of raw meat and poultry may drip onto other foods.
5.	<b><i>Choose foods processed for safety</i></b> : Many foods, such as fruits and vegetables, are best in their natural state. However, in disasters and emergencies, they may not be safe and should be peeled before consumption if eaten raw. Foods that have been processed (e.g. canned food and packed dried food) may be safer. Dry rations may be easier to keep safe, as they do not need cold-storage, but they do need to be kept dry.
6.	<b><i>Wash hands repeatedly</i></b> : Hands should be washed thoroughly before preparing, serving or eating food and after every interruption, especially after use of the toilet or latrine, changing a baby or touching animals. After preparing raw foods, hands should be washed again before handling cooked or ready-to-eat foods.
7.	<b><i>Keep all food preparation premises meticulously clean</i></b> : Since foods are so easily contaminated, any surface used for food preparation must be kept absolutely clean. Scraps of food and crumbs are potential reservoirs of germs and can attract insects and animals. The immediate surrounding of the temporary shelter, especially the kitchen and food storage areas should be cleaned and sullage and solid kitchen waste should be disposed of properly. Food should be stored in closed containers to protect it from insects, rodents and other animals. Fly and rat traps should be used if necessary.
8.	<b><i>Use safe water</i></b> : Safe water is just as important for food preparation as for drinking. If the supply of safe/potable water has been disrupted, the water intended for drinking or food preparation should be boiled. For example, condensed or powdered milk must be reconstituted with potable water only. Ice made from unsafe water will also be unsafe and may be a source of food contamination.
9.	<b><i>Be cautious with foods purchased outside</i></b> : Sometimes food served in restaurants and by street food-vendors is not prepared under hygienic conditions. In times of disasters or emergencies, the risk that such foods are contaminated is greater. Therefore, caution must be exercised in the choice of food: only food that has been thoroughly cooked and is still hot when served should be eaten. Food bought from street food-vendors should be thoroughly cooked in the presence of the customer. Apart from fruits and vegetables that can be peeled, raw or undercooked foods should be avoided. Only water that has been boiled, or disinfected with chlorine or iodine, should be drunk. Beverages such as hot tea or coffee, wine, beer, carbonated water or soft drinks, packaged fruit juices and bottled water are usually safe to drink, if not damaged by the disaster. Ice should be avoided, unless it is made from safe water.
10.	<b><i>Breast-feed infants and young children</i></b> : Breast milk is the ideal source of nourishment for infants during their first months of life. It protects infants against diarrhoea through its anti-infective properties, and minimizes their exposure to food borne pathogens. Breast milk will ensure a safe and nutritionally adequate food for infants from birth up to the age of 4-6 months. Continued breast-feeding after this age can also contribute to the prevention of food-borne infections in older infants and young children.



would go a long way in preventing gastroenteritis.

**(f) Concurrent Disinfection** : All underclothings, soiled linen, bedding, and particularly the excreta should be treated by concurrent disinfection.

**(g) Personal Hygiene** : Thorough hand washing with soap before handling food must be stressed.

**(h) Epidemiological Investigation** : For the source of infection and modes of transmission, epidemiological investigation should be carried out and appropriate control measures instituted.

**(j) Control of Flies** : Control and destruction of flies is the most important method of controlling an outbreak of dysentery. Persistent attention to exterminate breeding places by proper disposal of faeces and manure, ensuring good general sanitation, prohibiting indiscriminate defaecation and the use of insecticides lead to control of flies. Health education of all personnel is very important.

## Summary

Gastroenteritis is an inflammation of the intestinal tract caused by a wide variety of micro - organisms including bacteria, virus, protozoa and heminthes. It is a major cause of morbidity and mortality, especially in children under five. A steady decline in the number of cases has been seen after improved sanitation and introduction of oral rehydration therapy.

The infectious agents can be broadly classified as those causing acute gastroenteritis with or without blood in stool. Man is the principal reservoir of the infections. Persons with asymptomatic infections play a major role in spread of the infection as they take no special hygienic precaution. The main source of infection is either contaminated food or water. Man has no natural immunity against these organisms. Both sexes are equally susceptible. Children and the aged suffer more. Increased intestinal motility associated with diarrhoea is an effective defence mechanism. Co - morbid conditions like under nutrition, recent measles and immunosuppression are associated with increased incidence, severity or duration of diarrhoea. Environmental factors like lack of access to clean drinking water, improper disposal of faecal waste and poor hygiene increases the chances of these infections. Mode of disease transmission is by faeco - oral route due to poor personal hygiene. Flies and cockroaches may also act as vehicles for transmission of disease. Adequate chlorination kills some of the disease causing organisms.

Incubation period varies from few hours to a few weeks depending on the infecting organism. It usually presents with diarrhoea, vomiting or occasionally both, abruptly in an otherwise healthy individual. The frequency and consistency of the stool depends on the causative organism and the dose of inoculum and varies from person to person. Diarrhoea less than 2 weeks is known as acute and more than 2 weeks as chronic. Pathophysiologically diarrhoea can be divided as secretory non - invasive and enteroinvasive diarrhoea. Microscopy and stool cultures may be done for the diagnosis of the causative organisms but, in majority of the cases, patients recover before the culture report is available.

Acute viral gastroenteritis is caused by two groups of viruses

- the rotavirus and the enteric calicivirus such as Norwalk virus. The rotaviruses primarily infect children while enteric calicivirus affects both children as well as adults. Children less than 3 years of age are most commonly infected. Both sexes are affected equally. The clinical manifestations of rotavirus infection range from sub - clinical infection to fatal dehydrating illness. Vomiting is an early feature and fever is common. Diarrhoea is usually watery and large in volume.

Majority of the cases of acute gastroenteritis recover with re - hydration only and do not require antibiotic therapy. Oral Rehydration Solution (ORS), introduced by WHO, is the single most important measure in the management of acute diarrhoea due to all aetiologies, in all age groups, and in all countries. Packets of oral re - hydration mixture are freely available. The contents of the packet are dissolved in 1 litre of drinking water. The prepared solution should be used within 24 h. If ORS is not available, then salt and sugar solution (SSS) or home available fluids (HAF) like yoghurt drink, lemon drink, rice or pulse based drinks, vegetable soup, green coconut water or plain water can also be safely given. The patient should be given as much ORS as they want. Intravenous infusion is usually required only for the initial re - hydration of severely dehydrated patients who are in shock or unable to drink. The use of antibiotics in selected cases may reduce the severity and duration of the illness.

A constant maintenance of a high standard of environmental sanitation, personal hygiene, safe water and milk supply, control of flies and health education will be helpful in preventing the infection in community. The measures to be taken during an outbreak are isolation, rehydration, breastfeeding, safe drinking water, food safety, concurrent disinfection, personal hygiene, control of flies and epidemiological investigation for the source of infection and modes of transmission should be carried out and appropriate control measures instituted.

## Study Exercises

**Long Questions** : (1) Discuss the steps to be taken for control of an out break of gastroenteritis (2) Principles of management of cases of dehydration.

**Short Notes** : (1) Oral rehydration solution (2) WHO golden rules for food safety (3) Discuss briefly the epidemiological factors in Gastroenteritis.

### MCQs

1. If ORS is not available which of the following fluids can be given to a case of gastroenteritis (a) Yoghurt drink (b) Vegetable soup (c) Salt and sugar solution (d) All of the above.
2. All cause bloody diarrhoea (dysentery) except (a) *Shigella* (b) *Campylobacter jejuni* (c) *Entamoeba histolytica* (d) Rotavirus.
3. All are causes of acute gastroenteritis without blood in stool except (a) Rotavirus (b) *Shigella* (c) Giardiasis (d) Cryptosporidiasis.
4. Which of the following is predominantly transmitted through contaminated food (a) *S. typhi* (b) *V. cholera* (c) *E. histolytica* (d) *S. aureus*.
5. Infection caused by which of the following has an incubation period of 1 - 3 days (a) Rotavirus (b) *V. cholera*

(c) *Shigella* (d) All of the above.

Answers : (1) d; (2) d (3) b; (4) d; (5) d.

### Further Suggested Reading

1. Last, John M, Wallace, Robert B. Wallace / Maxcy - Rosenau - Last's Public Health & Preventive Medicine. 15th ed, New York, McGraw - Hill Companies, Inc. 2008
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## Cholera

Rajesh Kunwar

### Definition

A serious acute intestinal disease caused by *Vibrio cholerae* 01 (Classical or El Tor) and characterized by sudden onset, profuse, effortless watery stools, vomiting, rapid dehydration, muscular cramps, acidosis and circulatory collapse. Fatality rates in untreated cases may exceed 30 - 40 per cent; inapparent and wholly asymptomatic infections are many times more frequent than clinically recognized cases, especially *Vibrio cholerae* biotype El Tor.

### Magnitude of the Problem

For centuries cholera has been one of the most feared diseases. Even today, it remains a global threat to public health and one of the key indicators of social development. While the disease no longer poses a threat to countries where minimum standards of hygiene are met, it remains a challenge in those countries where access to safe water and adequate sanitation can not be guaranteed for all.

Six cholera pandemics, caused by the classical biotype, were reported from South Asia during 19th and early 20th century. The El Tor biotype was first recognized in 1906 but remained localized in Sulawesi in Indonesia. In 1961, an unexpected situation arose. Cholera El tor suddenly became widespread, starting the seventh pandemic. India became involved in 1964. It has since affected more than 80 countries in Asia, Africa & Europe. In India, cholera biotype El Tor has almost completely replaced the age old classical cholera. Currently the large endemic foci of cholera are found in Maharashtra, Tamil Nadu, Karnataka, Delhi, Gujarat & Kerala, which account for 80 percent of the reported incidence in the country.

During the year 2007, a total of 11, 325 cases and 37 deaths were reported from 8 Asian countries. The Indian subcontinent reported 23% of all cases notified from Asia, with India notifying a total of 2635 cases and 3 deaths.

### Epidemiological determinants

#### Agent factors

(a) **Agent** : The causative agent, *Vibrio cholerae* was first isolated in 1883 by Koch from the stools of patients with cholera. It is a Gram - negative, aerobic, comma - shaped rod that is oxidase positive and ferments both sucrose and glucose but not lactose. It is best identified by inoculating stool into taurocholate - tellurite - gelatin (TTG) agar or thiosulfate - citrate - bile salts - sucrose (TCBS) agar. *V. cholerae* colonies are relatively small on TTG agar after 24 hours and are translucent with a dark centre and a cloudy zone surrounding the colonies. On TCBS agar *V. cholerae* are easily recognized as large yellow colonies on a blue - green medium.

The antigenic classification of vibrios depends on the specific somatic (O) antigens. The flagellar antigen (H) is non specific and common to all. The group A vibrios which include both cholera and cholera like vibrios have been divided into six sub groups (I to VI) based on the antigenically different 'O' antigens. Cholera vibrios belong to serological O sub - group I of Gardner and Venkataraman and other serological Sub - group (II to VI) are NAG vibrios (non agglutinable to O group I antisera). The O subgroup I vibrios comprises of classical *V. Cholera* and *V. El Tor* biotype. Based on the O antigenic components, both classical *V. cholerae* and biotype El tor have been divided into 3 serotypes Ogawa, Inaba and Hikojima. The former two are common.

Epidemiologically, cholera due to El Tor biotype differs from classical cholera. In El Tor :

- There is a higher incidence of mild and asymptomatic infection. This implies that the characteristic picture of rice-water stools and other signs of classical cholera described above may not be seen often.
- There are fewer secondary cases in the affected families
- Occurrence of chronic carriers are common
- Since El Tor vibrios are more resistant than classical cholera vibrios, they survive longer in the extra intestinal environment and hence epidemics continue longer.

Classical *Vibrio cholerae* can be distinguished from El Tor by the following tests as shown in Table - 1 :

**Table - 1 : Differences between Classical and El Tor *Vibrio Cholerae***

Test	Classical <i>V. cholerae</i>	Biotype El tor
Chick erythrocyte agglutination	Negative	Positive
Polymyxin B sensitivity	Sensitive	Resistant
Cholera phage IV	Sensitive	Resistant
Haemolysis test	Negative	Positive

**(b) Resistance :** *V. cholerae* O1 is killed by heating at 55°C for 15 mins and by most disinfectants, yet it can survive on a variety of foodstuffs for up to five days at ambient temperature and up to 10 days at 5 - 10 degrees Celsius. The organism can also survive freezing. Low temperatures, however, limit proliferation of the organism and thus may prevent the level of contamination from reaching an infective dose. The cholera vibrio is sensitive to acidity and drying, and commercially prepared acidic (pH 4.5 or less) or dried foods are therefore without risk. Gamma irradiation and temperatures above 70 degrees Celsius also destroy the vibrio.

**(c) Toxin production :** Vibrios multiply in the lumen of small intestine and produce enterotoxins which act on adenyl cyclase - cyclic AMP system of mucosal cells and produce diarrhoea.

**(d) Reservoir of infection :** The only reservoir of infection is man, either a case or a carrier. The ratio of severe cases to mild or inapparent infections has been shown to be about 1 : 5 for classical cholera and 1 : 25 to 1 : 100 for El Tor cholera. Carriers in cholera are of four types viz. incubatory carriers, convalescent carriers, healthy carriers and contact carriers. Duration of carrier period is short, about 4 or 5 days. Chronic carriers who harbour the vibrio for more than 3 months are not common.

**(e) Infective material :** Stools and vomit of cases and carriers are infectious in nature. However, carriers excrete fewer vibrios as compared to cases.

**(f) Period of communicability :** A case of cholera is infectious for a period of 7 to 10 days. While convalescent carriers are infectious for 2 - 3 weeks, chronic carrier state may last from one month to 10 years or more.

**Host Factors :** Cholera usually affects persons belonging to the low socio - economic strata because of poor environmental sanitation. Their standard of personal hygiene is low. When cholera epidemic occurs in non - endemic areas, male adults are more affected. In contrast, in endemic areas, attack rate is equal in both the sexes and it is distinctly higher for children than for adults. This phenomenon is due to development of naturally acquired immunity with increasing age in the endemic areas.

**Environmental factors :** Contaminated water and food are the most important environmental factors in the causation of cholera. Unusually heavy rains, which have caused flooding, are blamed, at times, for the high incidence of the disease outbreak. Flies may carry *V. cholerae* but are not vectors of proven importance. Social factors responsible for the endemicity of the disease include poor literacy, poor personal hygiene, poor

living standards and unhealthy habits in relation to water and food.

**Mode of Transmission :** Infection by *V. cholerae* is invariably by ingestion. Most important mode of transmission is through contaminated water. Disease may spread through food contaminated by food handlers and flies. Fruits and vegetables washed with contaminated water may transmit the infection. Person to person contact particularly in overcrowded dwellings without sanitary facilities is very important due to careless handling of human excreta under such conditions.

**Incubation Period :** It varies from a few hours upto 5 days, but commonly 1 to 2 days. Infectivity of cholera is high, but the disease rate is low; as a rule, although many members of family may be infected, usually one of them falls ill.

**Pathogenesis :** According to current concepts, the cholera vibrio gets through the mucus which overlies the intestinal epithelium. It probably secretes mucinase, which helps it move rapidly through the mucus. Then it gets attached or adhered to the intestinal epithelial cells, and this it probably does by an adherence factor on its surface. When the vibrio becomes adherent to the mucosa, it produces its enterotoxin which consists of 2 parts - the light or L toxin and the heavy or H toxin. The L toxin combines with substances in the epithelial cell membrane called gangliosides and this binds the vibrio to the cell wall. Binding is irreversible. The mode of action of H toxin is not fully clear. What we know is that there is a substance called "adenylcyclase" in the intestinal epithelial cells, and H toxin activates this substance. The activated adenyl cyclase causes a rise in cAMP. cAMP provides energy which drives fluid and ions into the lumen of the intestine. This fluid is isotonic and is secreted by all segments of small intestine. This increase in fluid is the cause of diarrhoea.

### Clinical Features

The severity of cholera is dependent on the rapidity and duration of fluid loss. Epidemiological studies have shown that more than 90 percent of El Tor cholera cases are mild and clinically indistinguishable from other acute diarrhoeas. However, a typical case of cholera shows 3 stages :

**(a) Stage of Evacuation :** The onset is abrupt with profuse, painless, watery diarrhoea followed by vomiting. The patient may pass as many as 40 stools in a day. The stools may have a "rice water" appearance.

**(b) Stage of Collapse :** The patient soon passes into a stage of collapse because of dehydration. The classical signs are : sunken eyes, hollow cheeks, scaphoid abdomen, sub - normal temperature, washerman's hands and feet, absent pulse, unrecordable blood pressure, loss of skin elasticity, shallow and quick respiration. The urinary output decreases and may ultimately cease. The patient becomes restless, and complains of intense thirst and cramps in legs and abdomen. Death may occur at this stage, due to dehydration and acidosis resulting from diarrhoea.

**(c) Stage of Recovery :** If death does not occur, the patient begins to show signs of clinical improvement. The blood pressure begins to rise, the temperature returns to normal and urine output is re - established. If anuria persists, the patient may die of renal failure. The classical form of severe cholera



occurs in only 5 - 10 percent of cases. In the rest, the disease tends to be mild characterised by diarrhoea with or without vomiting or marked dehydration. As a rule, mild cases recover in 1 - 3 days.

### Laboratory Diagnosis of Cholera

The diagnosis of cholera can never be made with certainty on clinical grounds alone. Laboratory methods of diagnosis are required to confirm the diagnosis. The details of collection, storage and dispatch, as well as examination under field conditions, of specimens for laboratory diagnosis of cholera have been discussed earlier in the chapter on microbiological procedures in public health and the readers are advised to refer to the same.

Recently developed dipsticks (sensitivity and specificity above 92 and 91%, respectively) for the rapid detection of *Vibrio cholerae* serotypes O1 and O139 from rectal swabs has been successfully used to diagnose cholera. This is likely to improve surveillance for cholera, especially in remote settings.

### Management

The successful management of cholera depends on the quick restoration of body fluids and electrolytes with appropriate and adequate fluids. Except in very severe cases or in cases with persistent vomiting, oral fluids are preferred. The volume of replacement depends on the degree of dehydration and the rate of fluid loss. Oral rehydration solution, as recommended by WHO is the most suited solution. In case it is not available, rice - water with sucrose or home available fluids may be used for rehydration.

In case of severe dehydration - characterized by 10% or more loss of body weight, lethargy, obtundation of sensorium and hypovolemic shock - rapid intra - venous infusion with wide - bore needle in both arms aiming to restore normal hydration and electrolyte balance within 2 - 3 hours, will be required. Of this, 50% losses must be restored within half an hour to 45 minutes. After the normal hydration is achieved, the maintenance phase will require replacement of continuing fluid loss in stool. As far as possible, this loss is made up with oral fluids; rare cases may require continuing intra - venous infusion.

Antibiotics, often required in the management of severe cases, have been shown to reduce the volume and duration of diarrhoea. Doxycycline given in a single dose of 300 mg orally or Tetracycline given 500 mg orally QID for three days is the drug of choice for adults (except pregnant women). For children and pregnant women, Co - trimoxazole in a dose of 30 mg/kg given orally in a single dose, has been found useful.

### Prevention & Control

Guidelines on prevention and control of cholera are as follows:

**(a) Improvement of environmental sanitation** : Main aspects of environmental sanitation are adequately chlorinated and protected water supply, proper disposal of night soil/ sewage and safe food supply. Food may be contaminated at the source, at different stages of processing, storing, serving and due to exposure to flies. Health education is important for improvement of personal hygiene.

**(b) Immunization** : Three types of cholera vaccines are

available

**(i) Whole cell killed vaccine** : given parenterally, provides protection for 5 months, has significant side effects and efficacy is only 50%.

**(ii) B - subunit whole cell killed vaccine** : given orally in 2 doses at an interval of 1 to 6 weeks and has an efficacy of 50 - 60%. Appears to provide herd immunity in endemic setting but role during outbreak less well defined. Several mass vaccination trials using Oral Cholera Vaccines (OCV) have been performed with the support of WHO. Based on these, OCVs are now being considered as complements to traditional preventive measures.

**(iii) CVD 103 - HgR** : It is the only licensed single - dose live attenuated oral cholera vaccine but is not available in the market.

As such, immunization against cholera is not regarded as an effective means of preventing the spread of cholera internationally. Cholera vaccination is not mandatory for international travel. However certain countries still insist on vaccination certificate against cholera. Before undertaking any travel one should consult the booklet issued by WHO every year "Vaccination Certificate Requirements for International Travel".

### (c) Action on Occurrence of the Disease

**(i) Isolation** : Even on the slightest of suspicion, the patient must be admitted immediately to the hospital where he must be strictly isolated in a special fly - proofed ward and diagnosis should be confirmed by identifying *V. cholerae* O1 in the stool. Generally several cases occur at the same time; therefore, adequate arrangements for hospitalization of all cases are essential. In a large outbreak a separate hospital in the vicinity of the main hospital may have to be opened.

**(ii) Disinfection** : Soiled bedding and clothing, which cannot be sterilized, must be burnt. The floors of wards, huts and barracks must be thoroughly scrubbed with 5 per cent cresol (cresoli liquid). The place in which bed pans, urinals and soiled linen are stored should be fly - proofed or carefully covered with a sheet soaked in and kept moist with 5 per cent cresol. The stool and vomit should be poured into a receptacle containing an equal quantity of 5 per cent solution of cresol and left covered for 4 hours before its final disposal. Fresh WSP thoroughly mixed in the proportion of 1.5 g to 1 lit of faeces/ vomitus may also be used as a disinfectant.

**(iii) Notification** : Previously, cholera was listed among the three communicable diseases - along with yellow fever and plague - whose notification to WHO was compulsory. Since 15 June 2005, the official notification of cholera is no longer mandatory but countries are required to inform WHO of public health events of international concern.

**(iv) Attendants** : They should be specially detailed and be isolated from the nursing staff of the main hospital. They should dip their hands in antiseptic solution after washing, after every contact with the patient, his bedding, objects or utensils. They should all be inoculated against cholera beforehand. The consumption of any food or drink by these attendants while in the cholera ward should be strictly prohibited. Gowns should always be worn while on duty.



(v) **Contacts** : They need not be isolated. All persons who are suspected of having partaken of the same infected food or drink as the patient, however remotely, should be kept under daily morning and evening surveillance for 5 days.

(vi) **Food and Drinks** : Control of food and drinks is the most important method of control of an outbreak. The following rules should be followed in the presence of an outbreak in the community :

- Drinking water should be super chlorinated. Washing and bathing water should be chlorinated. Soda water and other drinks should be used only after the most careful investigation of their source of supply. Ice should not be used unless from an authorized source.
- Milk must be boiled. Cream and butter should be obtained only from reliable sources. Consumption of ice cream, unless its origin is absolutely beyond suspicion, should be strictly prohibited.
- Uncooked vegetables and fruits which are customarily eaten unpeeled should be avoided during epidemics. Others should always be washed and then soaked in a solution made by adding 3 scoopfuls or 6 g WSP to a bucketful of water, before peeling. Cut fruits exposed for sale should not be eaten.
- All food must be protected against flies. Strict supervision of cookhouses and cooks are necessary to ensure that food is prepared, cooked stored and served under clean conditions. Golden rules for safe food preparation, as suggested by WHO and given in the Box - 1 (WHO Golden rules for food safety) of the previous chapter on gastroenteritis.

A search for mild cases should be carried out by examination of the stools of all those who are suffering from diarrhoea. All diarrhoea cases, however, should be treated with suspicion until proved otherwise.

## Summary

It is an acute intestinal disease caused by *Vibrio cholerae* 01 (Classical or El Tor). It is one of the key indicators to social development.

*Vibrio cholerae* is a gram negative rod shaped organism. The antigenic classification of vibrios depends on the specific somatic (O) antigens. The flagellar antigen (H) is non specific and common to all. The group A vibrios have been divided into six sub groups (I to VI) based on the antigenically different 'O' antigens. The O subgroup I vibrios comprises of classical V. Cholera and V. El Tor biotype. Based on the O antigenic components, both classical *V. cholerae* and biotype El tor have been divided into 3 serotypes Ogawa, Inaba and Hikojima.

The infection caused by V. El tor differs from *V. Cholera* in that the classical signs of cholera might not be seen, few secondary cases, more chronic carriers and since they are more resistant than *V. cholera* the epidemics last longer. The two biotypes can be differentiated by chick erythrocyte agglutination, polymixin B sensitivity and cholera phase IV.

Vibrios multiply in the lumen of small intestine and produce enterotoxins which act on adenyl cyclase - cyclic AMP system of mucosal cells and produce diarrhoea. Either a case or a carrier in man is the reservoir of infection. A case of cholera is infectious for a period of 7 - 10 days. Cholera is seen in

communities where there is poor personal hygiene and low levels of environmental sanitation. The contamination of food and water are the most important factors in the causation of the disease. The incubation period varies from a few hours upto 5 days, but commonly 1 to 2 days.

The severity of cholera depends on rapidity and duration of fluid loss. A typical case of cholera goes through stages of evacuation, collapse and recovery. The diagnosis of cholera can never be made with certainty on clinical grounds alone. Laboratory methods of diagnosis are required to confirm the diagnosis.

The management of cholera depends on restoration of body fluids and electrolytes with appropriate and adequate fluids. Except in very severe cases or in cases with persistent vomiting, oral fluids are preferred. ORS has been recommended for cases with dehydration by WHO. Antibiotics that can be given in severe cases are Doxycycline given in a single dose of 300 mg orally or Tetracycline given 500 mg orally QID for three days for adults (except pregnant women) and for children and pregnant women, Co - trimoxazole in a dose of 30 mg/kg given orally in a single dose.

Guidelines for prevention and control of cholera are improvement in environmental sanitation and immunization. Several mass vaccination trials using Oral Cholera Vaccines (OCV) have been performed with the support of WHO. Based on these, OCVs are now being considered as complements to traditional preventive measures.

On occurrence of epidemic following steps should be taken isolation, disinfection, notification, care of attendants and contacts and food and water safety.

## Study Exercises

**Long Question** : Discuss the steps to be taken during a cholera epidemic.

**Short Notes** : (1) Outline the preventive and control measures for cholera (2) Cholera vaccine and its importance during an epidemic.

### MCQs

1. A case due to V. El tor differs from *V. Cholera* in the following respects except (a) Higher carrier rate (b) Large number of secondary cases (c) Classical signs of cholera not seen (d) Positive chick erythrocyte agglutination.
2. The steps taken during control of an outbreak of cholera would be all except (a) Food safety (b) Super chlorination of water (c) Immunization with whole cell killed parenteral vaccine (d) Proper excreta disposal.
3. Notification to WHO is not required anymore for which of the following diseases (a) Yellow fever (b) Cholera (c) Plague (d) None of the above.
4. What is the correct order of stages in a case of cholera (i) Stage of evacuation (ii) Stage of recovery (iii) stage of collapse (a) iii, ii, i (b) ii, i, iii (c) i, iii, ii (d) None

**Answers** : (1) b; (2) c; (3) b; (4) c.

## Further Suggested Reading

1. Last, John M, Wallace, Robert B. Wallace/Maxcy - Rosenau - Last's Public Health & Preventive Medicine. 15th ed, New York, McGraw - Hill Companies, Inc. 2008

2. Cook, Gordan C, Zumla, Alimuddin. Manson's Tropical Diseases, 21st ed, London, ELST with Saunders, 2003
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## Food Poisoning

*Rajesh Kunwar, Rajul Gupta*

### Definition

Food poisoning is an acute gastro - enteritis caused by ingestion of food or drink contaminated with either living bacteria or their toxins or inorganic chemical substances and poisons derived from plants and animals. Food poisoning outbreaks are usually recognized by the sudden occurrences of an illness in a group of people who have consumed common food and have similar signs and symptoms. The food poisoning may occur as a result of eating any of the following :

- (a) Substances containing specific poisons like eating fungi like *Amanita phylloides* instead of edible mushroom or eating sprouting potatoes which contains excess of alkaloid solanine.
- (b) Food contaminated by poisons due to agricultural or industrial activities, fertilizers and pesticides in food or food contaminated with metallic poisons as a result of faulty cooking or storing such as use of cheap enamel dishes or galvanized pans.
- (c) Foods infected with organisms mainly by three bacterial groups - Salmonella, Clostridium and Staphylococcus. This bacterial food poisoning is the commonest form and will be discussed in detail in subsequent paragraphs. Their characteristic features are summarized in Box - 1.

### Salmonella Food Poisoning

It is the most common form of food poisoning. The causative organisms belong to Salmonella Group of which several dozens are known to cause food - borne outbreaks. The species most commonly incriminated in human outbreaks is *Salmonella typhimurium*; others are *S. enteritidis*, *S. cholera - suis*. The organisms are natural commensals of rodents, pigs, cattle, poultry, ducks, eggs and also some healthy human carriers. Man acquires the infection from animals and poultry i.e. through contaminated meat, milk and milk products. *S. enteritidis* is present in raw uncooked eggs even if the shell is sound. Most often bacteria is transferred from raw food to processed food by cross contamination. Incubation period usually varies from 12 to 24 hours. On ingestion, the organism multiplies in the intestine and causes acute enteritis and colitis. The onset is generally sudden with chills, fever, nausea, vomiting, abdominal pain and profuse watery diarrhoea. It may be preceded by headache and fever. The illness usually lasts for 2 to 3 days. Mortality is usually low but may be considerably higher in vulnerable groups i.e. very young and elderly. Convalescent carriers are known to occur. Diagnosis is based on the typical history of intake of contaminated food and is confirmed by isolation of the bacteria from faecal samples. Careful rehydration and supportive care is usually sufficient for the management of the case.

### Staphylococcal food poisoning

It is as common as food poisoning caused by salmonella. The causative organism is coagulase positive *staphylococcus aureus* which cause the illness by production of heat stable

**Box - 1 : Distinctive Features of Common Food Poisoning**

Entity	Incriminating food	Incubation period (h)	Clinical features
<i>Salmonella spp</i> food poisoning	Meat, poultry, dairy products	12 - 24	D, V, AP, F
<i>S. aureus</i> food poisoning	Meat, poultry, dairy products	1 - 6	V, D, AP
<i>Cl. Perfringens</i> food poisoning	Cooked meat	6 - 24	D, AP, V
<i>C. botulinum</i> food poisoning	Poorly canned foods, smoked meats	12 - 36	Diplopia, paralysis
<i>C. jejuni</i> food poisoning	Poultry, raw milk, eggs	3 - 5 days	D, AP
<i>B. cereus</i> food poisoning	Type I Fried rice	1 - 6	V
	Type II Soup, sauce	8 - 16	D, AP
<i>E coli</i> O157 food poisoning	Dirty water, raw milk, raw apple juice, ground beef	3 - 4 days	D, V

D = Diarrhoea V = Vomiting F = Fever AP = Abdominal pain

entero - toxins. At least 5 different types of toxins have already been identified, and a sixth one is likely to exist. The toxin resists boiling for 30 minutes. High protein and starch food favour bacterial growth and hence the toxin production. Staphylococcus are ubiquitous in nature and are found in nose, throat and on the skin surface of human beings. They are common agents for pyogenic infections in man and animals. Cows suffering from mastitis have been responsible for the outbreaks. Tinned meat or fish inadequately processed, pickled meats, creams, milk and milk products contaminated with staphylococcus have been incriminated in various outbreaks. Problem occurs most frequently with foods prepared at home or at food service establishments where gross temperature abuse has occurred. The incubation period varies from 1 to 6 hours. The disease manifests as sudden onset of uncontrolled vomiting, due to effect of toxin on the vagus nerve in the stomach, with abdominal cramps and diarrhoea. In severe cases blood and mucous may appear. Fever is uncommon and so is mortality.

### **Clostridium perfringens food poisoning**

*Clostridium perfringens (welchii)* is found in faeces of man and animals; and in soil, water and air. The spores of the organism are heat resistant and survive cooking, and if the cooked meat and poultry are not cooled enough, the spores germinate and produce a variety of toxins which cause the illness. Outbreaks have resulted from problems in cooling and storage of food cooked in bulk. Generally the implicated meat is cooked, allowed to cool down slowly and then inadequately heated the following day just before the serving. The incubation period varies from 6 to 24 hours. The commonest symptom is explosive diarrhoea with abdominal cramps. Fever, nausea and vomiting are rare. Illness is of short duration. Recovery is fast and mortality is rare.

### **Botulism**

The food borne botulism (the others being wound botulism and infant botulism) is caused by *Clostridium botulinum* - a gram - negative, strict anaerobe, spore forming bacillus whose natural habitat is soil. It produces at least seven types of exotoxins of which type A, B and E are incriminated in food poisoning in humans. The food most frequently responsible are home preserved foods such as smoked or pickled fish, home made cheese and similar low acid foods. The toxin is preformed in food under suitable anaerobic conditions and acts on parasympathetic nervous system. Incubation period is usually 12 to 36 hours. Early symptoms include nausea, vomiting; and occasionally diarrhoea. Other features include dysphagia, diplopia, ptosis, blurring of vision, dysarthria, muscular weakness and even quadriplegia. Gastrointestinal symptoms are very slight, fever is usually absent. Condition is frequently fatal - death occurring 4 to 8 days later due to respiratory or cardiac failure. Non - fatal cases may last for several months.

### **Campylobacter food poisoning**

Three species of Campylobacter - *C. jejuni*, *C. coli*, and *C. laridis* - are known to cause epidemics of food poisoning in nurseries, paediatric wards, and communities in developing countries. *C. jejuni* is the commonest of the three and is most often associated with poultry. Foods linked to outbreak include raw

milk, raw meat and mushrooms. The average incubation period varies from 3 to 5 days. The illness presents as fever, abdominal pain, vomiting and bloody diarrhoea. Headache may be present. Disease is usually self - limiting with complete recovery in 5 - 7 days but the patient may continue to excrete bacteria up to 3 weeks. Relapses and chronic sequelae are known to occur. Guillian - Barre Syndrome and Reiter's Syndrome are rare but serious consequences of campylobacteriosis. Diagnosis depends on Gram stain and dark field microscopy of faecal smear and/or stool culture. In severe cases colonoscopy may be required.

### **Bacillus Cereus Food Poisoning**

*Bacillus cereus* is an aerobic, spore bearing, motile, gram positive rod. It is ubiquitous in soil, and in raw, dried and processed foods. The spores survive cooking and germinate when the food is held at favourable temperature. It produces 2 types of entero - toxins leading to the causation of the emetic syndrome and the diarrhoeal syndrome. The emetic syndrome (Type I) is similar to *S. aureus* intoxication and has an incubation period of 1 to 6 hours. Symptoms are upper gastrointestinal, including nausea and vomiting, diarrhoea being rare, and usually subside within a day. The causation of this syndrome is linked to the consumption of fried rice, mashed potatoes and pasta. The diarrhoeal syndrome (Type II) is similar to *C. perfringens*, has an incubation period of 8 to 16 hours, and presents with lower intestinal symptoms i.e. watery diarrhoea. Nausea and vomiting is rare and the disease subsides in 12 to 24 hours. The food items commonly incriminated include soup, sauce, meat loaves and gravy, custard and pudding.

### **E coli O157 Food Poisoning**

Food poisoning due to *E coli* O157 - the most common form of Enterohaemorrhagic *E. coli* (EHEC) - has grown to prominence as an emerging public - health hazard since the first cases were reported in the early 1980s. The predominant serotype, incriminated in food poisoning is *E coli* O157 : H7. Far less common than Salmonella and Campylobacter, it can survive for up to 6 months in mud. Vehicles of transmission include ground beef, raw milk, and raw apple juice. The incubation period is 3 to 4 days. The symptoms include bloody diarrhoea associated with severe abdominal pain. Fever is typically absent. While most food - poisoning events are short - lived and resolve without intervention, 2 - 7% of individuals (and up to 15% of children) infected with *E coli* O157 develop haemolytic uraemic syndrome about a week after the onset of diarrhoea. It is characterized by thrombocytopenia, renal failure and CNS involvement. Stool culture is necessary to make the definitive diagnosis. Management includes oral rehydration and supportive care.

### **Prevention and Control of Food Poisoning**

The common measures recommended for the prevention and control of food poisoning have been earlier outlined under the heading "golden rules for food safety" in the chapter on cholera and they will go a long way in preventing food poisoning. The specific actions include the following :

(a) *Eat Freshly cooked and hot food* : The most important measure is the consumption of freshly cooked food while it is still hot. The food which was cooked earlier and cooled, must be reheated adequately, at least up to 60°C, before consumption.



**(b) Meat and Meat products** : Animals should be slaughtered in a hygienic, rat proof, vermin free butchery. Strict supervision should be kept on the whole cycle of meat processing.

**(c) Milk and Milk Products** : Milk should be pasteurized or boiled and every care should be taken against subsequent contamination.

**(d) Protection of Foods** : Adequate precautions should be taken against contamination of food during storage or during processing. The food items should not be left overnight in warm pantries and those not eaten immediately should be kept in cold storage to prevent bacterial multiplication and toxin production.

**(e) Food Handlers** : They should be periodically examined and those suffering from boils, ulcers throat or eye infections and with history of having suffered from enteric fever or diarrhoea in recent past should not be employed as food handlers. A high standard of personal hygiene among food handlers must be maintained. Food handlers should be educated in matters of clean habits and personal hygiene.

### **Hazard Appraisal and Critical Control Point (HACCP) system**

A simple and effective method for preventing food borne illnesses is by undertaking a detailed analysis of the steps in which food items are procured / prepared / stored / served, followed by identification of critical points where hygiene and sanitation can be breached / contamination can be introduced and finally making a check list of these critical control points for taking action for control / preventive action. The system has been recommended by the WHO.

### **Steps in investigations of an epidemic of food poisoning**

The details have been discussed earlier in the chapter on investigations of an epidemic in the section on epidemiology. Distinctive features of common food poisoning are listed in Box - 1.

## **Summary**

Food poisoning is an acute gastro - enteritis caused by ingestion of food or drink contaminated with either living bacteria or their toxins or inorganic chemical substances and poisons derived from plants and animals. Bacterial food poisoning is the commonest form and is caused mainly by three bacterial groups - Salmonella, Clostridium and Staphylococcus.

Salmonella food poisoning is the most common form. The species most commonly incriminated in human outbreaks is *Salmonella typhimurium*; others are *S. enteritidis*, *S. cholerae - suis*. Man acquires infection through meat, eggs, milk and milk products. Incubation period usually varies from 12 to 24 hours. Onset is generally sudden with chills, fever, nausea, vomiting, abdominal pain and profuse watery diarrhoea which lasts for 2 to 3 days. Mortality is usually low.

Staphylococcal food poisoning is as common as food poisoning by Salmonella. It is caused by heat stable enterotoxin of Coagulase positive *Staphylococcus aureus*. Staphylococcus is ubiquitous in nature and usually tinned meat or fish, pickled meats, creams, milk and milk products are incriminated in

outbreaks. Incubation period varies from 1 to 6 hours. The disease manifests as sudden onset of uncontrolled vomiting, abdominal cramps and diarrhoea. Mortality is uncommon.

*Clostridium perfringens* food poisoning is caused by a variety of toxins produced during germination of spores. Generally the implicated meat is cooked, allowed to cool down slowly and then inadequately heated the following day just before the serving. Incubation period varies from 6 to 24 hours. Common symptom is explosive diarrhoea with abdominal cramps. Mortality is rare.

Food borne botulism is caused by Exotoxins A, B and E of *Clostridium botulinum*. The foods most frequently responsible are home preserved foods. The toxin acts on peripheral nervous system. Incubation period is usually 12 to 36 hours. Symptoms include nausea, vomiting, dysphagia, diplopia, ptosis, blurring of vision, dysarthria, muscular weakness and even quadriplegia. Condition is frequently fatal in 4 to 8 days due to cardiac or respiratory failure.

Campylobacter food poisoning is caused by *C. jejuni*, *C. coli*, *C. laridis*. Foods linked to outbreaks include poultry, raw milk, raw meat and mushrooms. Incubation period averages 3 to 5 days. The illness presents as fever, abdominal pain, vomiting and bloody diarrhoea. Disease is usually self - limiting but relapses and chronic sequelae are known to occur.

*Bacillus cereus* food poisoning is caused by two types of enterotoxins leading to causation of Emetic syndrome and the diarrhoeal syndrome. The emetic syndrome (Type I) has incubation period of 1 to 6 hours. It is linked to consumption of fried rice, mashed potatoes and pasta. Symptoms are upper gastrointestinal i.e. nausea and vomiting. The diarrhoeal syndrome (Type II) has incubation period of 8 to 16 hours. Symptoms are lower gastrointestinal i.e. diarrhoea. It is linked to consumption of soup, sauce, meat loaves and gravy, custard and pudding.

*E. coli* O157 food poisoning is the most common form among all Enterohaemorrhagic *E. coli* (EHEC). The predominant serotype is *E. coli* O157 : H7. Vehicles of transmission include ground beef, raw milk, and raw apple juice. The incubation period is 3 to 4 days. The symptoms include bloody diarrhoea associated with severe abdominal pain. While most food poisoning events are short lived and resolve spontaneously, 2 - 7% of individuals develop Haemolytic uraemic syndrome about a week after onset of diarrhoea.

The common measures recommended for prevention and control of food poisoning include consumption of freshly cooked food while it is still hot, cold food should be adequately reheated at least up to 60°C before consumption, strict hygienic measures in whole cycle of meat processing, boiling or pasteurization of milk and periodic examination of food handlers.

Hazard Appraisal and Critical Control Point (HACCP) system is an effective method for preventing food borne illnesses and is recommended by WHO.

## **Study Exercises**

**Long Question** : Discuss the various types of bacterial food poisonings, their differentiating features and methods of prevention



**Short Notes :** (1) Botulism (2) Salmonella food poisoning (3) *Bacillus cereus* food poisoning (4) Prevention and control of food poisoning

#### MCQs

- Salmonella food poisoning is most commonly caused by : (a) *Salmonella typhimurium* (b) *S. enteritidis* (c) *S. cholerae-suis* (d) *S. typhi*
- Shortest incubation period of food poisoning is seen with : (a) Salmonella (b) Staphylococcus (c) Clostridium (d) Campylobacter
- A group of people suffer from abdominal cramps, diarrhoea and vomiting two hours after consuming Kheer. The suspected aetiological agent is : (a) Salmonella (b) Clostridium (c) Staphylococcus (d) Campylobacter
- Following food poisonings are due to preformed toxins except : (a) Staphylococcal (b) Botulism (c) Salmonella (d) *Bacillus cereus*
- Which of the following is true about Botulism : (a) Most fatal food poisoning (b) Toxin acts on parasympathetic nervous system (c) Occurs due to consumption of home made cheese (d) All of the above
- All of the following are true of *clostridial perfringens* food poisoning except : (a) Incubation period 6 - 24 hours (b) illness is of short duration with rapid recovery (c) Nausea and vomiting is common (d) Common with intake of meat and poultry
- Following are true of Botulism except : (a) Frequently fatal (b) Bloody diarrhoea (c) Dysphagia (d) Absence of fever
- Following are true of Staphylococcal food poisoning except : (a) High grade fever (b) Due to preformed toxins (c) Death uncommon (d) Abdominal cramps

- Bacillus cereus* causes : (a) Emetic syndrome (b) Diarrhoeal syndrome (c) Both (d) None
- The incubation period of *Bacillus cereus* Type II food poisoning is (a) 1 - 6 hours (b) 8 - 16 hours (c) 12 - 24 hours (d) 3 - 5 days
- Match the Type of food poisoning (A) with correct incubation period (B) :

A		B	
(a)	Salmonella	(I)	6 to 24 hours
(b)	Staphylococcal	(II)	12 to 36 hours
(c)	<i>Clostridium perfringens</i>	(III)	12 to 24 hours
(d)	<i>Clostridium botulinum</i>	(IV)	1 to 6 hours
(e)	Campylobacter	(V)	8 to 16 hours
(f)	<i>E coli</i> O157	(VI)	3 to 5 days
(g)	<i>Bacillus cereus</i> Type II	(VII)	3 to 4 days

**Answers :** (1) a; (2) b; (3) c; (4) c; (5) d; (6) c; (7) b; (8) a; (9) c; (10) b; (11) a-III; b-IV; c-I; d-II; e-VI; f-VII; g-V.

#### Further Suggested Reading

- Last, John M, Wallace, Robert B. Wallace/Maxcy - Rosenau - Last's Public Health & Preventive Medicine. 15th ed, New York, McGraw - Hill Companies, Inc. 2008
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## Enteric Group of Fevers

Rajesh Kunwar

### Definition

This is a group of clinically similar, but immunologically distinct fevers, caused by *Salmonella spp* and characterized by typical continuous fever for 3 - 4 weeks, relative bradycardia, with involvement of lymphoid tissues and considerable constitutional symptoms. The disease varies in severity, and many mild cases occur. The term 'enteric fever' includes both the typhoid and paratyphoid fevers.

### Magnitude of the Problem

Enteric fever, though occurs in all parts of the world, is a serious public - health problem in developing countries. The disease has been virtually eliminated from the industrialized

world because of the provisioning of clean water and good sewage systems. But the under - developed and the developing countries continues to face the brunt. In an outbreak in the Democratic Republic of Congo, between 27 September 2004 and early January 2005, 42,564 cases of typhoid fever were reported, including 214 deaths and 696 cases of peritonitis and intestinal perforations. *S. paratyphi* is becoming predominant in some provinces in China and increasing numbers of cases are being reported from Pakistan.

Few established surveillance systems for typhoid exist in the developing world, especially in community settings, so the true burden is difficult to estimate. According to an estimate of US Centers for Disease Control and Prevention there are 21.6 million typhoid cases annually, with the annual incidence varying from 100 to 1000 cases per 100,000 population. The incidence is highest in the age group of 5 - 19 years but population based studies from South Asia suggest that the incidence is highest in children aged less than 5 years, with

higher rates of complications and hospitalization. The overall ratio of disease caused by *S typhi* to that caused by *S paratyphi* is about 10 to 1 to 4 to 1.

Enteric fevers are not notifiable diseases throughout India and hence the correct incidence is not known. Limited studies in the country reveal more than three lac cases and more than 650 deaths (approx.) annually in our country. Recent population based incidence data demonstrate that the children under 5 years of age are at increased risk of typhoid fever, when compared with school - aged children and adults.

### Epidemiological determinants

#### Agent factors

(a) **Agent** : Typhoid fever is caused by *Salmonella enterica* serovar Typhi (*S typhi*), a Gram negative, flagellated, non - lactose - fermenting bacillus. It is characterized by somatic (O) antigen 9 and 12, and a single flagellar antigen (H). Paratyphoid fever - a similar but often less severe disease - is caused by *S paratyphi* A and, less commonly, by *S paratyphi* B (Schotmulleri) and *S paratyphi* C (Hirschfeldii). The organism survives well in water and sewage but is readily killed by heating at 60°C, drying, pasteurization and common disinfectants.

(b) **Reservoir** : Man is the only reservoir of infection. The case may be mild, moderate or severe and is infectious as long as the bacilli is excreted in stool or urine. The carriers are more important. Convalescent carriers excrete the bacilli for 6 - 8 weeks. Chronic carriers are those who excrete the bacilli for more than one year after clinical attack. A chronic carrier may excrete the bacilli for several years, either continuously or intermittently. *S. typhi* once lodged in human carrier may persist for 20 - 50 years. Faecal carriers are commoner than urinary carriers. The carrier state is commoner in middle aged persons; females predominating over males. The famous case of "Typhoid Mary" who gave rise to more than 1,300 cases is a good example of a chronic carrier. Urinary carriers, though less common, are more dangerous to the community than faecal carriers because of greater chances of contamination of hands during micturition. Detection of carriers is by isolation of organisms from faeces or urine of suspects; agglutination tests are much less reliable.

(c) **Source of Infection** : The sole source of infection is the faeces or urine of cases and carriers. The bacilli are excreted for varying periods in faeces and urine.

#### Host factors

(a) **Age** : Enteric fever can occur at any age. Highest incidence of this disease occurs in the 5 - 19 years of age group but population based studies from South Asia suggest that the incidence is highest in children aged less than 5 years, with higher rates of complications and hospitalization.

(b) **Sex** : More cases are reported among males probably as a result of increased exposure to infection but carrier rates are more common in females.

(c) **Immunity** : An attack of the disease gives lasting immunity; second attacks however are not uncommon.

(d) **Genetic factors** : Involvement of host genetic factors has also been implicated in the pathogenesis of typhoid fever. HLA - DRB1\*12 is associated with protection against complicated

typhoid fever .

#### Environmental Factors

Enteric fevers are observed all through the year. The peak incidence is reported during July - September. This period coincides with the rainy season and an increase in fly population. Outside the human body, the bacilli are found in water, ice, food, milk and soil for varying periods of time. Typhoid bacilli do not multiply in water; many of them perish within 48 hours, but some may survive for about 7 days. They may survive for over a month in ice and ice-cream and up to 70 days in soil irrigated with sewage under moist winter conditions. Food being a bad conductor of heat, provides shelter to the bacilli in which they may multiply and survive for sometime. Typhoid bacilli grow rapidly in milk without altering its taste or appearance in anyway. Vegetables grown in sewage farms or washed in contaminated water are a definite health hazard. These factors are compounded by such social factors as pollution of drinking water supplies, open air defecation and urination, low standards of food and personal hygiene and health ignorance. Typhoid fever may therefore be regarded as an index of general sanitation in any country.

**Incubation Period and Period of Communicability** : Incubation period is usually 10 - 14 days but in many cases it may well be outside the range. When the disease is water - borne, the incubation period tends to be longer. The incubation period for paratyphoid is 4 to 5 days. The case is infectious during the later part of incubation period and for a variable period thereafter.

**Mode of Transmission** : Enteric fever is spread chiefly through the medium of contaminated water, food, milk and vegetables. Flies constitute an important subsidiary vehicle for sporadic incidence. A small proportion of cases may occur due to direct transmission of infection from an actual case/ carrier through contamination of hands, while handling patients or their excreta. The mode of transmission for explosive outbreaks of any considerable size, is, however water, milk or milk products adulterated by contaminated water or handling by carriers.

#### Clinical features

Typhoid fever is characterized by high grade remittent fever associated with headache and malaise. Non - productive cough and constipation may be present. Diarrhoea is uncommon and vomiting not severe. By the second week, in the absence of treatment, the patient becomes toxic and apathetic, high fever continues and abdomen becomes distended. Relative bradycardia, leucopenia, abdominal tenderness and hepato - splenomegaly are characteristic. Ill defined rose - spots, hardly visible in dark skinned person, may be present. Complications of typhoid fever include confusion, delirium, intestinal perforation, myocarditis and death. Up to 20% of cases relapse after treatment and initial recovery.

#### Diagnosis

Blood culture done during the first week of illness, is the most common diagnostic test for typhoid. The organism can also be isolated from urine and stool in the second and third week of illness. Bone marrow cultures are frequently positive (90% of cases) and are more likely to yield *s. typhi* than culture from any other site. Widal test which measures the antibody response to

'O' and 'H' antigens, is not definitive and only suggests the diagnosis. A rising titer is more suggestive than a single raised titer of Widal test.

### Treatment

Chloramphenicol (1 g 6 hourly) or Amoxycillin (250 - 500 mg 8 hourly) or Co - trimoxazole (2 tabs given twice a day) have been used successfully for the management of typhoid fever. But Fluoroquinolones (Ciprofloxacin) in the dose of 500 - 750 given orally twice a day for 10 to 14 days is the best choice for the empirical treatment of typhoid fever, although resistance to the strains circulating in SE Asia have been reported. Resistance to Chloramphenicol has become widespread including our country.

### Prevention & Control

In the endemic areas, the most cost effective strategy for reducing the incidence of enteric fever is the institution of public health measures as enumerated below :

- (a) Provision of protected, clarified and chlorinated water supply
- (b) Efficient pasteurization or boiling of milk
- (c) Proper sanitary disposal of night soil
- (d) Strict anti - fly measures
- (e) Protection and cleanliness of fruits and vegetables
- (f) High standard of food handlers' hygiene
- (g) Personal hygiene and avoidance of unhygienic food habits
- (h) Protective inoculation

### Immunization

**(a) Heat killed, phenol preserved whole cell *S. typhi*** : These were utilized as parenteral vaccines as far back as 1896 in England and Germany, and are still in use in many countries. Efficacy is about 70%.

**(b) Vi capsular polysaccharide vaccine** : This vaccine is licensed for use in individuals older than 2 years and is given in a single subcutaneous or intramuscular dose. The vaccine is moderately effective for about 3 years after vaccination. Revaccination is recommended every 3 years. The Vi vaccine can be given simultaneously with other vaccines relevant for international travellers such as yellow fever and hepatitis A. Efficacy is approximately 70%.

**(c) Live Oral Vaccine** : The attenuated *S. typhi* strain Ty21a was generated in Switzerland by chemical mutagenesis of wild - type strain Ty2 and developed as the first live oral typhoid fever vaccine. This live oral vaccine, available in enteric - coated or liquid formulation, is approved for use in people 6 years of age and older. The liquid formulation for younger children is currently marketed in only a few countries. Three doses are recommended each given 2 days apart. Antimicrobials should be avoided for 7 days before or after vaccination. The vaccine is moderately effective for up to about 3 years after vaccination. A booster dose is recommended every 3 years in endemic areas and travellers should be revaccinated annually. The vaccine can be given simultaneously with other vaccines and with anti

- malarial prophylaxis. Efficacy is about 70%.

### Summary

Typically continuous fever for 3 - 4 weeks caused by *Salmonella* spp (*S.typhi*, *S.paratyphi A*, *S.paratyphi B* and *S.paratyphi C*) along with associated relative bradycardia and involvement of lymphoid tissue, occurs through out the world but is a serious public health problem in developing world. The agent is gram negative, flagellated, non lactose fermenting bacillus characterized by somatic O antigen 9 and 12 and a single flagellar H antigen. Human beings are the only reservoir of infection and carriers (convalescent and chronic) are the most important source of infection, fecal carriers being more important than urinary though urinary carriers are more dangerous. Males in age group 5 yrs to 19 yrs are the most susceptible and the subjects with HLA DRB 1\*12 are protected from severe complications of typhoid. The peak incidence is in rainy season with favourable conditions for house fly breeding, the medium of transmission being water, food, ice, milk, vegetables and soil. The incubation period is usually 10 to 14 days for fever caused by *S.typhi* and upto 4 - 5 days for *S.paratyphi*. For a proper diagnosis blood culture in 1st week and urine or stool culture in 2nd week are helpful, widal test which measure the antibody titer is only suggestive. Fluoroquinolones are the best choice for the empirical treatment of enteric fever. Institution of public health measures like supply of chlorinated water supply, proper pasteurization of milk, food and personal hygiene and strict fly control measures are the most cost effective control measures. Vi capsular polysaccharide vaccine is licensed for use in individuals older than 2 years and is given in a single subcutaneous or intramuscular dose. Revaccination is recommended every 3 years. The attenuated *S. typhi* strain Ty21a was developed as the first live oral typhoid fever vaccine. This live oral vaccine is approved for use in people 6 years of age and older. Three doses are recommended each given 2 days apart. Antimicrobials should be avoided for 7 days before or after vaccination. A booster dose is recommended every 3 years in endemic areas.

### Study Exercises

**Short Notes** : (1) Typhoid vaccine (2) Epidemiological determinants of enteric fever (3) Clinical features and treatment of enteric fever (4) Prevention and control strategies for enteric fever.

### MCQs and Fill in the Blanks :

- 1) \_\_\_\_\_ is the reservoir of enteric fever.
- 2) The incubation period of typhoid is \_\_\_\_\_ and the same for paratyphoid is \_\_\_\_\_
- 3) The most commonly used diagnostic test for confirming typhoid fever in 1st week of illness is \_\_\_\_\_
- 4) The Typhoral vaccine requires booster every \_\_\_\_\_ yrs in the endemic region
- 5) Antibiotics should be avoided for the following number of days after vaccination with typhoral vaccine (a) 3 days (b) 5 days (c) 7 days (d) 10 days
- 6) The best antibiotic for the empirical treatment of enteric fever is (a) chloramphenicol (b) ciprofloxacin (c) amoxicillin (d) none

- 7) The somatic antigen is known as \_\_\_\_\_ antigen and the flagellar antigen is known as \_\_\_\_\_
- 8) Rose spots are characteristic of the following diseases (a) chicken pox (b) malaria (c) rubella (d) none
- 9) \_\_\_\_\_ carriers are commoner and \_\_\_\_\_ carriers are more dangerous in enteric fever.
- 10) Chronic carriers of typhoid are those who excrete the bacilli for more than \_\_\_\_\_ yrs

**Answers :** (1) Human beings; (2) 10 to 14 days, 04 to 05 days; (3) Blood culture; (4) three; (5) c; (6) b; (7) O, H; (8) d; (9) faecal, urinary; (10) one

## Further Suggested Readings

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## Shigellosis

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### Definition

Shigellosis is a "bacillary dysentery" caused by *Shigella spp* and characterized by diarrhoeal illness with fever, abdominal pain and blood and pus in the stool.

### Magnitude of the Problem

Shigellosis is endemic throughout the world. Of the 165 million cases of severe dysentery reported every year, more than 163 million come from developing world. Majority of the affected population includes children below 5 years of age. Approximately 580,000 cases of shigellosis are reported among travellers from industrialized countries. Each year 1.1 million people are estimated to die from *Shigella* infection.

*Shigella* dysentery is caused by *S. dysenteriae*, *S. sonnei*, *S. flexneri* and *S. boydii*. *S. sonnei* is the causative agent of most shigellosis in industrialized countries where it accounts for 77% of cases (compared to 15% in developing countries), *S. flexneri* is endemic in developing countries (60%) and is the most frequently isolated species worldwide. *S. dysenteriae* (Sd1) is the cause of epidemic dysentery and can cause vicious outbreaks in confined populations, especially refugee camps. A major obstacle to the control of Sd1 is its resistance to antimicrobial drugs.

Since 1969, *S. dysenteriae* have caused extensive outbreaks in many countries. Notable among these being outbreak in Central America in 1969 - 1972; in Zaire, Rwanda and Burundi in 1979 - 1982; in India in 1984; in Burma in 1985; in Bangladesh in 1988; and in Zimbabwe and Zambia in 1992 - 1994. The causative strains in all these outbreaks were resistant to the commonly used antimicrobials.

In India, the outbreak in 1984 was due to multi - resistant strain of *S. dysenteriae* type 1 and the most affected state was

West Bengal. Since then many outbreaks have been reported from various parts of the country.

### Epidemiological Determinants

#### Agent factors

(a) **Agent** : *Shigellae* are aerobic, gram - negative, non - motile, slender bacilli which are lactose negative (except *S. sonnei* which is a late lactose fermenter) and produce acid but not gas from glucose. The 'O' antigens are located on the outer cell wall but the 'H' antigen is typically absent.

(b) **Reservoir** : The primary reservoir of the infection is human being, though it can occasionally infect other primates. The human case may be mild, moderate or severe and is infectious as long as the bacilli is excreted in stool. Asymptomatic carriers up to one year duration have been reported, but prolonged carrier are not known to occur.

(c) **Source of Infection** : *Shigella* are present in the diarrhoeal stools of infected persons while they are sick and for up to a week or two afterwards. *Shigella* species are transmitted by ingestion of contaminated food or water, or by person - to - person contact (i.e. from cases or asymptomatic excretors to susceptible hosts), a most common source of transmission. However, clinically ill persons are more likely to transmit the disease as compared to asymptomatic excretors.

(d) **Infective dose** : The infective dose is very small. For *S. dysenteriae* an inoculum as low as 10 to 100 bacilli is sufficient to cause severe infection in a human being.

#### Host factors

(a) **Age** : Though the disease can occur in any age group, but it has a predilection for the paediatric age group, majority of the cases occur in children below 10 years of age.

(b) **Sex** : Both the sexes are affected equally.

(c) **Immunity** : Immunity following *Shigella* infection provides short term immunity to the species causing infection. With each subsequent infection with the same serotype, the clinical illness becomes milder and milder and may be absent. This, it is believed, is perhaps because of local gut immunity. Cross



immunity i.e. immunity to the other species of shigella, is not known to exist.

**Environmental Factors** : Shigellosis is often found in day care centers, nursing homes, refugee camps, and other places where conditions are crowded and sanitation is poor. Shigellosis can also result from drinking or swimming in contaminated water; water may become contaminated if sewage runs into it or if someone with shigellosis swims in it. Lack of safe piped water, inadequate sewage disposal and poor personal hygiene are the conditions which can lead to an outbreak of shigellosis.

**Incubation Period** : The usual incubation period is about 48 hours but can range from 12 hours to 6 days.

**Mode of Transmission** : Most Shigella infections are transmitted by oro - faecal route. Food may become contaminated by infected food handlers who forget to wash their hands with soap after using the bathroom. Vegetables can become contaminated if they are harvested from a field with sewage in it. Flies can breed in infected feces and then contaminate food. Water may become contaminated with Shigella bacteria if sewage runs into it, or if someone with shigellosis swims in or plays with it. Shigella infections can then be acquired by drinking, swimming in, or playing with the contaminated water. Outbreaks of shigellosis have also occurred among men who have sex with men.

### Clinical features

Although asymptomatic illness can occur, majority of the cases begin with fever, abdominal pain and watery diarrhoea, initially without blood. The fever may be transient and the temperature may rapidly rise up to 40 - 41°C. In young children, the fever may be associated with seizures. The stools are initially watery but with the invasion of colonic mucosa, it become bloody, mucoid or scanty. Dysentery is characterized by frequent passage, usually 10 to 30 times a day, of small volume of stools associated with abdominal cramps and tenesmus. Mild dehydration is common, but severe dehydration is rare. Frequent motion and straining during the act can cause, especially in young children, rectal prolapse. Severe dysentery is most likely in infection with *S. dysenteriae*, occurs less commonly in *S. flexneri* and is least likely in *S. sonnei* infection.

Extra - intestinal manifestations following shigella infection, are rare, but can be of importance. These include convulsions and rectal prolapse (esp in children), post - infectious arthritis and hemolytic - uremic syndrome.

### Diagnosis

Shigella is the principal cause of bacterial dysentery and must be considered in all cases of dysentery presenting with fever. Specific diagnosis can be established by culture of shigella from the stool.

### Treatment

Persons with mild infections usually recover quickly without antibiotic treatment. Mild to moderate dehydration is corrected by oral rehydration. Antibiotic treatment is required for the management of severe cases. It reduces the duration of illness by a few days and shortens the carriage stage. The antibiotics commonly used for treatment are ampicillin (50 - 100 mg per

kg body weight in children and 2 grams per day in divided doses in adults) and co - trimoxazole (8 mg of trimethoprim per kg body weight per day in children and 2 regular strength tablets twice a day in adults). Fluoroquinolones (Ciprofloxacin) are highly effective, but are costly and are not indicated for treatment of children.

### Prevention & Control

The spread of Shigella infection from an infected person to other persons can be prevented by frequent and careful handwashing with soap. Handwashing among children esp those who have not been fully toilet trained, should be frequent and supervised by an adult.

Basic food safety precautions and disinfection of drinking water prevents shigellosis from food and water. People with shigellosis should not prepare food or drinks for others until they have been shown to no longer be carrying the Shigella bacterium, or if they have had no diarrhoea for at least 2 days. At swimming beaches, having enough bathrooms and handwashing stations with soap near the swimming area helps keep the water from becoming contaminated.

Simple precautions like drinking of bottled or boiled water, and eating of only cooked hot foods, taken while travelling to the developing world can prevent shigellosis as well as other types of traveller's diarrhoea.

Some prevention measures in place in most communities help to prevent shigellosis. Making municipal water supplies safe and treating sewage are highly effective prevention measures that have been in place for many years.

**Immunization** : At present no vaccine is available for protection against shigellosis. Candidate vaccines, both killed and live, are in pre - clinical stage of testing. Definite progress has been made with candidate live oral shigellosis vaccines, but the main problem remains the small margin that exists between under - attenuation responsible for excessive reactogenicity of the strains and over - attenuation leading to poor immunogenicity in human subjects.

### Summary

A type of bacillary dysentery presenting with symptoms of fever, abdominal pain and blood and pus in the stool with an average incubation period of 48 hrs. Its endemic throughout the world having caused a number of outbreaks in various countries. Shigellae (*S. dysenteriae*, *S. sonnei*, *S. flexneri*) are aerobic, gram negative and non motile bacilli with 'O' antigen on the outer cell wall but the 'H' antigen is typically absent. Human beings are the main reservoir and the infected, sick person being the main source of infection transmitting the disease agent mainly through oro fecal route. Both sexes and all ages are susceptible with over crowding and poor sanitation being the major contributing factors. Mild cases can be treated with proper oral rehydration but the severe cases will require antibiotics in the form of ampicillin, cotrimoxazole or fluoroquinolones. As no vaccine is available so preventive measure like frequent and careful hand washing, food safety precautions and disinfection of water should be practised.

## Study Exercises

**Short Notes :** (1) Epidemiological determinants of shigellosis  
(2) Prevention and control of shigellosis.

### MCQs and fill in the blanks

- 1) The causative agent of most cases of shigellosis in industrialized countries is \_\_\_\_\_
- 2) The average incubation period of shigellosis is \_\_\_\_\_
- 3) The cause of most vicious outbreaks of shigellosis (a) *S.dysenteriae* (b) *S.sonnei* (c) *S.flexneri* (d) none
- 4) Following is lactose fermenter (a) *S.dysenteriae* (b) *S.sonnei* (c) *S.flexneri* (d) none
- 5) Type of vaccine for *S.sonnei* (a) live attenuated (b) killed (c) both (d) none
- 6) The causative agent of most cases of shigellosis in developing countries is \_\_\_\_\_
- 7) The infective dose of shigellosis is \_\_\_\_\_
- 8) The principal cause of bacillary dysentery is \_\_\_\_\_
- 9) The most common route of transmission of shigella is \_\_\_\_\_
- 10) The outbreak of shigellosis in India in 1984 was caused by (a) *S.dysenteriae* (b) *S.sonnei* (c) *S.flexneri* (d) none

**Answers :** (1) *S. sonnei*; (2) 48 hrs; (3) a; (4) *S. sonnei*; (5) d; (6) *S. flexneri*; (7) 10 to 100 bacilli; (8) Shigella; (9) oro faecal; (10) *S. dysenteriae*

### Further Suggested Reading

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## Helminthiasis

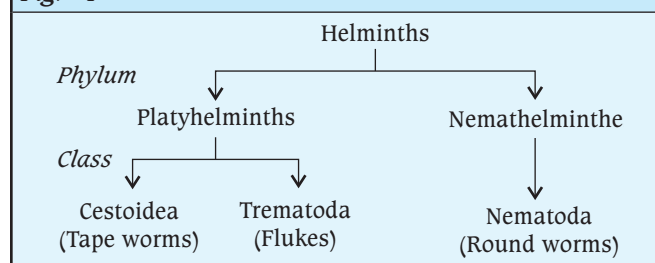
Rajesh Kunwar

Helminths - a word derived from Greek meaning worms - are known to affect the mankind since time immemorial. It is estimated that approximately one - third of the almost three billion people living in the under - developed and developing countries especially the inhabitants of thousands of rural, impoverished villages are infected with one or more helminths. Majority of these are soil transmitted and include round worm (*Ascaris lumbricoides*), whip worm (*Trichuris trichiura*), and hook worm (*Ancylostoma duodenale* and *Necator americanus*). The other category is food borne helminths which include liver flukes (*Clonorchis sinensis*) and intestinal flukes (*Fasciola hepatica* and *Fasciola buski*).

### Classification

The helminths of importance to human beings are classified as in Fig. - 1.

Fig. - 1



Based on the mode of transmission, helminths can be classified as follows :

- Soil transmitted helminths e.g. *Ascaris lumbricoides*, *Trichuris trichura*, *Ancylostoma duodenale* and *Necator americanus*.
- Food borne helminths e.g. *Clonorchis sinensis*, *Fasciola hepatica* and *Fasciola buski*.
- Arthropod borne helminths e.g. *Wuchereria bancrofti* and *Brugia malayi*

In the present discussion we will restrict ourselves to the soil transmitted and food borne helminths. Filariasis caused by arthropod borne helminths have been discussed elsewhere.

## Soil Transmitted Helminths (STH)

Soil - transmitted helminths commonly known as intestinal worms, are the most common worm infections worldwide. According to an estimate, *A. lumbricoides* infects over 1 billion people, *T. trichiura* 1050 million, and hookworms (*Ancylostoma duodenale* and *Necator americanus*) 1300 million (Table - 1). This is being increasingly recognized as a significant public health problem, particularly in developing countries where poverty, poor nutrition, inadequate sanitation, lack of clean drinking water and minimal health care prevail.

**Table - 1 : Estimated global number of Soil Transmitted Helminth infections and related morbidity and mortality**

Helminth	No. of Infections (millions)	Morbidity (cases, millions)	Mortality (deaths per year, thousands)
<i>A. lumbricoides</i>	1450	350	60
Hookworms	1300	150	65
<i>T. trichiura</i>	1050	220	10

Source : WHO, TRS 912

Although these helminths can infect all members of a population, the most vulnerable - those who are at most risk and would benefit most from the preventive intervention - are pre - school and school age children, adolescent girls and women of child bearing age. Based on the prevalence and the intensity of the infection, the communities can be classified in to three categories -

**(a) Category I (high) transmission community :** Prevalence greater than 50%, heavy infection more than 10%

**(b) Category II (medium) transmission community :** Prevalence greater than 50%, heavy infection less than 10%

**(c) Category III (low) transmission community :** Prevalence less than 50%, heavy infection less than 10%

Based on their life cycle, STH can be classified into three types:

**(a) Type 1 - Direct :** The Eggs are embryonated. They hatch and reinfect within 2 - 3 hours by direct carriage from anal margin to the mouth. Eggs do not reach the soil, and if they do, do not require a period of development there. Example - *Enterobius vermicularis* (threadworm), *Trichuris trichiura* (whipworm).

**(b) Type 2 - Modified direct :** Eggs are passed in stools and undergo a period of development in soil to become the infective stage, before being ingested. After ingestion, eggs hatch and release larva which penetrate mucous membrane of stomach and enter circulation and pass up the respiratory tract, enter oesophagus, reach intestine and grow into adult. Example - *Ascaris lumbricoides* (roundworm).

**(c) Type 3 - Penetration of the skin :** Eggs are passed in the stool to soil. In soil, eggs hatch into larvae which

undergo development till they are ready to penetrate the skin. The Larvae penetrate the skin, reach circulation and lungs where they penetrate lungs to reach respiratory tract, enter oesophagus, reach small intestine and grow into adult. Example - *Ancylostoma duodenale* (hookworm).

**General Measures of Prevention and control of STH :** A comprehensive control strategy for helminths infection should include the following :

**Chemotherapy :** Ensuring wide availability of anthelmintics for soil transmitted infections in all health services in endemic areas; providing regular treatment of all children at risk, including adolescent girls, through school or community based programmes, and treating pregnant women at risk through antenatal care programmes.

**Sanitation :** Ensuring safe water supply and adequate sanitation facilities in all schools and provisioning and use of safe and adequate water supply at household/ community level

**Health education :** Promoting good hygiene and sanitation practices (hand washing, use of latrines, use of foot wear etc) among school children and care givers

**Community participation :** Involving community for planning and execution of the control programme.

**Monitoring and evaluation :** Monitoring and evaluation of the programme to ensure cost - effectiveness and clearing the road block, if any.

The following important points should be kept in mind in planning a programme for control of helminth infection :

- Long term control can be achieved only if regular treatment of at risk people is accompanied by improvements in hygiene and sanitation.
- Full impact on health can be achieved only if helminth control is implemented as part of a larger maternal and child health strategy, aimed at reducing the burden of anaemia in women, children and adolescent girls

**Deworming in schools :** The most cost - effective way of deworming the school - age children is through schools because:

- Schools offer a readily available, extensive and sustained infrastructure
- All children including the disadvantaged (such as girls and poor) are available at one place
- Teachers are a skilled workforce that is in close contact with the community
- Teachers need only a few hours training to understand the rationale for deworming
- Teachers can deliver the drug safely

School - based deworming has its full impact when delivered within an integrated school health program which includes the following :

- Health policies that advocate the role of teachers in health promotion and delivery;
- Adequate sanitation and access to safe water to reduce worm transmission
- Skills - based health education that promotes good hygiene to avoid worm infection;

- Basic health and nutrition services that include regular deworming

#### Do's in school deworming

- Make deworming an integral component of a school health program. Combine deworming with iron and other micronutrient supplements.
- Ensure that teachers and health agents work in unison
- Help teachers understand the benefits of deworming, so that they are supportive
- Make sure that treatment is given regularly and sustained.
- Protect children throughout their development by starting treatment early and continuing treatment throughout primary school.
- Reach out to non - enrolled school aged children.

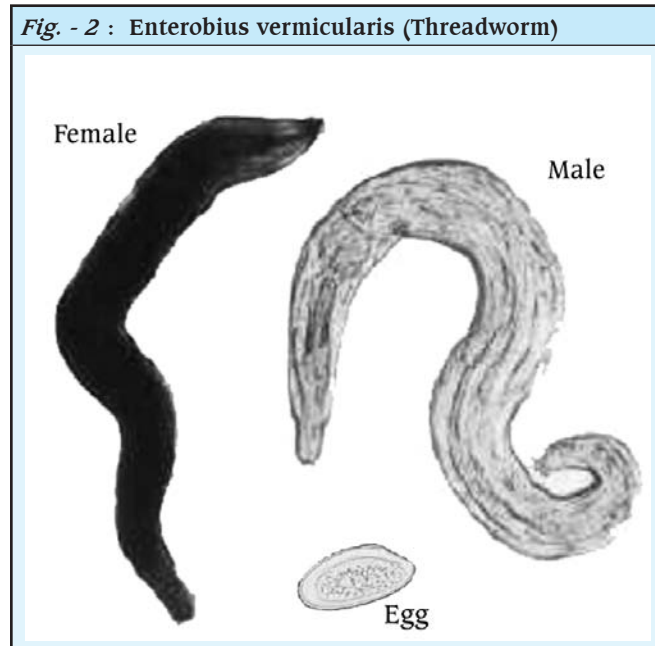
#### Don'ts in school deworming

- Waste time and resources trying to examine each child. Anthelmintics are safe and can be given to uninfected children over 1 year of age.
- Exclude adolescent girls from systematic treatment. The drugs are safe, even in pregnancy.
- Wait for sanitation to improve before starting deworming - regular treatment will help all children avoid the worst effects of infection.

### Enterobius vermicularis (Threadworm)

It is cosmopolitan in distribution and is found all over the world. Essentially an infection of human beings, can affect any age but children are the usual victim. Familial infection is common. Occasional infections in chimpanzees and gibbons have been reported.

#### Epidemiological Determinants



**Agent :** The adult worm is small and white in colour. It is more or less like a spindle and resembles a short piece of thread. Male is shorter measuring 2 - 4 mm compared to females which

are 8 - 12 mm in length. Both males and females have a pair of cervical alae (wing like expansion) at the anterior extremity.

The egg is colourless i.e. not bile - stained, plano - convex in shape, surrounded by a transparent shell, contains a coiled tadpole like larva and floats in saturated solution of common salt.

**Life cycle :** The infection is acquired by ingestion of the eggs. In the stomach, due to gastric juices, egg shells are dissolved and larvae so released, escape to small intestine where they develop into sexually mature worms. There is no multiplication inside the body. After fertilization the male (2.5 mm) dies and the gravid female (9 - 12 mm) migrates to caecum, vermiform appendix and colon and remains there till eggs develop. After this the female worm wanders down the rectum, works its way out of the anus and deposits the eggs, after the patient has retired to bed, on the perianal skin. There, in the presence of oxygen, the eggs complete its development in 24 - 36 hours. No intermediate host is required and the life cycle is completed in 2 - 4 weeks time.

**Host :** Man is the definitive host. Both sexes are affected equally. Infection is more common in children than in adults.

**Environment :** Enterobius is soil transmitted and prefers warm moist conditions. The infection is more common in conditions of overcrowding like family groups, asylums and schools.

**Mode of transmission :** Transmission is effected from one person to another by ingestion of eggs. This can occur by following methods :

- Auto - infection - the patient carries the infection from perianal regions to mouth on his fingernails or soiled night clothes.
- By ingestion of contaminated food or drink
- Air - borne transmission by contaminated dust
- Retrograde infection - the eggs laid on peri - anal skin immediately hatch into infective - stage larvae and migrate through the anus to develop into adult forms in the colon.

#### Clinical Features

Majority of the cases remain asymptomatic till the eggs are deposited in the peri - anal area. In the peri - anal area, eggs induce pruritus ani which is the most common symptom and varies from mild itching to acute pain especially during the night. On entering the vulva in females, it leads to vulvitis causing mucoid discharge and pruritus vulvi. The general symptoms include insomnia, restlessness, irritability, loss of appetite and weight loss. Very rarely the worm may gain access to abdominal cavity and cause peritonitis.

#### Diagnosis

Diagnosis is established by :

- Demonstration of adult worms often seen in the peri - anal region at the time of pruritus or in stool after a purge or enema
- Demonstration of eggs on stool microscopy

#### Treatment

Albendazole given in a single oral dose of 400 mg or 10 - 14 mg/ kg for children, is the drug of choice. Mebendazole given in a single oral dose of 100 mg is a good alternative. Besides the patient, all the members of the family - wherever possible



- should be treated.

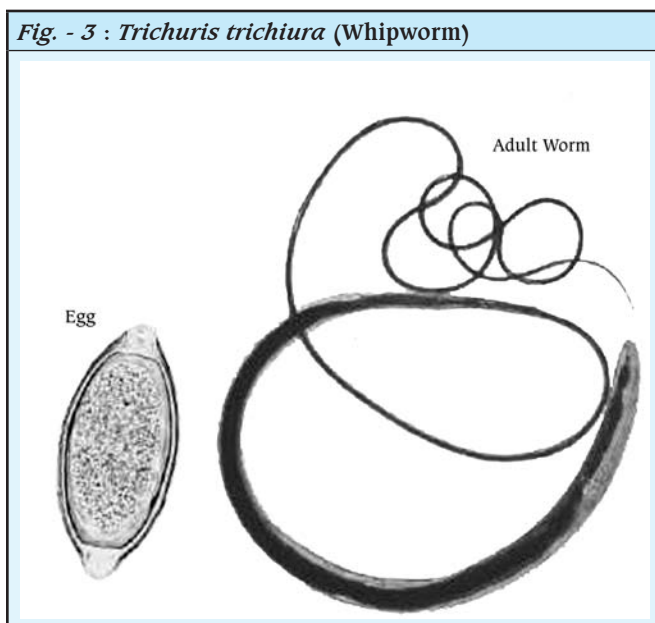
### Prevention and control

Prevention and control is as for other soil transmitted helminths. Simple measures as outlined below are the key to preventing re - infection :

- Improving personal hygiene
- Scrubbing children's hands before meals and after defecation
- Keeping finger nails short
- Regular washing of bedclothes

### Trichuris trichiura (Whipworm)

Though *T. trichiura* is cosmopolitan in distribution, it is more commonly found in warm moist regions of the world. Recent estimates suggest infection with *T. trichiura* among 795 million people of the world. The infection is often associated with *Ascaris* and *Toxocara* infection.



**Agent :** The adult worm appears like a whip - the anterior three fifth being very thin and hair like and posterior two fifth being thick and stout like the handle of a whip. The male of the species is 3 - 4 cm long while the female is 4 - 5 cm long. The worm lives in the large intestine with whole of its anterior portion embedded in the mucous membrane. The adult worm survives in humans for many years.

The egg is barrel shaped with a mucous plug at each end. It is bile stained, contains an unsegmented ovum and floats in saturated solution of common salt.

**Life cycle :** The life cycle is completed in one host, but change of host is necessary for the continuation of the species.

The infection is acquired by ingestion of the eggs. In the stomach, due to gastric juices, egg shells are dissolved and larvae emerges through one of the poles of the egg. The liberated larvae pass down to caecum where it localizes. The worm becomes sexually mature within a month from the time of ingestion of the eggs. After fertilization the gravid female

begins to lay eggs which are passed out in the stool. In water or damp earth, rhabditiform larva develops within the egg in 3 - 4 weeks in tropical climate and in 6 - 12 months in temperate climate. These embryonated eggs are infective to man.

**Host :** *T. trichiura* is primarily an infection of human beings. All age group can be affected but the most commonly affected are children of primary school age group who pollute the soil around the house and acquire heavy infection. The infection is more common in those who are already infected with *Ascaris* and *Toxocara*.

**Environment :** The infection is common in areas of high rainfall, high humidity, dense shade, poor sanitation and contaminated soil.

**Mode of transmission :** Transmission is direct from mature eggs to the mouth via fingers contaminated with infected soil. Infection is also acquired by consumption of food and water contaminated with embryonated eggs.

### Clinical Features

Mild infections are generally asymptomatic. But when associated with *Ascaris* or hook worm infection, it produces upper gastro intestinal symptoms like epigastric pain, nausea, vomiting and abdominal distension. Lodged in appendix, it can often mimic acute appendicitis. Anorexia, weight loss, mucous diarrhoea, often streaked with blood can also occur. Prolapse of rectum has often been reported in massive infections with *T. trichiura*.

### Diagnosis

The diagnosis is established by the finding of characteristic eggs by a direct microscopical examination of a saline emulsion of stool. An egg count reveals the degree of infection. A count of 30,000 eggs per gram of faeces or more is considered as heavy infection. Adult worms may occasionally be present in stool. Proctoscopy in cases of dysentery due to *T. trichiura* also demonstrates adult worms in abundance.

### Treatment

Albendazole and Mebendazole 400 mg and 500 mg respectively as a single dose are highly effective.

### Prevention and control

Prevention and control is as for other soil transmitted helminths.

### Ascaris lumbricoides (Roundworm)

*Ascaris lumbricoides* is found worldwide. In human beings, it is one of the most common intestinal worms of tropical and sub - tropical countries and is the cause of worm infestation in up to 10% of the population of the developing world. Worldwide, severe *Ascaris* infections cause approximately 60,000 deaths per year, mainly in children. In endemic areas three distinct patterns have been observed :

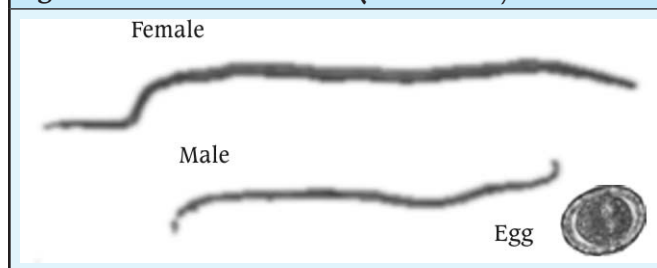
- High prevalence (over 60%) in the population above 2 years of age, intensity of infection is lower in adults, transmission of infection takes place through invasive eggs on fingers or in food.
- Moderate prevalence (below 50%) maximum prevalence in pre - school and primary school age children, intensity of

infection in adults low, transmission household or family type

- Low prevalence (below 10%) only focal distribution of infection, seen in association with poor housing and sanitary conditions and unhealthy behavioural practices.

**Agent :** The adult worm when fresh from the intestine is light brown or pink in colour which gradually changes to white. The worms are cylindrical, rounded and tapers at both ends, the anterior end being thinner than the posterior. While the male of the species measures 15 - 25 cm in length with maximum diameter of 3 - 4 mm, the female measures 25 - 40 cm in length with maximum diameter of 5 mm. The tail end of the male is characteristically curved ventrally in the form of a hook having a conical tip.

**Fig. - 4 : *Ascaris lumbricoides* (Roundworm)**



The fertilized egg is round in shape, surrounded by thick smooth translucent shell with an outer albuminous coat thrown into rugosities (outer coat is lost in decorticated eggs), contains large unsegmented ovum and has a clear crescentic area at each pole. It is always bile stained and floats in saturated solution of common salt. The unfertilized egg is elliptical in shape, has thinner shell with irregular coating, is bile stained but does not float in saturated salt solution.

**Life cycle :** The infection is acquired by ingestion of the embryonated eggs which pass down to duodenum where egg shells are dissolved. The newly hatched larvae burrow their way through the mucosa of small intestine and carried by portal circulation, lodge themselves in liver for 3 - 4 days. From here, through the heart, they enter pulmonary circulation. While in lungs, they undergo two moultings and grow bigger in size. Subsequently, in 10 - 15 days, they pass from lung alveoli, bronchi, trachea, larynx, and pharynx and are finally swallowed. Passing down the esophagus to stomach, the larvae localize in upper small intestine - their normal abode - and moult once again. They grow into adult worms and mature sexually in 6 - 10 weeks. The gravid female starts discharging eggs in stool in about two months from the time of infection. Outside the human body and in soil, a rhabditiform larva develops within the egg in 10 - 40 days time. Before hatching, the larva undergoes fourth moulting. The ripe egg containing the coiled up embryo is infective to man.

**Host :** All age groups are affected. Infection rates are highest in children who are the disseminators of infection. Adult human beings seem to acquire resistance to the infection. A high degree of host - parasite tolerance has been reported.

**Environment :** The eggs remain viable in the soil for months and years under favourable climatic conditions. Clay soils are

most favourable for the development of eggs. Ecological factors regulating the development of eggs include temperature, humidity, oxygen pressure in the environment and sun light. A low temperature inhibits the development of eggs.

**Mode of Transmission :** The mode of transmission is essentially oro - faecal. The infection is effected by ingestion of embryonated eggs with raw vegetables on which fecal matter containing eggs has been deposited. Transmission can also occur through recycling of wastewater into crop fields. This is quite common in emerging industrial economies, and poses serious risks for not only local crop sales but also exports of contaminated vegetables. Drinking of water where water supplies are contaminated with ripe eggs, may also transmit infection. Infection may also occur by inhalation of desiccated eggs in the dust reaching pharynx and swallowed. The eggs instead of being swallowed may hatch on moist mucous surface of upper respiratory tract and the larvae may directly penetrate into the blood stream. Transmission from human to human by direct contact is impossible.

**Incubation period :** The incubation period after swallowing eggs to the first appearance of eggs in the stool is about 2 months.

#### Clinical features

Individuals with mild infection are usually asymptomatic though a single large worm, when migrate to aberrant sites, can cause diseases like biliary colic, cholecystitis, cholangitis and pancreatitis. During the lung phase of larval migration i.e. 9 to 12 days after egg ingestion, patient may develop irritating non - productive cough and substernal discomfort. Dyspnoea and blood tinged sputum is less common but fever is usual. Eosinophilia develops and chest X-ray may suggest eosinophilic pneumonitis (Löffler's syndrome). In heavy infections, particularly in children, the bolus of worms can cause intestinal obstruction and sometimes perforation.

#### Diagnosis

Diagnosis of ascariasis is confirmed by demonstration of characteristic eggs on stool microscopy. Adult worm may often be present in the stool which can be identified by its large size and smooth cream coloured surface. In ascariasis with complications, eosinophil count, X-ray chest, X-ray abdomen, ultra sound and endoscopic retrograde cholangiopancreatography (ERCP) may be useful.

#### Treatment

Ascariasis should always be treated to prevent complication. Albendazole and Mebendazole given in usual dose are effective in uncomplicated cases but are contraindicated in pregnancy and in heavy infections. Pyrantel pamoate given in a single dose of 10 mg per kg body weight is safe as well as effective in pregnancy. Complications are managed conservatively or surgically depending on the nature of the illness.

#### Prevention and Control

For the prevention and control of ascariasis in the community, following measures should be adopted :

- Sanitary disposal of human excreta to prevent faecal contamination of soil
- Provisioning of safe drinking water availability of water

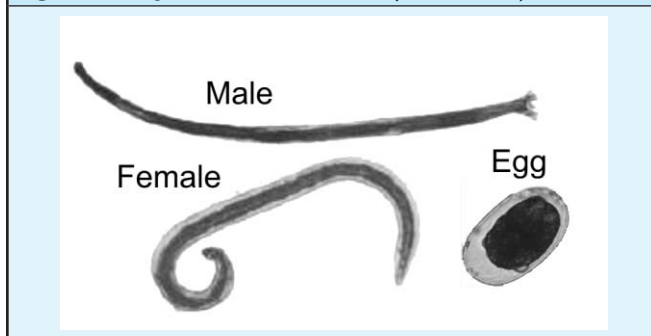
for use in personal hygiene as well as proper disposal of human faeces

- Health education providing the following messages reduces the number of infected people :
  - avoid contact with soil that may be contaminated with human faeces;
  - wash hands with soap and water before handling food;
  - wash, peel or cook all raw vegetables and fruits;
  - protect food from soil and wash or reheat any food that falls on the floor.
- Where wastewater is used for irrigation, waste stabilization ponds are effective in decreasing transmission due to food grown in contaminated soil.
- Regular repeated mass chemotherapy, especially to school going children, with Albendazole, Mebendazole or Pyrantel pamoate.

### Ancylostoma duodenale (Hookworm)

Hookworms are thought to infect 800 million people worldwide. It is an extremely common helminthic infection in human beings and is caused by *Ancylostoma duodenale* and *Necator americanus*. *A. duodenale* predominates in the Middle East, North Africa, India, Japan, China and in southern Europe while *N. americanus* predominates in the Americas, Sub-Saharan Africa, Southeast Asia, China and Indonesia. In India, hookworm infection is widely prevalent with *N. americana* predominantly in South and *A. duodenale* predominantly in North. More than 200 million people are estimated to be infected with hookworms. The most affected states are Bihar, Jharkhand, West Bengal, Assam, Andhra Pradesh, Tamil Nadu, Kerala and Maharashtra. Investigations in rural West Bengal have shown marked aggregation of both hookworm species in individual villagers, with more than 60% of the infections found in less than 10% of the people.

Fig. - 5 : *Ancylostoma duodenale* (Hookworm)



**Agent :** The adult worm is a small (male measures about 8 mm in size while female measures about 12.5 mm in size), greyish white, cylindrical worm. The anterior end of the worm is bent slightly dorsally in the same direction as the curvature of the body. The buccal capsule is large and conspicuous and is provided with 6 teeth and triangular plates - 4 hook-like on ventral surface and 2 knob-like on dorsal surface. Posterior end is expanded in an umbrella-like fashion in males but it is tapering in females.

The eggs are oval or elliptical in shape, not stained by bile and contain four segmented ovum. It floats in saturated solution of common salt.

**Life cycle :** The eggs containing 4 blastomeres are passed out in faeces. Within 48 hours in soil, the rhabditiform larva hatches out. It undergoes two moultings on third day and fifth day to develop into filariform larva which is the infective stage of the worm. The filariform larvae gain entrance to the human body by piercing the skin. There it enters the lymphatics and reaches pulmonary alveoli through lympho-vascular system, right heart and pulmonary capillaries. They then migrate upwards the respiratory system and get ultimately swallowed. During its entry to oesophagus, third moulting takes place and a terminal buccal capsule is formed. The growing larvae settle down in small intestine and undergo a fourth moulting to develop into adolescent worms. In three to four weeks time they become sexually mature and following fertilization, the female starts laying eggs. The whole cycle is completed in about six weeks.

**Host :** Hookworms may reach a considerable intensity in children but commonly remain high throughout adulthood. Whites are much more susceptible than non-whites of similar socio-economic status, suggesting a genetic predisposition. Gender differential in infection has been attributed to difference in habits and exposure. Farmers, gardeners, miners, agriculture workers and individuals working in the fields are more prone to acquire infection as compared to those who are not exposed to such conditions.

**Environment :** Hookworm larvae live in the upper half inch of the soil. The most favourable conditions for their survival and completion of life cycle include loose, moist, shady, sandy soil with decaying vegetation or improperly treated human faeces. Rainfall is required to provide adequate moisture for the larvae to migrate and reach human skin on grass or other moist surfaces. Temperature is also an important factor for determining the type of infection because *N. americanus* can tolerate higher temperatures as compared to *A. duodenale*. The infective larvae may remain viable in the soil for months during the period of drought or low temperature. Human habits as guided by illiteracy, ignorance, social conditions and low standard of living are important contributing factors for the survival and transmission of hookworm infections.

**Mode of transmission :** The man acquires the infection when filariform larvae penetrate the skin. The common site of their entry is the skin between toes, the dorsum of the feet, and the inner side of the sole. They may also gain entry through the skin of hands in case of gardeners and miners. Infection can rarely be acquired by drinking contaminated water or ingesting contaminated food materials.

**Incubation period :** Symptoms usually start appearing 1 to 2 weeks after primary infection. In established infection eggs appear 42<sup>nd</sup> day onwards after infection.

### Clinical features

Most hookworm infections are asymptomatic. A pruritic maculo-papular lesion without any constitutional symptom may develop at the site of entry of the filariform larva.

During migration of larva through lungs, a mild transient pneumonitis, though less severe than that in case of Ascariasis,



can occur. In the early intestinal phase, the infected person may have symptoms of dyspepsia, epigastric pain, vague abdominal symptoms and diarrhoea associated with eosinophilia. The main consequence of chronic hookworm infection is iron deficiency anaemia. Such an infection can result in a daily loss of 1 mg of iron per 10,000 ova per gm of faeces, irrespective of the species. Heavy infection may also lead to malabsorption and hypoproteinemia.

### Diagnosis

The diagnosis is clinched by demonstrating characteristic eggs in the stool. Stool concentration may be required for demonstration of eggs in case of mild infection. The blood smear shows hypochromic, microcytic anaemia indicating presence of iron deficiency anaemia. Occasionally eosinophilia may also be present.

### Treatment

Albendazole, Mebendazole and Pyrantel pamoate given in usual dose is generally adequate for the treatment. Oral iron supplementation may be required for the management of mild iron deficiency anaemia. Severe hookworm infections with protein loss and malabsorption necessitate nutritional support and iron replacement with deworming.

### Prevention and control

The prevention and control of hookworm infection involves, in addition to the general principle as outlined earlier, the following :

- Prevent skin/ soil contact - do not walk bare foot
- Do not defecate out in open, use sanitary latrines
- Do not use human excrement or raw sewage as manure/ fertilizer in agriculture lest it should come in contact with skin
- Iron supplementation for treatment of anaemia and nutritional supplementation in severe hookworm infections leading to hypoproteinemia

## Strongyloides stercoralis

*S. stercoralis* is widely distributed and is endemic in many regions of the world like Vietnam, Cambodia, Papua New Guinea and parts of Africa. High prevalence is reported from some areas of Brazil, Central America and tropical Australia. Knowledge of the geographic distribution of strongyloidiasis is of significance to travellers who may acquire the parasite during their stay in endemic areas.

**Agent :** The adult worms are small (male measures about 0.9 mm in size while female measures about 2 to 2.5 mm in size) cylindrical worms. Males are distinguished from their female counterparts by two structures : the spicules and gubernaculum. Both genders have a tiny buccal capsule and cylindrical esophagus without a posterior bulb. In the free - living stage, the esophagi of both sexes are rhabditiform. The *Strongyloides* life cycle is of two types :

**Free - living cycle :** The rhabditiform larvae passed in the stool can molt twice and become infective filariform larvae which penetrate the human host skin to initiate the parasitic cycle. Alternatively the rhabditiform larvae can molt four times and become free living adult males and females that mate and produce eggs from which rhabditiform larvae hatch.

**Parasitic cycle :** Filariform larvae in contaminated soil penetrate the human skin, and are transported to the lungs. Passing through the bronchial tree and the pharynx, they reach small intestine. In the small intestine they molt twice and become adult female worms. The females by parthenogenesis in the epithelium of the small intestine, produce eggs which yield rhabditiform larvae. The rhabditiform larvae can either be passed in the stool, or can cause autoinfection. In autoinfection, the rhabditiform larvae molts twice to become infective filariform larvae, which can cause internal autoinfection (i.e. penetrate the intestinal mucosa) or external autoinfection (i.e. penetrate the skin of the perianal area).

**Host :** Strongyloidiasis is less prevalent than infections due to other intestinal nematodes. Travellers and immigrants acquire infection in endemic areas and then harbour the parasite for decades. Risk is highly increased among the residents of mental asylums due to oro - faecal transmission and geophagia. Autoinfection is amplified in immunocompromised hosts.

**Environment :** *S. stercoralis* has a very low prevalence in societies where fecal contamination of soil or water is rare. Hence, it is more prevalent in rural areas in developing countries, where sanitation standards are poor.

**Mode of transmission :** The man acquires the infection when filariform larvae penetrate the skin. An unusual feature of *S. stercoralis* is autoinfection. Only one other species in the *Strongyloides* genus, *S. felis*, has the trait of autoinfection. Because of autoinfection, a host once infected with *S. stercoralis*, remains infected life - long unless effective treatment eliminates all adult parasites and migrating autoinfective larvae.

### Clinical features

Strongyloidiasis is frequently asymptomatic. Transient pruritus can occur at the site of entry of the filariform larva. Pulmonary symptoms (including Loeffler's syndrome) can occur during pulmonary migration of the larvae. Gastrointestinal symptoms include abdominal pain and diarrhoea. Disseminated strongyloidiasis occurs in immunosuppressed patients. Common predisposing factors include corticosteroid therapy, immunosuppressive chemotherapy, malignancy, tuberculosis and malnutrition. Hyperinfection with *S. stercoralis* can present with abdominal pain, distension, shock, pulmonary and neurologic complications and septicemia, and is potentially fatal. Blood eosinophilia is generally present during the acute and chronic stages, but may be absent with dissemination.

### Diagnosis

Diagnosis rests on the microscopic identification of larvae (rhabditiform and occasionally filariform) in the stool or duodenal fluid. Because of the low rate of egg production, examination of serial samples may be necessary. Stool culture for *S. stercoralis* is available at few places only. The duodenal fluid examined using techniques such as the Enterotest string or duodenal aspiration is positive in 90% of the cases. Larvae may be detected in sputum from patients with disseminated strongyloidiasis. Serologic testing may be useful for screening of patients in endemic areas.

### Treatment

Ivermectin is the drug of choice, given in a dose of 100



microgram per kg per day for 1 - 2 days is usually sufficient for the management of chronic intestinal strongyloidiasis. For patients with underlying immunodeficiency, the treatment should be repeated at two weeks. Albendazole not as effective as Ivermectin and Thiabendazole, though effective but not well tolerated, have also been used.

### Prevention and Control

The prevention and control measures include sanitary disposal of human faeces in endemic areas and wearing of appropriate footwear. Hyperinfection syndromes are prevented by early identification and eradication of strongyloidiasis infection.

### Food Borne Helminths

Food borne helminths include a variety of flukes and tapeworms. The notable among these are *Fasciola buski* (intestinal flukes), *Fasciola hepatica* (liver flukes), *Clonorchis sinensis* (liver flukes, Chinese liver fluke, Oriental liver fluke), *Paragonimus westermani* (lung flukes), *Taenia saginata* (beef tapeworm) and *Taenia solium* (Pork tapeworm).

All these worms and flukes are cosmopolitan in nature and are found worldwide but majority of these are found in South East Asia and Western Pacific region. *T. saginata* is common in India but not among Hindu community as they do not eat beef. *F. buski* is common in Bangladesh, China, Indonesia, Malaysia, Taiwan, and Thailand. *Clonorchis sinensis* is common in Southern China, Taiwan, Hong Kong and Vietnam. According to an estimate, Clonorchis infections in China, have more than tripled over the past decade (approximately 15 million people were infected with *C. sinensis* in 2004).

The most important epidemiologic features responsible for transmission of food borne helminths especially flukes include ecologic and environmental factors, behavioural factors, and socioeconomic and cultural factors. Residents living near freshwater bodies have been found to have a 2.15 fold higher

risk of infections than persons living farther from the water. Exponential growth of aquaculture may be the most important risk factor for the emergence of food borne infection with flukes. Socio - economic development, urbanization, adequate food inspection and increased awareness have been found to be associated with a decrease in prevalence of food borne helminths infection. A summary of food borne helminthic infection, drug of choice for treatment and its dose is given in Table - 2. The general measures of prevention and control are given subsequently.

### General Measures of Prevention and control

Public health interventions that will affect the pool of parasites and will also reduce the prevalence of major food borne helminths infections, are enumerated as under :

- (a) Chemotherapy with antihelminthics in adequate doses for adequate duration
- (b) Sanitation and Hygiene
  - Proper disposal of human and animal wastes to prevent contamination of foods and drinking water sources
  - Sterilization/ composting of night soil before using it as fertilizer.
  - Thorough washing of raw vegetables and fruits may remove eggs of parasites, but it is difficult to adequately clean some leafy vegetables and berries.
  - Control of flies, cockroaches, and other insects may prevent dispersal of infective stages of parasites to foods.
  - Frequent handwashing, use of clean utensils, and measures to prevent cross - contamination during food processing
- (c) Food Inspection and food safety
  - Naked eye inspection can detect parasites in pork, beef, and fish.
  - Soaking of vegetables in a 1.5% bleach solution, potassium permanganate solution (24 mg/L), or saturated salt destroys infective larvae of some food borne helminths

**Table - 2 : Food - borne helminth infections and their management**

Helminth	Infective form	Food item	Drug of choice	Adult dose and duration
<i>Fasciolopsis buski</i> (intestinal flukes)	Metacercariae encysted in aquatic vegetation	Fruits, raw vegetables	Praziquantel	25 mg/ kg; 3 doses in 1 day
<i>Fasciola hepatica</i> (liver flukes)	Metacercariae encysted in aquatic vegetation	Fruits, raw vegetables	Triclabendazole	10 mg per kg once
<i>Clonorchis sinensis</i> (liver flukes)	Metacercariae in fish flesh	Fish	Praziquantel	25 mg/ kg; 3 doses in 1 day
<i>Paragonimus westermani</i> (lung flukes)	Metacercariae in fish flesh	Crabs, shrimp	Praziquantel	25 mg/ kg; 3 doses per day for 2 days
<i>Taenia saginata</i> (beef tapeworm)	Cysticercus bovis in muscles	Beef	Praziquantel	5 - 10 mg/ kg; single dose
<i>Taenia solium</i> (Pork tapeworm)	Cysticercus cellulosae in muscles	Pork	Praziquantel	5 - 10 mg/ kg; single dose
<i>Diphyllobothrium latum</i> (fish tapeworm)	Plerocercoid larvae in fish flesh	Fish	Praziquantel	5 - 10 mg/ kg; single dose
<i>Trichinella spiralis</i> (trichina worm)	Encysted larvae in muscles	Pork	-	-

- All infective stages of parasites are destroyed by adequate cooking of foods and boiling of water. Microwave cooking does not reliably kill all parasites in meat and fish because heating is uneven and cooler spots may permit survival. It is advisable to cook pork and fish for 10 min at 60°C or 7 min at 70°C.
- For foods to be eaten raw, such as fish and some meats, freezing for several days can inactivate or kill some parasites. - Fish should be frozen at - 30°C for ≥15 hours in a commercial blast freezer or at - 20°C for ≥7 days in a domestic freezer. Freezing meat at 5°F ( - 17°C) for 20 days, - 10°F ( - 23.3°C) for 10 days or - 20°F ( - 29°C) for 6 days destroys trichinae in pork.
- Irradiation can destroy parasites on some raw foods. Lower doses of irradiation (0.5 - 0.7 kGy) damage larvae and inhibit infectivity, but larger doses (6 - 7 kGy) are required to kill all the trichinae in meat. Irradiation doses of 0.1 - 0.15 kGy have been reported to kill trematode cysts in fish.
- Fermentation of meat to produce dry sausages and ham inactivates larvae of parasitic worms. Low pH and low water activity combine to kill parasites.
- (d) IEC activities
  - To teach proper cooking methods for fish and other potentially contaminated aquatic foods.
  - To discourage human consumption of raw water plants like watercress and water chestnuts.

### Taenia saginata (Beef Tapeworm)

*Taenia saginata* is widely distributed and is most prevalent in sub - Saharan Africa and Middle Eastern Countries.

#### Epidemiological Determinants

*Taenia saginata* lives in small intestine (upper jejunum) of man. The adult worm is white, semi - transparent and measures 5 to 10 meters in length. The body of the worm is divided into scolex, neck and proglottides, the number of which may vary from 1000 to 2000. The life span of the adult worm is more than 10 years.

The eggs are spherical and brown in colour (bile stained), has an outer shell and an inner thick walled, radially striated embryophore, contains three pairs of hooklets, and do not float in saturated solution of common salt.



**Life cycle :** *Taenia saginata*, in its life cycle, passes through one definitive host (man) and one intermediate hosts (cattle - cow or buffalo)

The eggs or segments are passed out with faeces on ground where they live for months or years till ingested by cattle while grazing. The embryo released after ingestion invades the intestinal wall and is carried to striated muscles where it transforms into a cysticercus. When ingested in raw or undercooked beef, this form infects human beings. After ingestion of cysticercus, it takes 2 months for an adult worm to develop.

**Modes of Transmission :** Human infection is acquired by eating undercooked beef.

#### Clinical Features

Majority of individuals with *Taenia saginata* infection are asymptomatic. They become aware of the infection by noting passage of proglottids in stool. Some patients also complain of vague abdominal pain, distension, nausea, anorexia and weight loss may occur.

#### Diagnosis

Diagnosis is by identification of characteristic eggs or proglottids in stool. Eggs may also be present in perianal area. Eosinophilia and raised IgE may be detected.

#### Treatment

Treatment is by Praziquantel as given in Table - 2.

#### Prevention and Control

As outlined above.

### Taenia solium (Pork tapeworm)

*Taenia solium* exists worldwide and is most prevalent in Africa, Latin America, South East Asia and Eastern Europe.

#### Epidemiological Determinants

*Taenia solium* lives in small intestine (upper jejunum) of man. The adult worm is white, semi - transparent and measures 2 to 3 meters in length. The body of the worm is divided into scolex, neck and proglottides. As compared to *T. saginata*, the scolex is smaller and the number of proglottids lesser, usually less than 1000. The life span of the adult worm is as much as 25 years. The eggs are similar to those of *T. saginata*.

**Life cycle :** Life cycle is the same as *T. saginata* except that the intermediate host is pig.

**Modes of Transmission :** Human infection is acquired by eating undercooked pork. Auto infection may occur if an individual ingests eggs derived from his own faeces.

#### Clinical features

Intestinal infection with *Taenia solium* may be asymptomatic. Symptoms of vague abdominal pain, distension, nausea, anorexia, and weight loss are infrequent. Extraintestinal manifestations due to cysticercosis which has a predilection for central nervous system are entirely different. Cysticercosis of brain may result in raised intra - cranial pressure, seizures and hydrocephalus. They can also cause chronic meningitis, arachnoiditis and stroke.

#### Diagnosis

Diagnosis is by identification of characteristic eggs or proglottids in stool. Diagnosis of cysticercosis is difficult. CT scan, MRI and serology may provide useful evidence.

## Treatment

Treatment for intestinal infection is by Praziquantel as given in Table - 2. For extra - intestinal manifestation, Praziquantel (50 - 60 mg / kg in 3 divided doses for 15 days) along with suitable surgical or non - surgical intervention may be required.

## Prevention and control

As outlined above.

## Summary

The word Helminths literally means worms. These are parasitic worms causing diseases of varying magnitude in humans. Nearly 01 billion people worldwide are estimated to be affected with worm infestation. They are divided primarily based on the route of their transmission - soil, food or arthropod borne.

Soil - Transmitted Helminths (STH) can be grouped in various ways, based either on prevalence and the intensity of the infection (into high, medium & low transmission community) or on their life cycle (into direct, modified direct & penetration of skin). They are transmitted by oro - faecal route and produce a wide range of non - specific symptoms which include intestinal manifestations and generalized weakness. Pre - school and school age children, adolescent girls and women of child bearing age are the most vulnerable and afflicted population groups.

Diagnosis of STH infections is established by stool microscopy and identification of characteristic eggs. Treatment of these infections is aimed at improving health; nutrition and overall vocational capability of the target age group population - the drugs used are Albendazole, Mebendazole and Praziquantel. A comprehensive control strategy for helminths infection should include Chemotherapy, Sanitation, Health education, Community participation and Monitoring and evaluation.

The most cost - effective way of deworming the school - age children is through School - based deworming, which has its full impact when delivered within an integrated school health program. While implementing this strategy, it would be prudent to adhere to certain Do's (like making deworming an integral component of a school health program & combining it with iron and other micronutrient supplementation) and Dont's (like excluding adolescent girls from systematic treatment or examining every child).

*Enterobius vermicularis* (Threadworm) is cosmopolitan in distribution and is found all over the world. The adult worm is like a spindle and the eggs are color - less. Infection is acquired by ingestion of eggs. Man is the definitive host. The infection is more common in conditions of overcrowding. Person - to - person transmission can occur by either Auto - infection, ingestion of contaminated food or drink, air - borne transmission by contaminated dust or by retrograde infection. Majority of the cases remain asymptomatic - in others, pruritus ani is the most common symptom. Diagnosis is by demonstration of adult worms in stool (even naked eye examination) or eggs in stool microscopy. Albendazole or Mebendazole may be used in treatment. Prevention and control includes improving personal hygiene, scrubbing children's hands before meals and after defecation, keeping finger nails short and regular washing of bedclothes.

*Trichuris trichiura* (Whipworm) is more commonly found in warm moist regions of the world. The adult worm appears like a whip; egg is barrel shaped with a mucous plug at each end. Infection is acquired by ingestion of embryonated eggs. Children and those already infected with *Ascaris* and *Toxocara*. are particularly affected. Transmission is direct, via fingers, food and water. Mild infections are generally asymptomatic, but upper GI symptoms are produced when co - infection with *ascaris* or hookworm takes place. The diagnosis is established by the finding of characteristic eggs by a direct microscopical examination of a saline emulsion of stool. Albendazole and Mebendazole are effective agents. Prevention and control is as for other soil transmitted helminths.

*Ascaris lumbricoides* (Roundworm) is found worldwide. In human beings, it is one of the most common intestinal worms. Ascariasis could be endemic, epidemic or sporadic. In endemic areas three distinct patterns have been observed - high, moderate & low prevalence. The adult worms are cylindrical, rounded and tapers at both ends. The fertilized egg is round in shape, surrounded by thick smooth translucent shell. The infection is acquired by ingestion of the embryonated eggs . All age groups are affected; nevertheless infection rates are highest in children. The eggs remain viable in the soil for months and years under favourable climatic conditions. Clay soils are most favourable for the development of eggs. The mode of transmission is essentially oro - faecal. Transmission can also occur through recycling of wastewater into crop fields or by inhalation of desiccated eggs in the dust. The incubation period is around 02 months. Clinical features range from asymptomatic to biliary colic, cholecystitis, eosinophilic pneumonitis (Löffler's syndrome), intestinal obstruction or perforation. Diagnosis of *ascaris* infection is confirmed by demonstration of characteristic eggs on stool microscopy. Adult worm may often be present in the stool which can be identified by its large size and smooth cream coloured surface. Treatment comprises of either Albendazole or Mebendazole . Pyrantel pamoate is preferred in cases of pregnant women. Proper sanitation, safe drinking water, health education, setting up of waste stabilization ponds and Regular repeated mass chemotherapy, especially among school children, are essential measures in prevention and control of ascariasis in the community.

Ancylostomiasis is an extremely common helminthic infection in human beings and is caused by *Ancylostoma duodenale* and *Necator americanus*. In India, hookworm infection is widely prevalent with *N. americana* predominantly in South and *A. duodenale* predominantly in North. The adult worm is a small greyish white, cylindrical worm. The life - cycle passes through stages of eggs, rhabditiform larva, filariform larva and adult; the whole cycle is completed in about six weeks. Hookworms may reach a considerable intensity in children. Hookworm larvae live in the upper half inch of the soil. Human habits as guided by illiteracy, ignorance, social conditions and low standard of living are important contributing factors in transmission of hookworm infection; the other ones are moist, shady, sandy soil with decaying vegetation, temperature and humidity. Man acquires the infection when filariform larvae penetrate the skin. Symptoms usually start appearing 1 to 2



weeks after primary infection. Most hookworm infections are asymptomatic; maculo - papular lesion, eosinophilia, anaemia, malabsorption, hypoproteinemia and pneumonitis are the other clinical manifestations. The diagnosis is clinched by demonstrating characteristic eggs in the stool. Albendazole, Mebendazole and Pyrantel pamoate given in usual dose is generally adequate for the treatment. Prevention and control involves among other measures, provision of sanitary latrines and iron supplementation.

Food borne helminths include a variety of flukes and tapeworms; all these worms and flukes are cosmopolitan in nature but majority of these are found in South East Asia and Western Pacific region. The most important epidemiologic features responsible for transmission of food borne helminths especially flukes include ecologic and environmental factors, behavioural factors, and socioeconomic and cultural factors. The transmission of the infection takes place by ingestion of the infective larvae along with raw or uncooked or improperly cooked fish, pork, beef or other food items. Clinical features depend upon the type of helminth and the system involved. The diagnosis is mainly established by demonstration of characteristic ova in stool or sputum (in case of lung fluke infection). The mainstay of treatment is Praziquantel. Essential components of prevention and control include IEC activities, chemotherapy with antihelminthics, maintenance of sanitation and hygiene and ensuring food inspection and food safety .

*Taenia saginata* (beef tapeworm) is widely distributed globally. The worm lives in small intestine (upper jejunum) of man. The adult worm is white, semi - transparent and measures 5 to 10 meters in length. The eggs are spherical and brown in colour (bile stained), contains three pairs of hooklets. *Taenia saginata*, in its life cycle, passes through one definitive host (man) and one intermediate hosts. Human infection is acquired by eating undercooked beef. Vague abdominal pain, distension, nausea, anorexia, and weight loss are some clinical manifestations. Diagnosis is by identification of characteristic eggs or proglottids in stool. Treatment is by Praziquantel. Preventive and control measures are the same as for food - borne helminthes.

*Taenia solium* (the Pork tapeworm) exists worldwide. The worm lives in small intestine (upper jejunum) of man. The eggs are similar to those of *T. saginata*. Life cycle is the same as *T. saginata* except that the intermediate host is pig. Human infection is acquired by eating undercooked pork. Auto infection may occur if an individual ingests eggs derived from his own faeces. Symptoms of vague abdominal pain, distension, nausea, anorexia, and weight loss are infrequent. Extraintestinal manifestations due to cysticercosis which has a predilection for central nervous system are entirely different. Diagnosis is by identification of characteristic eggs or proglottids in stool. Treatment for intestinal infection is by Praziquantel. Preventive and control measures are the same as for food - borne helminthes.

## Study Exercises

**Long question :** Discuss food borne helminthes and their control measures.

**Short notes :** (1) Deworming in schools (2) *Taenia saginata*

### MCQs

- In the classification of communities based on prevalence and intensity of infection of soil - transmitted helminthic infections, a high - transmission community is one wherein (a) Prevalence greater than 50%, heavy infection less than 10% (b) Prevalence less than 50%, heavy infection less than 10% (c) prevalence greater than 10%, heavy infection less than 50% (d) Prevalence greater than 50%, heavy infection more than 10%
- All of the following are types of soil - transmitted helminthes based on the life cycle, except : (a) Direct (b) Indirect (c) Penetration of the skin (d) Modified direct
- Anthelminthics are contra - indicated in pregnancy. Yes / No
- All of the following are examples of food borne helminthes examples except (a) *Wuchereria bancrofti* (b) *Clonorchis sinensis* (c) *Fasciola hepatica* (d) *Fasciola buski*.
- Retrograde infection is a significant mode of transmission of (a) Ascariasis (round worm) (b) Paragonimus (lungfluke) (c) Enterobius (thread worm) (d) Ankylostoma (hook worm)
- For whipworm infection to be termed as "heavy infection", the number of eggs per gram of faeces is more than or equal to : (a) 10000 (b) 20000 (c) 30000 (d) 40000
- In areas where Ascariasis is endemic and maximum prevalence is found in pre - school and primary school age children, intensity of infection in adults low, transmission household or family type, the pattern is known as : (a) mild prevalence (b) moderate prevalence (c) intense prevalence (d) high prevalence
- A safe and effective drug in the management of Ascariasis in a pregnant woman is : (a) Praziquantel (b) Mebendazole (c) Albendazole (d) Pyrantel Pamoate
- Diphyllobothrium latum* (fish tapeworm) in its life cycle, passes through : (a) 01 definitive host & 02 intermediate hosts (b) 02 definitive hosts & 01 intermediate host (c) 01 definitive host & 01 intermediate host (d) 02 definitive hosts & 02 intermediate hosts
- Drug of choice in cases of Cysticercosis is : (a) Albendazole (b) Mebendazole (c) Praziquantel (d) Pyrantel pamoate.
- Consumption of raw or incompletely cooked crabs, crayfish and shrimps harbouring metacercariae, leads to infection with : (a) liverfluke (b) lungfluke (c) bloodfluke (d) intestinal fluke.
- Reservoir of infection in man , in cases of Intestinal fluke (*Fasciola hepatica*) is : (a) pig (b) cow (c) snail (d) dog
- Encysted larvae in muscles of pork, when ingested, is the infective form in cases of infection with (a) *Fasciola hepatica* (liver flukes) (b) *Trichinella spiralis* (trichina worm) (c) *Ascaris lumbricoides* (round worm) (d) *Paragonimus westermani* (lung flukes)



14. What amount of iron is approximately lost in cases of chronic hookworm infection, leading to Iron deficiency anaemia : (a) 10 mg of iron per 10,000 ova per gm of faeces (b) 0.1 mg of iron per 10,000 ova per gm of faeces (c) 5 mg of iron per 10,000 ova per gm of faeces (d) 1 mg of iron per 10,000 ova per gm of faeces

**Answers :** (1) d; (2) b; (3) No; (4) a; (5) c; (6) d; (7) b; (8) d; (9) a; (10) c; (11) b; (12) a; (13) b; (14) d.

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## Amoebiasis & Giardiasis

Rajesh Kumar

### Amoebiasis

Amoebiasis is an infection caused by a protozoan parasite *Entamoeba histolytica*. The infection is acquired by faeco - oral route and the disease is manifested by intestinal as well as extra - intestinal symptoms.

#### Magnitude of the Problem

Amoebiasis occurs worldwide but the majority of the cases are reported from developing countries mainly because of poor hygiene and sanitary conditions. These areas include India, Mexico, Central and South America and countries of Africa and Asia in tropical regions. In developed countries, the affected population is mainly constituted by travellers. At anyone time approximately 10% of the world population is affected by Amoebiasis. It is the third commonest cause of death, after schistosomiasis and malaria, from parasitic diseases. In India, the prevalence of Amoebiasis ranges from 3.5% to 45% with an average of about 15%.

#### Epidemiological Determinants

##### Agent factors

**(a) Agent :** Amoebiasis is caused by *Entamoeba histolytica* which, in human, exists in two forms - the vegetative form or trophozoite and the cystic form. The trophozoites are found in large intestine where they multiply and encyst. The cysts are excreted in the stool. On gaining entrance by ingestion, the cysts release trophozoites which colonize in the large bowel which may cause ulceration, mainly in ascending colon and caecum. Some may gain entry in the circulation and cause liver abscess and other extra - intestinal illnesses. Efforts have been made to further classify *Entamoeba histolytica* on the basis of the migration of isoenzymes. More than 10 different zymodenes (similar group of organisms with different movement of one or

more enzymes on electrophoresis) have already been identified. The cyst is the infective form of the organism and survives in soil, water, sewage and faeces for several days. It is not affected by the routine chlorination of the water but is readily killed if dried, frozen or heated to 55°C or more. The trophozoites do not survive outside human body for long and are not important for the transmission of the disease.

**(b) Reservoir :** Cysts carriers are the main reservoirs of the infection. They discharge up to  $1.5 \times 10^7$  cysts daily. They are most risky when made responsible for handling food.

**(c) Source of Infection :** The source of infection is the food and drink contaminated with human faeces. Contamination of water supplies with raw sewage has been reported to cause epidemics.

##### Host factors

**(a) Age :** Amoebiasis can occur at any age.

**(b) Sex :** Both the sexes are affected equally.

**(c) High Risk Group :** The high risk group includes travellers, migrants, immigrant workers, immunocompromised individuals, prisoners and children in day - care centres. Severe infections occur in very young children, pregnant women, malnourished and people taking corticosteroids. Patients with AIDS do not have an increased risk of severe infection.

**(d) Immunity :** Immunity following an invasive infection with *E. histolytica* is cell mediated type and is protective against a reinfection. The risk of recurrence is increased if the treatment failed to eradicate the pathogenic form from the colon.

**Environmental factors :** Amoebiasis is closely associated with poor hygiene and sanitary conditions and low socio - economic status. Prevalence of the infection is found to be higher in places where human faeces are used as fertilizers.

**Incubation Period and Period of Communicability :** The incubation period is 2 to 4 weeks but may range from few days to several months or years.

Since the infected person may continue to excrete *E. histolytica* cysts for years, the period of communicability could be

prolonged. Asymptotically infected persons tend to excrete a much higher proportion of cysts and hence are more likely to transmit infection than persons who are acutely ill, who tend to excrete trophozoites.

**Mode of Transmission :** The disease transmission takes place by faeco - oral route when food and drink get contaminated with human faeces. Viable cyst under finger nails may be directly transmitted from hand to mouth. Sexual transmission can also take place. Transmission through vectors such as flies and cockroaches is possible.

### Clinical Features

The clinical spectrum of the disease ranges from asymptomatic carriers to acute colitis, to fulminant colitis and to amoebic liver abscess.

The commonest intestinal manifestation of the disease is abdominal discomfort associated with diarrhoea which subsequently turns into dysentery. Lower abdominal pain and tenesmus is common and tenderness is present over caecum and colon. Patient may pass 10 to 12 stools per day. The stools contain little faecal material and consist mainly blood and mucous. Fever is usually absent (fever is common in bacillary dysentery) in amoebiasis.

Fulminant intestinal infection with severe abdominal pain, high fever and profuse diarrhoea is rare. In such cases patient may develop toxic megacolon.

The most common extra - intestinal manifestation of Amoebiasis is amoebic liver abscess which commonly affects the posterior lobe of the liver and presents as right upper quadrant pain associated with hepatomegaly. Fever is common, jaundice rare. The complications include pleuropulmonary involvement, hepatobronchial fistula and rupture in peritoneum or pericardium. Other extra - intestinal manifestations are cerebral and genito - urinary involvement.

### Diagnosis

Diagnosis of amoebic colitis depends upon the demonstration of trophozoites in the stool. ELISA, sigmoidoscopy and colonoscopy are useful in the diagnosis of invasive Amoebiasis. Ultrasound, CAT scan and MRI are useful for the diagnosis of amoebic liver abscess.

### Treatment

Metronidazole is the drug of choice for the treatment of both intestinal Amoebiasis and amoebic liver abscess. It is given in a dose of 750 mg orally or IV three times a day for 5 to 10 days. Tinidazole 2g once a day for 3 days is an alternative to metronidazole. In addition to the above, one of the following luminal amoebicides should be prescribed as an adjunctive treatment, either concurrently or sequentially, to destroy *E. histolytica* in the colon :

- Paromomycin 500mg three times a day for 10 days
- Diloxanide furoate 500mg three times a day for 10 days
- Iodoquinol 650mg three times a day for 20 days

### Prevention

The preventive measures should aim at :

#### (a) Community

**Sanitation :** Safe disposal of human excreta coupled with

elementary sanitation practices like washing of hands with soap and water is the most important measure.

**Water Supply :** Water supplies must be protected from faecal contamination. Sand filters are quite effective in removing amoebic cysts and hence filtration along with close monitoring of water pipe lines to check faecal contamination is useful. Boiling of water at individual levels are more useful than routine chlorination.

**Food Safety :** Measures should be taken to protect food and drink from faecal contamination. Foodhandlers with amoebiasis must be excluded from work and should not be permitted back till one stool specimen is negative. In outbreak circumstances, a second consecutive negative stool specimen will be required prior to returning to work.

**Health Education :** Health education must emphasise the following points;

- Always wash hands thoroughly with soap and water before eating or preparing food, after using the toilet, and after changing diapers.
- After changing diapers, wash the child's hands as well as your own.
- Dispose of faeces in a sanitary manner.
- Avoid sexual practices that may permit fecal - oral transmission.
- Do not eat fruit that already has been peeled or cut.
- Drink only pasteurized milk or dairy products.

**(b) Individual :** Early diagnosis and treatment - All known cases must be adequately treated with metronidazole or suitable alternative. At present no chemoprophylaxis or vaccination is available.

### Giardiasis

Giardiasis is a diarrhoeal illness caused by a protozoan parasite *Giardia lamblia* that commonly inhabits the small intestines of human beings and other mammals. From epidemiological and public health perspective, giardiasis is quite akin to amoebiasis as regards modes of transmission and preventive modalities.

The disease is caused by *Giardia lamblia*, which is a flagellate protozoan parasite of human being. It exists in two forms - the trophozoite which inhabits the duodenum and upper part of jejunum and the cyst which exists outside the host and is the form that transmits the infection. The trophozoite is rounded and broad at the anterior end that tapers to a sharp point at the posterior end. It has a bilaterally symmetrical body with paired organs and four pairs of flagella. The cysts are oval and have four nuclei which may remain clustered at one end or lie in pairs at opposite end. The cysts are resistant to the routine dose of chlorine used for purification of water. It can survive in the environment up to 16 days at a temperature of 8°C.

The disease occurs world - wide. It occurs more commonly in developing countries of Asia, Africa and South & Central America which are poor in resources and where access to clean water and basic sanitation is lacking. The prevalence of giardiasis in such countries varies from 20 to 30% as compared to 2 to 5% in developed countries. It is a disease of young age and nearly all children, especially those of developing countries, do acquire the infection sometime or other during their childhood.

In developed countries, the Giardia infection is associated with ingestion of contaminated water, person - to - person spread, recent foreign travel, and recreational swimming. The infection is common among travellers who travel from developed countries to developing countries. Up to 12% of the traveller's diarrhoea is said to be because of the giardia infection.

Human being, most importantly the asymptomatic carrier, is the main reservoir of Giardia. However, several other mammals like dogs, sheep and cattle are also known to harbour the organism. The source of infection is food and drink contaminated with human faeces.

The preventive modalities are the same as those for amoebiasis. Giardiasis often clears up without treatment. It responds promptly to treatment with metronidazole in a dose of 250 mg orally three times a day.

## Summary

### Amoebiasis

It is an infection caused by a protozoan parasite *Entamoeba histolytica*. It occurs worldwide but the majority of the cases are reported from developing countries. At any one time approximately 10% of the world population is affected by amoebiasis. In India the prevalence ranges from 3.5% to 45% with an average of 15%.

*E. histolytica* exists in humans in two forms - the vegetative trophozoite and the cystic form. On ingestion of the cyst by humans, trophozoites are released which colonize the large bowel mainly ascending colon and caecum. The cyst is the infective form of the organism and survives in soil, water, sewage and faeces for several days. Cyst carriers are the main reservoir of the infection and the source of infection is the food and drink contaminated with human faeces. The high risk group includes travellers, migrants, immigrant workers, immunocompromised individuals, prisoners and children in day - care centres. Severe infection occurs in very young children, pregnant women, malnourished and people taking corticosteroids. It is closely associated with poor hygiene and sanitary conditions and low socio - economic status.

The Incubation period is 2 to 4 weeks but may range from few days to several months or years. Disease transmission mainly takes place through faeco - oral route and sexual transmission or transmission through vectors such as flies may also occur.

Clinical spectrum varies from asymptomatic carriers to acute colitis, to fulminant colitis and to amoebic liver abscess. The commonest intestinal manifestations are abdominal discomfort associated with diarrhoea which subsequently turns into dysentery. Pain and tenesmus are common. The most common extra - intestinal manifestation is amoebic liver abscess which commonly affects the posterior lobe of the liver and presents as right upper quadrant pain with hepatomegaly and fever.

Diagnosis of amoebic colitis depends upon the demonstration of trophozoites in the stool. ELISA, Sigmoidoscopy and colonoscopy are useful in the diagnosis of invasive amoebiasis.

Metronidazole is the drug of choice for the treatment of both intestinal amoebiasis and amoebic liver abscess. Tinidazole is an alternative. In addition one of the luminal amoebicides i.e. Paromomycin or Diloxanide furoate or Iodoquinol should be

prescribed as an adjunct.

Preventive measures should aim at safe disposal of human excreta coupled with elementary sanitation practices, protecting of water supplies from faecal contamination, protection of food and drinks from faecal contamination, stool examination of food handlers and exclusion from work till one stool sample becomes negative, health education and early diagnosis and treatment.

### Giardiasis

It is a diarrhoeal illness caused by a flagellate protozoan parasite *Giardia lamblia*. It exists in two forms - the trophozoite which inhabits the duodenum and the cyst which exists outside the host and is the form that transmits the infection. The disease occurs worldwide but is more common in developing countries where access to clean water and basic sanitation is lacking. The prevalence of Giardiasis in such countries varies from 20 to 30% as compared to 2 to 5% in developed countries. Up to 12% of Traveller's diarrhoea is said to be because of the Giardia infection. Human being, most importantly the asymptomatic carrier, is the main reservoir of Giardia. The source of infection is food and drink contaminated with human faeces. The preventive modalities are the same as those for Amoebiasis. It responds promptly to treatment with Metronidazole.

## Study Questions

**Long Question :** Discuss Amoebiasis in details and its prevention and control measures.

**Short Notes :** (1) Giardiasis (2) Prevention of Amoebiasis (3) Clinical features of Amoebiasis (4) Epidemiological determinants of Amoebiasis

### MCQs

1. In India, the prevalence of Amoebiasis is : (a) 5% (b) 10% (c) 15% (d) 20%
2. The form of *E. histolytica* usually infective to man is (a) Trophozoite (b) Merozoite (c) Egg (d) Cyst
3. Reservoir of infection of *E. histolytica* is : (a) Housefly (b) Man (c) Soil (d) Dog
4. *E. histolytica* trophozoite causes ulceration commonly in (a) Rectum (b) Duodenum (c) Transverse and descending colon (d) Caecum and ascending colon
5. All are true of epidemiology of Amoebiasis except (a) No sex difference (b) Does not affect children (c) More among low socio - economic status (d) Incubation period is 2 - 4 weeks
6. Severe infection of *E. histolytica* occurs in all except (a) Very young children (b) Pregnant women (c) Malnourished individuals (d) Patients with AIDS
7. Drug of choice for Amoebic liver abscess is (a) Metronidazole (b) Tinidazole (c) Diloxanide furoate (d) Iodoquinol
8. Worldwide prevalence of Amoebiasis is (a) 5% (b) 10% (c) 15% (d) 20%
9. In outbreak circumstances the number of consecutive negative stool samples required for food handlers to return back to work is/are : (a) 1 (b) 2 (c) 3 (d) 4
10. The trophozoite of *Giardia lamblia* inhabits : (a) Caecum (b) Rectum (c) Ascending and transverse colon (d) Duodenum and upper jejunum

11. What percentage of Traveller's diarrhoea is due to Giardia infections : (a) 8% (b) 12% (c) 16% (d) 20%

**Answers :** (1) c; (2) d; (3) b; (4) d; (5) b; (6) d; (7) a; (8) b; (9) b; (10) d; (11) b.

### Further Suggested Reading

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## Sexually Transmitted Infections (STI)

Sunil Agrawal

As a general convention, the term Sexually Transmitted diseases has been replaced by Sexually Transmitted Infections (STI) since 1999 as it better incorporates asymptomatic infections. STI are a group of contagious diseases transmitted predominantly by sexual contact and caused by a wide range of bacteria/viruses, protozoa, fungi and ectoparasites. During the past two decades, STDs have undergone a dramatic transformation like, attention is now given not only to specific diseases but also to clinical syndromes associated with STIs. Most of the recently recognised STIs are now referred to as second generation STIs. AIDS is the most recently recognized STI(1). Sexually Transmitted Infections are among the most common causes of illness in the world and have far reaching health, social and economic consequences for many countries. The emergence and spread of HIV infection and AIDS have

had a major impact on the management and control of STIs. At the same time, resistance of several sexually transmitted pathogens to antimicrobial agents has increased, adding to therapeutic problems (2).

### Classification of Sexually Transmitted Infections

This is shown in Table - 1.

#### Magnitude of the Problem

**(a) Global :** True incidence of STI's is not known because of stigma involved but the trend in gonorrhoea and primary syphilis is on the increase. The matter of concern is emergence of antimicrobial resistance agents of STI. Second generation STIs are tending to replace the classical bacterial diseases (syphilis, gonorrhoea, chancroid). Minimal estimates of new cases for major STDs are given in Table - 2 :

On an average 9,00,000 people are believed to be infected each day. WHO estimates that worldwide about 340 million new cases of curable STIs occur annually, a large proportion of them among women in the reproductive age (3). Surveys in family planning and antenatal clinics in developing countries indicate that the prevalences of syphilis, gonorrhoea and chlamydial

**Table - 1 : Classification of STIs**

(a) Bacterial	(b) Viral agents
<ul style="list-style-type: none"> <li>• <i>Neisseria gonorrhoea</i> (Gonorrhoea)</li> <li>• <i>Chlamydia trachomatis</i> (Lympho granuloma Venereum, LGV)</li> <li>• <i>Treponema pallidum</i> (Syphilis)</li> <li>• <i>Haemophilus ducreyi</i> (Chancroid)</li> <li>• <i>Mycoplasma hominis</i></li> <li>• <i>Ureaplasma urealyticum</i></li> <li>• <i>Calymmatobacterium granulomatis</i> (Granuloma Inguinale, Donovanosis)</li> <li>• Shigella</li> <li>• Campylobacter</li> <li>• Group B Streptococcus</li> <li>• Bacterial vaginosis related Organism</li> </ul>	<ul style="list-style-type: none"> <li>• Human (alpha) herpes virus 1 and 2</li> <li>• Human (beta) herpes virus 5</li> <li>• Hepatitis virus B</li> <li>• Human papilloma virus (genital warts)</li> <li>• <i>Molluscum contagiosum</i></li> <li>• HIV</li> </ul>
	(c) Protozoal agents
	<ul style="list-style-type: none"> <li>• <i>Entamoeba histolytica</i></li> <li>• <i>Giardia lamblia</i></li> <li>• <i>Trichomonas vaginalis</i></li> </ul>
(d) Ectoparasites	(e) Fungal agents
<ul style="list-style-type: none"> <li>• <i>Sarcoptes scabiei</i></li> <li>• <i>Phthirus pubis</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Candida albicans</i></li> </ul>



infections range between 6% and 40%. In many countries, STIs are among the top five conditions for which both men and women seek care, representing a considerable drain on health services. Although infection rates are similar in both men and women, the burden of serious consequences of STIs falls mostly on women and their infants.

Table - 2 : Major STDs	
Gonorrhoea	62 million/yr
Genital chlamydial infection	92 million/yr
Syphilis	12 million/yr
Chancroid	07 million/yr
Genital herpes	20 million/yr
Genital human papilloma infection	30 million/yr

**(b) India :** In India the yearly incidence of STI's is 4 - 5% which accounts for 40 million cases per year.

**(i) Syphilis :** Prevalence of 1.4 - 2.4% has been reported in serological surveys. The total number of cases due to Syphilis in 2007 was 47,718 with maximum cases coming from Andhra Pradesh, Karnataka, Maharashtra, Madhya Pradesh, Chattisgarh and Gujarat. The cases are almost equally distributed amongst males (24,181) and females (23,235) (4).

**(ii) Gonorrhoea :** More widely prevalent than syphilis. The total number of cases due to Gonococcal Infection in 2007 was 1,53,050 with maximum cases coming from Andhra Pradesh, Uttar Pradesh, Madhya Pradesh, Karnataka, Maharashtra, Assam, Jammu and Kashmir and Chattisgarh. There are more cases in females (99,699) than males (51,311).

**(iii) Chancroid :** Widely prevalent in India.

**(iv) LGV :** It is more prevalent in southern states of Tamil Nadu, AP, Maharashtra and Karnataka than in northern states. Greater prevalence in coastal areas is found.

Table - 3 : Vulnerable Groups for STI
Commercial Sex Workers (earlier known as prostitutes) - female and male
Identifiable groups of clients of prostitutes, such as : <ul style="list-style-type: none"> <li>Persons staying away from families due to compulsions of occupation;</li> <li>Long - distance truck drivers;</li> <li>Tourists/businessmen;</li> <li>Migrant workers, refugees, displaced persons;</li> <li>Single men in urban settings.</li> </ul>
Men who have sex with men, such as : <ul style="list-style-type: none"> <li>Self - identifying homosexual men;</li> <li>Bisexual and covert homosexual men.</li> </ul>
Substance users, e.g. injecting drug users and their sexual partners (particularly of importance where there is a high HIV level amongst injecting drug users and/or where prostitution is used to support a drug habit).
Prisoners, especially where juveniles are mixed with long - stay inmates.
Young people (age 10 - 24 years), especially when out of school and unemployed (e.g. street children). WHO has defined adolescents as persons in the 10 - 19 years age gp, Youth as the 15 - 24 years age gp and Young People as combination of these two overlapping groups covering the range 10 - 24 years.

## Vulnerable Groups for STIs

This is shown in Table - 3

## Syphilis

Syphilis is a systemic disease from the outset and is caused by the spirochaete, *Treponema pallidum* (*T. pallidum*). The organism is 6 to 15 microns in length to 0.15 micron wide. The incubation period has a mean of 21 days with extremes of 10 to 90 days.

**Mode of Transmission :** Syphilis is usually acquired by sexual contact. Infants acquire congenital infection by transplacental transmission of *T. pallidum*.

## Stages of Syphilis

Both congenital and acquired syphilis are divided into early and late stages. Early stage is one which is diagnosed within two years of infection, while the one which is diagnosed after two years is late syphilis. Early acquired syphilis is further subdivided into an incubation period, primary, secondary and early latent stages. Late syphilis includes the late latent stage, late benign stage (stage of gummas), and stages of cardiovascular & neurosyphilis.

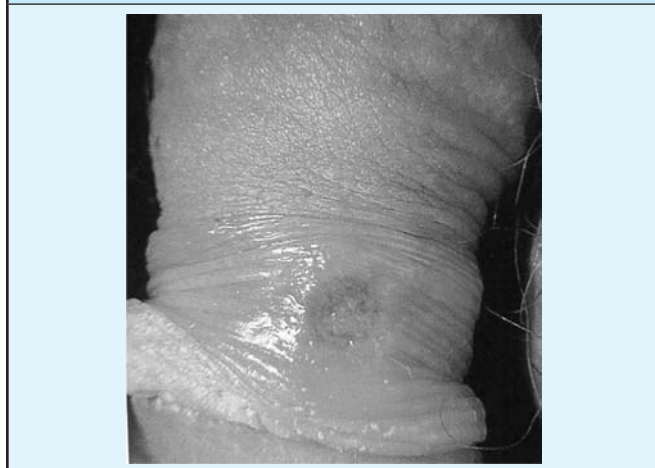
**Primary Syphilis :** The first clinical manifestation is usually a local lesion at the site of entry. The lesion starts as dull red macule, which rapidly becomes papular and then ulcerate. A small, clean, painless, hard ulcer (Hunterian chancre) appears on the site (See Fig. - 1). The early chancre has a clear red base, but later covers with a gray slough. Untreated, a chancre will persist for 3 to 6 wks and then heal. Regional lymphadenopathy develops within a week and the nodes are painless, nontender, small to moderate in size, rubbery and nonsuppurative.

**Secondary Syphilis :** *T. pallidum* disseminate widely throughout the body. After 3 - 6 weeks, the disease is seen to be systemic. The more common symptoms include sore throat, malaise, headache, weight loss, fever, musculoskeletal pains. A rash of early secondary stage appears on the back, chest, abdomen, arms and thighs, and also on the mucous patches in the mouth. Rash characteristically includes the palms and the soles. Rashes can be of follicular, annular or papular type. Papular rashes may become large and raised and may resemble viral warts, but they are characteristically broad and flat so called *Condylomata lata*. Generalised lymphadenopathy is common with moderately enlarged nodes rubbery, discrete and nontender. Even the rash may subside with a little treatment but infective relapses occur with varying intervals of latent periods.

**Latent Syphilis :** Latent syphilis has no clinical manifestations of treponemal infection. Early latent syphilis is infection of less than two years whereas infection of more than two years is referred as late latent

syphilis. Involvement of other systems occurs in 10 percent of cases or less. After 3 to 4 years, the benign manifestations as gumma in bones, deeper parts of the skin, muscles or liver make their appearance. After about 5 - 10 years or upto even 20 years the vital organs like the brain, heart, nerves and big arteries are affected and the severe signs of cardiovascular and neuro - syphilis may appear. The predominant features of cardiac syphilis are aortic regurgitation, aortic aneurysm, arrhythmias and angina. The neurosyphilis can present in a variety of ways meningovascular syphilis, tabes dorsalis and general paresis (8).

**Fig. - 1 : Syphilitic Ulcer**



### Congenital Syphilis

If the infection is transmitted from mother to child in utero then it is called as congenital syphilis. Prevention of congenital syphilis is feasible by effective screening in pregnant women. Screening for syphilis should be conducted at the first prenatal visit. If the expectant mother has syphilis then giving penicillin during pregnancy can prevent transmission to child. All infants born to seropositive mother should be treated with a single dose of Benzathine benzylpenicillin, 50,000 IU/Kg given I.M. whether or not the mothers were treated during pregnancy (with or without penicillin). Such infants should be examined at birth, at monthly interval for 3 months.

### Syphilis and HIV Infection

All patients with syphilis should be encouraged to undergo HIV testing because of high frequency of dual infection and its implication for clinical assessment and management. Conventional syphilis treatment often fails in HIV infected patients. Moreover HIV patients demonstrate accelerated progression to early neuro syphilis. As a result of AIDS epidemic neurosyphilis is becoming more common in young adults. In case of congenital syphilis, the mother should be encouraged to undergo HIV testing. Recommended therapy for early syphilis in HIV infected patients is no different; however, careful follow up is necessary to ensure adequacy of treatment.

### Diagnosis

The diagnosis of the primary hard chancre is confirmed by finding of *T. pallidum* on the dark - ground examination of the

discharge from the ulcer. In the late primary or further stages and in congenital infection it is confirmed by the WR, Kahn or VDRL reaction. Skin biopsy may be quiet helpful. Other tests are FTA - ABS (Fluorescent Antibody Absorption Test, MHA - TP (Microhaemagglutination Assay for Antibodies to *T. pallidum*) and HATTS (Haemagglutination Treponemal Test for Syphilis).

### Treatment

#### (a) Early Syphilis

**In HIV Negative patients :** Benzathine Penicillin 2.4 million IU IM after test dose divided half in each buttock, at a single session or Procaine Penicillin 1.2 million IU IM OD after test dose for 10 days.

**In HIV Positive patients :** Procaine Penicillin 2.4 million IU IM OD after test dose for 14 days or Crystalline Penicillin 30 lac QID IV for 10 days after test dose.

**Penicillin allergic non pregnant patients :** Doxycycline 100 mg orally, twice daily for 14 days or Tetracycline, 500 mg orally, 4 times daily for 14 days.

**Penicillin allergic pregnant patients :** Erythromycin, 500 mg orally, 4 times daily for 14 days.

#### (b) Late Syphilis

**In HIV Negative patients :** Benzathine Penicillin 2.4 million IU IM after test dose divided half in each buttock, once weekly for 3 consecutive weeks or Procaine Penicillin 1.2 million IU IM OD after test dose for 14 - 21days.

**In HIV Positive patients :** Procaine Penicillin 2.4 million IU IM OD after test dose for 14 days or Crystalline Penicillin 20 - 40 lac IU 4 hrly IV for 14 days after test dose.

**Penicillin allergic non pregnant patients :** Doxycycline 100 mg orally, twice daily for 30 days or Tetracycline, 500 mg orally, 4 times daily for 30 days.

**Penicillin allergic pregnant patients :** Erythromycin, 500 mg orally, 4 times daily for 30 days.

#### (c) Neurosyphilis

**Recommended regimen :** Crystalline Penicillin 12 - 24 million IU IV after test dose administered daily in doses of 2 - 4 million IU IV, every 4 hrs for 14 days.

**Alternative regimen :** Procaine Penicillin 1.2 million IU IM OD after test dose and probenecid, 500 mg orally, 4 times daily, both for 10 - 14 days.

**Penicillin allergic non pregnant patients :** Doxycycline 200 mg orally, twice daily for 30 days or Tetracycline, 500 mg orally, 4 times daily for 30 days.

### Surveillance

Post hospital surveillance must be carried out to ensure radical cure. All clinics should maintain a STD register. The clinic should ensure that the person reports on due dates to MO who should carry out the treatment or send him to hospital whichever is indicated. The examination and treatment of his wife and, if necessary, of the children should also be arranged.

### Gonorrhoea

This is the commonest cause of urethritis in India. Gonorrhoea is caused by *Neisseria gonorrhoeae*, a Gram - negative intracellular diplococcus. In women, the cervix is the most

common site of infection. However, the disease can also spread to the uterus and fallopian tubes, causing pelvic inflammatory disease leading to infertility. Gonorrhoea is most commonly spread during genital contact, but can also be passed from the genitals of one partner to the throat of the other during oral sex. Gonorrhoea of the rectum can occur in people who practice anal intercourse. In pregnant women, gonorrhoea can be passed from an infected woman to her newborn infant during delivery if left untreated.

Although transmission from males to females is easier, in females the infection is often mild, and many women who are infected have no apparent symptoms of the disease. Most patients who report are males only. If symptoms of gonorrhoea develop, they usually appear within 2 to 10 days after sexual contact with an infected partner, although a small percentage of patients may be infected for several months without showing symptoms.

Men are more likely to show symptoms than women. The symptoms in men include burning sensation during urination and yellowish - white discharge from the penis that usually stains the undergarments. The symptoms in women include Painful, Burning sensation when urinating, Yellowish or bloody discharge from the vagina, Bleeding between periods, and Abdominal pain. The complications of Gonorrhoea in males include posterior urethritis, urethral stricture, cystitis, prostatitis, seminal vesiculitis, epididymo - orchitis and urethral fistulae (Watercan Perineum). In females, pelvic inflammatory disease, salpingitis with resultant infertility or ectopic pregnancy are important complications.

Diagnosis is made through detection of bacteria in samples taken from the urethra, cervix, throat or rectum. It is generally more cost effective to treat presumptive chlamydial infection also in all persons with gonorrhoea. The treatment includes single dose Ceftriaxone 125 mg IM or Cefixime 400 mg orally or Ciprofloxacin 500 mg orally or Ofloxacin 400 mg orally along with Doxycycline 100 mg orally twice a day for 7 days.

### Granuloma Inguinale (Donovanosis)

Donovanosis is caused by the intracellular Gram Negative bacterium *Klebsiella granulomatis*. The disease present clinically as painless, progressive, ulcerative lesions without regional lymphadenopathy. The lesions are highly vascular and can easily bleed on contact.

Recommended regimen is Azithromycin, 1 gm orally on first day, then 500 mg orally, once a day or Doxycycline, 100 mg orally, twice daily.

### Chlamydia

Chlamydia is one of the most common and fastest spreading sexually transmitted disease. It stems from a bacterium, *Chlamydia trachomatis*. Women diagnosed with Chlamydia can also infect their newborn infant during delivery. Symptoms usually appear approximately 7 to 21 days after infection and differ for men, women and children. In men, these are Inflammation of the urethra (the bladder duct within the penis), Stinging feeling when passing urine, Clear discharge from penis and possible itchiness around the opening, Pain or tenderness in the testicles. The usual symptoms in women are Stinging

feeling when passing urine, Unusual vaginal discharge, Pain caused by pelvic inflammation (PID), Pain during intercourse, and, in some cases, bleeding between periods. Among new borns of infected mothers, conjunctivitis is an important occurrence. Treatment consists of antibiotics, and should also be given to the patient's partner. A further swab is recommended once treatment has ended to check whether the infection has cleared. The recommended regimens are : Doxycycline 100 mg orally 2 times a day for 7 days or Azithromycin 1 gm orally, once.

### Chancroid

Chancroid is a sexually transmitted ulcerative disease often associated with an inguinal bubo. The infection is common in several parts of the world including Africa, the Caribbean and South East Asia. The causal organism of chancroid is a Gram negative bacillus, *Haemophilus ducreyi*. The incubation period ranges between 3 to 10 days. Men usually present with ulcerative lesion or inguinal tenderness. The chancre begins with tender papule surrounded by erythema and within 2 to 3 days after the infection, sloughing ulcer appears on the penis and goes on increasing until it affects a large portion of the penis. Women often present with less obvious symptoms including pain in voiding, pain on defecation, rectal bleeding, dyspareunia or vaginal discharge. Most lesions in males are on either the external or internal surface of the prepuce, on the frenulum, or in the coronal sulcus. In females, most lesions are at the entrance to the vagina and include lesions on the fourchette, labia, vestibule and clitoris. Diagnosis of chancroid depends on the isolation of *H. ducreyi* from a genital ulcer or bubo. Direct examination by a gram stain reveals gram -ve organisms.

The patients of chancroid who are HIV positive are more likely to have treatment failure. If both pathogens are present they act synergistically with increased infectivity, susceptibility and failure to respond to treatment. Chancroid is one of the major reason for the rapid heterosexual spread of HIV - 1 in eastern and southern Africa. The recommended treatment regimen are Ciprofloxacin, 500 mg orally, twice daily for 3 days; Or, Erythromycin, 500 mg orally, 4 times daily for 7 days; Or Azithromycin, 1 gm orally, as a single dose.

### Trichomonas Vaginalis

The flagellate protozoan *T vaginalis*, is almost exclusively sexually transmitted in adults (10). The vaginal discharge is offensive alongwith vulval itching in women and urethritis in man. The infection may be asymptomatic also. Recommended regimens are Metronidazole, 2 g orally, in a single dose or Tinidazole, 2 g orally, in a single dose.

### Prevention and Control of STIs

Professional, commercialized and, to some extent, amateur female prostitution provides opportunity for male promiscuity. Various chains and combinations of complex social, economic behavioural, environmental, and other intrinsic and extrinsic factors are at the root of this social evil. Economic distress, lack of security in childhood and adolescence, disharmony in married life, social persecution of or an apathy for abandoned, abducted, waylaid, 'fallen' or forlorn women and failure to rescue and rehabilitate them are some of the important causes



which lead women to take refuge in prostitution. Adolescent delinquency is the next important cause. The aim of the control programme is to prevent infections and the ill health resulting from the above conditions through various interventions. Some studies have demonstrated that STD treatment is an important prevention strategy in HIV infection in a general population. The main aims of STD control are :

- To interrupt the transmission of sexually acquired infections;
- To prevent the development of diseases, complications and sequelae;
- To reduce the risk of HIV infection.

These objectives can be achieved by programmes through primary prevention directed at reducing the incidence of disease, and through secondary prevention directed at reducing prevalence by shortening the duration of disease, thus minimizing the probability of complications or sequelae. The determinants of STD epidemiology are as multifaceted as the approaches to prevention and care should be (11).

### Primary prevention

Primary prevention activities will be the responsibility of integrated or coordinated AIDS/STD programmes. In primary prevention the aim is to prevent the acquisition of infection and disease. This can be done by promoting :

- Safer sexual behaviour;
- The use of condoms for penetrative sexual acts.

**Health education (HE)** : Education should be carried out through lectures, multimedia, flip charts, group or individual discussions and articles in the periodicals/journals/newspapers read by general population. Most of the prevention messages will apply to both HIV and conventional STDs but the educational messages which specifically relate to STDs will include :

- Though not necessarily practical or desirable, abstinence is the only way to completely prevent STIs.
- Avoid sex with many different partners. The less sexual partners a person has, the lower the risk of infection.
- Sexually transmitted diseases can be avoided to a large extent by practicing safe sex (e.g. using condoms).
- Information that symptoms and signs may not be noticed, particularly in women, until complications appear.
- Description of recognizable signs and symptoms.
- A list of places where STD advice may be obtained (i.e. basic health care services) and, where available, categorical STD clinics and voluntary counselling centres.
- Assurance that wherever services are obtained in the public sector privacy, confidentiality and respect are guaranteed.
- Advice on assessing one's personal risk of having acquired an STD, and also that of sexual partner(s). (If the assessment suggests a possibility of STD, attendance for STD advice is indicated).

In order to provide realistic, acceptable and culturally appropriate STD messages it is important to appreciate the knowledge, attitudes and practices of the audience. Simple research will be needed to obtain information from communities including :

- Knowledge and perceptions of the importance of STDs.
- Health care seeking behaviour.
- Constraints to seeking STD care.

### Secondary prevention

Secondary prevention entails the provision of treatment and care for infected and affected persons. The activities should include :

- Promotion of health care seeking behaviour directed not only at those with symptoms of STDs, but also at those at increased risk of acquiring STDs, including HIV infection.
- The provision of clinical services that are accessible, acceptable and effective, and which offer diagnosis and effective treatment for both symptomatic and asymptomatic patients with STDs, and their partners.
- Support and counselling services for both STD and HIV patients.

### Early Detection & Treatment

#### Intervention Strategies

**1. Case Detection** : It is an essential part of any control programme. The usual methods of early case detection are :

- a) Screening* : Screening of special high risk or vulnerable groups is done for early detection of disease.
- b) Contact Tracing* : The sexual partners of diagnosed patients are identified, located, investigated and treated.
- c) Cluster Testing* : The patients are asked to name other persons of either sex who move in the same socio - sexual environment.

**2. Effective STD care** : Adequate treatment of patients and their contacts is the mainstay of STD control. Holding patient to ensure complete and adequate treatment is key to effective management. The STI care, should aim to provide the comprehensive case management that includes diagnosis, curative treatment, reduction of risk - taking behaviour and the treatment of sexual partners. The objective of case management of patients with STIs is :

- To make a correct diagnosis;
- To provide effective treatment;
- To reduce/prevent future risk - taking behaviour;
- To advise on treatment compliance;
- To promote and provide condoms;
- To ensure sexual partners are notified and appropriately treated.

**3. Syndromic Management of STI** : Many STIs can be identified and treated on the basis of characteristic symptoms and signs. Some examples of common syndromes are upper respiratory infection, gastroenteritis and vaginal discharge, etc. It is often difficult to know exactly what organism is causing the syndrome, and treatment may need to cover several possible infections. Syndromic management refers to the approach of treating STI symptoms and signs based on the organisms most commonly responsible for such syndrome. Many health care facilities in developing countries lack the equipment and trained personnel required for etiological diagnosis of STIs. More so, laboratory tests require resources, add to the cost of treatment, may require clients to make extra visits to the clinic and almost always result in delays in treatment.

For these reasons, syndromic management guidelines are widely used for syndromes such as lower abdominal pain, urethral discharge and genital ulcer (5), even in developed countries



with advanced laboratory facilities. Comparison of traditional, laboratory assisted approach and syndromic approach is given in Table - 4 . Syndromes of women and men are given in Table 5 & 6 respectively. STD management kits under National AIDS Control Program III are given in Table - 7.

**4. Notification of sexual partners :** Breaking the cycle of infection is a critical part of STI prevention, and so the client should be encouraged to refer his or her partner(s) for treatment, even when no clinical signs of infection are evident. This is known as '*contact tracing*' and providers should advise clients to notify their partners (including those without symptoms) of their exposure and encourage them to seek treatment. These actions should be carried out with sensitivity and consideration of social and cultural factors to avoid ethical and practical problems such as rejection and violence, particularly against women. Partner notification should be conducted in such a way that all information remains confidential. The process should be voluntary and non coercive. WHO recommends two approaches to contacting sexual partners.

**Patient referral :** In this option the patient is given the responsibility, after adequate health education and counselling, to contact sexual partners and ask them to present for treatment.

**Provider referral :** This is the situation where the patient is asked to provide the names and addresses of the partners to the health worker so that members of the health staff can contact the partners. It is a costly exercise and will usually not be successful if it is perceived to threaten patient confidentiality.

## Support Components

**1. Access to services :** The provision of accessible, acceptable and effective services is important for the control of STIs. A balanced and comprehensive programme may require strengthening of public sector, the private sector and the informal sector who are providing STI services. It is recommended that routine STI services be integrated into primary health care. Specialized clinics in urban settings are useful for specific groups such as sex workers and their clients, migrant workers, truckers etc.

**2. Training of Health Care Providers :** Activities may include:

- On - the - job training;
- Training within basic courses;
- Post - basic courses utilizing venereology expertise concentrated in those specialized clinics selected as referral/reference centres;
- Training of trainers so that the health workers are encouraged to train their colleagues ("cascade" principle);
- Distribution of national guidelines in a form that can be understood and used without special additional training.

**3. Healthy Diversions :** Provide alternative healthy diversions, incentives and facilities for education and betterment in careers and providing a healthy psychological atmosphere for a tranquil life. Excellent facilities should be provided for indoor and outdoor recreation, organized games, educational and recreational outings, amateur dramas and concerts. The leaders, managers and officers should themselves set an example by always maintaining a high moral and ethical standard.

**Table-4: Management of Sexually Transmitted Infections**

Traditional clinical approach	Laboratory - assisted approach	Syndromic approach
Interviews patient for symptoms	Interviews patient for symptoms	Interviews patient for symptoms (Picks the relevant flowchart)
Does a clinical examination	Does a clinical examination	Does a clinical examination for finding signs; Uses flowcharts as tools
Uses clinical experience to identify symptoms and signs of a specific STI	Collects samples for testing/refers to laboratory for tests	Syndrome identification
Treats for the specific STI	Treats for STIs identified by the results of the laboratory test	Treats patients for the most common organisms responsible for that syndrome (usually 2-3 STIs)
Educates patients for compliance and prevention, promotes condoms and emphasises the importance of partner management	Educates patients for compliance and prevention, promotes condoms and emphasises the importance of partner management	Educates patients for compliance and prevention, promotes condoms and emphasises the importance of partner management

**Table - 5 : RTI/STI syndromes for Women**

Symptoms	Syndromes	RTIs/STIs
Vaginal discharge	Vaginal discharge syndrome	Gonorrhoea, Chlamydia, Trichomoniasis, Herpes Simplex Candidiasis, Bacterial Vaginosis Cervicitis
Lower abdominal pain	Lower abdominal pain syndrome	Gonorrhoea, Chlamydia, Mycoplasma Gardnerella, Anaerobic Bacteria (Bacteroids, e.g gram positive cocci)
Genital Ulcers	Genital ulcer syndrome	Syphilis, Chancroid, Genital Herpes, Genital Warts, Molluscum Contagiosum, Pediculosis Pubis, Scabies

**Table - 6: RTI/STI syndromes of Men**

Symptoms	Syndromes	RTIs/STIs
Urethral Discharge	Urethral/Vaginal discharge syndrome	Gonorrhoea, Chlamydia, Trichomonas
Genital ulcers	Genital ulcer syndrome	Chancroid, Syphilis, Genital Herpes
Inguinal bubos	Inguinal buno syndrome	Lymphogranuloma venereum, Chancroid
Scrotal swelling	Painful Scrotal Swelling	Gonorrhoea, Chlamydia
Genital skin conditions	Genital skin conditions	Genital Warts, Molluscum Contagiosum, Pediculosis Pubis, Scabies

**Table - 7 : STD management kits under NACP III**

Kit No.	Syndrome	Colour	Contents
1.	Urethral discharge, Anorectal discharge, Cervicitis	Grey	Tab Azithromycin 1 g (1) and Tab cefixime 400 mg (1)
2.	Vaginitis	Green	Tab Secnidazole 2 g (1) and Tab Fluconazole 150 mg (1)
3.	Genital Ulcer Disease	White	Inj. Benzathaine Penicillin 2.4 MU (1) and Tab Azithromycin 1g a disposable syringe 10 ml with 21 gauge needle (1) and sterile water 10 ml (1)
4.	Genital Ulcer disease	Blue	Tab Doxycycline 100 mg (30) and Tab Azithromycin 1g (1)
5.	Genital Ulcer Disease	Red	Tab Acyclovir 400 mg (21)
6.	Lower Abdominal pain	Yellow	Tab Cefixime 400 mg (1) Tab Metronidazole 400 mg (28) Cap Doxycycline 100 mg (28)
7.	Inguinal Bubo	Black	Tab Doxycycline 100 mg (42) and Tab Azithromycin 1g (1)

## Summary

Sexually Transmitted Diseases have been replaced by Sexually Transmitted Infections since 1999. STIs are a group of contagious diseases transmitted predominantly by sexual contact and caused by a wide range of bacteria / viruses, protozoa, fungi and ectoparasites. Classification of sexually transmitted infections is based on their etiological agents. True incidence of STI's is not known because of stigma involved. The matter of concern is emergence of antimicrobial resistant agents of STI. Second generation STIs are tending to replace the classical bacterial diseases (syphilis, gonorrhoea, chancroid). Surveys in family planning and antenatal clinics in developing countries indicate that the prevalence of syphilis, gonorrhoea and chlamydial infections range between 6% and 40%. In India the yearly incidence of STI's is 4 - 5% which accounts for 40 million cases per year. Infection rates are similar in both men and women; the burden of serious consequences of STIs falls mostly on women and their infants. The Vulnerable groups for STIs are : Commercial Sex Workers, Identifiable groups of clients of prostitutes, Men who have sex with men, Substance users, Prisoners & Young people. Important STIs are as follows:

SYPHILIS caused by the spirochaete, *Treponema pallidum*, incubation period has a mean of 21 days with extremes of 10 to 90 days. Both congenital and acquired syphilis are divided into early and late stages. Early stage is one which is diagnosed within two years of infection, while the one which is diagnosed after two years is late syphilis. Early acquired syphilis is further subdivided into an incubation period, primary, secondary

and early latent stages. Late syphilis includes the late latent stage, late benign stage (stage of gummas), and stages of cardiovascular & neurosyphilis. Diagnosis of the primary hard chancre is confirmed by finding of *T. pallidum* on the dark - ground examination of the discharge from the ulcer. In the late primary or further stages and in congenital infection it is confirmed by the WR, Kahn or VDRL reaction, Skin biopsy, FTA - ABS (Fluorescent antibody absorption test, MHA - TP (Microhaemagglutination assay for antibodies to *T. pallidum*) and HATTs (Haemagglutination Treponemal Test for Syphilis). Penicillin is the mainstay of treatment.

GONORRHOEA is the commonest cause of urethritis in India and caused by *Neisseria gonorrhoeae*, a Gram - negative intracellular diplococcus. In women, the cervix is the most common site of infection. If symptoms of gonorrhoea develop, they usually appear within 2 to 10 days after sexual contact with an infected partner. Men are more likely to show symptoms than women. The symptoms in men include burning sensation during urination and yellowish - white discharge from the penis that usually stains the undergarments. The symptoms in women include painful, burning sensation when urinating, yellowish or bloody discharge from the vagina. Diagnosis is made through detection of bacteria in samples taken from the urethra, cervix, throat or rectum. The treatment includes single dose Ceftriaxone 125 mg IM or Cefixime 400 mg orally or Ciprofloxacin 500 mg orally or Ofloxacin 400 mg orally along with Doxycycline 100 mg orally twice a day for 7 days.

DONOVANOSIS is caused by the intracellular Gram Negative

bacterium *Klebsiella granulomatis*. The disease present clinically as painless, progressive, ulcerative lesions without regional lymphadenopathy. The lesions are highly vascular and can easily bleed on contact. Recommended regimen is Azithromycin, 1 gm orally on first day, then 500 mg orally, once a day or Doxycycline, 100 mg orally, twice daily.

CHLAMYDIA is one of the most common and fastest spreading sexually transmitted disease. Symptoms usually appear approximately 7 to 21 days after infection and differ for men, women and children. In men, these are inflammation of the urethra, tingling feeling when passing urine, clear discharge from penis and possible itchiness around the opening, pain or tenderness in the testicles. The usual symptoms in women are stinging feeling when passing urine, unusual vaginal discharge, pain caused by pelvic inflammation (PID), Pain during intercourse, and, in some cases, bleeding between periods. Treatment consists of antibiotics, and should also be given to the patient's partner. A further swab is recommended once treatment has ended to check whether the infection has cleared. The recommended regimens are : Doxycycline 100 mg orally 2 times a day for 7 days or Azithromycin 1 gm orally, once.

CHANCROID is a sexually transmitted ulcerative disease often associated with an inguinal bubo. The causal organism is a Gram negative bacillus, *Haemophilus ducreyi*. The incubation period ranges between 3 to 10 days. Men usually present with ulcerative lesion or inguinal tenderness. Women often present with pain in voiding, pain on defecation, rectal bleeding, dyspareunia or vaginal discharge. Diagnosis of chancroid depends on the isolation of *H. ducreyi* from a genital ulcer or bubo. Direct examination by a gram stain reveals gm - ve organisms. The recommended treatment regimen are Ciprofloxacin, 500 mg orally, twice daily for 3 days; Or, Erythromycin, 500 mg orally, 4 times daily for 7 days; Or Azithromycin, 1 gm orally, as a single dose.

TRICHOMONAS is caused by the flagellate protozoan *T. vaginalis*, is almost exclusively sexually transmitted in adults. The vaginal discharge is offensive along with vulval itching in women and urethritis in man. The infection may be asymptomatic also. Recommended regimens are Metronidazole, 2 g orally, in a single dose or Tinidazole, 2 g orally, in a single dose.

**Prevention and Control of STIs :** The main aims of STD control are: To interrupt the transmission of sexually acquired infections; to prevent the development of diseases, complications and sequelae; to reduce the risk of HIV infection.

These objectives can be achieved by programmes through primary prevention directed at reducing the incidence of disease, safer sexual behaviour by using condoms for penetrative sexual acts & IEC and through secondary prevention directed at reducing prevalence by shortening the duration of disease, thus minimizing the probability of complications or sequelae through the provision of clinical services that are accessible, acceptable and effective, and which offer diagnosis and effective treatment for both symptomatic and asymptomatic patients with STDs, and their partners & support and counselling services for both STD and HIV patients.

**Syndromic Management of STI** - refers to the approach of treating STI symptoms and signs based on the organisms most commonly responsible for such syndrome. Many health care facilities in developing countries lack the equipment and trained personnel required for etiological diagnosis of STIs. More so, laboratory tests require resources, add to the cost of treatment, may require clients to make extra visits to the clinic and almost always result in delays in treatment. For these reasons, syndromic management guidelines are widely used for syndromes such as lower abdominal pain, urethral discharge and genital ulcer, even in developed countries with advanced laboratory facilities. WHO has developed simple flowcharts to guide health care providers in using the syndromic approach to manage STIs.

**Notification of sexual partners :** Breaking the cycle of infection is a critical part of STI prevention, and so the client should be encouraged to refer his or her partner(s) for treatment, even when no clinical signs of infection are evident. This is known as 'contact tracing' and providers should advise clients to notify their partners (including those without symptoms) of their exposure and encourage them to seek treatment.

## Study Exercises

**Long Question :** Discuss the epidemiology of STIs and methods of prevention and control of STIs.

**Short Notes :** (1) Syndromic management of STIs (2) Health education in STIs (3) Prevention and control of STIs

### MCQs

1. Main aims of STD control are : (a) To interrupt the transmission of sexually acquired infections; (b) To prevent the development of diseases, complications and sequelae (c) To reduce the risk of HIV infection; (d) All
2. Vulnerable groups for STIs are all except (a) Commercial Sex Workers (b) Men who have sex with men, (c) Couples in monogamous relationship (d) Substance users, Prisoners & Young people
3. Health education for STIs should include educational messages viz : (a) Avoid sex with many different partners (b) Description of treatment for different syndromes (c) Description of recognizable signs and symptoms (d) Advice on assessing one's personal risk of having acquired an STD.
4. The usual methods of early case detection is/ are : (a) Screening (b) Contact Tracing (c) Cluster Testing (d) All .
5. Objective of case management of patients with STIs is/ are : (a) To make a correct diagnosis (b) To provide costly treatment (c) To reduce/prevent future risk - taking behaviour (d) To advise on treatment compliance.
6. Presence of Vaginal discharge in syndromic management could be presentation of : (a) Chlamydia, (b) gonorrhea, (c) bacterial vaginosis infection, (d) all
7. All of the following are STIs except; (a) Ureaplasma urealyticum (b) Shigella (c) Candida albicans (d) Staphylococcus.

### True or False

1. Regional lymphadenopathy is common with moderately enlarged nodes rubbery, discrete and non - tender in secondary syphilis. T / F
2. In India the yearly incidence of STI's is 10 % which accounts for 40 million cases per year. T/ F
3. Characteristic lesion of secondary syphilis is condyloma lata. T / F
4. Patients of chancroid who are HIV positive are more likely to have treatment failure T/ F
5. Chancroid is one of major reasons for the rapid heterosexual spread of HIV - 1 in eastern & southern Africa T/ F
6. For Neurosyphilis, recommended regimen is crystalline Penicillin 12 - 24 million IU IV after test dose administered daily in doses of 2 - 4 million IU IV, every 4 hrs for 14 days. T/F

**Answers : MCQs :** (1) d; (2) c; (3) b; (4) d; (5) b; (6) d; (7) d;

**True or False :** (1) F; (2) F; (3) T; (4) T; (5) T; (6) T

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### Further Suggested Reading

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## Yaws : The Story of Successful Elimination

Sunil Agrawal

Yaws is a nonvenereal endemic treponematoses caused by the bacterium *Treponema pallidum*, subspecies *pertenue*, a Gram-negative spirochete. Infection is transmitted by skin-to-skin contact among people with poor hygiene practices living in certain warm and humid tropical areas of Africa, the Americas and Asia. Children aged 2 - 5 years are the most vulnerable to infection, which targets the skin, bones and cartilage, causing destruction of tissue and deformities in the late stages. It is characterised by a primary skin lesion (mother yaw) followed by a generalised eruption and late stage of destructive lesions of the skin and bones. Although highly amenable to eradication epidemiologically (humans are the only reservoir of infection, and the disease is localized to a few endemic areas), technologically (curable by a single injection of penicillin) and in terms of cost effectiveness, the disease has not attracted global attention. Yaws is also known as Pian, Bubas or Framboesia.

Reports suggest that yaws was non-existent in India until 1887, when cases were first noticed among tea plantation labourers in Assam. It later spread to a geographically contiguous and predominantly tribal area in central India.

### Epidemiology

**Agent Factors :** Yaws is caused by *T. pertenue* which measures 20 microns in length and found in the epidermis, lymph glands, spleen and bone marrow. The organism rapidly dies outside the tissues. Man is the only known reservoir of infection which is an infected person. The source of infection is usually the skin lesions and the exudates from early lesions. A case can remain infectious for several years intermittently as moist lesions break out.

**Host Factors :** Yaws is primarily a disease of childhood and adolescence with greater prevalence in males than females. Man has no natural immunity.

**Environmental Factors :** Yaws is endemic in warm and humid regions with average rainfall of at least 40 inches. Yaws is endemic in tribal and poor population who wear scanty clothes, poor personal hygiene, overcrowding, bad housing, low standard of living etc. which are important socioeconomic factors favouring transmission.

**Mode of Transmission :** Yaws is transmitted non venerally by Direct contact; Contact with secretions from infectious lesions; by Fomites, since organism remain alive on fomites in suitable climate long enough to cause infection; through Vectors by small flies and insects feeding on lesions, may transmit infection.

**Incubation Period :** 3-5 weeks.



## Clinical Features

**Early Yaws** : After inoculation of organism on exposed parts of body, the primary lesions appear after incubatory period. The lesion is extra genital, mainly seen on legs, arms, buttocks or face. A generalised large yellow crusted granulomatous eruptions appear resembling Condylomata lata in secondary syphilis along with lymphadenopathy. During next 5 years skin, mucous membrane, periosteal and bone lesions may develop, subside and relapse at irregular intervals. The early lesions are highly infectious.

**Late Yaws** : After around 5 years the deforming and destructive lesions appear. The lesions of sole and palms are called '*Crab Yaws*', the lesions of soft palate, hard palate, and nose are called '*Gangosa*' and swelling by the side of the nose due to osteo-periostitis of the superior maxillary bone is called '*Goundu*'.

## Yaws Eradication Programme

In 1952, a yaws control programme was started in India with assistance from WHO and UNICEF. From 1952 to 1964, about 0.2 million cases of yaws were detected and treated in endemic states; an estimated 9 million people were at risk for the disease. The campaign reduced the incidence of yaws by 93% and the prevalence fell from 14% to <0.1%. Eradication thus became a distinct possibility. Following this dramatic decline in transmission of the disease, active anti-yaws activities were abandoned in most Indian states, and surveillance and treatment of residual cases were to be undertaken through the general health services. The emphasis was on infectious foci rather than on a re-survey of extinct foci. In 1996, 49 districts in 10 states were endemic for this disease.

The Government formulated strategies and approaches to achieve its elimination and a Yaws Eradication Programme was launched in all endemic areas of the country in Mar 1999 to interrupt disease transmission, with the ultimate goal of eliminating yaws. The National Health Policy of 2002 set a target date of 2005 for eradication of yaws. This date was subsequently revised following cases reported in 2003. It was therefore agreed that elimination status should be achieved and maintained for 3 years before declaring eradication.

### Objectives of the Yaws Eradication Programme

The Yaws Eradication Programme had 2 objectives :

- (i) Elimination of yaws, defined as zero reporting of cases based on high-quality case searches validated by independent appraisals.
- (ii) Eradication of yaws, defined as the absence of new cases for a continuous period of 3 years, supported by the absence of evidence of transmission through serosurveys among children aged <5 years, i.e. no seroreactivity to rapid plasma reagin or venereal disease research laboratory tests.

### Programme strategy

The Yaws Eradication Programme adopted a 2-pronged strategy:

- (i) Using active case-finding through 6-monthly aggressive search operations, and treatment of cases together with prophylaxis of contacts with long-acting penicillin.

- (ii) Generating awareness and mobilizing the community through Information, Education and Communication (IEC) programmes.

To operationalize the strategy, awareness of yaws was created among health professionals and training was provided. All activities were rigorously monitored, evaluated and supervised.

### Programme management

The Yaws Elimination Programme was managed and implemented by 2 agencies :

- The NICD was designated by the Government of India as the main agency for planning, guidance, coordination, and monitoring and evaluation of the Programme.
- The State Health Directorates of yaws-endemic states implemented the Programme by utilizing the existing health-care delivery system in coordination and collaboration with the Department of Tribal Welfare and other related departments and institutions.

### Programme implementation

The Yaws Elimination Programme was implemented in 10 steps:

**1. Identification of affected areas** : Affected areas were identified on the basis of historical data obtained from the literature; reports received from state governments; geographical contiguity and epidemiological evidence. A total of 49 districts in 10 states were identified as affected areas where the Programme needed to become operational.

**2. Advocacy** : Advocacy was essential for focusing attention on the public health challenge posed by yaws and for resource allocation to the Programme. The following points were emphasized :

- Yaws is eradicable with minimal inputs.
- A cost-effective intervention is available in the form of a single injection of benzathine penicillin.
- The Programme would have collateral advantages such as providing an entry point for primary health care among the most marginalized populations.

Advocacy meetings were organized under the chairmanship of the District Magistrate, inviting representatives from departments such as the Panchayati Raj, Integrated Child Development Services Scheme, Education, Tribal Welfare and Forestry.

**3. Piloting and expansion of the project** : In accordance with the decision of the Government of India, a pilot project was instituted in the Koraput district of Orissa in 1996 - 1997. Based on the observations of the pilot project, the Programme was expanded to other areas so that all endemic districts were covered by 2000.

**4. Staff development** : The training of medical officers and paramedical staff was given top priority. The training was conducted at NICD, medical colleges, community or primary health-care centres. The NICD prepared the training materials.

**5. Community mobilization through IEC** : Before active search campaigns were started for the detection and treatment of cases, community awareness was generated in all areas identified as yaws-endemic in the local language. This promoted

self-reporting and encouraged people to seek treatment free of charge at all health facilities. Weekly markets (or *haats*) in tribal areas provided a good opportunity to disseminate information.

**6. Detection and treatment of cases and contacts :** Trained paramedical workers and community-level functionaries detected cases by making house-to-house visits in the affected areas at frequent intervals. These cases were then confirmed by the medical officer. Case detection was the most important component of the Programme and was done twice a year (once in the post-monsoon period when cases were common). Cases detected during active searches were treated immediately after detection along with their contacts with an injection of long-acting penicillin (1.2 million units for children aged >10 years and 0.6 million units for those aged <10 years).

**7. Surveillance :** Besides active search campaigns, intersearch surveillance was also done by routine reporting of cases during the visits of health workers to the villages and reporting of cases to the local health facilities. Cross-notification of cases and migratory populations was also carried out. As per the protocol, serosurveys were also undertaken in children aged <5 years to investigate evidence of transmission.

**8. Intersectoral coordination :** Close intersectoral coordination was maintained between the health and other departments. Examples of intersectoral coordination included community-oriented activities such as the distribution of rice to cases by the Integrated Tribal Development Agency in Andhra Pradesh to motivate them to receive the injections for treatment.

**9. Supportive supervision and monitoring :** Programme activities were monitored using monthly reporting of cases; reports of active searches; visits of officers from the NICD and central government hospitals, and state or district programme officers; review meetings of programme officers; and by independent appraisals.

**10. Validation and certification :** After achieving a zero case status in the country, validation was done by a group of experts consisting of dermatologists and public health professionals who visited the areas and interacted with the programme officers, health personnel and community members. Their observations were examined by a group of experts. This exercise will be undertaken annually for 3 years. If the status is maintained for this period, the process of certification for eradication will be initiated.

### Declaration of Yaws Elimination

Following nationwide implementation of the Programme, the number of reported cases fell from 3571 in 1996 to 735 in 1997 to 0 cases in 2004, and India reached zero yaws case status. As per the Programme guidelines, this status had to be validated before yaws elimination could be formally declared. At the third Task Force meeting in 2005, it was decided to incorporate laboratory confirmation of yaws in the case definition to ensure elimination status. In May 2006, the Task Force accepted the recommendation of the expert group that yaws had been eliminated from India. This was formally declared by the Minister of Health of India on 19 September 2006.

### Factors Contributing to the Success of the Yaws Elimination Programme in India

The success of any public health programme, particularly a programme aimed at elimination or eradication, depends on high-level political commitment and adequate resources. The 2002 National Health Policy statement regarding the target of achieving yaws eradication by 2005 was an indicator of national commitment to rid India of this disease. This gave an impetus to Programme activities, which were reviewed regularly at the highest level, making it possible to ensure the provision of adequate resources. Periodic advocacy meetings with policy-makers, administrators and stakeholders, focusing on the availability of a cost-effective intervention and the knowledge that the disease is eradicable with marginal inputs, paid rich dividends.

Active case-finding was one of the most important strategies and was vigorously pursued. Every year, at least 1 search was organized in the post-monsoon period. All suspected cases and contacts were treated. An effective monitoring and supervision mechanism to support peripheral-level health workers and review their activities helped to identify constraints and take the necessary corrective measures. The establishment of a high-level Task Force under the chairmanship of the Director General of Health Services was useful for advocacy, resource mobilization, undertaking periodic reviews, monitoring progress and advising on annual Plans of Action. A simplified information system was developed and integrated into general public health services. Prompt action ensured prevention of further spread of infection.

India eliminated Yaws in 2006, showing that this is possible if there is political will, a well-structured delivery system and a modest amount of funding. It now hopes to declare eradication of Yaws in 2010, which will be a remarkable public health success. Following India's example, the WHO South-East Asia Region has set a target of 2012 for the elimination of yaws in the remaining 2 endemic countries - Indonesia and Timor-Leste.

### From Elimination to Eradication : The Road Map

India aims to declare eradication of yaws by 2010. The professional commitment of health staff combined with strong policy and administrative support has to be ensured until the goal of eradication is achieved. To overcome the tendency for complacency, a mechanism for supportive supervision and monitoring has been strengthened. The following activities are ongoing to ensure that success is achieved :

- Yearly active case searches and concurrent serosurveillance
- Surveillance and IEC activities
- Verification of reports by the states and districts
- Validation of the zero report through yearly appraisal of the Yaws Elimination Programme by independent experts
- Meeting of State Programme officers
- Verification of cases and investigation of rumoured cases
- Constitution of the National Commission for Certification of Eradication of Yaws from India and validation by international organizations.

## Summary

Yaws is a non-venereal endemic treponematosi s caused by the bacterium *Treponema pallidum*, subspecies *pertenue*, a Gram-negative spirochete. Infection is transmitted by skin-to-skin contact among people with poor hygiene practices living in certain warm and humid tropical areas of Africa, the Americas and Asia. Man is the only known reservoir of infection which is an infected person. The source of infection is usually the skin lesions and the exudates from early lesions. Children aged 2 - 5 years are the most vulnerable to infection, which targets the skin, bones and cartilage, causing destruction of tissue and deformities in the late stages. Reports suggest that yaws was non-existent in India until 1887, when cases were first noticed among tea plantation labourers in Assam. It later spread to a geographically contiguous and predominantly tribal area in central India. Yaws is endemic in tribal and poor population who wear scanty clothes, poor personal hygiene, overcrowding, bad housing, low standard of living etc. Yaws is transmitted non venerally by direct contact, contact with secretions from infectious lesions and by fomites. Incubation Period is 3-5 weeks. In 1952, a yaws control programme was started in India with assistance from WHO and UNICEF. The campaign reduced the incidence of yaws by 93% and eradication thus became a distinct possibility. The Government formulated strategies and approaches to achieve its elimination and a Yaws Eradication Programme was launched in all endemic areas of the country in Mar 1999 to interrupt disease transmission. It adopted a 2-pronged strategy : (i) Using active case-finding through 6-monthly aggressive search operations and (ii) Generating awareness and mobilizing the community through Information, Education and Communication (IEC) programmes. The Yaws Elimination Programme was implemented in 10 steps : Identification of affected areas; Advocacy; Piloting and expansion of the project; Staff development; Community mobilization through IEC; Detection and treatment of cases and contacts; Surveillance; Intersectoral coordination; Supportive supervision and monitoring; Validation and Certification. At the third Task Force meeting in 2005, it was decided to incorporate laboratory confirmation of yaws in the case definition to ensure elimination status. In May 2006, the Task Force accepted the recommendation of the expert group that yaws had been eliminated from India. This was formally declared by the Minister of Health of India on 19 September 2006.

## Study Exercises

**Long Question :** Discuss the Yaws eradication programme in India and factors contributing to its success.

**MCQs :**

1. Factors contributing to the success of the Yaws Elimination Programme in India are (a) high-level political commitment (b) adequate resources (c) active case-finding (d) effective monitoring and supervision (e) all
2. The Yaws Elimination Programme was implemented in following steps, except (a) Community mobilization through IEC (b) Detection and treatment of cases and contacts (c) Passive surveillance (d) Supportive supervision and monitoring validation and certification.
3. Yaws Eradication Programme adopted following strategy (a) using active case-finding through 6-monthly aggressive search operations and treatment of cases together with prophylaxis of contacts with long-acting penicillin (b) generating awareness and mobilizing the community through Information, Education and Communication (IEC) programmes (c) both (d) none
4. Name the agency which is responsible for implementation of Yaws Elimination Programme in our country (a) NICD (b) State Health Directorates of yaws-endemic states (c) WHO (d) a & b
5. Following India's example, the WHO South-East Asia Region has set a target of 2012 for the elimination of yaws in the remaining 2 endemic countries, which are : (a) Indonesia & Timor-Leste, (b) Nepal & Sri Lanka (c) Bangladesh & Bhutan (d) none

**Fill in the Blanks**

1. The lesions of sole and palms are called \_\_\_\_\_, the lesions of soft palate, hard palate and nose are called \_\_\_\_\_ and swelling by the side of the nose due to osteo-periostitis of the superior maxillary bone is called \_\_\_\_\_.
2. India aims to declare eradication of yaws by \_\_\_\_\_.
3. In 1952, a yaws control programme was started in India with assistance from \_\_\_\_\_.
4. The National Health Policy of 2002 set a target date of \_\_\_\_\_ for eradication of yaws.
5. As per programme document 'elimination of yaws', defined as \_\_\_\_\_ reporting of cases based on high-quality case searches validated by independent appraisals.
6. In the year \_\_\_\_\_ India reached zero yaws case status.

**Answers : MCQs :** (1) e; (2) c; (3) c; (4) d; (5) a.

**Fill in the Blanks :** (1) Crab Yaws, Gangosa, Gondu; (2) 2010; (3) WHO & UNICEF; (4) 2005; (5) Zero; (6) 2004

## Further Suggested Reading

1. Weekly Epidemiological Record, World Health Organisation, Geneva, Number 15, 2008, 83, 125-132. ([http : //www.who.int/wer/](http://www.who.int/wer/)).



Sunil Agrawal

The human immunodeficiency virus (HIV) is a retrovirus that infects cells of the human immune system, destroying or impairing their function. In the early stages of infection, the person has no symptoms. However, as the infection progresses, the immune system becomes weaker, and the person becomes more susceptible to opportunistic infections. The most advanced stage of HIV infection is acquired immunodeficiency syndrome (AIDS). It can take 10-15 years for an HIV-infected person to develop AIDS; antiretroviral drugs can slow down the process even further.

HIV is transmitted through unprotected sexual intercourse (anal or vaginal), transfusion of contaminated blood, through contaminated needles (either due to sharing or iatrogenic) and between a mother and her infant during pregnancy, childbirth and breastfeeding.

AIDS is a severe life threatening clinical condition first recognized as a clinical syndrome in 1981. This syndrome represents the late clinical stage of infection with the human immunodeficiency virus (HIV), which most often results in progressive damages to the immune and other organ systems, including the CNS (1). This means that a person who carries the HIV virus is prone to many different illnesses and may die from diseases that are harmless to healthy people.

### Epidemiology

#### Magnitude of the Problem

**Worldwide** : HIV/AIDS is one of the most urgent threats to global public health. Global efforts to address the AIDS epidemic, including increased access to effective treatment and prevention programmes have also been commendable. Estimates of the size and course of the HIV epidemic are updated every year by UNAIDS and WHO. In 2007, improved survey data and advances in estimation methodologies led to substantially revised estimates of numbers of people living with HIV, of HIV related deaths and of new infections worldwide (See Box - 1).

The number of people living with HIV was estimated at 33.2 million; these may be as few as 30.6 million or as many as 36.1 million. There were 2.5 million new infections and 2.1 million deaths during 2007. The findings are presented in Table - 1.

**Table - 1 : WHO / UNAIDS estimates for year 2007 (numbers in million)**

Age group	Living with HIV	Newly infected	Died of HIV
Adults	30.8	2.3	1.8
Children < 15 yrs	2.0	0.37	0.27
Total	33.0	2.7	2.0

Notes : (A) Half, may be slightly more of the adults living with HIV were women. (B) For adults living with HIV, the lowest and highest estimates were 30 and 36 million respectively.

Over 6800 new HIV infections takes place every day out of which more than 96% are in low and middle income countries. About 1200 are in children under 15 years of age and rest about 5600 are in adults aged 15 years and older .

Sub-Saharan Africa continues to bear the brunt of the global epidemic. Two thirds of all adults and children with HIV globally live in this region, a total of 22.5 million. Although other regions are less severely affected, 4 million people in south and south east Asia and 1.6 million in eastern Europe and central Asia were living with HIV/AIDS. Almost 72% of all adult and child deaths due to AIDS in 2006 were in the sub Saharan Africa region. More adult women are now getting infected with HIV, for every 10 adult men there are 14 adult women who are living with HIV. The interaction of HIV/AIDS with other infectious diseases is an increasing public health concern (2, 3, 4).

As of Dec 2007, an estimated 4 Million people are living with HIV in the South and South East Asia region. The number of people who become infected every day (over 6800) is greater than the number who die of the disease (around 6000). On 01<sup>st</sup> Dec 2003, WHO and UNAIDS announced a detailed plan to reach the "3 by 5 target" of providing antiretroviral treatment (ART) to three million people living with HIV in the developing countries by the end of 2005.

#### Box - 1 : Understanding the data and downward estimates

HIV infection is detected by testing for HIV antibodies in the blood, although in practice only a small proportion of people ever have an HIV test. For many years, scientists trying to estimate HIV prevalence had to rely on tests carried out on ladies attending Ante-natal care clinic (low risk groups) and certain defined high risk groups (as STD patients). More recently, it has been possible to introduce antibody testing into household surveys that have large samples of the population selected at random. This gives a more unbiased estimate of the overall prevalence of HIV infection, provided survey participation rates are high. It was found that prevalence estimates from these surveys are generally lower than those calculated earlier on the basis of pregnant women or high risk groups. Currently, new infection rates and deaths due to HIV/AIDS are estimated from the application of statistical models using data on:

- HIV prevalence
- Average time between HIV infection and death in the absence of treatment
- Survival rates of people receiving treatment

For the same level of prevalence, this longer average survival period has resulted in lower estimates of new infections and deaths due to AIDS. For the aforesaid reasons, there seems to have been a downward revision in the worldwide and national estimates of HIV infections.



**National Scenario :** The changing trend in the country indicates that HIV infection is spreading in two ways : From urban to rural areas and from individuals practicing high risk behaviour to the general population called Type 4 pattern, first described in Thailand. Revised estimates at the National level are 2.47 million people living with HIV which was released by National AIDS Control Organization (NACO) in July 2007. In India, 0.28% of adults aged 15-49 are infected with HIV, (including 0.35% in urban and 0.25% in rural areas or 0.36% in males and 0.22% in females). The cumulative number of AIDS cases in the country has risen to 1,99,453 by Dec 2007 (5). Majority of the HIV infections (88.5%) are in the age group of 15-49 years, out of which 31.8% are in the 15-29 years age group. Amongst injecting drug users the infection has spread very rapidly in Manipur with HIV prevalence of more than 70% (6). The estimated prevalence (adults aged 15 to 49 years) in some of the states is shown in Table - 2 :

Table - 2	
State	Prevalence rate (%)
Manipur	1.13
Andhra Pradesh	0.97
Karnataka	0.69
Maharashtra	0.62
Tamil Nadu	0.34
Uttar Pradesh	0.07
Source : NFHS - 3, 2007	

#### Agent Factors

**Reservoir :** The only reservoir are Humans - cases and carriers. Once a person is infected, the virus remains in the body life long. Since symptoms takes years to manifest, the carrier can infect other people for years.

**Source of Infection :** The virus has been found in greatest concentration from blood, semen and CSF. Lower concentrations in tears, saliva, breast milk, urine, and cervical and vaginal secretions.

**Virology :** HIV belongs to a class of viruses called retroviruses. Two types have been identified : Type-1 (HIV-1) and Type-2 (HIV-2). Retroviruses are RNA (Ribonucleic Acid) viruses, and in order to replicate (duplicate), they must make a DNA (Deoxyribonucleic Acid) copy of their RNA. It is the DNA genes that allow the virus to replicate. Like all viruses, HIV can replicate only inside cells, commandeering the cell's machinery to reproduce. Only HIV and other retroviruses, however, once inside a cell, use an enzyme called reverse transcriptase to convert their RNA into DNA, which can be incorporated into the host cell's genes (11).

**Survival in Nature :** HIV is a fragile virus. It cannot live for very long outside the body. As a result, the virus is not transmitted through day-to-day activities such as shaking hands, hugging, or a casual kiss. You cannot become infected from a toilet seat, drinking fountain, doorknob, dishes, drinking glasses, food, or pets. You also cannot get HIV from mosquitoes.

#### Host Factors

**Age :** Most cases occur in sexually active persons aged 20-49 yrs. This group represents the productive members of the society, and those responsible for child bearing and child rearing.

**Sex :** AIDS is still most common among homosexual and bisexual men. However, in more developed countries the disease is becoming more frequent among heterosexuals, especially young people. In the UK, new cases of HIV are now more prevalent among heterosexuals.

**High risk groups :** Intravenous drug users and people with many sexual partners are particularly at risk from HIV. Higher rate of HIV infection is found in CSWs and their clients, transfusion recipients of blood and blood products, haemophiliacs. Certain persons are at high risk due to the compulsions of their occupation, as truck drivers, military personnel, and migratory labour.

**Social factors in Epidemiology :** HIV is truly a social disease with medical background. Rapid industrialization, increasing availability of Commercial Sex Workers (CSWs), migration of young persons to urban areas in search of jobs and away from the traditional social control of their families, compulsively staying away from family due to occupational requirements, poverty with consequent resorting to sex for money, trafficking of women and girl children, availability of pornographic literature and visuals which has been further enhanced by internet, are some of the important social causes of the causation and perpetuation of this disease. Lack of knowledge about the causation and prevention and the intense stigma associated with HIV/AIDS further accentuate the problem.

#### Transmission Dynamics (1, 7)

**Incubation period :** It is widely variable. Although the time from infection to the development of detectable antibodies is generally 1-3 months, the time from HIV infection to diagnosis of AIDS has an observed range of less than 1 year to 10 years or more. However, it is estimated that 75% of those infected with HIV will develop AIDS by the end of ten years.

**Period of Communicability :** Presumed to begin early after onset of HIV infection and extend throughout life. Infectiousness increases with increasing immune deficiency; clinical symptoms and other STDs. Recent studies indicate that it may be high during initial period after HIV infection. However patients on ART are less likely to transmit HIV infection to others (12).

**Transmission of HIV :** HIV can be transmitted from person to person through :

(a) **Sexual contact :** Sexual intercourse is the leading way of transmission of HIV. This form of transmission occurs mainly among high-risk groups, such as men who have sex with men and CSWs. During intercourse, the virus can enter the body through the mucosal linings of the vagina, vulva, penis, or rectum or, rarely, via the mouth and possibly the upper gastrointestinal tract after oral sex. The risk of sexual transmission is in direct relationship with the amount of trauma and laceration of the recipient's genital mucosa. So, receptive anal intercourse provides the greatest risk. The rate of transmission from a man to a woman is greater than the opposite. The likelihood

of transmission is increased by factors that may damage these linings, especially other sexually transmitted infections that cause ulcers or inflammation.

**(b) Sharing of HIV contaminated needles and syringes :** Users of illicit parenteral drugs continue to account for a large number of infections. Needle-sharing and dilution of drug with blood are common practices, as well as engagement in high-risk sexual practices like exchanging sex for drugs and money.

**(c) Transfusion of infected blood or its components (platelets, factor VIII and IX etc.) :** The risk of contracting HIV infection from transfusion of a unit of infected blood is estimated to be over 95%. The HIV transmission through blood is dose dependent, hence the risk of getting infected through a contaminated needle, syringe or any other body piercing equipment is very much lower than with transfusion.

**(d) Vertical transmission (i.e. from infected mother to foetus) :** Vertical (mother to child) transmission is the number one cause of HIV infection in children. It occurs mostly during the perinatal period, and during breastfeeding. The risk of transmission is related to maternal factors (viral load, disease stage and CD4 cell count), obstetric factors, infant prematurity and the extent of breastfeeding. There is no threshold in viral load below which transmission will not occur. The risk of transmission increases in linear fashion with viral load. However, mothers whose viral load has been reduced to <1000 RNA copies per ml are not likely to transmit infection to their babies. From 15% to 30% infants born to HIV-infected mothers are infected before, during, or shortly after birth; treatment of pregnant women results in marked reduction in infant infections.

Factors which increase the risk of transmission are outlined in Table - 3.

### Course of HIV infection in Host

Once it enters the body, HIV infects a large number of CD4+ cells and replicates rapidly. During this acute or primary phase of infection, the blood contains many viral particles that spread throughout the body, seeding various organs, particularly the lymphoid organs. Two to 4 weeks after exposure to the virus, up to 70 percent of HIV-infected people suffer flu-like symptoms related to the acute infection, characterized by fever, myalgias, arthralgias, and generalized non-specific lymphadenopathy. Some patients develop a generalized papulomacular rash, and a few develop hepatitis and aseptic meningitis. This illness is known as the acute sero-conversion illness or *acute retroviral syndrome or primary HIV infection*. It is usually a benign, self-limited illness, and few patients seek medical attention. The infection is frequently unrecognized even in those patients who go to their health care provider. The resolution of symptoms coincides with the appearance of specific immunity and seroconversion. Their immune system fights back with killer T cells (CD8+ T cells) and B cell-produced antibodies, which dramatically reduce HIV levels.

Following this initial phase, a person may then remain free of HIV-related symptoms for years despite continuous replication of HIV in the lymphoid organs that had been seeded during the acute phase of infection. These patients are asymptomatic, many don't know they are infected, but they are very infectious

<b>Table-3: Factors Increasing the Risk of Acquisition of HIV</b>	
<b>Common to all transmission categories</b>	
- High Viral Load	- Presence of AIDS
- Lower CD4 cell count	- Seroconversion illness
<b>Vertical transmission</b>	
- Older gestational age	- Prolonged rupture of membranes
- Vaginal delivery (lower in caesarian)	- No peripartum prophylaxis
- Chorioamnionitis	- Lower birth weight
- First born of the twins	
<b>Breast Feeding</b>	
- Longer duration feeding	- Younger age
- Lower parity	- Mastitis
<b>Sexual transmission</b>	
- STIs especially genital ulcers	- Cervical ectopy
- Male to male vs heterosexual sex	- Non circumcised
- Receptive vs insertive anal sex	- Rectal or vaginal trauma
	- Menstruation
	- Increased no. of partners
<b>IV drug use</b>	
- Sharing equipment	- Linked commercial sex
- Intravenous use	- Incarceration
- Frequency of use	- Lower income
- Cocaine use	
<b>Occupational transmission</b>	
- Previous arterial or venous siting	- Deep injury
	- Visible blood on device

and may spread the disease to their sexual and parenteral drug partners, and to their offspring. One reason that HIV is unique, is the fact that despite the body's aggressive immune responses, which are sufficient to clear most viral infections, some HIV invariably escapes. This is due in large part to the high rate of mutations that occur during the process of HIV replication. Finally, the virus may hide within the chromosomes of an infected cell and be shielded from surveillance by the immune system. Such cells can be considered as a latent reservoir of the virus. Because the antiviral agents currently in our therapeutic arsenal attack actively replicating virus, they are not effective against hidden, inactive viral DNA (so-called provirus).

Results from large epidemiologic studies indicate that the median time from infection with HIV to the development of AIDS-related symptoms has been approximately 10 to 12 years in the absence of antiretroviral therapy. However, there is a wide variation in disease progression. Approximately 10 percent of HIV-infected people in these studies have progressed to AIDS within the first 2 to 3 years following infection, while up to 5 percent of individuals in the studies have stable CD4+ T cell counts and no symptoms even after 12 or more years called "*chronic non-progressor*" state, by which a small percentage of

infected patients maintain the integrity of their immune system throughout the years. Cohort studies of HIV infected adults indicate that about 15%-20% develop AIDS within 5 years, about 50% within 7-10 years and close to 70% within 15 years. The case fatality of AIDS is very high and most patients (80-90%) die within 3-5 years after the diagnosis of AIDS is made (7). The presence of either generalized Kaposi sarcoma or cryptococcal meningitis is sufficient for the case definition of AIDS. Patients with AIDS are more likely to acquire a variety of diseases that persons with a stronger immune system would not. At this stage, patients frequently develop a hypercatabolic state due to increased levels of cytokines related to their chronic disease. This leads to weight loss, progressive weakness, and often chronic diarrhoea. They are also prone to develop *Pneumocystis carinii* pneumonia. This predisposition increases as the CD4+ count declines. Patients with a CD4+ count below 50 cells/mm<sup>3</sup> are at risk of developing disseminated *Mycobacterium avium* infection, cytomegalovirus disease, and Progressive Multifocal Leukoencephalopathy (PML).

### Case Definitions

#### Expanded WHO case definition for AIDS surveillance :

An adult or adolescent (>12 yrs) is considered to have AIDS if a test for HIV antibody is positive, and one or more of the following criteria are present :

- Weight loss > 10% or cachexia, with diarrhoea or both, intermittent or constant, for > 1 month.
- Tuberculosis with weight loss > 10%, or disseminated, miliary, or extrapulmonary tuberculosis.
- Kaposi's sarcoma.
- Neurologic impairment preventing independent daily activities.
- Oesophageal candidiasis.
- Cryptococcal meningitis.
- Life threatening or recurrent episodes of pneumonia.
- Invasive cervical cancer.

**WHO case definition for AIDS surveillance :** For the purpose of AIDS surveillance an adult or adolescent (>12 years of age) is considered to have AIDS if at least 2 of the following major

**Table - 4 : WHO case definition for AIDS surveillance - Adults**

Major signs
Weight loss > 10% of body weight
Chronic diarrhoea for more than 1 month
Prolonged fever for more than 1 month (intermittent or constant)
Minor signs
Persistent cough for more than 1 month
Generalized pruritic dermatitis
History of herpes zoster
Oropharyngeal candidiasis
Chronic progressive or disseminated herpes simplex infection
Generalized lymphadenopathy

signs are present in combination with at least 1 of the minor signs listed in Table - 4 & 5, and if these signs are not known to be due to a condition unrelated to HIV infection.

#### WHO Clinical Staging of HIV/AIDS and Case Definition :

The clinical staging and case definition of HIV for resource-constrained settings were developed by the WHO in 1990 and revised in 2005. Staging is based on clinical findings and does not require a CD4 cell count. This staging system is used in many countries to determine eligibility for antiretroviral therapy. Clinical stages are categorized as 1 through 4, progressing from primary HIV infection to advanced HIV/AIDS. For the purpose of the WHO staging system, adolescents and adults are defined as individuals aged ≥13 years. The details of this staging and case definition is shown in Table - 6.

### HIV Testing

**Screening tests (HIV Testing) :** Once HIV enters the body, the body starts to produce antibodies. Most HIV tests look for these antibodies rather than the virus itself. There are many different kinds of HIV tests, including rapid tests and home test kits. At first a highly sensitive test is used called ELISA, while a second confirmatory test is used to weed out any false positive or to confirm indeterminate results. The confirmatory test, Western Blot is a highly specific test. Alternatively, for confirmation 3 ELISA/rapid/simple tests based on different biological systems may be performed. The "Window Period" is the interval between entry of HIV into the body and appearance of antibodies to it. This period may range between 1- 6 months and during this period the individual may test negative for HIV by conventional tests.

**Other tests for HIV infection :** There are certain circumstances, such as screening a baby born to an HIV-positive mother, or diagnosing acute retroviral syndrome, or research purposes, in which antibody testing is not reliable. In those situations, the diagnosis should be made by looking for viral particles, such as RNA, pro-viral DNA (RT-PCR or bDNA assays), or proteins (p24 antigen levels), or viral culture and its ability to form syncytium in culture. The viral RNA viz. PCR (Polymerase Chain Reaction) method and the bDNA method (branched chain DNA) can detect the number of viral particles (virions) in blood and are being increasingly used to predict prognosis and monitor efficacy of antiviral therapy.

**Table - 5 : WHO case definition for AIDS surveillance - Children**

Major signs
Weight loss or abnormally slow growth
Chronic diarrhoea for more than 1 month
Prolonged fever for more than 1 month
Minor signs
Recurrent common infections, e.g. ear infection, pharyngitis
Persistent cough
Generalized rash
Oropharyngeal candidiasis
Generalized lymphadenopathy

<b>Table - 6 : WHO Clinical Staging of HIV/AIDS for Adults and Adolescents (Interim Definitions)</b>
<b>Primary HIV Infection</b>
• Asymptomatic • Acute retroviral syndrome
<b>Clinical Stage 1</b>
• Asymptomatic • Persistent generalized lymphadenopathy <i>Performance scale 1 : Asymptomatic, Normal activity</i>
<b>Clinical Stage 2</b>
• Moderate unexplained weight loss (<10% of presumed or measured body weight) • Recurrent respiratory infections (respiratory tract infections, upper respiratory infections, sinusitis, bronchitis, otitis media, pharyngitis) • Herpes zoster • Minor mucocutaneous manifestations (angular cheilitis, recurrent oral ulcerations, seborrheic dermatitis, prurigo, papular pruritic eruptions, fungal fingernail infections) <i>Performance scale 2 : Symptomatic, Normal activity</i>
<b>Clinical Stage 3</b>
<i>(a) Conditions for which a presumptive diagnosis can be made on the basis of clinical signs or simple investigations</i> Severe weight loss (>10% of presumed or measured body weight); Unexplained chronic diarrhoea for >1 month; Unexplained persistent fever for >1 month (intermittent or constant); Oral candidiasis (thrush); Oral hairy leukoplakia; Pulmonary tuberculosis within the last 2 years; Severe presumed bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteremia); Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
<i>(b) Conditions for which confirmatory diagnostic testing is necessary</i> Unexplained anaemia (hemoglobin <8 g/dL); Neutropenia (neutrophils <500 cells/ $\mu$ L); Thrombocytopenia (platelets <50,000 cells/ $\mu$ L) <i>Performance scale 3 : bedridden &lt;50% of the day during the last month</i>
<b>Clinical Stage 4</b>
<i>(a) Conditions for which a presumptive diagnosis can be made on the basis of clinical signs or simple investigations</i> HIV wasting syndrome; <i>Pneumocystis jiroveci</i> (formerly carinii) pneumonia; Recurrent severe or radiologic bacterial pneumonia; Chronic herpes simplex infection (oral or genital, or anorectal site) for >1 month; Esophageal candidiasis; Extrapulmonary tuberculosis; Kaposi sarcoma; Central nervous system toxoplasmosis; HIV encephalopathy
<i>(b) Conditions for which a confirmatory diagnostic testing is necessary</i> Cryptococcosis, extrapulmonary; Disseminated nontuberculosis Mycobacteria infection; Progressive multifocal leukoencephalopathy; Candida of the trachea, bronchi or lungs; Cryptosporidiosis; Isosporiasis; Visceral herpes simplex infection; cytomegalovirus infection (retinitis or organ other than liver, spleen or lymph node); Any disseminated mycosis (e.g. histoplasmosis, coccidioidomycosis, penicilliosis); Recurrent nontyphoidal Salmonella septicemia; Lymphoma (cerebral or B-cell non-Hodgkin); Invasive cervical carcinoma; Visceral leishmaniasis. <i>Performance scale 4 : Bedridden &gt;50% of the day during the last month</i>

Several laboratory markers are available to provide prognostic information and guide therapy decisions. The most widely used marker is the absolute CD4 lymphocyte count. As the count decreases, the risk of opportunistic infections increases. People with healthy immune system usually have counts above 950 CD4 cells per cu mm of blood. The number falls over the course of HIV infection. People with AIDS usually have CD4 cell count below 200 per cu mm. The trend of the count is more important than a single reading (9).

**Who should be offered the HIV test :** It is recommended that the following category of persons should be offered HIV testing, after adequate risk assessment, counselling and after obtaining their informed consent :

- Persons with high-risk behaviour
- Men who have sex with men (MSM)
- Injection drug users
- Persons with multiple sex partners
- Persons who have exchanged money or drugs for sex
- Persons who have had sexual contact with an HIV-positive person or a person at risk for HIV infection
- Persons who request testing, regardless of risk
- Persons with certain medical conditions
  - AIDS-defining illness
  - Oral candidiasis
  - Generalized unexplained lymphadenopathy
  - Symptoms consistent with acute retroviral syndrome
  - Any sexually transmitted disease



- Tuberculosis
- Pregnancy
- Other (e.g. pneumonia, herpes zoster, recurrent vulvovaginal candidiasis, Seborrhoeic dermatitis, new onset psoriasis or oral hairy leukoplakia)
- Persons who have been sexually assaulted
- Persons who have had occupational exposures
- All blood donors (for blood safety)
- All antenatal cases and the husbands/children of the HIV positive cases
- Spouses and dependant children of HIV infected persons
- Patients on dialysis
- Other high risk cases e.g. those who test positive for HbsAg/ HCV/ VDRL etc.
- Duty/travel overseas.

#### The process of testing a person for HIV involves five steps

**1. Risk assessment :** The health care provider should elicit information about high-risk sexual behaviour and lifestyle, illicit drug use, and medical conditions that may be associated with an increased incidence of HIV infection. Counselling and testing is then offered as appropriate. All pregnant women should be offered an HIV test. Treatment for her and her baby should be available if the woman tests positive.

**2. Pre-test counselling :** Pre-test counselling is no longer required, except in the case of a provider who attends a pregnant woman for conditions related to her pregnancy. Pre test counselling should include information about the purpose of the HIV test; the indications for testing (medical and/or high risk); the possible need for retesting; information on how to avoid contracting and transmitting HIV infection; the potential social, medical, and economic effects of a positive test result; and, options for eliminating/reducing risk behaviour.

**3. Informed consent :** An informed consent must ALWAYS be obtained.

**4. Testing :** Testing for HIV is performed by looking for HIV-specific antibodies in the patient's blood. The usual screening test is by the ELISA (Enzyme-Linked Immunosorbent Assay) method. Even though it is a very specific method, a positive result must always be confirmed by a second confirmatory test.

**5. Post-test counselling :** All reasonable efforts must be made to notify the test subject of his or her test result. Post test Counselling should be offered to all test subjects and should be based on the test result and the individual's needs as determined during the risk assessment. Following information should be provided :

- *If test result is negative*
  - Discuss transmission and need for behaviour modification
  - Safer sex
  - Advice second test 3 months after last exposure
- *If test result is positive*
  - Explain significance and implications
  - Organize urgent medical follow up (the availability of appropriate medical and support services)

- Assess coping strategy
- Provide verbal and written information
- Discuss confidentiality issues
- Organize emotional and practical support
- Information on preventing transmission of HIV
- Importance of notifying sex and/or needle-sharing partners

#### Prevention and Control

Preventing new HIV infections is a priority in any HIV control program. There needs to be a strong political and resource commitment from the government and the community for this purpose. Education, support, access to healthcare and effective treatment all must be included in a successful program. Sexual education is an important component, and should be always provided at an age-appropriate level. Primary care physicians need to teach their patients to avoid high-risk sexual behaviour and promote safe sex practices. Patients who inject illicit drugs should also be taught about the risks of needle-sharing. Healthcare workers and any person with occupational exposure to blood borne pathogens need to be proficient in using standard infection control precautions.

Other components of a prevention program include extensive HIV testing programs and treatment of HIV infection and other STDs in the community. The various strategies of HIV/AIDS prevention includes :

##### (a) Information, Education and Communication (IEC)

IEC should promote :

- (i) Delay in first sexual encounter (targeting adolescents and young adults)
- (ii) Reduction in number of sexual partners (ideally mutually monogamous relationship)
- (iii) Promoting safe sex through use of condoms.

##### (b) Prevention of blood-borne HIV transmission

All blood should be screened for HIV before transfusion. All blood banks will transfuse blood only after it has been tested and found negative for HIV I & 2, HBsAg, Malaria, Syphilis, and other tests as specified in the National Blood Policy (14). All blood banks should therefore obtain the necessary license. Concerned Medical Officers are advised to acquaint themselves with the provisions of afore-mentioned Govt of India Gazette (15).

Strict sterilization practices should be ensured in hospitals and clinics. Autoclaved syringes and needles and other instruments should be used. Sharing of needles among drug addicts should be eliminated by health education.

##### (c) Antiretroviral prophylaxis

The prohibitive cost precludes the use of antiretroviral drugs on a mass scale in management of HIV infection in developing countries. Its use at present is limited to prevent perinatal transmission and for post exposure prophylaxis in cases of occupational exposure of Health Care Worker (HCW).

Primary prophylaxis against *P. carinii* pneumonia is indicated when CD4 count falls below 200 cells per cu mm. The regimens available are trimethoprim - sulphamethoxazole, aerosolized pentamidine and dapsone.

#### (d) Administration of Antiretroviral Therapy

Once diagnosed, HIV-positive patients should be evaluated by a healthcare provider experienced in the care of these patients. The assessment will include establishing the stage of their disease, concomitant conditions like tuberculosis, other sexually transmitted diseases, and hepatitis B and C. A multidisciplinary approach is preferred, with the intervention of psychologists, clinical pharmacists, clinical educators, nutritionists, and social workers. Antiretroviral therapy is available in the form of a multi-drug regimen known as "HAART" (*Highly-Active AntiRetroviral Therapy*). The goals of therapy are to achieve maximal and durable suppression of viral load, restoration or preservation of immunologic function, improvement in quality of life, and reduction of HIV-related morbidity and mortality.

These goals are achieved by maximizing adherence to the antiretroviral regimen and using drug-resistance testing in selected clinical settings. How the available drugs are sequenced and the preservation of future treatment options are also important tools. A typical starting HAART regimen consists of 2 Nucleoside Reverse-Transcriptase Inhibitors (NRTI), and either a Non-Nucleoside Reverse-Transcriptase Inhibitors (NNRTI) or a Protease Inhibitor (PI). Ritonavir is used in certain regimens to boost the serum level of another PI by inhibiting its metabolism by the cytochrome P450 enzyme system. These regimens should be designed by a practitioner experienced in the treatment of patients infected with HIV.

There has been significant discussion about the best time to start HAART in an HIV-positive patient. There is no doubt that HAART is beneficial in patients with AIDS or symptoms related to immunosuppression and these patients should be offered therapy. For asymptomatic patients with CD4+ count greater than 200 cells/mm<sup>3</sup>, the benefit is less clear. The decision to initiate treatment in these patients should take into account the readiness of the patient for treatment, consideration of the prognosis for disease-free survival as determined by baseline CD4+ T cell count and viral load levels, and assessment of the risk and potential benefits associated with initiating antiretroviral therapy. See Table - 7.

#### Adherence

Adherence rates >95% are necessary to maximize the effects of ART (17). Good adherence is associated with improved virological, immunological and clinical outcomes. Key to any successful adherence strategy is the education of patients before the initiation of ART to assess their understanding of ART and their treatment readiness as well as regarding the potential side effects of ART.

#### (e) HIV and the Healthcare Worker

Standard precautions are generally adequate for the care of patients with HIV. They include hand washing before and after each patient contact and the use of gloves. Other personal protective equipment, such as gowns, eye shields and masks, are only necessary when exposure to blood or other body fluids is anticipated. Healthcare workers may occasionally have an accidental parenteral exposure to HIV.

**Post - Exposure Prophylaxis (PEP)** : An occupational exposure is a percutaneous injury, contact of mucous membrane or contact of skin (when skin is chapped, abraded or afflicted with dermatitis or the contact is prolonged or involving extensive area) with blood, tissue or other body fluids to which universal precautions apply causing considerable risk of HIV infection especially to HCW.

**Action to be taken on occurrence of occupational exposure to HIV** : On exposure to a needle stick injury, blood and body fluids from a known HIV positive, the individual should go for HIV testing and take Tab Zidovudine (300 mg) and Lamivudine (150 mg) at the earliest (preferably within 24 hours) and continue this twice daily for four weeks. The objective of the PEP is to prevent HIV infection of cells.

#### When to give PEP?

- (i) *No drugs required*
  - Small volume exposure over intact skin /mucous membrane from a low risk individual.
- (ii) *2 drug regimen*
  - Small volume exposure over non intact skin /mucous membrane from a high risk individual or from a Low risk individual.
  - Large volume exposure over non intact skin /mucous membrane from a low risk individual.
  - Solid needle, superficial (Not severe), exposure from a low risk individual
- (iii) *3 drug regimen*
  - Large volume exposure over non intact skin /mucous membrane from a high risk individual.
  - Severe injury (Large bore, deep injury, visible blood in device, needle in patient artery/vein) from either a low risk or high risk individual.
  - Solid needle, superficial (Not severe), exposure from a high risk individual.

(Small volume = few drops, low risk individual = Asymptomatic HIV or viral load <1,500 c/ml, high risk individual = Symptomatic HIV, AIDS, acute seroconversion, and high viral

**Table - 7 : Drugs Used in the Treatment of HIV Infection**

NRTI	NNRTI	Protease Inhibitors	Fusion Inhibitors
Zidovudine (ZDV or AZT) Stavudine (d4T) Tenofovir Lamivudine (3TC) Didanosine (ddI) Emtricitabine Abacavir (ABC) Zalcitabine (ddC)	Efavirenz (EFV) Nevirapine (NVP)	Nelfinavir (NFV) Saquinavir (SQV) Indinavir (IDV) Amprenavir (APV) Fosamprenavir Lopinavir (LPV) Atazanavir Ritonavir (RTV)	Enfuvirtide

load, Large volume exposure = major blood splash)

### Monitoring

**Testing source :** If there is no recent positive or negative serology, a rapid test is preferred, since results should be available in <10 minutes. Standard serologic tests may take 3 to 7 days, but a negative EIA screening assay is usually available in 24 to 48 hours and is adequate for the decision to discontinue PEP.

**Testing health care worker :** HIV serology should be performed at the time of injury, and repeated at 6 weeks, 3 months, and 6 months. Most health care workers who seroconverted had symptomatic acute HIV syndrome, usually 2 to 6 weeks post exposure.

**Caution :** The health care worker should be advised to practice safe sex or abstain until serology is negative at 6 months post exposure. The greatest risk is the first 6 to 12 weeks.

**Time :** PEP should be initiated as quickly as possible, preferably within 1 to 2 hours of exposure and up to 36 hours post exposure.

**Side effects :** For health care workers who receive PEP, about 74% experience side effects, primarily nausea (58%), fatigue (37%), headache (16%), vomiting (16%), or diarrhoea (14%). About 53% discontinue treatment before completion of the 4-week course due to multiple factors including side effects of drugs. The HCWs should therefore be properly briefed on these aspects to ensure compliance.

### (f) Prevention of Parent To Child Transmission (PPTCT)

Good prenatal care, adequate antiretroviral therapy to the mother and child, cesarean section, and exclusive or no breastfeeding are all associated with decreased transmission of HIV. Even in mothers without chronic therapy for HIV and without prenatal care, antiretroviral agents like Zidovudine given through labor and delivery, together with early treatment of the newborn, decrease significantly the risk of transmission. Zidovudine is administered to women during pregnancy, labour and delivery and to their newborns; the rate of HIV transmission is decreased by two third. In addition to the use of ARV drugs, the following obstetric practices will reduce the risk of mother to child transmission :

- Avoidance of early rupture of membranes
- Avoidance of routine episiotomies
- Using non traumatizing suction cups on vacuum extractors where possible
- Avoid fetal scalp puncture

### Follow up of the HIV positive Mothers, their Spouses & Children

The Mothers who have tested positive will be followed up every 6 months after their delivery along with their children and spouses.

### (g) HIV infected couples/discordant couples

Discordant couples are those in which either the wife or husband is infected while the partner remains HIV negative. HIV infected couples or discordant couples are advised to practice safer sex. However such advise is not likely to be followed if the couple may wish to have child. Such couples should be Counselling for adoption; but should they wish to have their own child, then

the risk of cross infection with potential mutant viruses could be minimized by limiting unprotected intercourse to the most fertile period.

### (h) Safer Sex

Safer sex (sex with condom) avoids passing on HIV infection to others and reduces the risk of contracting other sexually transmitted infections, which might harm a person already infected with HIV. It is possible that one partner can reinfect the other with a strain of HIV, which is resistant to some treatments. People with HIV infection who continues to have unprotected sex are likely to develop AIDS sooner and also run the risk of STIs such as Human Papilloma Virus (the wart virus) that can lead to genital cancers.

### (j) Nutrition in HIV/AIDS

Nutrition is important to people with HIV infection in two ways:

- HIV positive individual should eat a well balanced diet to ensure that one gets all the essential nutrients that the body needs.
- They should avoid infection that come through contaminated food or drink.

Everyone needs to observe good hygiene when preparing food, avoid raw eggs, avoid partially cooked meat, fish etc. Boiling all water used for cooking or drinking is considered safer than drinking bottled mineral water or filtered tap water.

### (k) HIV with TB (18)

In patients with HIV related TB, the priority is to treat TB, especially smear positive Pulmonary Tuberculosis. However, patients with HIV related TB can have ART and anti TB treatment at the same time, if managed carefully. Careful evaluation is necessary in judging when to start ART. Serious patients with disseminated TB and CD4 count less than 200, may require to start ART concomitantly with TB treatment. On the other hand, for a patient with smear +ve PTB with asymptomatic HIV requires to be deferred for ART until initial phase of TB treatment has been completed. This decreases the risk of immune reconstitution syndrome and avoids the risk of drug interaction between Rifampicin and a Protease inhibitor.

### (l) Immunisation of HIV infected children

The immunization schedule of HIV infected children is more or less similar to other children. The details are as in Table - 8.

Table - 8 : Immunisation of HIV infected children	
Vaccine	Schedule for HIV +ve children
OPV	Instead of OPV, Inactive Polio Vaccine (IPV) should be given
BCG	Not administered to symptomatic HIV children, but can be given at birth even if mother is HIV +ve
DPT	Can be given as it is
Measles/ MMR	Can be given normally except to those who are severely immunocompromised
Hepatitis B	Can be given as it is
DT/TT	Can be given as it is



### (m) HIV Vaccines

Since 1983 the development of a vaccine against diverse strains of HIV has become an urgent global need. There are several approaches to vaccination for prevention of HIV-1 infection (19).

**a) Subunit vaccines** : These vaccines use HIV-1 surface glycoproteins gp120 or gp160 as immunogens.

**b) Recombinant vector vaccines** : The viral vectors are genetically engineered to carry HIV-1 genes. These vectors multiply in the body and generate HIV antigens, which are processed by the endogenous pathway and generate cytotoxic T lymphocyte response in the body.

**c) DNA vaccines** : These vaccines consist of segments of genome or plasmid, and are administered either IM or ID. After injection the DNA plasmids are taken up by the host cells, and the encoded protein antigens are expressed.

A vaccine preparation may be used either alone or in combination with another HIV vaccine. Combination vaccines are used with 'Prime Boost strategy' in which administration of one type is followed by second type of HIV vaccine. However no candidate vaccine has been proved effective till date due to extensive genetic diversity of HIV strains.

### Summary

The Human Immunodeficiency Virus (HIV) is a retrovirus that infects cells of the human immune system. Acquired Immuno Deficiency Syndrome (AIDS) is the most advanced stage of HIV infection. It can take 10-15 years for an HIV-infected person to develop AIDS.

In 2007 the number of people living with HIV was estimated at 33.2 million and there were 2.5 million new infections and 2.1 million deaths. Two thirds of all adults and children with HIV globally live in sub-Saharan region (22.5 million). As of Dec 2007, an estimated 4 Million people are living with HIV in the South and South East Asia region. There are 2.47 million people living with HIV in India. Majority of the HIV infections (88.5%) are in the age group of 15-49 years. 0.28% of adults aged 15-49 are infected with HIV. The changing trend in the country indicates that HIV infection is spreading in two ways; from urban to rural areas and from individuals practicing high risk behaviour to the general population (type 4 pattern).

Two types of HIV have been identified type - 1 (HIV-1) and type - 2 (HIV-2). HIV uses an enzyme called *reverse transcriptase* to convert their RNA into DNA. Once a person is infected, the virus remains in the body life long. Humans- cases and carrier are only reservoir. HIV is a fragile virus, cannot live for very long outside the body. The virus has been found in greatest concentration from blood, semen and CSF.

High risk groups are IV drug users, multiple sexual partners (esp. homosexual, bisexual); transfusion recipients of blood and blood products, haemophiliacs. Rapid industrialization, availability of Commercial Sex Workers (CSWs), migration of young persons are some of the important social causes of the causation and perpetuation of this disease.

Disease can be transmitted through sexual contact with infected person, sharing of HIV contaminated needles and

syringes, transfusion of infected blood or its component and vertical transmission from infected mother to fetus. The risk of contracting HIV infection from transfusion of a unit of infected blood is estimated to be over 95% and 15-30% from infected mother to fetus. Inside body HIV infects a large number of CD4 + cells and replicates rapidly and this virus enter into the blood leading to viremia and spread to distant places esp. lymphoid tissue. During this period patient suffers flu like symptoms known as the acute sero-conversion illness which is self limited. After this patient is asymptomatic but infectious. Body immune system is not able to clear HIV infection due to high mutation and incorporation of viral DNA into cell chromosome and forming a latent infection. Cohort study of HIV infected adults indicates that about 15%-20% develop AIDS within 5 years, about 50% within 7-10 years and close to 70% within 15 years. The case fatality of AIDS is very high 80-90%, most die within 3-5 yrs, which is because of opportunistic infections.

An adult or adolescent (>12 yrs) is considered to have AIDS if a test for HIV antibody is positive, and one or more of the following are present : (a) Weight loss > 10% or cachexia, with diarrhoea or both, intermittent or constant, for > 1 month (b) Tuberculosis with weight loss > 10%, or disseminated, miliary, or extrapulmonary tuberculosis (c) Kaposi's sarcoma (d) Neurologic impairment preventing independent daily activities (e) Oesophageal candidiasis (f) Cryptococcal meningitis (g) Life threatening or recurrent episodes of pneumonia (h) Invasive cervical cancer.

For the purpose of AIDS surveillance, an adult or adolescent (>12 years of age) is considered to have AIDS if at least 2 of the following major signs are present in combination with at least 1 of the minor signs listed below, and if these signs are not known to be due to a condition unrelated to HIV infection. In Adults, Major signs are Weight loss > 10% of body weight, chronic diarrhoea for more than 1month, prolonged fever for more than 1 month (intermittent or constant). Minor signs are persistent cough for more than 1 month, generalized pruritic dermatitis, history of herpes zoster, oropharyngeal candidiasis, chronic progressive or disseminated herpes simplex infection, generalized lymphadenopathy. For children, major signs are weight loss or abnormally slow growth, chronic diarrhoea for more than 1month, prolonged fever for more than 1 month and minor signs are Recurrent common infections, e.g. ear infection, pharyngitis, persistent cough, generalized rash, oropharyngeal candidiasis & generalized lymphadenopathy. Clinical staging of HIV/AIDS based on clinical findings (not on CD4 cell count) in which they are categorized as 1 through 4, progressing from primary HIV infection to advanced HIV/AIDS are developed by WHO for resource- constrained settings.

HIV test should be offered to Persons with high-risk behaviour, Persons with AIDS related medical conditions, voluntary basis, Persons who have been sexually assaulted, Persons who have had occupational exposures, All blood donors (for blood safety), All antenatal cases and the husbands/children of the HIV positive cases, Spouses and dependant children of HIV infected persons, Patients on dialysis, Other high risk cases e.g. those who test positive for HbsAg/ HCV/ VDRL etc, Duty/ travel overseas.



A highly sensitive test (ELISA) which detect antibody against HIV is used for screening purposes. A highly specific test, Western Blot is used for confirmation. Alternatively, for confirmation 3 ELISA/rapid/simple tests based on different biological systems may be performed. The individual may test negative for HIV in window period with ELISA. Other test for HIV infection are PCR (Polymerase Chain Reaction) method, the bDNA method (branched chain DNA) etc. Absolute CD4 lymphocyte count is most widely used prognostic marker. Process of testing of HIV is done in five stages, first is risk assessment of the individual, then is pre-test Counselling in which information about all aspects of disease and its subsequent medical, social and economic impact is given, next informed consent of the patient is taken. And then testing for HIV is done and lastly post test Counselling for both negative and positive subjects.

Prevention of new HIV infection should be priority. The various strategies for prevention include Information, Education and Communication (IEC), Prevention of blood-borne HIV transmission, Antiretroviral prophylaxis, Administration of Antiretroviral Therapy, Prevention of Parent To Child Transmission (PPTCT), HIV infected couples/discordant couples, Safer Sex, Nutrition in HIV/AIDS, HIV with TB, Immunization of HIV infected children.

## Study Exercises

**Long Question :** Describe the epidemiology of HIV/AIDS. Enumerate the strategy for its prevention.

**Short Notes :** (1) Pretest & Post test Counselling (2) HIV vaccines (3) HIV and TB (4) Transmission dynamics of HIV (5) WHO case definition for AIDS surveillance (6) Role of Counselling in HIV (7) PPTCT (8) HIV testing.

### MCQs

- The risk of contracting HIV infection from transfusion of a unit of infected blood is estimated to be \_\_\_\_\_ from infected mother to fetus : (a) 15-30% (b) 30-60% (c) 10-15% (d) 5-15%
- In adults for surveillance of AIDS major signs are all except (a) Weight loss > 10% of body weight (b) Chronic diarrhoea for more than 1 month (c) Prolonged fever for more than 1 month (d) Disseminated TB.
- For children major signs for AIDS surveillance are all except : (a) Weight loss or abnormally slow growth (b) Chronic diarrhoea for more than 1 month (c) Prolonged fever for more than 1 month (d) Persistent cough for more than 1 month.
- Absolute CD4 count in HIV is used as (a) screening test (b) confirmatory test (c) prognostic marker (d) diagnostic marker.
- HIV can be transmitted from person to person through all methods except (a) sexual contact (b) social contact (c) vertical transmission (d) blood transfusion
- Cytomegalovirus disease occurs when CD4 counts fall below (a) 200 per cu mm (b) 50 per cu mm (c) 500 per cu mm (d) 1000 per cu mm
- Efavirenz belongs to (a) NRTI (b) NNRTI (c) PI (d) Fusion inhibitors
- Post exposure prophylaxis should be started (a) preferably within 1-2 hours (b) between 24-48 hrs (c) after 48 hours (d) after 72 hours
- Currently, new infection rates and deaths due to HIV/AIDS are estimated from : (a) HIV prevalence (b) Average time between HIV infection and death in the absence of treatment (c) Survival rates of people receiving treatment (d) All
- Patients with a CD4+ count below 50 cells/mm<sup>3</sup> are at risk of developing disseminated (a) *Mycobacterium avium* infection, (b) Cytomegalovirus disease (c) PML (d) All (e) a & b
- Obstetric practices will reduce the risk of mother to child transmission except : (a) avoidance of early rupture of membranes (b) conduct routine episiotomies (c) using non traumatizing suction cups on vacuum extractors where possible (d) avoid foetal scalp puncture.
- Who should be offered the HIV test (a) Persons with high-risk behaviour (b) Persons who request testing, regardless of risk (c) Persons with certain medical conditions (d) All

### Fill in the Blanks

- Estimates of the size and course of the HIV epidemic are updated every year by \_\_\_\_\_ and \_\_\_\_\_.
- In 2007, the number of people living with HIV was estimated at \_\_\_\_\_ million with \_\_\_\_\_ million new infections and about \_\_\_\_\_ million deaths.
- More adult women are now getting infected with HIV; for every \_\_\_\_\_ adult men, there are \_\_\_\_\_ adult women who are living with HIV.
- On 01st Dec 2003, WHO and UNAIDS announced a detailed plan to reach the "3 by 5 target" of providing antiretroviral treatment (ART) to \_\_\_\_\_ million people living with HIV in the developing countries by the end of \_\_\_\_\_.
- \_\_\_\_\_ pattern of HIV transmission i.e. from individuals practicing high risk behaviour to the general population was first described in \_\_\_\_\_.
- In India approx \_\_\_\_\_ million people living with HIV was estimated by National AIDS Control Programme (NACO) in July 2007.
- The only reservoir for HIV are \_\_\_\_\_ cases and carriers.
- HIV infection in children occurs mostly during the \_\_\_\_\_ and during \_\_\_\_\_.
- Median time from infection with HIV to the development of AIDS-related symptoms is approximately \_\_\_\_\_ years in the absence of antiretroviral therapy.
- The case fatality of AIDS is very high and most patients i.e. \_\_\_\_\_ % die within 3-5 years after the diagnosis of AIDS is made.
- The \_\_\_\_\_ is the interval between entry of HIV into the body and appearance of antibodies to it. This period may range between \_\_\_\_\_ months and during this period the individual may test \_\_\_\_\_ for HIV by conventional tests.
- HAART regimen consists of two \_\_\_\_\_, and either a Non-Nucleoside Reverse-Transcriptase Inhibitors (NNRTI) or a \_\_\_\_\_.
- Several approaches to vaccination for prevention of HIV-1 infection available are \_\_\_\_\_, Recombinant vector vaccines and \_\_\_\_\_.

**Answers : MCQs :** (1) a; (2) d; (3) d; (4) c; (5) b; (6) b; (7) b; (8) a; (9) d; (10) d; (11) b; (12) d. **Fill in the Blanks :** (1) UNAIDS; WHO;

(2) 33.2; 2.5; 2.1; (3) 10; 14; (4) 3; 2005; (5) Type 4; Thailand; (6) 2.1; (7) Humans; (8) Perinatal period; breast feeding; (9) 10-15; (10) 80-90%; (11) Window period; 1-6; negative; (12) Nucleoside Reverse Transcriptase Inhibitors (NRTI); protease inhibitor; (13) Subunit vaccines; DNA vaccines.

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## 207 Leprosy (Hansen's Disease)

Sunil Agrawal

Leprosy is a chronic granulomatous immunological disorder caused by *M. leprae* primarily affecting the peripheral nerves and secondarily involving skin and mucosal membrane etc. It also affects eye, certain internal organs such as the kidney, liver, adrenal glands and in the male, testicles (1). The disease is clinically characterized by one or more of hypopigmented patches or partial/ total loss of sensation in the affected area or presence of thickened nerves or presence of acid fast bacilli in the skin smears.

### Epidemiology

#### Magnitude of the Problem

**World :** The overall target for the global elimination of leprosy as a public health problem has been attained (2). The fall in prevalence rate is mainly due to an improvement in management of cases, very low rates of relapse, high cure rates, absence of drug resistance and shorter duration of treatment with MDT (3). The WHO estimates for 1994 were 2.4 million cases, a reduction of more than three fourths as compared to the estimated 10.6 million cases in 1976 (4). At the beginning of 2008, the registered prevalence of leprosy globally was 212,802; the number of new cases detected during 2007 was 254,525 (5). The global detection of new cases declined by >11,100 cases (4%) during 2007 compared with 2006 and global prevalence rate of leprosy was below 1 per 10,000 population. About 2.9

lakh cases are newly detected in 2005 which is 27% fall as compared to 2004. No drug resistance to MDT was reported (6). At present the highest burden is concentrated in 6 countries (India, Brazil, Indonesia, DRC, Bangladesh and Nepal). At the beginning of 2008, the Democratic Republic of the Congo and Mozambique reached the leprosy elimination goal however, 3 countries with populations >1 million that have yet to achieve the elimination goal are Brazil, Nepal and Timor - Leste. Together, these 3 countries account for about 17% of the new cases detected during 2007 and 23% of registered cases at the beginning of 2008. Prevalence of leprosy and number of new cases detected, by WHO regions is given in Table - 1.

**Table - 1 : Prevalence of leprosy and number of new cases detected, by WHO region, beginning of 2008**

WHO Regions	Registered prevalence beginning 2008 (Rate per 10,000)	New cases detected 2007 (Rate per 100,000)
Africa	30,055 (0.47)	31,037 (4.85)
America	49,388 (0.96)	41,978 (8.15)
South - East Asia	1,20,967 (0.72)	1,71,552 (10.22)
Eastern Mediterranean	4,240 (0.09)	4,091 (0.85)
Western Pacific	8,152 (0.05)	5,867 (0.34)
Total	2,12,802	2,54,525

**India** : In last few years there is marked reduction in cases of Leprosy. As of Mar 2007 the number of reported cases came down to 82,801 giving Prevalence Rate (PR) of 0.72 cases per 10,000 population (7). India achieved elimination level of less than one case per 10,000 population by 31st Dec 2005. The disease shows high prevalence in 6 states (PR of 1 - 2 per 10000 population) viz. Bihar, Chattisgarh, Jharkand, Chandigarh, Dadra and Nagar Haveli and Delhi. These states contribute 67% of the total case load (8). The total cases discharged as cured (151,601) were more than total new cases detected (139,252). Now the focus of attention under national Leprosy Control Programme has shifted from endemic states to high priority districts and blocks. A Focused Leprosy Elimination Plan (FLEP) was carried out in 2005 targeting high endemic districts and blocks which included Block Leprosy Awareness Campaign (BLAC).

**Agent** : In 1873, Gerhard Armauer Hansen, a Norwegian scientist demonstrated these bacilli in leprosy lesions. Later they are called *Mycobacterium leprae*. The bacilli are acid fast and with ZN stain appear pinkish red resembling the tubercle bacilli morphologically. The bacilli may be arranged in small or large clumps or bundles (called Globi) or may occur singly. The incubation period of the disease is much longer than that of most other infectious diseases. Other than man, it has multiplied in the footpads of mice, in tissues of immunosuppressed rodents and in the nine - banded armadillo.

**Reservoir** : Man is the only known reservoir. Though natural infection has been reported in Armadillo and certain primates but it is not epidemiologically important. "Active or Open" cases who are shedding the organisms mainly through nasal discharges more so in Lepromatous cases are the chief source of infection.

**Host** : Infection can take place at any age, to any sex, depending upon the opportunities for exposure in endemic areas. In areas where leprosy is rare, the first contact may not take place early in life and thus the disease may appear late. However, a high incidence of infection among children means the disease is active and spreading. Incidence rates are highest in 10 to 20 yrs of age gp and then fall. In general, leprosy is more commonly seen in men than women due to their greater mobility and increased opportunity to contact the infection. Only a few people exposed to infection develop clinical signs of leprosy, although immunological conversion takes place in large proportions of contacts. It is now recognized that the effective immune response in leprosy is a cell - mediated one. In lepromatous leprosy there is a complete breakdown in the cell mediated immune response.

**Diagnosis** : The following features assist in the diagnosis of the disease :

**(a) Clinical features**

- (i) Skin lesions (Infiltration, macules, papules, tubercles and nodules)
- (ii) Paraesthesia (History of numbness and loss of hot and cold sensations in the extremities)
- (iii) Thickening of nerve trunks
- (iv) Anhidrosis

**(b) Histamine test** : 0.1 ml of 1/1000 solution of histamine

chlorhydrate or phosphate is injected intradermally into the hypopigmented patches. In normal persons it gives rise to wheal surrounded by an erythematous flare (Lewis triple response) within a few minutes. In cases of leprosy where nerve supply is destroyed this response is lost.

**(c) Skin smears** : The skin smears, nasal smears and nasal scrapings are collected, fixed and stained with ZN method. This is used to distinguish between paucibacillary and multibacillary leprosy. A negative result, which is usual in indeterminate and tuberculoid cases, does not eliminate the diagnosis of leprosy. In certain cases histopathological examination may be necessary.

**(d) Immunological Tests**

**Lepromin Test** : The lepromin test, also called Mitsuda reaction, was first described by the Japanese worker, K Mitsuda in 1916. It is an intradermal immunological test employed to detect CMI and classify the type of disease and to find out the prognosis in a given case. Lepromin is a suspension of lepromatous tissue rich in *M. leprae* in an isotonic solution of sodium chlorides sterilized by heating. The test is performed by injecting intradermally 0.1 ml of lepromin or lepra antigen in the forearm of a patient and the reaction is examined at the end of 48 hours and 21 days. The test results in 2 types of reaction.

- (i) **Early reaction (Fernandez reaction)** : If there is erythema and induration measuring more than 10 mm in diameter at the end of 48 hours at the site of injection it is considered positive.
- (ii) **Delayed reaction** : At the end of 21 days, if there is a nodule more than 5 mm in diameter at the site of inoculation, it is said to be positive. This delayed reaction is also known as the classical or Mitsuda reaction. In strongly positive individuals there may be ulceration.

The early positive reaction shows that person has been previously sensitized by exposure to leprosy bacilli. The test is often positive in healthy persons and in those suffering from tuberculoid form of leprosy, and positivity gets weaker as we pass to lepromatous form of disease indicating a failure of CMI. The lepromin test is not a diagnostic test, its value lies in estimating prognosis, positive test indicating good prognosis.

**(e) Other tests** : These include Lymphocyte Transformation Test (LTT), Leucocyte Migration Inhibition Test (LMIT), Fluorescent Leprosy Antibody Absorption Test (FLA - ABS test), and, ELISA

**Reactions in Leprosy** : Reactions are acute exacerbations of disease either due to alteration in CMI status (type 1 reaction) or immune complexes (type II or ENL reaction). Clinically there is increase in number and infiltration of lesions, neuritis, associated with constitutional symptoms and involvement of various organs like eyes, bones, testis and viscera. Reactions are best managed in hospital, whereby along with specific antileprosy treatment, anti - inflammatory drugs, steroids or antireactional drugs (Clofazimine, thalidomide) may be administered.

**Incubation Period** : Leprosy has a long incubation period, an average of 3 - 5 years. Tuberculoid type has shorter incubation period.



**Communicability** : A patient is infective, if morphologically solid - staining (viable) bacilli are demonstrable.

**Mode of Transmission** : The exact mechanism of transmission is still unclear (9). The major exit points of *M. Leprae* from untreated lepromatous patients are the nose, mouth, and in some cases abraded skin lesions. As regards mode of entry, most likely sites of entry are skin and nasal mucosa. The bacilli from nasal discharges of infectious patients gain entrance through the skin or respiratory tract. House hold contact is important. Untreated lepromatous patients act as 'source case' or 'pool of infection' in the community. The different mode of transmission are :

(a) **Droplet infection** : This is likely to be the major route. This includes aerosols containing bacilli discharged from Respiratory tract.

(b) **Contact transmission** : Including Direct (skin - to - skin) and Indirect (soil and fomites).

(c) **Other routes (Doubtful)** : These include possibly Breast milk and Tattooing needles.

**Classification of Leprosy** : Leprosy is a disease of classifications. This is probably a reflection of great variation in individual host resistance to the disease. These classifications are based on clinical, bacteriological, immunological and histological status of patients. The various classification in use are :

- 1) Indian Classification
- 2) Madrid classification
- 3) Ridley and Jopling classification
- 4) WHO operational classification

The Indian classification is the official classification of the Indian Leprosy Association (10) and most widely used in India. It is clinico - bacterial classification and described as under :

(a) **Indeterminate type** : Early cases with one or two vague hypopigmented macules and with and without sensory impairment. Lesions are bacteriologically negative.

(b) **Tuberculoid type** : Cases with one or two well defined lesions which may be flat or raised, hypopigmented or erythematous and are anaesthetic.

(c) **Borderline type** : Cases with four or more lesions which may be flat or raised, well or ill defined, hypopigmented or erythematous and shows sensory impairment or loss. Bacteriological positivity is variable and if left untreated can progress to lepromatous type.

(d) **Lepromatous type** : Cases with diffuse infiltration or numerous flat or raised lesions, symmetrical without any sensory loss.

(e) **Pure neuritic type** : Cases show nerve involvement but do not have any lesion in skin. Cases are bacteriologically negative.

In 1987, WHO study group endorsed that all the patients showing smear positivity should be classified as having multibacillary leprosy for the purpose of MDT treatment. Same study group in 1993 gave clinical classification into two groups:

- (a) Paucibacillary leprosy (1 - 5 skin lesions)
- (b) Multibacillary leprosy (more than 5 skin lesions)

## Prevention and Control

(a) **Problem estimation and early diagnosis** : A quick random sample survey is done to collect base line data in the community. Contact surveillance of households with a lepromatous case is recommended for a minimum period of 10 years after case is declared bacteriologically negative, and for 5 years in households with a non - lepromatous case from the time of diagnosis of the index case. Mass surveys are expensive but repeated annual examinations of school children yield better results at relatively low cost (11,12).

(b) **Chemotherapy** : WHO study group has recommended multi - drug therapy for both multi - bacillary and pauci bacillary leprosy (13). Principles of Leprosy Treatment are given in Table - 2.

**Table - 2 : Principles of Leprosy Treatment (14)**

- |  |
|--|
| 1. Stop the infection with chemotherapy.             |
| 2. Treat infections                                  |
| 3. Educate the patient about leprosy.                |
| 4. Prevent disability.                               |
| 5. Support the patient socially and psychologically. |

## Objectives of Treatment

- (i) To interrupt transmission of infection in the community by sterilizing infectious patients as rapidly as possible with bactericidal drugs
- (ii) To ensure early detection and treatment of cases, to prevent deformities
- (iii) To prevent drug resistance
- (iv) Curtailing the duration of treatment

## Recommended Regimens

(i) **Multibacillary leprosy** : As per the recent recommendations, following groups of patients are to be given MDT :

- All smear positive cases
- Skin lesions more than five in number
- More than one nerve trunk thickening
- All cases of relapse/reactivation and all cases who have been treated with Dapsone monotherapy earlier.

*The drugs and dosages are :*

Rifampicin : 600mg once monthly, supervised

Dapsone : 100mg daily, self administered

Clofazimine : 300mg once monthly, supervised and 50mg daily, self administered.

(ii) **Paucibacillary leprosy** : The drugs and dose schedule is Rifampicin 600mg once a month for 6 months supervised  
Dapsone 100mg daily for 6 months self administered

*MDT is not contraindicated in patients with HIV infection.*

## Duration of treatment

**Multibacillary leprosy** : For 12 months, can be extended to 18 months and continued where possible upto smear negativity. Highly bacilliferous LL/BL patients may need 2 - 3 years or more of MDT for achieving bacteriological negativity.



**Paucibacillary leprosy** : for 6 months.

**Follow - up of cases** : Follow up of patients after completion of treatment is an important part of MDT. For paucibacillary cases follow up for at least once a year for 2 yrs after completion of treatment and for multibacillary cases at least once a year for 5 yrs.

**(c) BCG vaccination** : Mycobacterium W vaccine has been released for human use for immuno modulation therapy.

**(d) Rehabilitation** : It is an important aspect of leprosy control. It means the medical, surgical, social, educational, and vocational restoration as far as possible of treated patients to normal activity so that they resume their place in the home, in society and industry. Early treatment helps in disability limitation.

**(e) Health education** : The education should be directed towards general public and to patients helping them develop attitudes and behaviour by their own actions and efforts and seeking professional help whenever required. Early recognition of symptoms, prompt diagnosis, health seeking behaviour, personal care, treatment adherence and rehabilitation are important aspects of health education.

## Summary

Leprosy is a chronic granulomatous immunological disorder caused by *M. leprae* primarily affecting the peripheral nerves and secondarily involving skin and mucosal membrane etc. The disease is clinically characterized by one or more of hypopigmented patches or partial/ total loss of sensation in the affected area or presence of thickened nerves or presence of acid fast bacilli in the skin smears.

There is a fall in number of new cases detected and prevalence rate due to an improvement in management of cases, very low rates of relapse, high cure rates, and absence of drug resistance and shorter duration of treatment with MDT. At present the highest burden is concentrated in 6 countries (India, Brazil, Indonesia, DRC, Bangladesh and Nepal). 3 countries (Brazil, Nepal and Timor - Leste) are yet to achieve the elimination goal. India has achieved elimination of leprosy in Dec 2005.

Leprosy is caused by *Mycobacterium leprae*. These bacilli are acid fast and with ZN stain appear pink/red, their generation time is around 13 - 14 days. Thus the incubation period is long (3 - 5yrs). Man is the only known reservoir. Lepromatous cases are the chief source of infection. A patient is infective, if morphologically solid - staining (viable) bacilli are demonstrable. Most likely mode of transmission is droplet infection and contact transmission. Only a few people exposed to infection develop clinical signs of leprosy, although immunological conversion takes place in large proportions of contacts. The diagnosis is made on the basis of clinical features, skin smears and immunological test. Clinical features include skin lesions, paraesthesia, thickening of nerve trunks and anhidrosis. The skin smears, nasal smears and nasal scrapings are collected, fixed and stained with ZN method. A negative result does not eliminate the possible diagnosis of leprosy. The lepromin test is an intradermal immunological test. The lepromin test is not a diagnostic test, its value lies in estimating prognosis, positive test indicating good prognosis. Other tests include LTT, LMIT,

FLA - ABS test, ELISA etc.

Reactions are acute exacerbations of disease either due to alteration in CMI status (type I reaction) or immune complexes (type II or ENL reaction). Reactions are managed in hospital, whereby along with specific anti - leprosy treatment, anti - inflammatory drugs, steroids or anti - reactional drugs (Clofazimine, thalidomide) may be administered. Leprosy can be classified on the basis of clinical, bacteriological, immunological and histological status of patients. There are various classification but Indian classification is the official classification of the Indian Leprosy Association (clinico - bacterial classification). According to this leprosy has been classified into indeterminate type, tuberculoid type, borderline type, lepromatous type and pure neuritic type. In 1987, WHO clinically classified leprosy into two groups : Paucibacillary leprosy (1-5 skin lesions) and Multibacillary leprosy (more than 5 skin lesions).

WHO study group has recommended multi - drug therapy for both multi - bacillary and pauci bacillary leprosy. Three drug (Rifampicin, clofazimine and Dapsone) regimen is used for treatment of multi - bacillary leprosy for duration of 12 - 18 months and two drug regimen ( Dapsone and Rifampicin) is used for 06 months for paucibacillary treatment. Follow up of patients after completion of treatment is an important part of MDT. For paucibacillary cases follow up for at least once a year for 2 yrs after completion of treatment and for multibacillary cases at least once a year for 5 yrs. Rehabilitation is an important aspect of leprosy control and it means the medical, surgical, social, educational, and vocational restoration as far as possible of treated patients to normal activity. Health education should be directed towards general public and to patients helping them develop attitudes and behaviour by their own actions and efforts and seeking professional help whenever required.

## Study Exercises

**Long Question** : Discuss the epidemiology of leprosy and principles of its prevention / control.

**Short Questions** : (1) Lepromin test (2) Principles of leprosy treatment (3) Diagnosis of leprosy case

### MCQs

1. Countries which are yet to achieve elimination of leprosy by 2008 includes all except (a) Brazil (b) Nepal (c) Timor - Leste (d) India
2. Leprosy is also known as (a) Hansen's disease (b) Koch's disease (c) Crippling disease (d) Weil's disease
3. Contact surveillance of households in lepromatous case is recommended for the period of \_\_\_\_\_ yrs (a) 10 (b) 5 (c) 15 (d) 7.
4. Contact surveillance of households in non lepromatous case is recommended for the period of \_\_\_\_\_ yrs (a) 10 (b) 5 (c) 15 (d) 7.
5. According to WHO clinical classification multibacillary leprosy have (a) 5 or more lesions (b) 6 or more lesions (c) 5 lesions (d) all of the above.
6. Follow up of multi - bacillary cases should be done for \_\_\_\_\_ yrs (a) 5 (b) 2 (c) 10 (d) 3

7. Lepromin test is read at \_\_\_\_\_ and \_\_\_\_\_ (a) 24 hrs and 21 days (b) 48 hrs and 21 days (c) 24 hrs and 7 days (d) 48 hrs and 7 days.
8. Duration of pauci - bacillary leprosy treatment is (a) 06 months (b) 09 months (c) 12 months (d) 18 months
9. Classification into pauci and multi bacillary leprosy is based on \_\_\_\_\_ features (a) clinical (b) histological (c) bacteriological (d) immunological.
10. According to Indian classification Leprosy is classified into \_\_\_\_\_ types (a) 5 (b) 4 (c) 3 (d) 2.

#### Match the following

1. Mitsuda reaction	a) Leprosy
2. Fernandez reaction	b) 6 or more lesions
3. Paucibacillary leprosy	c) 21 days
4. Multibacillary leprosy	d) 5 lesions
5. Ridley - Jacob classification	e) 48hrs

#### True or False

1. Highest burden of leprosy is in 6 countries : India, Brazil, Indonesia, Srilanka, Bangladesh and Nepal T/ F
2. Generation time of leprosy bacilli is around 13 - 14 days. T/ F
3. Following 6 states of India viz. Bihar, Chattisgarh, Jharkand, Chandigarh, Dadra and Nagar Haveli and Delhi have PR of 1 - 2 per 10000 population. T/ F
4. Lepromatous cases are the chief source of infection. T/ F

5. Lepromin test employed to detect CMI and classify the type of disease T/ F
6. Duration of treatment for paucibacillary leprosy is for 12 months, can be extended to 18 months. T/ F

**Answers : MCQs :** (1) d; (2) a; (3) a; (4) b; (5) b; (6) a; (7) b; (8) a; (9) a; (10) a. **Match the following :** 1 - e; 2 - c; 3 - d; 4 - b; 5 - a. **True or False :** (1) - F; (2) - T; (3) - T; (4) - T; (5) - T; (6) - F.

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Sunil Agrawal

The disease is one of the earliest recorded eye afflictions, having been identified in Egypt as early as 15 B.C. Its presence was also recorded in ancient China and Mesopotamia. Trachoma became a problem as people moved in crowded settlements or towns where hygiene was poor. Today, most victims of trachoma live in underdeveloped and poverty-stricken countries in Africa, the Middle East, and Asia. Blindness due to trachoma has been eliminated from the United States.

#### Definition

Trachoma (Ancient Greek : "rough eye") is an infectious eye disease, and the leading cause of the world's infectious blindness. It is a chronic communicable kerato-conjunctivitis of insidious or abrupt onset, characterized by conjunctival inflammation with lymphoid follicles and papillary hyperplasia associated with vascular invasion of the cornea (pannus) and

in its later stages by conjunctival cicatrization which may lead to gross deformity of the eyelids, progressive visual disability and blindness(1).

#### Epidemiology

**Magnitude of the problem :** Trachoma is a major preventable cause of blindness in developing countries. Globally, 84 million people suffer from active infection and nearly 8 million people are visually impaired as a result of this disease. Globally this disease results in an estimated US \$2.9 billion in lost productivity every year. The incidence and prevalence of trachoma has shown a significant decrease in many endemic countries of SEAR during the past few decades. The decrease is due to improved sanitation, water, housing and implementation of control measures but it still remains a problem in parts of Myanmar, western region of Nepal and in few rural areas in India (2). It is estimated to be responsible for 0.2 percent of visual impairment and blindness in India. Blindness due to trachoma is irreversible once it has occurred, but it can be prevented. With the SAFE strategy (described later), the World Health Organization (WHO) and its partners are targeting the Global Elimination of Trachoma (GET) as a cause of blindness

by the year 2020. GET2020 is one element of a broader strategy known as 'VISION 2020: The Right to Sight', which has as its goal the elimination of all avoidable blindness by the same year.

**Agent** : The infectious agent is *Chlamydia (Bedsonia) trachomatis*, obligatory intracellular bacteria, which includes several antigenic types. Man is the only reservoir. The eyes of infected individuals (especially children from 1 to 15 years of age) are the sources of infection. Trachoma is a disease of low infectivity and only infective when active lesions are present along with ocular discharges and not when cicatrization takes place.

**Host** : No person is immune. In endemic areas children have active disease more frequently than adults especially from the age of two to five years. At younger age, prevalence is equal in both sexes however, females are more commonly infected in older age group as they remain more close to infected children than males. The severity of the disease often is related to environmental conditions. Lack of water and exposure to dry winds, dust and fine sand may contribute to the severity of the disease.

**Environmental factors** : The incidence is found high during the month of April-May and July-September. The higher temperature and rainfall favours the increase in eye seeking fly population. Trachoma is a disease of poverty, ignorance, poor personal hygiene, illiteracy, and poor housing. The hygiene and sanitation is inversely proportional to incidence of trachoma cases.

**Mode of Transmission** : Transmission occurs by close contacts, hands, towels, handkerchief, pillow cases, flies and dust. A dry and hot climate with dust, dirt, squalor and crowding in houses, dormitories, hostels, barracks, swimming pools and general unhygienic conditions leading to fly breeding and midget breeding favour the spread of disease. The use of common family vial of eye cosmetics, such as 'surma' and 'kajal' or towels and wipe clothes is a potent cause of spread in families and close institutions such as schools, hostels and so on. One can, thus, summarize the main environmental risk factors which are involved in the transmission of trachoma as six Ds [Dry, Dusty, Dirty, Dung, Discharge and Density (over-crowding)] or five Fs [Flies, Faeces, Face (eyes), Fingers and Fomites] (3).

**Incubation Period** : 5 to 12 days, while the period of communicability is very prolonged and starts before the appearance of the follicles and continues until cicatrization has occurred.

### Clinical Features

The affected individual experiences symptoms of conjunctivitis, or irritation similar to "pink eye." Trachoma is classified as Blinding and Non-blinding. Trachoma inflammation may undergo spontaneous resolution or may progress to conjunctival scarring which can cause inward deviation of eyelashes (trichiasis) or of the lid margin (entropion). The abrasion of the cornea by eyelashes frequently results in corneal ulceration, followed by scarring and visual loss.

The conjunctival inflammation is called "Active Trachoma" and is usually seen in children, especially pre school children.

It is characterized by white lumps in the undersurface of the upper eye lid (conjunctival follicles or lymphoid germinal centres) and by non-specific inflammation and thickening often associated with papillae. Follicles may also appear at the junction of the cornea and the sclera (limbal follicles). Active trachoma will often be irritating and have a watery discharge. Bacterial secondary infection may occur and cause a purulent discharge.

The later structural changes of trachoma are referred to as "Cicatricial Trachoma". These include scarring in the eye lid (tarsal conjunctiva) that leads to distortion of the eye lid with buckling of the lid (tarsus) so the lashes rub on the eye (trichiasis). These lashes will lead to corneal opacities and scarring and then to blindness. In addition, blood vessels and scar tissue can invade the upper cornea (pannus). Resolved limbal follicles may leave small gaps in pannus (Herbert's Pits). The World Health Organization recommends a simplified grading system for trachoma (Box - 1).

<b>Box-1: The Simplified WHO Grading System for Trachoma</b>	
Trachomatous inflammation, Follicular (TF)	Five or more follicles of >0.5mm on the upper tarsal conjunctiva
Trachomatous inflammation, Intense (TI)	Papillary hypertrophy and inflammatory thickening of the upper tarsal conjunctiva obscuring more than half the deep tarsal vessels
Trachomatous Trichiasis (TT)	At least one ingrown eyelash touching the globe, or evidence of epilation (eyelash removal)
Corneal Opacity (CO)	Corneal opacity blurring part of the pupil margin

The prevalence of TF in children aged 1-9 years is the key index for determining whether an area needs intervention with the A, F and E components of SAFE. The prevalence of TT determines the probable need for surgical services. The prevalence of CO is a (rough) measure of the burden of blindness and visual impairment due to trachoma.

### Prognosis

If not treated properly with oral antibiotics, the symptoms may escalate and cause blindness, which is the result of ulceration and consequent scarring of the cornea.

### Prevention and Control

The World Health Organization (WHO) has set a goal of eliminating blinding trachoma as a public health concern by 2020, using the SAFE strategy, which includes:

<b>WHO Recommended SAFE Strategy</b>
S-urgery to correct advanced stages of the disease
A-ntibiotics to treat active infection, using Zithromax (azithromycin)
F-acial cleanliness to reduce disease transmission
E-nvironmental change to increase access to clean water and improved sanitation



**Surgery** : For individuals with trichiasis, a bilamellar tarsal rotation procedure is warranted to direct the lashes away from the globe.

**Antibiotic therapy**: WHO Guidelines recommend that a region should receive community-based, mass antibiotic treatment when the prevalence of active trachoma among one to nine year-old children is greater than 10 percent (4). Subsequent annual treatment should be administered for three years, at which time the prevalence should be reassessed. Annual treatment should continue until the prevalence drops below five percent. At lower prevalences, antibiotic treatment should be family-based. WHO recommends Azithromycin (single oral dose of 20mg/kg) or topical tetracycline (one percent eye ointment twice a day for six weeks). Azithromycin is preferred because it is used as a single oral dose and can be used in children from the age of six months and in pregnancy.

**Facial cleanliness** : Children with grossly visible nasal discharge, ocular discharge or flies on their faces are at least twice as likely to have active trachoma as children with clean faces. Intensive community-based health education programs to promote face-washing can significantly reduce the prevalence of active trachoma, especially intense trachoma (TI).

**Environmental improvement** : Modifications in water use, fly control, latrine use, health education and proximity to domesticated animals have all been proposed to reduce transmission of *C. trachomatis*. These changes pose numerous challenges for implementation. It seems likely that these environmental changes ultimately impact on the transmission of ocular infection by means of lack of facial cleanliness. Particular attention is required for environmental factors that limit clean faces.

## Summary

Trachoma (Ancient Greek: “rough eye”) is a chronic communicable kerato-conjunctivitis of insidious or abrupt onset. Trachoma is a major preventable cause of blindness in developing countries. The incidence and prevalence of trachoma has shown a significant decrease in many endemic countries of SEAR during the past few decades due to improved sanitation, water, housing and implementation of control measures. In India, it is responsible for 0.2 percent of visual impairment and blindness. Blindness due to trachoma is irreversible once it has occurred, but it can be prevented. Trachoma is caused by *Chlamydia (Bedsonia) trachomatis*, obligatory intracellular bacteria. Man is the only reservoir. It has low infectivity and spread through eyes of infected person having active lesions. Both sexes are equally affected in younger age group but in older age prevalence is more in females. No person is immune. The incidence is found high during the month of April-May and July-September. It is a disease of poverty and poor environmental condition. The higher temperature and rainfall favours the increase in eye seeking fly population. Transmission occurs by direct or indirect contact with ocular discharges of infected persons or fomites. Incubation period is 5 to 12 days. Communicability Period is very prolonged and starts before the appearance of the follicles and continues until cicatrization has occurred. Conjunctival inflammation is called “active trachoma”. Trachoma is classified as Blinding and non-blinding. Trachoma inflammation may undergo spontaneous

resolution or may progress to corneal scarring and blindness. It is characterized by conjunctival inflammation with lymphoid follicles and papillary hyperplasia associated with vascular invasion of the cornea (pannus) and in its later stages by conjunctival cicatrization which may lead to gross deformity of the eyelids, progressive visual disability and blindness. WHO grading system grade trachoma as Trachomatous Inflammation, Follicular (TF); Trachomatous Inflammation, Intense (TI); Trachomatous Trichiasis (TT); Corneal Opacity (CO). The World Health Organization (WHO) has set a goal of eliminating blinding trachoma as a public health concern by 2020. WHO Recommended SAFE strategy. Surgery for individuals with trichiasis, a bilamellar tarsal rotation procedure is warranted to direct the lashes away from the globe. Antibiotic therapy: Mass antibiotic treatment when the prevalence is more than 10 among 1-9 yrs old children followed by annual treatment till prevalence drop below 5%. At lower prevalences, antibiotic treatment should be family-based. Azithromycin and topical tetracycline are recommended. Intensive community-based health education programs to promote face-washing can significantly reduce the prevalence of active trachoma, especially Intense Trachoma (TI). Environmental changes include improvement in hygiene and sanitation which make transmission of disease difficult.

## Study Exercises

**Long Question**: Describe briefly WHO strategy for elimination of Trachoma.

### MCQs

1. Trachoma is responsible for \_\_\_\_\_ percent of total blindness in India (a) 0.2 (b) 0.5 (c) 0.7 (d) 1
2. Antibiotics of choice in Trachoma is (a) Penicillin (b) Ciprofloxacin (c) Co-trimoxazole (d) Azithromycin
3. In SAFE strategy for elimination of trachoma ‘S’ stands for (a) surgery (b) soiling (c) scarring of conjunctiva and cornea (d) none of the above.
4. Mass antibiotic treatment in trachoma is recommended when the prevalence is more than \_\_\_\_\_ percent (a) 5 (b) 10 (c) 7 (d) 3
5. WHO grading system grade trachoma as 1) Trachomatous inflammation, Follicular (TF) 2) Trachomatous Trichiasis (TT); 3) Trachomatous inflammation, Intense (TI) 4) Corneal Opacity (CO) arrange the following in order (a) 1,2,3,4 (b) 1,3,2,4 (c) 3,2,1,4 (d) 2,1,3,4

**Answers** : (1) a; (2) d; (3) a; (4) b; (5) b.

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## Further Suggested Reading

1. Solomon, AW; Zondervan M, Kuper H, et al. (2006). “Trachoma control: a guide for programme managers.”. World Health Organization.



# 10

**Non Communicable Diseases**



Section 10 : Non Communicable Diseases			
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RajVir Bhalwar

*"....The Japanese smoke a lot and suffer fewer heart attacks than Australians or New Zealanders; The French eat a lot of fat and also suffer fewer heart attacks than Australians or New Zealanders; The Italians drink a lot of wine and also suffer fewer heart attacks than Australians or New Zealanders....."*

(Conclusion : Eat, drink, Smoke and enjoy the way Japanese, French and Italians do; Actually it is speaking English that gives so many heart attacks to Australians & New Zealanders!)

With rapid urbanization, industrialization and increasing level of affluence (the so called "modernization"), the price that the society is paying is a tremendous load of "Non - Communicable" diseases, also referred to as "Chronic" diseases" and, often, as "Lifestyle Diseases". The list of major lifestyle diseases is displayed in the Box - 1. The issue is a global phenomena and not simply restricted to the developed, rich countries. In the context of our country, too, the problem of lifestyle and its consequent diseases needs to be addressed vigorously by all public health care personnel.

**Box - 1 : Major "Lifestyle Diseases"**

Obesity	Heart Disease
Hypertension	Diabetes Mellitus
Oral cancer	Lung cancer
Breast cancer	Colonic cancer
Other cancers	Sexually Transmitted Diseases
HIV & AIDS	Mental Stress and its sequelae
Osteoarthritis	Osteoporosis
Liver Disease	Asthma and Bronchitis
Road accidents	

### What is "Lifestyle"

"Lifestyle", in the context of preventive health care, indicates the behavioural patterns which we routinely adopt and the way we tend to (involuntarily) live our daily life, unless coerced to change by some external stimulus. Lifestyle is thus mainly dependent on psycho - social and environmental factors and, to a smaller extent, on genetic influences. Lifestyle is developed in the form of a set pattern of behaviour, very gradually, over many years, in the way we eat, drink, exercise, use intoxicants, are predisposed to own health care and personal protection, sexual practices and so on. Since these behavioural patterns are acquired very gradually, changing them becomes a difficult proposition and needs a lot of persuasiveness as well as persistent approach on the part of the health care providers

including health educators.

**What are the major components of "Lifestyle"** : As said earlier, lifestyle is more of attitudes and behaviours, about "predispositions". Thus, there would be a large number of components of "lifestyle" which affect health, in the form of the way we exercise, to sexual mores to habitual hand washing before eating meals. However, from preventive point of view, the major facets of lifestyle are summarized in Box - 2.

**Box - 2 : The Major Components of Unhealthy Lifestyle**

- Lack of physical activity
- Faulty dietary habits
- Tobacco use
- Excessive alcohol intake
- Mental Stress
- Disregard to personal safety regarding
  - Accidents
  - Personal hygiene
  - Promiscuous Sex
  - Insect Vectors of Diseases

**The National Scenario** : India is experiencing a rapid health transition, with large and rising burdens of chronic diseases, which were estimated to account for 53% of all deaths in 2005. Earlier estimates projected that the number of deaths attributable to chronic diseases would rise from 3.78 million in 1990 (40.4% of all deaths) to 7.63 million in 2020 (66.7% of all deaths) (1). Many of these deaths occur at relatively early ages. Compared with all other countries, India suffers the highest loss in potentially productive years of life, due to deaths from cardiovascular disease in people aged 35 - 64 years (9.2 million years lost in 2000). By 2030, this loss is expected to rise to 17.9 million years - 940% greater than the corresponding loss in the USA, which has a population a third the size of India's (2).

The estimated prevalence of coronary heart disease is around 3 - 4% in rural areas and 8 - 10% in urban areas among adults older than 20 years, representing a two - fold rise in rural areas and a six - fold rise in urban areas over the past four decades. About 29.8 million people were estimated to have coronary heart disease in India in 2003; 14.1 million in urban areas and 15.7 million in rural areas (3). The prevalence of stroke is thought to be 203 per 1,00,000 population among people older than 20 years (4).

Data on cancer mortality are available from six centres across the country, which are part of the National Cancer Registry Programme of the Indian Council of Medical Research (ICMR). About 8 Lac new cases of cancer are estimated to occur every year. The age - adjusted incidence rates in men vary from 44 per 1,00,000 in rural Maharashtra to 121 per 1,00,000 in Delhi (5). The major cancers in men are mostly tobacco - related (lung, oral cavity, larynx, oesophagus, and pharynx). In women, the leading cancer sites include those related to tobacco (oral cavity, oesophagus, and lung), and cervix, breast, and ovary cancer.

Lifestyle diseases or "Non-Communicable Diseases" have common risk factors as listed in Box-2. Thus, by becoming physically active, eating a healthy diet, avoiding alcohol and tobacco and by managing mental stress, we will not only prevent IHD; we will prevent IHD, diabetes, hypertension, cancers, road accidents and stroke, since the determinants are common.

India has the largest number of oral cancers in the world, due to the widespread habit of chewing tobacco.

India also has the largest number of people with diabetes in the world, with an estimated 19.3 million in 1995 and projected 57.2 million in 2025 (6). The prevalence of type 2 diabetes in urban Indian adults has been reported to have increased from less than 3.0% in 1970 to about 12.0% in 2000 (7). On the basis of recent surveys, the ICMR estimates the prevalence of diabetes in adults to be 3.8% in rural areas and 11.8% in urban areas. The prevalence of hypertension has been reported to range between 20 - 40% in urban adults and 12 - 17% among rural adults (8). The number of people with hypertension is expected to increase from 118.2 million in 2000 to 213.5 million in 2025, with nearly equal numbers of men and women (9).

These advancing epidemics are propelled by demographic, economic and social factors, of which urbanisation, industrialisation, and globalisation, are the main determinants. The Indian economy is growing at 7% per year. With increasing life expectancy, the proportion of the population older than 35 years is expected to rise from 28% in 1981 to 42% in 2021 (10). During the decade 1991 - 2001, the population grew by 18% in the rural areas and 31% in urban regions (11). Urbanisation and industrialisation are changing the patterns of living in ways that increase behavioural and biological risk factor levels in the population. For these social reasons, the lifestyle epidemic is not simply restricted to non - communicable diseases in our country; the same social changes are leading to other forms of lifestyle diseases, related to sexual lifestyle and have resulted in an HIV - AIDS epidemic that has reached concerning proportions.

An excess risk of death from coronary disease has been observed in men and women of south - Asian origin, by comparison with other ethnic groups, and there is a progressive rise in risk from rural to urban migrant environments (12, 13). The increased risk of cardiovascular problems noted in Indian migrants is a portent of the further rise in risk that Indians are likely to experience alongside the developmental transition of their country. A high frequency of diabetes, central obesity, and other features of the metabolic syndrome (especially the characteristic dyslipidaemia of reduced HDL cholesterol and raised triglycerides) have been reported in migrant and urban Indian population groups (14, 15). The INTERHEART study (16) found that the cluster of nine coronary risk factors identified in the global population was also applicable to south Asians as a group.

In the past few years, two surveillance systems have been established to provide risk factor data from different parts of the country (17). In 2002, ICMR, with technical assistance from WHO, established a community - based surveillance system involving five centres. The prevalence of tobacco use has been estimated in the National Sample Survey and the National Family Health Survey (18). In the Global Youth Tobacco Survey 25.1% of the students aged 13 - 15 years reported that they had ever used tobacco, whereas current use was reported by 17.5% (19). A national survey in 2002, reported that the overall prevalence of current tobacco use in men and boys aged 12 - 60 years was 55.8%, ranging from 21.6% in those aged 12 - 18

years to 71.5% in the 51 - 60 year age group (20). Many cross - sectional surveys have recorded a high urban prevalence of central obesity and overweight (especially when the lower thresholds recommended by WHO for Asian people are used). Though the prevalence of obesity (BMI 30) is usually lower than that observed in the western population, the overweight category (BMI 25) includes almost a third to half the population in every survey. Women and men are equally affected (21, 22). Small birth size, with rebound obesity in early childhood, predicted diabetes and glucose intolerance in adulthood occurs in an Indian cohort (23).

The few available standardised studies of physical activity revealed low levels in urban areas (compared with rural) and in the upper - income and middle - income groups (compared with low - income). Low levels of physical activity have been reported in 61 - 66% of men and 51 - 75% of women, in urban surveys (22, 24). Most surveys have also shown higher mean concentrations of plasma cholesterol in urban population groups (4.6 - 5.2 mmol/L) compared with rural groups (4.3 - 4.6 mmol/L), with a low mean concentration of HDL cholesterol (25). The ICMR surveillance project observed that the prevalence of dyslipidaemia (ratio of total cholesterol to HDL cholesterol 4.5) was 37.5% in individuals aged 15 - 64 years. Even in a relatively young industrial population (20 - 59 years), 62.0% had dyslipidaemia (26). Levels of awareness, treatment, and adequate control are low for hypertension, diabetes, and dyslipidaemia, especially in rural areas (26, 27).

With advancing health transition, the poor are increasingly affected by chronic diseases and their risk factors. Low levels of education and income now predict not only higher levels of tobacco consumption, but also increased risk of coronary heart disease (19, 28). Since India's daily consumption of fruits and vegetables is 130 g per person per day, poor people may also have deficiencies of protective phytonutrients. Urban slums in Delhi have high rates of diabetes and dyslipidaemia (29).

Lack of awareness of risk factors and diseases, and inadequate access to health care, increase the risk of early death or severe disability in such disadvantaged groups. The major socio - economic determinants of unhealthy lifestyle in populations are listed in Box - 3.

**World - wide Magnitude of the Problem :** Chronic diseases represent a huge proportion of human illness. They include cardiovascular disease (30% of projected total worldwide deaths in 2005), cancer (13%), chronic respiratory diseases (7%), and diabetes (2%). Three risk factors underlying these conditions are key to any population - wide strategy of control - tobacco use, physical inactivity and obesity. These risks and the diseases they engender are not the exclusive preserve of rich nations. An estimated total of 58 million deaths worldwide in a year, heart disease, stroke, cancer, and other chronic diseases will account for 35 million, more than 15 million of which will occur in people younger than 70 years. Approximately four out of five of all deaths from chronic disease now occur in low - income and middle - income countries, and the death rates are highest in middle - aged people in these countries (30).

We shall discuss the major components of healthy lifestyle and the methods of addressing them from the preventive angle.



**Box - 3 : What Socio-Environmental Changes have Led to Increasingly Unhealthy Lifestyles in Populations**

Rapid Industrialisation / Market economy
Increased global earnings
Materialism / consumerism
Mechanisation
Ad - Driven Competitive Food Industry
TV, Cables, VCDs
Computers, Internet
Increasing market of tobacco and alcohol, more so driven by ads
Academic competitiveness among children
Career Competitiveness
Migration towards urban areas
Loss of traditional "cushion" provided by traditional family life
Prove your capabilities by pushing the files! Compounded by InfoTech

## Lack of Physical Fitness & Physical Inactivity

Substantial progress has been made during the past decades in scientifically substantiating the role of physical exercise and fitness in a number of human diseases and more recently, the role of physical exercise & fitness in positive lifestyle. Indeed, of all the lifestyle factors, physical exercise seems to be one of the most important in relation to health. It has been quite aptly said that physical exercise is the nature's panacea for preventing ill health.

'Physical Activity' and 'Physical Fitness' are two distinct entities. One may be physically active but may still not achieve a high level of fitness. For instance, if a 70 Kg man walks slowly, covering 8 kilometers in 3 hours, he would burn off almost 550 kilocalories (Kcal); however he may not achieve 'fitness' by such activity, since the 'Intensity' is quite low. On the other hand if the same person does a 'Walk and Jog' schedule, overcoming half the distance (4 km) in half an hour, he may burn off only half the numbers of calories, but will achieve a pretty good level of fitness. The point to be noted is that both are important - some work (activity / exercise) needs to be performed to burn off calories and, additionally, such activities / exercises should be undertaken with reasonable amount of intensity (vigorousness) so that, in addition to burning the calories, "fitness" is also achieved. The above point is important since recent research has pointed out that most of the health benefits of physical exercise (as brought out later in a separate section) are actually due to the "Fitness" that results from the exercise and not from simply burning off the calories during such activities (31). For instance, a housewife, during the course of her daily chores, or a person playing golf without carrying the clubs and walking at a slow pace for 2 hours, may burn off substantial amount of calories but may not be able to reap the complete benefits of exercise.

However, for those who are not exercising at all or else cannot exercise at moderate intensity levels even mild exercises will help. For planning a physical exercise program, the dictum

should be 'Any exercise is good; more the better' (32 - 35). In fact, people who have not been exercising for a long time should be encouraged to start with low intensity exercises or even by bringing about "life style changes" so that they become more active. Coaxing them to undertake more strenuous exercises from the very outset could be counter - productive. Subsequently, as they progress, they may be encouraged to gradually increase the level of exercise intensity.

## Benefits of Exercise and Diseases Due to Physical Inactivity

It is often thought that physical exercise is a very good way of reducing the body weight and that is all which is good about physical exercise. This notion is correct only to a very small extent which should be emphasised upon the individuals and communities so that they draw the maximum benefits of physical exercise. Alone and by itself physical exercise is not a very efficient method of reducing weight. The major emphasis, if weight reduction is the issue, should be control on diet. Physical exercise can only be a useful adjunct. For example, just one average sized slice of bread will give 65 to 70 Kilocalories (Kcal), to burn off which, one would need to go running for a Kilometer. Just four innocuous looking slices of bread, or a small sized "Samosa" will push in 300 Kcal, which would need 4 kilometers of running/ walking to burn off these calories. If one doesn't do that, these 300 additional Kcal per day will finally result into an extra 1 kg every month or an additional dozen of Kgs at the end of a year. Thus, to reiterate, if the major objective is weight loss or weight maintenance, proper diet should be the mainstay; physical exercise can be used only as a supplementary modality. Notwithstanding the above, there are large number of health benefits of physical exercise and fitness, which are over and above the issue of weight maintenance, as shown in Box - 4.

## Epidemiological Evidence - Hazards of Physical Inactivity

WHO estimates indicate that globally, physical inactivity accounts for more than one fifth of the IHD, one tenth each of stroke and breast cancer and one sixth of all colon cancers. Physically inactive lifestyle accounts in 3.3% of all deaths (i.e. 1 death out of every 30 deaths in the world can be attributed to physical inactivity). Physical inactivity also accounts for almost 19 million Disability Adjusted Life Years (DALYs), world - wide. World wide estimates as per a recent WHO report indicate that, on a long term average, *physical inactivity* carries an increased risk (as measured in terms of RR) of 1.05 to 2.63 for IHD, 1.2 to 2.89 for hypertension and stroke, 1.08 to 4.31 times for diabetes type - 2, 1.02 to 2.5 for colonic cancer, 1.02 to as much as 5 times for breast cancer and 1.02 to 1.37 for osteoporosis (36).

In the 1980s and 1990s, various epidemiological studies demonstrated that less intensive physical activity also provides considerable health benefits. The focus has therefore shifted now, to advocate, for the general population at large, to take to moderate intensity exercise by all adults and children, as brisk walking (5-6.5 kmph), recreational cycling and recreational

<b>Box - 4 : Health Benefits of Physical Exercise &amp; Fitness</b>
Helps keeping body weight in check.
Increases the action of insulin hormone, thereby increasing the insulin sensitivity and the peripheral utilization of glucose, thus protecting against Insulin Resistance Syndrome (Syndrome X; Metabolic Syndrome) and NIDDM (Type-2 diabetes), both major risk factors for IHD.
Has a preferential action in mobilizing the fat depots, particularly the “Visceral” (Intra abdominal, peritoneal) fat. By preferentially mobilizing this dangerous type of accumulated fat, physical exercise protects against dyslipidemias, IHD & NIDDM.
Has a specific role in altering the lipid profile in a healthy fashion. Various studies have shown that the HDL levels are much higher while the triglycerides, LDL and Total cholesterol levels are much lower, among those who exercise regularly.
Is associated with lowered levels of systolic and diastolic blood pressure, thereby protecting against hypertension.
Has cardio-protective effect. Besides the improvements in insulin sensitivity, blood pressure, lipid profile and visceral fat deposition, physical exercise exerts its cardio-protective role by opening up the collateral blood vessels; increases the stroke volume and maximal ventilatory capacity; reduces myocardial oxygen demand at a given level of work; reduces fibrinogen levels, platelet aggregation and tendency of thrombus formation.
Brings about a reduction in the level of anxiety and stress and induces a sense of confidence and well-being. To some extent, this effect is believed to be brought about by the release of “beta endorphins” which are natural occurring, opiate-like chemicals.
Tones up muscles and increases flexibility, thus protecting from injuries and falls.
Helps in maintaining adequate bone mass density, thereby protecting from osteoporosis and its complications.
Protective against cancers of colon, prostate and breast.
Is of use in prevention as well as in rehabilitation of low backache.

swimming. In addition, the focus has also shifted to inculcate healthy lifestyle, by increasing activity levels in all the four ‘domains’ of life viz., at workplace, in transport, at home and during recreation time.

**Does past physical activity / fitness help ?** : This aspect needs to be clearly understood by all medical personnel and explained to the community members. There is enough evidence to indicate that the various health related benefits of physical exercise are always due to “current” physical activity and not “past” activity. Thus, for one to draw the benefits of exercise, one should continue to be active; the benefits will occur only as long as one continues to be active. Physical activity in the past does not seem to help - one may have been an international level athlete during one’s heydays, but that does not protect if one becomes inactive later in life.

**Does “Spot - reduction - exercise” works ?** : Often, obese people, especially those with abdominal obesity are led to believe that abdominal strengthening exercises (as ‘sit ups’ or equivalent gymnasium gadgets) will “burn off” the fat around the abdomen. It needs to be explained that for burning off the fat “around” (actually inside) the abdomen, one has to burn off overall calories and restrict the diet. Abdominal exercises may only slightly help by ‘toning’ up the abdominal muscles but the energy spent in such exercises will be too little to have any impact on overall weight loss. It needs to be emphasised that ‘sit ups’ do not, by any chance, push away the fat from the abdomen. Vibrator belts and massage systems used over the abdomen are equally unscientific. The best (and generally the only) way to lose fat from the “tummy” is to do brisk aerobic exercise and cut down on dietary calories - this is the only

“tummy trimmer” and there is none else.

**The Exercise Program** : A physical exercise and fitness schedule should be incorporated into the daily lifestyle. It needs to be emphasized that such program does not include only walking or jogging or only weight - training. An optimum physical fitness program should cater to three major facets of physical fitness, viz, Endurance (Stamina : Cardio - respiratory efficiency); Muscular Strength; and Flexibility.

**Endurance** : It is the capacity to undertake sustained aerobic physical exercise using a high proportion of maximal oxygen uptake. The ideal means of improving endurance is by undertaking sustained aerobic training at the near maximal level, which a person can tolerate. Gradually, with continued training, at near maximal level, the maximal aerobic capacity increases, i.e. the person increases the ‘Stamina’. Concurrently, with increase in stamina, the level of physical fitness increases and the person starts reaping more and more health benefits of physical exercise, as have been cited earlier. Any endurance training program has three distinct components, viz. :

**Frequency** : This is measured by the number of sessions per week that are devoted to endurance training. Ideally, there should be 4 to 5 sessions per week; the minimum recommended is 3 per week.

**Intensity** : Intensity is measured by the ‘strenuousness’ of the exercise. We shall deliberate on the measures of strenuousness a little later in a separate section. In general, it is recommended that to achieve the maximum gains, the physical exercise should be of at least “moderate” intensity. As one becomes more and more fit, one could (and should) aim to undertake

more strenuous (high intensity) exercises.

**Duration** : This is the time spent on exercise, in a given session. In general, during a session, approximately 60 minutes should be devoted for mild intensity exercises, 40 to 45 minutes for moderate intensity activities, while 20 to 30 minutes and 10 to 15 minutes are adequate for high intensity and very high intensity exercises, respectively. It also needs to be emphasized that the above suggested plans are only recommendations based on overall consensus and evidence. Ultimately, the program has to be tailored to meet the individual / community needs.

**Measuring the level of intensity** : Out of the 3 components of endurance training, while measuring the duration and frequency is quite straightforward, measuring the various levels of intensity often gets shrouded with confusion, particularly at the level of the user. A summary of various available guidelines to measure intensity of exercises and the overall recommendations are given in the succeeding paragraphs.

**Measuring exercise intensity on the basis of heart rate** : One of the oldest and quite widely used measure of exercise intensity is based on "Maximum Permissible Heart Rate (MxPHR)". The MxPHR for any individual is calculated as  $220 (-) \text{ Age in years}$ . For example, for a person aged 50 years, the MxPHR will be  $220 (-) 50 = 170$  beats per minute. In general, during an exercise session, this limit should not be exceeded. If a person is exercising at 50% to 60% of his MxPHR, it is taken as Low intensity exercise, 60% to 70% is Mild intensity, 70% to 80% is Moderate intensity, while 80% to 90% and 90% to 100% are taken as Severe intensity & Very severe intensity exercises respectively.

For example, the MxPHR for a 50 years old person would be 170. If the heart rate achieved by the person during a session of exercise is 50 to 60% of 170 (i.e. 85 to 102 beats per minute) he is exercising at low intensity level. Accordingly, for this person, the heart rate levels from 103 to 119, 120 - 136, 137 - 153, and 154 to 170 or even more, would qualify for mild, moderate, severe intensity and very severe intensity exercise respectively.

**How to measure the heart rate achieved during an exercise session.** A practical method is as follows : Immediately on completion of an exercise session and definitely within 5 seconds of completion the individual starts counting the radial pulse, for 10 seconds. The first beat is counted as zero. The number of beats so counted in 10 seconds is multiplied by '6' to obtain the heart rate achieved during exercise.

**Measuring Exercise intensity according to Borg's scale of "Rating of Perceived Exertion (RPE)"** : The scale has the advantage of simplicity and can be used by anyone in the general community. The scale rates the intensity of exercise, as perceived by the person himself, on a visual analogue scale of

0 to 20, as per Box - 5.

To start with, the exercise should be at a level of '12'score, i.e. the subject feels that the exercise intensity is between "Light" and "Somewhat hard". This level, in most subjects, is approximately equal to 60% of MxPHR. As fitness improves, the subjects should increase the intensity of exercise so that they are finally working at a level of 16 i.e. the perception about the exercise they are undertaking is that it is more than 'hard' but less than 'Very hard'. This level usually represents approximately 85% of MxPHR in most subjects.

**Measuring exercise intensity using Metabolic Equivalents (METs)** : Recently the concept of METs is being increasingly used to prescribe the level of exercise for individual subjects. 1 MET is actually equal to a level at which a person will spend 1 Kcal energy per kg body weight per hour and this level usually corresponds to the resting stage. This level also corresponds to an oxygen uptake level of 3.5 ml / kg body weight per minute (37). As the level of MET increases, the intensity of exercise increases.

Thus, a person weighting 70 kg at rest, i.e. at activity level of 1 MET will spend 70 K cal per hour while the same person exercising at the level of 6 MET will be spending  $6 \times 70 = 420$  K cal in an hour. Moreover, the level of 6 MET will correspond to "moderate" level of exercise intensity. Thus, MET have dual advantage, in that in a single value they gave an indication of both, the amount of energy expenditure as well as the intensity of exercise. According to general agreement, the MET levels corresponding to various intensity levels of exercise are shown in the Box - 6 and the METs for common physical exercises are shown in the Box - 7 (37, 38). For example, let us say a subject weighing 70 kg is exercising by cycling at a speed of 16 km/h. He cycled for 8 km in half an hour. He will be exercising at 7 MET which is the upper limit of 'moderate intensity', rather almost touching the level of high intensity exercise. During this half an hour, he will burn off  $(70 \times 7 \times \frac{1}{2}) = 245$  K cal of energy, this will be equivalent to burning off 30 grams of body fat.

<b>Box - 6 : MET Levels for Different Exercise Intensities</b>		
Level of exercise Intensity	Usual MET level	
	Men	Women
Rest	1	1
Very low intensity	1 - 1.5	1 - 1.2
Light	1.6 - 3.9	1.2 - 2.7
Moderate	4 - 5.9	2.8 - 4.3
Heavy	6 - 7.9	4.4 - 5.9
Very Heavy	8 - 9.9	6.0 - 7.5
Unduly heavy	> 10	> 7.6

<b>Box - 5</b>																				
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Nil	Almost Nil exercise		Very, Very Light			Quite Light			Light				Somewhat Hard		Hard		Very Hard		Excruciatingly Hard	

Box - 7			
Activity	MET level	Activity	MET level
Walking 4.8 km/h (slow pace)	3.0	Badminton leisure	3 - 6
Walking 5.4 Km / h (slow pace)	3.6	Badminton match	7 - 9
Walking 6 km / h (brisk pace)	4.3	Dancing social	3 - 7
Walking 6.4 km/h (brisk pace)	4.6	Dancing aerobic	6 - 9
Walking 7 km / h (very fast pace)	6.0	Circuit weight training	8 - 9
Jogging 8 km/h	8.7	Roller skates	5 - 8
Running 9.6 km/h	10.0	Squash leisure	8 - 10
Running 12 km/h	12.5	Squash match	11 - 12
Bicycling 16 km/h	7.0	Tennis leisure	6 - 8
Swimming 20 mtr from	6.0	Tennis match	9 - 10
Swimming 40 metre from	12.0	Volleyball	3 - 6
Golf, walking	4.0	Basket ball match	7 - 12
Golf, walking carrying bag	5 - 6	Basket ball non game	3 - 9

### Recommendations for Physical Exercise

**Recommendations based on calorie expenditure** : The minimum amounts of calories to be expended in programmed physical exercise by the general population have been recently forwarded by CDC Atlanta and American College of Sports Medicine. These recommendations state that every adult should spend at least 200 Kcal per day (i.e. 1400 k cal in a week) by physical exercise and this should be undertaken on "most days" (Preferably all days of a week) (39). This could be achieved by having a half - hourly session every day of brisk walking. The point to be noted in that these are the minimum recommendations and *more exercise* (in terms of more time or more intensity) *is always better*.

More comprehensive recommendations on adequate calories to be spent have come from large scale studies among Harvard alumni and British civil servants. These recommendations in general suggest that to obtain the maximum health benefits of physical exercise, individuals should spend about 2500 k cal per week through regular, (and at least moderate intensity) exercises. To spend these 2500 calories, an average person weighing about 65 kg will need to walk or jog about 35 kms in a week or roughly 5 kms every day.

**Comprehensive Recommendations Based on Intensity, Duration & Frequency** : Besides the intensity of exercise and

the calories to be burnt off, the duration (generally to indicate "how long during a given session") and frequency (to answer "how many times in a week?") are also equally important. The general guidelines are set out in Box - 8.

The good news is that the above mentioned exercise can be "accumulated" i.e., it is not necessary to undertake a given session of exercise in 60 minutes at a stretch. Rather, 2 session of 30 mts each or even 3 session of 20 mts each over the day may also be good enough. It is generally recommended that for achieving weight loss and subsequently maintaining it, people should accumulate 60 to 80 minutes of moderate intensity exercise every day. Although, to the general public, devoting 60 to 80 mts to exercise may sound a bit too much, even impossible; however, once we emphasize on them that these 60 to 80 mts of exercise can be accumulated by undertaking frequent, short sessions, things seem to become manageable for most individuals.

Most experts agree that the best schedule is to have 4 to 5 sessions per week, of moderate intensity exercises of 5 to 8 MET level, with each session lasting for 45 to 60 minutes. This will provide recesses for recovering, as also improve compliance, since the exercise - off days (2 - 3 per week) leave the participants with ample opportunities for other pursuits and social obligations. The optimum linear distance to be

Box - 8						
Intensity of Exercise			Target Heart rate as % of MxPHR	Kcalorie spent per mt	Recommended Duration (Mts per session)	Recommended Frequency (sessions per week)
By description	By MET level	By Borg's RPE scale				
Low Moderate	4 - 5.9	13	70-80%	5 - 7.4	60 - 75	5 - 6
High Moderate	6 - 7.9	16	80-90%	7.5 - 9.9	45 - 60	4 - 5
Heavy	8 - 9.9	18	90-95%	10 - 12.4	20 - 30	3 - 4



covered by brisk walking or jogging in a week is recommended to be about 32 km (20 miles).

**Resistance Training** : Weight training and isometrics are often grouped under a general category of “resistance training”. Current opinion is to encourage mild weight training as a part of exercise - fitness program. It is recommended that mild weights (20 - 30 pounds for men and 10 - 20 pounds for women) may be used, exercising all major muscle groups (chest, back, shoulders, arms, forearms, glutei, thighs and legs) keeping about 3 sets for each major muscle group and 10 - 15 repetitions in each set. Two or three weekly sessions of the above schedule are recommended. Care should be specifically taken not to indulge in “Valsalva’s maneuver” (breathing forcefully against closed glottis, as happens while straining at stools), while undertaking resistance training and even while undertaking aerobic exercises.

**Flexibility** : Gentle stretching exercises as forward bending, side bending and calf stretch are ideal. Yoga exercises are excellent for flexibility. It is best to incorporate flexibility exercises as part of overall exercise plan, during the initial “warming up” for 5 to 10 minutes and the final “Cool down” phase for another 5 to 10 mts.

**Progressing on the exercise program** : It is generally advisable to progress in three phases. In the first phase the subject starts at a low level of about 3 MET (as walking 4.8 Kms in an hour) and over the next 4 - 6 weeks, gradually working up to a level of 4 - 5 MET (eg., brisk walking at speed of 6.5 to 7 km per hour) for 30 mts in a session, and having 4 - 5 such sessions per week. This level should be maintained for 4 - 6 weeks. Once the subject is comfortable at this level for 4 - 6 weeks (as evidenced

by a reduction of about 5 beats per minute in the exercise heart rate at that intensity level of exercise or by a decreased feeling of exertion on the RPE scale or by ability to undertake higher level of MET exercises), the subject moves to phase - 2, wherein he/she undertakes exercises at MET level of 6 to 7 (see table of MET values, e.g., brisk walk - jogging, covering 7 to 7.5 km in an hour) for about 30 to 45 minutes every session, and maintaining at this level for 4 - 6 weeks. In the last phase, the subject again gradually works up, over 4 - 6 weeks to a level of 8 to 9 MET (Jogging, covering 7.8 to 8.5 km per hour). The overall recommendations are summarised in Box - 9.

### Bringing about “Physically Active” Lifestyle Changes

“Structured Physical Activity” programmes, as have been discussed till now, are only one side of inculcating physical activity among individuals and communities. What is equally important is to educate and motivate persons and communities to inculcate a “physically active lifestyle” so that physical activity gets incorporated in each and every action of life. Emphasis should not only be towards incorporating “exercise sessions” in the daily time table or advising gymnasium activities. Equal emphasis should be placed on changing the overall lifestyle from one of luxury and sloth to one of physical activity at every possible moment, integrating physical activity into lifestyle with short, frequent bouts of mild or moderate intensity exercise. This seems to provide the best answer and can be even better than structured exercise programmes. Some examples of positive lifestyle habits are shown in Box - 10.

The principal goal of active lifestyle is to increase energy expenditure without concern for the intensity of activity. The basic principle is that very mild, even inapparent increases

#### Box - 9 : Key Messages to be Given to Individuals & Communities

There are two clear components : firstly, a formal, structured exercise and fitness programme; secondly, inculcating “physically active lifestyle” as a part of day to day life. Both are equally important.

##### Structured Program

Develop & meticulously follow a structured programme. Include all the three components (Endurance, Strength & Flexibility)

##### Endurance

- *Most minimum* : Brisk walking at least 2 miles (3.2 Km) every day or at least most days a week, covering 3.2 Km in 30 to 35 mts.

- *Ideal* : Exercise at 6 to 8 MET (e.g. walking / jogging covering 7 to 8 Km in an hour), 45 to 60 mts per day, every day or at least 4 to 5 days a week.

- If you can exercise at even higher intensity or longer duration, the better it is.

- Instead of walking or jogging, substitute any other aerobic exercise (cycling, swimming, sports, etc.) which makes you happy.

**Strength** : Advisable to undertake resistance training with light weights (10 to 30 lbs) exercising all major muscle groups 2 or 3 times a week.

**Flexibility** : Undertake 5 to 10 mts of Yoga or other gentle stretching exercises before and after an exercise session.

##### Physically Active Lifestyle

Develop the attitude to be physically active always. Use stairs instead of lift, walk instead of driving, Remove the remote controls of TV, Fetch a glass of water yourself rather than asking your orderly, walk to your colleague’s office and discuss rather than using the intercom, park your car at the farthest, and so on.

##### Ensure Compliance

Biggest hurdle in structured physical exercise or active lifestyle program is that you tend to lose out on compliance. Watch out.

(as going out for shopping rather than ordering for grocery on telephone) may make much difference. In fact, emphasis should be on promoting low - intensity, leisure pursuits, which are seen as pleasurable (as walking a dog, gardening, etc.) rather than simply stressing on occasional or periodic vigorous exercises. Similarly, “structured exercise” should also be encouraged but should not be presented as one which requires excessive physical effort; target should be on activities that can be easily incorporated in daily schedule.

<b>Box - 10 : Changing the Daily Lifestyle : Examples</b>
Take stairs instead of the lift; make several trips.
Put away the remote control of TV.
Stand while answering the telephone.
After every half an hour of office job, go out and walk in the corridor for 3 minutes.
Park your car at the farthest possible point.
Take a longer way around, to walk to the due destination.
Don't use servants / children for “fetch-it” jobs; do them yourself.
Go out for entertainment (e.g. see a Movie in the theatre) rather than sitting before the TV.
Wash / mop your car yourself.
Clean your house on holidays.

**Practice Advocacy rather than Health Education** : The effort of all health care professionals, whether in public health or in clinical domains, should be not simply to educate the community / individuals / patients, but rather to socially market the concept of physically active lifestyle. Such advocacy becomes especially important when dealing with high risk groups or with individual persons or patients.

**Role of physicians in improving the lifestyle of subject/patient** : Physicians may play a catalytic role in improving the lifestyle of people they come in contact with. An initial counselling session of 5 to 7 minutes by the physician followed by periodic telephone calls or personal interview sessions to keep up the motivation have been shown to be quite successful. Some motivational examples to be conveyed to the community members are shown in Box - 11.

## Diet & Lifestyle

Detailed deliberations have been made regarding diet, nutrition and lifestyle diseases in the next chapter.

## Tobacco & Lifestyle

Tobacco is one of the major causes of deaths and disease in India, accounting for over eight lakh deaths every year. The variety of forms of tobacco use is unique to India. Apart from the smoked forms that include cigarettes, bidis and cigars, a plethora of smokeless forms of consumption exist and they account for about 35 percent of the total tobacco consumption.

According to the National Family Health Survey - 2, the prevalence rate among males for chewing tobacco was 28.3% and for smoking tobacco, 29.4%. For females, the corresponding prevalence rates were 12.4 and 2.5 percent respectively.

### Box - 11 : Motivating the Community Members & Subjects : Driving away any Excuses for not Exercising

<b>Lack of time</b>
<ul style="list-style-type: none"> <li>Take several spurts of 10 mts each, of exercise during lunch, tea time &amp; dinner time.</li> <li>Park farthest away in the parking lot.</li> <li>Turn off TV/computer for at least 30 minutes and exercise instead.</li> </ul>
<b>Bad weather</b>
<ul style="list-style-type: none"> <li>Get a “treadmill” for home.</li> <li>Try an exercise video at home.</li> <li>Do stationary jogging / walking.</li> </ul>
<b>Holidays</b>
<ul style="list-style-type: none"> <li>Put a lot of effort into cleaning your house.</li> <li>Wash your car/two wheeler</li> <li>Go shopping and carry your packets of grocery.</li> <li>While going for shopping, park your vehicle far off, so that you walk for at least 2 to 3 Kms.</li> </ul>
<b>Feeling Fatigued</b>
<ul style="list-style-type: none"> <li>Remind yourself that exercise will give you more energy</li> <li>Try and “force” yourself for just 10 minutes of walk. Once you start off, chances are that you will continue for longer.</li> </ul>

Based on the National Family Health Survey - 2 age specific data, it is estimated that in the thirty plus age group, smoking prevalence among men is 41.2%. Further, 35.4% of men and 18.2% of females use chewing tobacco in this age group.

The prevalence of tobacco use among the youth has been surveyed by the Global Youth Tobacco Survey (GYTS) supported by CDC and WHO. GYTS is a tobacco specific survey to track the prevalence of tobacco use among 13 - 15 year age group school going students. GYTS has been conducted in different states of India in the period 2000 - 2004. As per this survey, 17.5% of 13 - 15 year old students are using tobacco in some form. In many states alarmingly high prevalence of use of tobacco products among the school - going youth has been reported. North Eastern states like Nagaland (63%), Manipur (46.7%), Sikkim (46.1%) have reported highest prevalence of tobacco use among school students.

As a result of collaborative efforts of Ministry of Health and WHO, the National Tobacco Control Cell was set up in February 2001 to provide impetus to the tobacco control efforts and to coordinate these activities at the national level.

The National Tobacco Control Cell assists in development of comprehensive anti - tobacco public awareness plans to provide health education among the masses; capacity building among NGOs working in the field of tobacco control; establishment and strengthening of tobacco cessation centers and providing key technical inputs on research and policy issues related to tobacco. The Cell has been recognized as an innovative approach towards effective tobacco control, which can be replicated by other countries.

Tobacco has been proven, beyond doubt, to be associated with a large number of serious diseases (see Box - 12). In fact, the single most important lifestyle factor as a risk for diseases is tobacco use. Globally, tobacco accounts for 27.8% of all

cardiovascular deaths, 13.6% of all lung cancer deaths, 6.6% of upper aerodigestive cancer deaths, 6.6% of other cancer deaths, 27.2% of deaths due to COPD and 12.8% of other respiratory deaths. Worldwide, tobacco use causes 4.83 million deaths, loss of 59 million DALYs and estimated economic loss of \$ 200 billion per year. The medical recommendations regarding tobacco are very clear - individuals and communities should completely give up use of tobacco. In public health practice, all functionaries should endeavour to educate and motivate individuals and communities regarding the adversities associated with tobacco use and to give up tobacco. In addition to educating and motivating, we must use all possible means to convince the community leaders, peers, politicians, and social groups to exert influence in this regards, with a view to obtain the following ends :

- Make availability difficult (e.g. banning the sale of tobacco products in major markets, near educational institutions, in hotels / restaurants, etc).
- Make the smokers feel that his smoking habit is "undesirable" (e.g. ban smoking in public places, transport systems, auditoria, offices, meetings / gatherings, parties; create separate restricted areas as earmarked smokers rooms for people to smoke).
- Exerting influence through influential socio - political groups
- Setting of personal example by influential persons as doctors, sports and theatre personalities, etc.
- Enforcement of relevant laws.

#### Box - 12 : Tobacco Related Diseases

IHD (RR 1.28 to 1.78)

Stroke (RR 1.17)

Lung cancer (RR 12 to 24)

Oral cancer (RR 6.95 to 7.87)

Liver Cancer (RR 1.40)

Cancers of upper aerodigestive tract

Peptic Ulcer

COPD

Buerger's Disease

Hypertension

Amblyopia

while the rest is in the form of country liquor. People drink at an earlier age than previously. The mean age of initiation of alcohol use has decreased from 23.36 years in 1950 to 19.45 years in 1980 to 1990. India has a large proportion of lifetime abstainers (89.6%). The female population is largely abstinent with 98.4% as lifetime abstainers. This makes India an attractive business proposition for the liquor industry. Changing social norms, urbanization, increased availability, high intensity mass marketing and relaxation of overseas trade rules along with poor level of awareness related to alcohol has contributed to increased alcohol use. Taxes generated from alcohol production and sale is the major source of revenue in most states (Rs.25,000 crores) and has been cited as a reason for permitting alcohol sale. Four states - Gujarat, Mizoram, Manipur and Nagaland - have enforced prohibition. Profile of clients in addiction treatment centers in 23 states (including states with prohibition) showed that alcohol was the first or second major drug of abuse in all except one state. The annual loss due to alcohol was estimated to be Rs.70,000 to 80,000 million.

Habitual alcohol use is another major lifestyle factor associated with ill health and a large number of serious diseases, as depicted in Box - 13.

#### Box - 13 : Alcohol Related Diseases

Hypertension & Stroke (RR 1.4 to 4.1, depending on intake)

IHD (mild consumption may be protective (RR = 0.68); heavy consumption carries risk (RR = 1.33)

Road Accidents

Obesity

Diabetes Mellitus type - 2

Cancers : Female Breast Cancer (RR 1.14 to 1.62); Oral Cancer (RR 1.45 to 5.39); Other cancers (aerodigestive tract, stomach, pancreas, kidneys, bladder) (RR 1.8 to 4.93 depending on intake and site)

Liver disease (RR 1.2 to 13 depending on intake) (cirrhosis, increased susceptibility to liver infections)

Pancreatitis

Degenerative neurological diseases

Social and emotional problems

Psychiatric problems and dependence

Lack of efficiency, productivity and organizational issues.

## Alcohol

62.5 million alcohol users are estimated in India. Per capita consumption of alcohol increased by 106.7% over the 15 - year period from 1970 to 1996. Due to its large population, India has been identified as the potentially third largest market for alcoholic beverages in the world which has attracted the attention of multi national liquor companies. Sale of alcohol has been growing steadily at 6% and is estimated to grow at the rate of 8% per year. About 80% of alcohol consumption is in the form of hard liquor or distilled spirits showing that the majority drink beverages with a high concentration of alcohol. Branded liquor accounts for about 40% of alcohol consumption

Besides the diseases, alcohol has additional social and emotional problems, and disrupts family and organizational health. A WHO report indicates that alcohol use accounts for 3.2% of all global deaths and 4% of all global burden of diseases; it also accounts for 3.5% of all DALYs lost due to all causes. What is even more concerning is the recent trend wherein lay magazines tend to put across a conveniently distorted version of the medical research findings, which tend to indicate that moderate drinking is good for health. This is, in fact, an issue which all public health persons would need to counter when talking to individuals and communities. While

it is agreed that “moderate” alcohol intake may be associated with lower HDL - cholesterol levels and lower IHD mortality, the fact also remains that continued alcohol intake, even in mild to moderate quantities, is associated with a number of other diseases like road accidents, various cancers, obesity and hypertension. Secondly, it is quite difficult to maintain “moderation” - many of those who are initially moderate may become heavy drinkers gradually. Thirdly, there are various other more healthy methods (as brisk, regular physical exercise) rather than drinking, to increase the HDL levels. All these aspects should be emphasized on the clientele.

The relationship between even mild drinking and obesity (with all the consequent ill health effects of obesity) is quite logical, as depicted in Box - 14. In addition, even two small pegs may raise the blood alcohol level beyond the legally acceptable in India (30 mg %), and may interfere with the protective reflexes, causing road accidents. The hazards of alcohol use should be well communicated to our clientele and they should be motivated to give up alcohol. The recommendations should be:

- There is nothing like medically prescribed or medically encouraged drinking to get good health; with all its well documented resultant diseases, alcohol should not be used.
- However, despite the above exhortation, if somebody still decides to drink, he or she may do so provided there is no other risk factor (Obesity, Diabetes, hypertension) and provided one drinks only in “moderation”. The guidelines for “moderation” are in Box - 15.
- Besides restricting to moderation, adhere to the following principles : firstly, never drive after drinks (even after very mild drinking); secondly, try not to drink on two consecutive days; thirdly, try not to drink in daytime; and, fourthly, drink along with food and not on empty stomach.

<b>Box - 14 : Alcohol even in mild quantities, promotes obesity by :</b>
Providing “blank” calories - each gram gives 7 Kcal; 1 small peg gives 70 Kcal, equal to running 1 Km!
Promotes overeating
Desire to eat rich, fattening food
Reduces desire of physical activity

<b>Box - 15 : Defining “Moderate” Drinking</b>
A “unit” of alcohol is defined as equivalent of 10 grams pure ethanol.
This will be equal to 1 small peg of hard drink or 100 ml of Wine or half a bottle of Beer.
Moderation means maximum of 3 units in a day for men (and 2 units a day for women)

### The Principles of Public Health Approach for Preventing Alcohol and Tobacco Use

As would be apparent from the facts mentioned above, tobacco and alcohol use a major cause of diseases, ill health, reduced

quality of life and lowered productivity, the world over. It is therefore a priority area for all public health systems and functionaries to develop and implement programs and strategies to combat these major ill - health issues. The following are the suggested which can be adopted for this purpose.

Tobacco and Alcohol control issues can be considered together from the preventive point of view since both are highly addictive substances, are used by a large proportion of human population, and are liable to cause a wide variety of serious diseases. The preventive strategy should focus on two levels, viz., firstly, the national / large community level and, secondly, at the individual / family level.

**Steps at the National / Large Community Level :** The approach would include a combination of three strategies, viz. Information, Education and Communication (IEC) steps, Statutory (legal or regulative) steps, and Fiscal steps, as follows :

**IEC Steps :** These would include the following

**Developing a nation wide educational strategy and program :** A comprehensive policy and programme should be developed by nations / states for informing the community members regarding the health hazards due to tobacco and alcohol, the seriousness of these diseases and regarding the potential methods of prevention. Educational programs should involve the departments of advertising and audio - visual media and those concerned with information and broadcasting. Educational messages should be adequately pilot tested and should be presented on various channels of mass media, not only on governmental but also private channels as well.

**Counter - Advertising (Counter - Marketing) Campaigns :** Experience in developed countries has shown that proactively conducted educational and advertising campaigns to highlight the seriousness of consequences of these substances can actually help a lot in increasing the proportion of population who would give up their use and reduce the proportion of persons who take up smoking. The strategy is, in fact, to counter the advertising/ marketing campaigns which are carried out by various liquor/ tobacco companies and under the influence of which a large number of young people actually initiate their smoking habit. It has also been seen that taking the help of prominent public personalities as cine stars and sports - persons may be of further help in this direction.

**School and Youth based IEC programs :** The persons who are most at risk of initiating the tobacco and alcohol habit are teenagers. It is therefore very logical that educational programs be developed, targeting these adolescents in the schools as well as at other youth forum as youth festivals, sports functions, etc.

**Quitlines / Helplines :** Experience in developed countries has provided evidence that developing telephonic helplines may be quite helpful in reducing the prevalence of smokers and increasing the duration of cessation. Such telephonic helplines/ quitlines may be part of governmental effort or NGO effort and are designed to provide total assistance to the smoker/ alcoholic who desires to quit smoking, maintain a state of cessation as well as for persons who want education and assistance for not initiating tobacco use habit.



**Fiscal Measures :** Increasing the prices of tobacco and alcoholic products definitely reduces the proportion of persons who use these substances; particularly, lesser number of adolescents are able to initiate these habits. This has been shown in a number of countries and has been (privately) acknowledged by tobacco companies. Public Health policy makers should suggest to the governments to consider an increase on excise on raw material and increased taxation on finished product.

**Legislative and Regulatory Measures :** To back up the educational and fiscal steps, the governments and communities would need to develop legal provisions, so as to make availability of tobacco and alcohol difficult to consumers as well as to ensure that users of these substances do not harm the other members of their family / community due to this habit. In general, the legislative measures focus on the following provisions :

- Printing of statutory warnings regarding the fact that alcohol / tobacco is bad for health, on the packets of tobacco/ alcoholic products.
- Clean indoor air laws and smoke free zone policies, including prohibition of use of these substances in public places, as railways, airlines and other transportation systems, offices, common rooms, restaurants, and such other public places.
- Prohibition of sale of these substances to vulnerable groups, especially children and adolescents.
- Ban on advertisements on promotion of tobacco products.

In our country an extensive law has been promulgated starting with the Cigarettes (Regulation of production, supply and distribution) Act of 1975 which specified the printing of statutory warnings on all cigarette packets. Subsequently, the statutory provisions were enlarged with the promulgation of "The cigarettes and other tobacco products (prohibition of advertisement, regulation of trade and commerce, production, supply and distribution) Act 2003. The act declares that it is expedient in public interest that the Union should take control of the tobacco industry. The act prohibits smoking in public places and provision of a separate smoker's room in restaurants having seating capacity of 30 or more and in airports (From 02 Oct, 2008, i.e. the birthday of the father of the nation, the Govt has extended the promulgation by imposing a blanket ban on all public places). The act also lays down a total prohibition on advertisements of cigarettes and other tobacco products. The act prohibits sale of tobacco products to any person aged less than 18 years and lays down restrictions on trade and commerce in and on production, supply and distribution of cigarettes and tobacco products including printing of statutory warnings on the packets of these products, the letter size, language and other specifications of these warnings, and also the powers of searching the premises and confiscation under this act, as well as the punishment and appeal under this act. The detailed rules (2004) for implementation of the act have been published vide Govt of India Gazette No. 200 dated 25 Feb 2004.

As regards alcohol, we do not have such well formulated legislative regulations as we have for tobacco, but the effort of the Government has been, in recent years, to develop a comprehensive policy as well as legislation to reduce alcohol intake among communities. The available statutory provisions

include the following :

- Printing of statutory warnings on bottles of alcoholic drinks
- Promulgation of "dry state" order by certain state wherein consumption of alcohol is totally banned, except for those having permit to drink
- Testing of motor vehicle drivers for breath test and alcohol level in blood. The upper limit for safety in driving, as far as statutory limits in our country are concerned are 30 mg per 100 ml of blood.

**Steps at the Family and Individual Level :** These are directed to educating, motivating and supporting the individuals and families for, firstly, not initiating the tobacco and alcohol habit and, secondly, to give up the habit. The following steps are documented to be beneficial :

- Educating and motivating the family members, especially the spouse and parents.
- Enrolling "peer groups" as religious teachers, school teachers, etc., in motivating and playing role model for the community.
- Developing support groups as "alcoholics anonymous" groups and informing the community members about their location, ways to contact them and the help that they can provide.
- Pharmaceutical measures as disulfuram for alcohol cessation and nicotine patches / tablets or bupropion for tobacco cessation. However, these measures should be used under medical supervision.

## Summary

With "modernization" there is tremendous increase in "Non - Communicable" diseases referred to as lifestyle diseases and this issue is a global phenomenon. "Lifestyle", in the context of preventive health care, indicates the behavioural patterns which we routinely adopt. The National Scenario estimated chronic diseases to account for 53% of all deaths in 2005. Mortality due to chronic diseases is expected to rise from 40% of all deaths in 1990 to 67% of all deaths in 2020. Prevalence of coronary heart disease is around 3 - 4% in rural areas and 8 - 10% in urban areas among adults older than 20 years. Data on cancer mortality estimates about 8 Lac new cases of cancer every year. The major cancers in men are mostly tobacco - related. In women, the leading cancer sites include those related to tobacco, and cervix, breast and ovary cancer. Further, India also has the largest number of people with diabetes in the world. World - wide estimated deaths due to cardiovascular disease is 30% of projected total worldwide deaths in 2005, cancer (13%), chronic respiratory diseases (7%), and diabetes (2%). Components of healthy lifestyle and addressing them through preventive angle. One of the very important facets of healthy lifestyle is Physical Fitness & Physical activity. Some work (activity / exercise) needs to be performed to burn off calories and additionally, such activities / exercises should be undertaken with reasonable amount of intensity (vigorousness) so that, in addition to burning the calories, "fitness" is also achieved. For planning a physical exercise program, the dictum is 'Any exercise is good; more the better. Physically inactive lifestyle accounts for 3.3% of all deaths, the focus has now shifted to inculcate healthy lifestyle, by increasing activity

levels in all the four 'domains' of life viz. at workplace, in transport, at home and during recreation time. The exercise program should cater to three major facets of physical fitness, viz. Endurance; Muscular Strength; and, Flexibility. Endurance training program has three distinct components, viz. Frequency, (minimum recommended is 3 per week); Intensity, which should be of at least "moderate" intensity; and, Duration, which can be tailored to meet the individual / community needs but is generally recommended to be 30 to 60 minutes on each day on which exercise is undertaken. The easily applicable recommendations are that every adult should spend at least 200 Kcal every day through brisk exercise - this can be achieved by undertaking at least 30 minutes of brisk walking, covering 2 miles (3.2 Kms) in that time, daily or on most days of the week. Measuring the level of intensity can be based on "Maximum Permissible Heart Rate [MxPHR, calculated as  $220 (-) \text{Age in years}$ ], Borg's scale of "Rating of Perceived Exertion (RPE), or by Metabolic Equivalents (MET), considering that one MET is equal to a level at which a person will spend 1 Kcal energy per kg body weight per hour and this level corresponds to the resting stage. In addition to a structured physical exercise programme, the lifestyle should be made habitually active. Principal goal of active lifestyle is to increase energy expenditure without concern for the intensity of activity. The basic principle is that very mild, even inapparent increases in physical activity may make much difference.

Proper diet is as important as physical exercise and fitness, in context of lifestyle diseases. A healthy daily diet should provide calories and all nutrients which are actually required by the body, depending on age, sex, existing body weight, amount of physical activity and other physiological requirements of growth, pregnancy, etc. Dietary fats should provide not more than 30% of the total daily energy intake; within this limit, saturated fats should not provide more than 10% of the total dietary energy. Dietary cholesterol should not exceed 300 mg in a day. Total salt intake should not exceed more than 6 grams a day, while sugars should not provide more than 10% of daily dietary energy. Fruits and Vegetables are rich source of Folic acid, antioxidant vitamins and minerals. In one day, an adult should consume about 400 to 500 grams of fresh fruits and vegetables (not including potatoes). Adequate consumption of dietary fiber has been shown to be protective against cardiovascular diseases, diabetes type - 2, obesity, gall bladder disease and certain cancers, particularly colonic cancers. Dietary consumption of fiber should be at least 30 grams per day.

In public health practice, all functionaries should endeavor to educate individuals and communities regarding the adversities associated with tobacco use and motivate them to give up tobacco.

Alcohol intake, even in mild to moderate quantities, is associated with a number of other diseases like road accidents, various cancers, obesity and hypertension in addition to diseases seen in chronic alcoholics like liver diseases, pancreatitis, hypertension and DM, psychiatric & social problems and dependence. Secondly, it is quite difficult to maintain "moderation" - many of those who are initially moderate may become heavy drinkers gradually. Thirdly, there are various other more healthy

methods (as brisk, regular physical exercise) rather than drinking, to increase the HDL levels. All these aspects should be emphasized on the clientele.

## Study Exercises

**Long Question :** What are the disease of lifestyle. Discuss their epidemiology with specific reference to major lifestyle factors.

**Short Notes :** (1) Community based guidelines for physical exercise (2) Dietary guidelines for prevention of non - communicable diseases (3) Moderation in alcohol intake (4) Health benefits of physical exercise (5) Measures for community prevention and control of tobacco use

## MCQs & Exercises

- Enumerate the major components of unhealthy lifestyle?
- Which of the following is not a life style disease?(a) Breast cancer (b) Mental Stress (c) Osteoporosis (d) RHD
- How many new cancer cases are known to occur every year in India? : (a) 1Lac (b) 5 lac (c) 8 lac (d) 10 lac
- What is India's daily consumption of fruits and vegetables per person per day? (a) 250 g (b) 500g (c) 130 g (d) 350g
- If a 70 Kg man walks slowly, covering 8 kilometers in 3 hours, he would burn off how many calories?
- In above question the activity done will be classified as fitness exercise or just an physical activity
- Those who exercise regularly have higher levels of : (a) LDL (b) HDL (c) Triglycerides (d) Total cholesterol
- Physical exercise bring about reduction in the level of anxiety and stress by release of which chemicals
- Effects of physical activity are long lasting - true/false?
- The minimum recommended frequency for endurance training is : (a) 4 - 5/wk (b) 7/wk (c) 3/wk (d) 1 - 2/wk
- How is Maximum Permissible Heart Rate (MxPHR) calculated?
- Rating of Perceived Exertion (RPE) is for rating which of the following : (a) Frequency of exercise (b) Duration of exercise (c) Intensity of exercise
- Match the following

RPE	1Kcal/Kg body wt/hr
MET	220 - Age in years
MxPHR	Visual analogue

- Moderate intensity of exercise level is equivalent to what MET level in men?
- A subject weighing 60 kg is exercising by Running at speed of 12 km/h. He ran 6 km in 30 min (MET level 12.5). Calculate the amount of energy in Kcal expended by the person and the amount of fat burnt off ?
- According to recommendations of CDC Atlanta and American College of Sports Medicine a person should spend how many calories per day by physical exercise?
- Saturated fats should not provide more than what percentage of the total dietary energy?
- What is the daily recommendation of salt intake by a person?
- Globally what percentage of cardiovascular deaths is contributed by tobacco intake?

20. What is the estimated RR of hypertension and stroke due to alcohol intake?

21. A "unit" of alcohol is defined as equivalent of how many grams pure ethanol? (a) 1 g (b) 10g (c) 50g (d) 100g

**Answers :** (1) Lack of physical activity; Faulty dietary habits; Tobacco use; Excessive alcohol intake; Mental Stress; and Disregard to personal safety (regarding accidents, Personal hygiene, Promiscuous Sex and towards Insect Vectors of Diseases); (2) d; (3) c; (4) c; (5) 550kcal; (6) Physical activity; (7) b; (8) endorphins; (9) False; (10) c; (11) The MxPHR for any individual is calculated as  $220 - (\text{Age in years})$ ; (12) c; (13) RPE = visual analogue, MET = 1 Kcal / kg body wt / hour, MxPHR =  $220 - \text{Age in years}$ ; (14) 4 to 5.9; (15) Energy spend is  $60 \times 12.5 \times 1/2 = 375$  Kcal i.e 42 gm of fat (1gm fat provides 9 Kcal); (16) 200kcal; (17) 10%; (18) 6 gm; (19) 27.8%; (20) 1.4 to 4.1; (21) b.

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Rajul K Gupta

*"Yuktahar Viharsya Yukt Chestsya Karmsu ; Yukta Swapnav Bodhayasya Yogo Bhavati Dukh Ha." (Yoga killeth out pain for him who is regulated in eating and amusement, regulated in performing actions, regulated in sleeping and waking")*

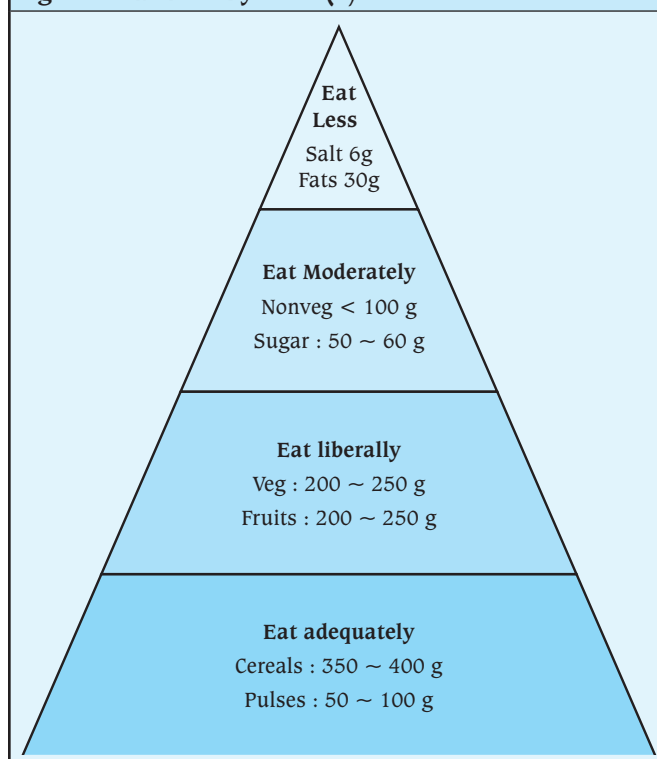
~Shrimad Bhagavad Gita

In an earlier chapter we have seen that a faltered diet, obesity and poor lifestyle puts the human body to a great risk for IHD, diabetes, hypertension and cancers. Many studies indicate that a change in lifestyle can reduce the risk of these conditions (1-5). The practical modifications that should be made in our day to day diet to reduce risk of lifestyle diseases are discussed in this chapter.

### The Food Pyramid

The principles of a healthy diet for an average adult (consuming 2500 to 2800 Kcal per day) can be summarized pictorially, through a food pyramid (Fig. - 1) (1). Foods depicted at the bottom of the pyramid (cereals, pulses, vegetables and fruits) are to be consumed in plenty, foods in the middle of the pyramid, meat products and refined sugars, are consumed in moderation and the foods at the top (salt and oils) are sparingly consumed.

Fig. - 1 : The Food Pyramid (1)



In other words, foods which give low calories (and low refined

sugars), enough proteins, low fats and salts but lots of antioxidants, vitamins and natural fibre constitute a healthy diet. Such a diet is contributed to by whole grains, cereals, pulses, milk, low fat foods and plenty of fresh fruits and vegetables, typically depicted at the bottom of the pyramid.

### The First Principle of Healthy Diet - It Should Provide the Required Energy, No More and No Less

Besides fulfilling the biological requirement of energy, food caters to the important psychological cue of satiety. So, one eats not only to meet the nutritional requirements, but also because one needs to be psychologically satiated each and every time he sits to dine. Such satiety depends on the "bulk" of food rather than the count of calories. Therefore the quantity of food, besides of course the quality also decides, as to which food is healthy or otherwise. Therefore one may aim to keep the bulk large and the calories low (Box - 1).

#### Box - 1 : Keeping bulk large and calories low! An example...

One liter of tomato soup and plain rice/dal will give the same level of satiety as one kg of butter chicken, but the former will provide only 500 Kcal while latter 4000 Kcal. Therefore food items which are thin, watery, or made of grains, legumes and pulses provide lesser calories than even much lesser quantities of fats and starchy foods. It is recommended to consume low energy dense items like fresh fruits, vegetables, raw salad or meals cooked with little amount of oil rather than highly energy dense food stuffs like oil dripping butter chicken, mattar paneer or cheese and chocolates!

**Low calorie foods** : As a general rule, food that is low in calories, but which can fulfill the daily requirements of energy in a balanced manner is considered as healthy. To keep the calories low in the diet the upper limit of calories intake must be limited to the recommended values for sex and activity level. Fats and oils are the most concentrated source of energy so intake of fats and oils must be restricted, as mentioned earlier. Similarly excessive intake of carbohydrates (cereals and starchy foods like potatoes) must also be discouraged. Some low calorie foods are given in Table - 1 (6).

Table - 1 : Some Low Calorie Foods

	Approximate quantity per serving	Calories per serving
Dalia	1 plate	80
Khichri	1 plate	160
Dhokla	2 pieces	100
Poha	1 plate	120
Biscuits	4 numbers	150
Kheer	1 katori	120
Bread	2 slices	125

**High calorie fatty foods** : High calories are provided by food rich in oils and fats. These foods could be any 'oil dripping' preparations or fried foods like the deep fried puris, kachories,



*samosas, pakoras, parathas, matar paneer, malai kofta*, cheese balls, meat preparations (mutton curry, butter - chicken) or simply lot of ghee on the *roti/dal*, sweets, cakes and pastries, etc. Table - 2 gives calories provided by one typical serving of these 'unhealthy fatty foods'. The high calories present in these foods increase weight and cause obesity. These foods are high in fats, esp saturated fatty acids and cholesterol, which are strong risk factors for cardiovascular diseases and some cancers. Repeated cooking/frying of these fats (saturated or unsaturated), turns them into a dangerous variety of fats called as the trans - fatty acids (t - fatty acids). The trans - fatty acids are considered as extremely dangerous for the cardiovascular system, as they reduce the HDL - c and increase LDL - c, thereby further augmenting the risk (2, 6).

**Table - 2 : Some High Calorie Foods**

	Approximate quantity per serving	Calories per serving
<i>Samosa</i>	1 number	256
<i>Masala Dosa</i>	1 number	360
<i>Kachori</i>	2 numbers	500
<i>Mathri</i>	1 plate	500
<i>Puri</i>	4 numbers	250
<i>Ghee roti</i>	4 numbers	360
<i>Cake</i>	1 small piece	250

### Recommendations on Fats - The Preventive Prescription (Box - 2)

Dietary intake of fats, esp the qualitative composition of fats in diet, strongly influences the risk of lifestyle diseases, through effects on blood lipids, thrombosis, blood pressure, endothelial function, arrhythmogenesis and inflammation. The general recommendations for dietary fats are :

- Not more than 20 to 30% of all calories should be obtained from fats.
- Out of this, not more than 7% (of the total energy) should be from saturated fatty acids.
- Adequate intake of Polyunsaturated Fatty Acids (PUFA) : 6 - 10% of daily energy intake, with an optimal balance of n - 6 PUFA (at 5 - 8%) and n - 3 PUFA (1 - 2%) levels of daily energy intake, respectively.
- Intake of Monounsaturated Fatty Acids (MUFA) should make up rest of the daily energy intake.
- Daily cholesterol consumption should be restricted to less than 300mg/day, (preferably < 200 mg) mainly through restriction of dairy fats and red meat.
- The trans - fatty acids intake should be negligible (less than 1%) of daily energy intake.
- Restrict intake of fats from dairy and red meat sources, avoiding use of hydrogenated oils and fats in cooking.

The dietary goals with respect to various kinds of fats can be achieved by limiting the intake of fat from dairy and meat sources, avoiding the use of hydrogenated oils and fats and substituting saturated fats with unsaturated plant oils.

Calculating at a scale of 20 to 30% of energy to be obtained from

fats, (which includes 7 to 10% from saturated fats), for a daily requirement of 2400 Kcal, a sedentary man needs to obtain about 700 Kcal from fats. Half of these come from invisible fats (which are mostly of unsaturated variety) and the other half needs to be provided through apparent dietary sources (350 Calories/day or about 40g of oil/fat per day since 1 gram fat gives 9 Kcal). So in a month, one would need to purchase (40gx30days=1200g) i.e. about 1.25 kg of oil / ghee / butter. Out of this, about one - fourths could come from saturated fats, thus one person needs about 250 grams of ghee / butter and about 1 Kg of edible oil per month.

Different vegetable oils available in the market have varied saturated and unsaturated (PUFA, MUFA) compositions. One must therefore use different oils like mustard, soyabean, groundnut, safflower, sunflower, rice bran, cottonseed, sesame etc. in rotation, to obtain all types of unsaturated fatty acids.

### Box 2 : The preventive prescription on fats for lifestyle diseases

One must cater for 1 Kg of vegetable oil and not more than 250 g of butter/ghee per adult in the family per month.

For a family of 4 adults it works out to 4 Kg of vegetable oil and about 1 Kg of butter/ghee per month.

Out of these 4 kgs of oil to be procured in a month, one may purchase different varieties of oils (or rotate the oils over few months) to get an all round benefit.

Regular intake of fish (1-2 times per week) provides PUFA and MUFA, rich in omega-3 fatty acids, beneficial for heart.

Non-frying methods must be resorted to, rather than deep frying and baking with lots of butter/fats.

*Puris, parathas* rich in oils should be substituted by plain *rotis*.

Sweets with plenty of ghee and oils must be shunned.

Snacks (*kachoris, pakoris, namkeens* etc.) which are rich in oils must be avoided.

### Cereals

A maximum of 60% of total energy intake i.e. about 1450 Calories should be obtained from carbohydrates for a sedentary male. About 360 g carbohydrates per day would provide these calories. Carbohydrates in excess of this amount would result in accumulation of surplus calories, eventually leading to obesity. Excess intake of starchy food (potato - as vegetables, chips, wafers, French fries, etc.) also provides plenty of 'easy' calories, liable to cause obesity. It is also recommended that different cereals must be consumed in one form or the other. One cereal could be the staple cereal say wheat, but it is advisable to consume one other cereal say rice as the second parallel cereal. In addition to this other cereals e.g. corn, millet (*bajra, ragi*) etc. should be used as snacks.

**Fibre** : It is recommended that 35 to 40 grams of fibre should be consumed every day (4). Intake of whole grain cereals must be encouraged. Excessive milling of cereals leads to loss of the outer layer of bran and fibre. Thus consumption of whole grains provide adequate fibre. These can be obtained from

brown rice, flour with higher level of bran i.e. coarse *atta*, *dalia* and porridge. To ensure maximum intake of fibre, the flour (*atta*) should not be strained with a thin strainer, so that bran is incorporated in the flour. The bran should not thus be discarded. Pulses, beans and other legumes also provide valuable fibre, so they must be consumed aplenty. The fruits and vegetables contain abundant amount of fibres and must be consumed regularly.

On the other hand, processed products of refined cereals such as refined flour and *maida* e.g. noodles, pasta, cake, white - bread, pizza, macaroni etc. are low in roughage and fibre. Their consumption may cause constipation as compared to a diet that is high in fibre.

### Recommendations on salt

Many studies have proved that the amount of sodium in diet is a definite risk factor for hypertension and heart disease. Sodium is present in common salt which is generally consumed without a second thought. The use of sodium should be limited to reduce the risk of lifestyle disease. An upper limit of 6 g of salt is recommended so its use should be restricted to less than this amount (6 g/day). For the preventive prescription on salt, see Box - 3.

#### Box - 3 : The preventive prescription on salt

At a rate of 6 g/day, for a family of four, salt consumption works out to about (6gX4) = 24 g per day; or about 750 g per month. The following recommendations are made :

For a family of four adults, buy a 1 kg pack of salt and about 1/4<sup>th</sup> should be left at the month end, which should either be discarded or included for in the next months 'quota' of 750g.

Avoid foods containing excessive salt like pickles, *chutneys*, *papads*, sauce, tinned and preserved food, processed cheese etc.

Consumption of fast foods like burgers, pizza, French fries, *chat*, *bhel-puri* which contain high amount of salt must be discouraged.

Remove saltcellars from dining table, to discourage sprinkling of salt on ready to eat food. Avoid sprinkling of salt on fresh salads.

**Potassium** : Dietary intake of potassium lowers blood pressure and is protective against stroke and cardiac arrhythmias. Potassium intake should be at the level which will keep the sodium potassium ratio close to 1, i.e. at the level of about 5 to 6 g/day. This could be achieved by adequate daily consumption of fruits and vegetables, in the amounts recommended subsequently.

### Recommendations for fruits and vegetables

Fruits and vegetables contribute to health through a variety of phytochemicals, antioxidants, flavanoids, potassium and fibre. A variety of seasonal fruits and vegetables should be consumed. Adequate intake of fruits and vegetables (400 - 500 g) (200 to 250 g each of fruits and vegetables) every day is recommended to reduce the risk of lifestyle disease. This recommendation of 400 to 500 g does not include potatoes. A family of 4 should

ideally consume 1.5 Kg fruits & vegetables in a day. Variety is as important as quantity. No single fruit or vegetable provides all the micronutrients needed to be healthy. The key lies in the variety of different fruits that one eats.

An average Indian takes a maximum of just three servings of fruits/ vegetables a day. The earlier dietary guidelines called for about 100 g of fruits to be taken per day. However the guidelines have been changing with the stronger emerging inverse relationship between lifestyle diseases and fruits. Now the American authorities recommend as many as five to thirteen servings of fruits and vegetables a day, depending on one's caloric intake. For a person who needs 2,000 calories a day this translates to nine servings, or about 5 cups/portions per day. This doesn't count potatoes (as potatoes are mostly starch). A typical portion can be defined as

- Melon, Pineapple : Large slice
- Fresh corn on the cob : 1 whole cob
- Apple, banana, orange : 1 fruit
- Small tomatoes : 6 tomatoes
- Grapes, cherries or berries : 1 cupful
- Fresh fruit salad : 2 - 3 heaped tbsps
- Dried fruit - raisins, apricots, dates, figs : 1/2 - 1 heaped tbsps
- Fruit juice : 1 glass (150ml)
- Vegetables, raw, cooked, frozen or canned : 2 heaped tbsps
- Salad : 1 dessert bowlful

### Sugary Foods

Such foods contain excessive refined sugar. Chocolates, cakes, candies, *halwa*, *laddoos*, ice creams, soft drinks etc. are some examples of such foods. These foods are also considered unhealthy. These foods have high glycaemic index and their consumption causes sudden spurt in blood glucose levels, which may be deleterious for health. They also contain high calories (e.g. 1 small piece of cake provides 250 Kcal), which leads to an increase in body weight causing obesity and other diseases. In addition to these calorie related drawbacks, since most of these foods are commercial products, they contain chemicals, artificial colours, flavours and preservatives, which are generally unnatural and harmful, many of them being carcinogenic. Moreover, excessively sugary foods are also liable to cause dental caries.

### Refined Sugar

Excessive intake of refined sugar is deleterious to health. Therefore its use must also be limited by all in general and by patients of diabetes, hypertension and heart disease in particular. As general guidelines, refined sugars should provide not more than 10% of daily dietary energy; for a sedentary man requiring 2400 Kcal per day, this comes to 240 Kcal i.e. 60 grams of sugar. The following recommendations are made :

- The recommended sugar intake is about 50 - 60g per adult per day.
- For a family of 4 the maximum sugar consumption works out to about (50 to 60gX4) = 200 to 250g per day.
- Thus, for such a family composition, maximum sugar purchase should not be more than 6 to 7.5 kg per month.

### Fish

Fish consumption is protective against CVD, stroke etc. For

those who eat fish, 250 to 300 grams of fish (avoiding deep frying) is recommended to be taken twice or thrice a week.

### Meat & Eggs

Non vegetarians should prefer lean meat (fish or chicken) rather than mutton and beef (5). Meat contains high amounts of fat so their use must also be limited quantitatively and qualitatively. The following recommendations are made :

- Restrict the consumption of red meat (beef, pork, mutton)
- Preserved meat (ham, bacon, salami, sausages) must also be limited
- Prefer lean meat (chicken and fish) to red meat
- Prefer marinated / baked / grilled dishes to oil dripping fried ones
- Discourage high fat meat / cooked in thick gravies
- Let meat be a part of meal, not the full meal
- Egg yolk too contains high cholesterol so its use should also be restricted. (Yolk of one egg gives 250 mg dietary cholesterol, which is almost upper limit of recommended dietary cholesterol)

### Hot foods

Consumption of very hot drinks and foods typically consumed in some cultures probably increase the risk of carcinoma of oral cavity, pharynx and oesophagus. It is recommended not to consume foods/drinks when they are very hot (scalding hot).

### Junk foods

Fast foods are served quickly and conveniently at a relatively low cost and so are very popular especially amongst youngsters. Fast food sales have increased dramatically over the past decade, becoming an integral part of our fast paced lifestyle. These include burgers, pizzas, chips, French fries, wafers, colas etc.

Junk food is generally a fast food that is devoid of nutritional value. Regular and consistent 'addiction' to fast foods may therefore be deleterious to health (7). For example burger and cola are nutritionally only refined carbohydrates and sugar. It contains empty calories and hardly any vitamins, minerals or proteins. Some common problems with these foods are :

- Most such menus lack vitamin A, folate, biotin, pantothenic acid and other vitamins
- They are deficient in iron, calcium and copper and other trace elements
- The calorie content of such a meal could be about 900 to 1800 k calories, which is only 33 to 66% of the RDA. Excessive consumption of these is liable to increase weight and cause obesity
- Their sodium content is very high and potassium content low
- Contain chemicals, artificial colours, flavours and preservatives
- The fat content of some of these meals may be as high as 50% of the total daily calories consumed
- The ratio of saturated to unsaturated fatty acids may be unfavourable
- The method of cooking may not be acceptable (deep frying/grilling). Also, the temperature at which food is fried, and if the cooking fat is reused, affects fat quality
- Very costly and less beneficial

## Obesity

One of the commonest expressions of unhealthy diet, often combined with lack of physical activity, is obesity. Indeed, we are amidst an epidemic of obesity. Over the past two decades there has been a dramatic rise in the prevalence of obesity throughout the world. It is estimated by the WHO that globally, over 1 billion (16%) adults are overweight and 300 million (5%) are obese. The highest rise in the number of obese is noted in the countries with fast growing economies especially of South East Asia. As many as 250 million people in the third world countries suffer from obesity. In India the prevalence of obesity is 12.6% in women and 9.3% in men (10). In other words, more than a 100 million individuals are obese in India. We are truly in the midst of an obesity epidemic, which has serious health ramifications (11).

### Epidemiological Determinants of Obesity

**Obesogenic environment** : Today the shared environmental factors like affluent lifestyle, rich food, sedentary home environment, vanishing old family traditions (with regards to eating, exercise and outdoor activities), the 'couch - potato' culture etc. substantially contribute to obesity. This environment is moulded towards a very favourable milieu for obesity.

The varied lifestyle and dietary habits of people play an important role in the causation of obesity. In India one important factor, which has ignited the obesity epidemic, is the 'nova - rich' culture. This is marked by a sudden increase in income, having more disposable income at hand, higher purchasing power and being able to spend more on food. Stress, time crunch, sedentary lifestyle and excessive television viewing add fuel to fire. Non - traditional foods and snacks are considered as more and more mainstream. Easy availability of fast foods, falling prey to food fads, pub and junk food culture and aping the west make the problem more complex.

Aggressive advertising, marketing and universal accessibility of chips, wafers and colas have made them not only a household item but a must for any outing or birthday party! These are some of the reasons of urban obesity. Subconsciously we are imparting the same 'unhealthy' eating - behaviour to the children, ensuring that the next generation too falls in the same vicious cycle of no return.

**Age** : The incidence of obesity increases with age till about 60 years. The vulnerability is maximum in the middle age (around 40 years of age), owing to certain hormonal changes, affluence and a more sedentary lifestyle at this age.

**Gender** : Females are more likely to be obese as compared to males, owing to inherent hormonal differences.

**Ethnicity** : There are large unexplained variations in the prevalence of obesity in the people from different ethnic groups.

**Education levels** : It is seen that in the Indian setting, people with a higher education level, are more likely to be obese, as compared to those who are less educated. It is because the educated are likely to be more affluent. In the west, however, the educated might be in a better state of health, as they are more aware and concerned about health issues.



**Income** : The effect of income too is varied, in India and in the West. Just like education, those with higher income are more likely to be obese in India, but not so in the West.

**Marital status** : Those who are married are more likely to be obese as compared to those who are not.

**Parity** : Women with higher parity are more likely to be obese. At an average the woman gains 1kg weight with each pregnancy

**Diet** : A diet rich in fats, refined sugar and carbohydrates predisposes to obesity. Excessive consumption of sweets, cold drinks, fried food, baked items, pickles and chutneys, fast foods, alcohol etc. is responsible for obesity. Consumption of as little as 100 extra calories per day would increase the weight of an individual by 4 kg in one year. More details on the relationship of diet and obesity are discussed in the subsequent paragraphs.

**Smoking** : Smoking per se reduces the likelihood of obesity, by virtue of nicotine being an anorexic agent. But this positive effect of smoking can by no means be endorsed for its promotion.

**Alcohol** : Alcohol provides 7kcal per gm, which is almost double the calorie content of carbohydrates or proteins (4kcal). Such a high calorific value in itself is a risk factor for obesity. The snacks consumed along with an alcoholic drink are invariably nutritionally rich (fried, fatty and oily), which add many more calories and predisposing the individual to obesity.

**Physical Inactivity** : High physical activity is a vital component that keeps accumulation of fat and obesity under check. One who is undertaking minimal activity and is leading a sedentary life is at a risk of obesity.

#### Causes of Obesity

Obesity results from an excess of dietary energy intake as compared to energy expenditure and thus both an increase in intake and a decrease in energy expenditure will lead to excess calories being stored as fat and, ultimately to obesity.

**Increased energy intake** : An increased energy intake due to lifestyle changes and affluence as seen in urban areas seems to be fuelling the obesity epidemic. A detailed discussion follows in the next paragraph.

**Passive overeating** : The term passive overeating is applied to the practice of eating without a biological need, and not expanding the calories thus gained. Such a situation is commonly seen in the urban setting today where one relishes French fries, wafers and other high calorie snacks while watching TV or using a computer.

**Binge eating** : It is the practice of overindulging in eating in a short time. This might occur in a party, on a weekend or with drinks. In the binge eating occasions become rather frequent; it certainly is a cause of obesity.

**Decreased energy expenditure** : There is a rapid decline in energy expenditure i.e. in manual labour resulting from vehicle ownership, availability of labour - saving devices, shunning outdoor sports and watching television and computer use for long hours. These factors contribute to obesity.

**Metabolic factors** : In some individuals endocrine disorders such as Cushing's syndrome and hypothyroidism, Prader - Willi

syndrome etc. are the cause of obesity.

**Genetic factors** : Obesity tends to run in families. Obesogenic genes are under study, which alter the metabolism or alter the response to obesity limiting hormones like Leptins etc.

**Fetal programming** : The Barker's hypothesis proposes that undernutrition during pregnancy may increase the susceptibility of that individual to obesity in adulthood.

#### Critical Periods for Weight Gain

Weight gained during certain critical periods, usually lead to an increased number of fat cells and makes obesity difficult to treat. It is important to be on guard during these critical periods, with an aim of preventing almost irreversible weight gain (12).

These periods include :

- Age range of 12 to 18 months
- Age range of 12 to 16 years
- Gain of 60% (or more) of his ideal weight by an adult
- Weight gain during pregnancy

#### Quantifying Obesity

**Body Mass Index (BMI)** : Overweight is usually determined by the Body Mass Index (BMI), which is a relationship of the person's weight to his height. BMI is computed by taking the body weight in kilograms and dividing it by the square of the height in meters.

$$\text{Body Mass Index (BMI)} = \frac{\text{Weight (Kg)}}{[\text{Height (m)}]^2}$$

BMI does not measure the body fat but relates well with the degree of obesity. The categories of obesity as pronounced by the WHO are depicted in Table - 3. A BMI of 25 - 30 is considered as a warning sign and may warrant intervention, especially in the presence of additional risk factors. A BMI of 30 or higher is generally considered the point at which some form of treatment is required. Obesity Class III i.e. BMI >40 or Morbid obesity, is a medical condition that impairs a person's overall health and therefore requires medical attention.

**Table - 3 : Grades of obesity based on BMI (13)**

BMI	Classification	Risk of comorbidities
< 18.5	Underweight	Low
18.5-24.9	Healthy/normal weight	Average
25 - 29.9	Pre-obese (Overweight)	Mildly increased
30 - 34.9	Obesity Class I	Moderate
35 - 39.9	Obesity Class II	Severe
> 40	Obesity Class III	Very severe

The guidelines have been revised lately for Asians, considering the fact that Asians (esp South East Asians including Indians) are more susceptible to metabolic syndrome. These are summarized in Table - 4.



**Table - 4 : Grades of Obesity for Asians (8)**

BMI	Classification	Risk of co - morbidities
< 18.5	Underweight	Low
18.5 - 23	Normal weight	Increasing but acceptable
23 - 27.5	Pre - obese	Increased
>27.5	Obese	High

**Waist circumference** : Measurement of the waist circumference is a practical method to assess obesity, esp. the degree of abdominal adiposity and the cardiovascular disease risk. Waist is measured at mid point of lower border of rib cage and iliac crest (at the level of umbilicus). A measure of less than or equal to 90 cm for men and 80 cm for women is considered healthy.

**Waist - Hip Ratio** : It is another measure of abdominal adiposity and the cardiovascular disease risk of the individual. A ratio of < 0.9 for men and < 0.8 for women is considered normal.

### Types of obesity

**Gynoid / 'Pear shaped'** : The fat is evenly distributed (globally distributed).

**Android/'Apple shaped'** : In this type of obesity, the fat is centrally distributed or deposited preferentially in the abdominal region. This expresses the peritoneal (visceral) distribution of fat in the individual. This type of obesity is commonly seen in men of the South East Asian region, including India. Such a distribution is a higher risk factor for coronary artery disease as compared to the global distribution of fat in the body. Higher waist circumference or higher WHR is a good indicator of visceral (peritoneal) deposition of fat.

### Hazards of obesity

Obesity is associated with a higher risk of mortality and morbidity. The life expectancy of a morbidly obese individual is about a decade lower than one with normal BMI. Most overweight and obese individuals exhibit certain symptoms like difficulty in walking, heavy breathing while walking, joint pains, snoring, morning headaches and shortness of breath. Some specific clinical consequences are listed below :

**Metabolic & Degenerative** : Diabetes type 2 (50 to 100 times more common in obese), hyperlipidaemia, ischaemic heart disease, hypertension (5 to 6 times commoner), stroke (2.5 to 6 times commoner), gall stones, breast and colon cancer, infertility (men and women), gout and polycystic ovary syndrome are seen more often in the obese.

**Physical** : Osteoarthritis, chronic back pain, respiratory problems, limited mobility, higher accidents, sleep apnoea and skin problems.

**Psychological** : Depression, low self - esteem, social isolation, poor employment status, impaired relationships and discrimination.

### Prevention of Obesity

*"Most obese people won't enter treatment, most who do won't lose weight and most who lose weight regain it" ~ Stukard*

The quotation by Stukard given above, very aptly summarizes, the importance of prevention of obesity vis-a-vis treatment.

Prevention is the the only viable long term strategy for many reasons.

### On the other hand, losing 10 kg is associated with :

- A reduction in total mortality by 20%
- A reduction in systolic blood pressure by 10 mmHg
- A reduction in diastolic blood pressure by 20 mmHg
- A reduction in fasting glucose by upto 50%
- A reduction in total cholesterol by 10%
- A beneficial rise of 8% in HDL cholesterol
- An improved self - esteem

### Levels of Prevention (9)

**1. Universal Prevention** : As the name suggests, universal preventive measures are meant for all the individuals in the community, irrespective of their weight status. These measures include healthy lifestyle practices, like consuming a prudent and healthy diet. This includes low consumption of fat and refined carbohydrates. Active physical activity and shunning sedentary lifestyle also forms a part of this strategy. Health and nutritional education is also imparted to everyone in order to create awareness amongst masses for prevention of obesity.

**2. Selective Prevention** : High risk individuals are targeted under this preventive strategy. The high risk individuals are those who are more likely to gain weight. These include affluent people especially adolescents, pregnant women, middle aged people and those with a rich sedentary lifestyle consuming high energy food (fats) and those under psychological stress. Those with a hormonal disorder, family history of obesity or on certain drugs like Lithium, Sodium valproate, hormones etc. are also at a high risk of obesity.

**3. Indicated Prevention** : Indicated Prevention or the Secondary preventive measures are to be taken for those with existing problems of overweight and obesity.

### How to Reduce Weight?

Nearly 2500 years ago, Socrates had very aptly said : *'Eat only when hungry and drink only when thirsty, and never to leave the table with a feeling of satiety'*.

The aim should be to maintain BMI below 25 kg/m<sup>2</sup> (preferably below 23.5) and the waist circumference below 90 cm in adult men and < 80 cm in adult women, by a prudent combination of diet and physical activity and avoid weight gain in adulthood. Details are discussed in subsequent sections. It is important to follow the height weight chart so that one could follow his BMI.

Being overweight, a high BMI or an overt obesity is probably the first indication of the fact that our diet is off - course and needs correction. If ignored at this stage other more sinister lifestyle diseases might soon follow. The origin of obesity could however be multifactorial. Many modalities for treatment/prevention of obesity are available. The dietary therapy (commonly known as 'dieting') remains the most practical and effective measure. Other measures are :

- (a) Behaviour therapy
- (b) Drug therapy
- (c) Surgical intervention

(d) Genetic approach.

In the present chapter we shall concentrate only on the dietary therapy.

**Reducing weight through dietary therapy (dieting)** : The first step to adopt a healthy lifestyle is to get educated on nutritional and health aspects. Understanding the nutritive values of Indian foods is perhaps a good beginning. One must learn about calorie content of different foods, food composition (fats, carbohydrates and proteins), nutrition labels, types of foods to buy and details on cooking procedures. Correct dieting technique involves instructions on how to make safe, sensible and gradual change in eating patterns. Moderate reduction in calorie intake is essential to achieve a slow but steady weight loss. This strategy also helps in maintaining this weight loss.

People should be encouraged to increase the intake of complex carbohydrates (unrefined cereals and sugars, fibre rich foods) and to decrease the intake of fats and simple carbohydrates (refined sugars, excessively milled cereals e.g. white bread, etc). Intake of low calorie and low fat foods must be emphasized. Fruits and vegetables must be made an integral part of the diet.

There are four areas to be considered in the use of dieting and nutritional education in treating obesity. These are :

- Ascertain the activity status : sedentary, moderate or hard worker. Assess the present BMI and the desired BMI (20 to 25 kg/m<sup>2</sup>). This would indicate the weight (in Kg) to be reduced.

- Set a practical time frame for weight reduction. It has to be achieved at a rate of around 1 to 1.5 kg per month.
- Assess the daily calorie intake from fats, proteins and carbohydrates. The weight to be reduced is then translated to the calorie restriction. These calories are distributed between carbohydrates, protein and fat so as to cut down calories preferably from fats and carbohydrates (in that order). This also helps balance all nutrients.
- Suitable substitutions should be made. The frequency with which the foods are to be eaten and the situation in which the food is ingested is also to be looked into.

An example is illustrated in Box - 4.

**Food substitutions that help in weight - loss (14,15)** : It is well known that one must try to eat a variety of foods, especially whole - grains and lots of fruits and vegetables. These foods can be filling and satisfying and are lower in calories than foods full of oils or fats. Some times it is not only scientific but easy and more palatable too, to substitute one (set of) food item with other, which is less fattening or healthier. While cooking, try to replace undesirable ingredients with healthier alternatives. Some such examples are given Box - 5.

While these substitutions help in a sustained weight loss, there are some other practical tips that would make the process of weight loss easy, worthy and fun. These tips must be incorporated into our lifestyle and they will help reduce weight in a 'natural' way (Box - 6).

<b>Box - 4 : Reducing weight - An example</b>
Let us take a 1.66 m tall, sedentary male, weighing 80 kg.
<i>Step 1</i> : His present BMI works out to 29 kg/m <sup>2</sup> . Let us presume that his desired target BMI is 25 kg/m <sup>2</sup> . To achieve this BMI his weight must be about 69 kg i.e. he must reduce 11kg.
<i>Step 2</i> : It is recommended that he reduces 1.5 kg weight per month, i.e. he would be able to reduce 11 kg in about 7 months.
<i>Step 3</i> : Assess his total daily calorie intake. As a rule, generally, a reduction of about 500 Kcal brings about a weight loss of about 500g per week. Conservatively, let us assume that a reduction of say, 1.5 kg per month can be achieved. 500 Kcal per day can be reduced by cutting down 16 g oil (150 Kcal), and about 85 g carbohydrates per day. Suitable modifications must also be made to other lifestyle factors like alcohol, junk foods, parties, snacks, physical activity etc.
<i>Step 4</i> : Make suitable substitutions as applicable (see next Para). For example, replace saturated fats with PUFA/MUFA, replace whole milk with skimmed milk, and refined flour with whole-wheat flour. More fruits and vegetables could be included.

<b>Box-5: Making Some Wise Substitutions - From Fat to Fit</b>
Refined carbohydrates (milled rice, white bread, biscuits) must be replaced with complex carbohydrates e.g. brown rice, whole-wheat <i>atta</i> and whole-wheat bread etc.
High starch foods (potatoes, rice) must be replaced with high fibre ones (whole grains, beans and some vegetables turnips, beet-root and carrots)
Fried nuts with plain nuts
Whole milk with low fat skimmed milk
Substitute mutton and beef with lean meat (e.g. chicken)
Substitute oily meat preparations with non-fried stews, soups
Substitute chips, wafers, burgers, <i>samosa</i> , cutlets with plain toast, fruits, salad and fruit juices
Sweet biscuits with plain ones and nuts
Substitute saturated fats (ghee, butter, t-FA) with vegetable oils : sunflower, safflower, groundnut, linseed or cotton seed oils

<b>Box - 6 : Some more tips on dieting</b>
Do not skip meals to reduce weight
Do not eat left over food after the meals
Eat many small but measured meals
Or eat a minimum of three meals
Do not snack while watching TV or using computer.
It is a myth that some foods can burn fat
Do not shop when hungry as you're likely buy 'junk food'
Reduce stress through relaxation like meditation
Develop a positive attitude and be cheerful
Exercise regularly to burn body fat, strengthen muscles reduce stress
Slow and steady weight loss of about 0.5 -1kg per week is safest

While going through the process of dieting and weight reduction some more precautions must be kept in mind. These cautions are summarized in Box - 7.

<b>Box - 7 : Other cautions on containing weight</b>
Food labels claiming 'low-fat' or 'no-fat' may still have lot of calories
Food labels claiming 'zero cholesterol' may not mean 'zero oil'
Drink enough water each day @ minimum of 8-10 glasses
Alcohol has high calorie content; Snacks taken along with drinks add to calories
Fruits and vegetables are low calorie and source of antioxidants

**Fad diets and their role in weight reduction :** Fad diets stress either the absence or presence of particular foods or combination of foods. These are commonly aimed at weight reduction. A fad diet is a set of menus advocated generally by people who have little or no knowledge of nutrition or on the basis of inadequate evidence by nutritionist as well. Even though such diets fail to meet the healthy diet specifications, they turn out to be beneficial for a short duration. They are so different from customary foods and are so unpleasant to follow that they are used for a short duration, generally not long enough to cause deficiency. People taking up fad diets skip from one such diet to other, which again saves them from deficiency states. The secret of the short - lived success of such diets is that, weight is rapidly lost, but is regained little later, once the former eating habits are resumed (16).

### Commercial 'Weight Reducing' Diets

Either the sheer number of obese and weight conscious people is so large or there is such a glamorization of good physique that today dieting is not only 'commercialized' but dieting and 'slimming centres' have attained industrial proportions. Visiting a well - known slimming centre is considered a prestige symbol for the affluent.

Popular diets have become increasingly prevalent and controversial. More than 1000 diet books are now available, with many popular ones departing substantially from mainstream medical advice. Public interest is being fuelled by cover stories of popular magazines and televised debates.

Out of the thousands of structured commercial diets, probably the more popular ones are the *Atkins diet*, *Ornish diet*, *Weight watchers diet* and the *Zone diet*. These are based on different 'principles' to reduce weight. For example, *Atkins diet*, the most popular of the lot, restricts intake of carbohydrates to less than 30 g a day and permits ad - libitum, the consumption of fats (fatty meat, butter, and other high - fat dairy products). The *Ornish diet* restricts fat, *Weight watcher's* diet restricts portion size and calories, *Zone diet* modulates macronutrient balance and glycemic load (17). Since all these diets are not natural, they have their own associated disadvantages, risks and controversies. Let us take the most popular of these, the Atkins diet for a more detailed discussion.

The *Atkins diet* books have sold more than 45 million copies over 40 years all over the world. In the present obesity epidemic, this diet and accompanying Atkins food products are popular. The diet claims to be effective at producing weight loss despite ad - libitum consumption of fatty meat, butter, and other high - fat dairy products, restricting only the intake of carbohydrates to under 30 g a day.

It eliminates carbohydrates from food without restricting protein and fat intake. Deprived of carbohydrates, the body uses fat for fuel. A small part of metabolized fat is eliminated in the urine as ketone bodies, and this is why such diets are called "ketogenic". In the short run, such diets produce rapid weight loss due to polyuria. The apparent paradox that ad - libitum intake of high - fat foods produces weight loss might be due to

- Severe restriction of carbohydrate depleting glycogen stores
- This leads to excretion of bound water causing weight loss
- The ketogenic nature of the diet being appetite suppressing
- The high protein - content being highly satiating
- High fat / protein diet reduces spontaneous food intake
- In the absence of carbohydrates the food choices are limited, leading to decreased energy intake

On the other hand in the long run, re - feeding carbohydrates cause water retention and weight gain. The diet decreases appetite : patients eat less without feeling severe hunger and without measuring their food intake. Orthostatic hypotension, fatigue and nausea are frequent. The diet increases plasma cholesterol and uric acid. It may be dangerous in diabetes (anorexia, acidosis) and in heart or kidney disease.

Low - carbohydrate diets have been regarded as fad diets. A systematic review of low - carbohydrate diets found that the weight loss achieved is associated with the duration of the diet and restriction of energy intake, but not with restriction of carbohydrates, per se (18). Perhaps more long - term studies are needed to measure changes in nutritional status and body composition during the low - carbohydrate diet, and to

assess fasting and postprandial cardiovascular risk factors and adverse effects of these diets (19). Without that information, low - carbohydrate diets cannot be recommended as a public health measure for weight reduction.

## Study Exercises

**Long Questions :** (1) Describe the epidemiology of obesity. How would you advice a middle aged man of 90 kg and 170 cms tall to reduce weight? (2) Discuss the principles of a healthy diet in context of lifestyle diseases.

**Short Notes :** (1) Fad diets (2) Food pyramid (3) BMI (4) Benefits of weight loss

## MCQs

- Which is true about substitution for weight reduction :  
(a) Substitute ghee with butter (b) Substitute buffalo milk with cow milk (c) Substitute groundnut oil with safflower oil (d) Substitute rice with wheat
- To have satiety and also reduce weight (a) Keep bulk large and calories low (b) Keep calories large and bulk low (c) Keep calories low and bulk low (d) Keep calories large and bulk large
- For good health (a) Prefer fish to poultry (b) Prefer poultry to mutton (c) Prefer sprouts to meat (d) All of the above
- A food label reading 'zero - cholesterol' indicates (a) Low cholesterol (b) Low animal fat (c) Low plant fat (d) Low animal and plant fat
- Which of these is not a triggering factor for obesity :  
(a) Pregnancy (b) Stopping smoking (c) Mental stress (d) Physical stress

**Answers :** (1) b; (2) a; (3) d; (4) b; (5) d.

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**Ischaemic Heart Disease (IHD)**  
**Syn: Coronary Heart Disease (CHD);**  
**Coronary Artery Disease (CAD)**

*RajVir Bhalwar*

IHD is the prototype example of the lifestyle diseases. In affluent countries, it is the most devastating disease, often accounting for almost a quarter of all deaths. It has also been the most researched disease in modern times regarding its epidemiology, risk factors, management and prevention. The term Cardio-vascular Diseases (CVD) encompasses a wider spectrum of diseases which include IHD, Heart Diseases other than IHD, Systemic arterial hypertension, Stroke, and,

Peripheral vascular disease (PVD). Within the gamut of the term IHD, we have a wide spectrum of conditions, starting from asymptomatic coronary insufficiency at the mildest end and sudden death at the other; in between we have typical angina, atypical angina and acute Myocardial Infarction, representing increasing severity along the spectrum.

## Definition

IHD is defined as a state of lack of supply of oxygen to the myocardium vis-a-vis the demands, due to narrowing of the coronary arteries as a result of the atherosclerotic process.

## Magnitude of the problem and Frequency

IHD places a mammoth load of disease and ill health on humanity. In developed countries, half of all deaths are due to CVD and a quarter due to IHD. In developing countries, the



problem is no less; as economic development will occur, IHD may, by the year 2025, become a leading cause of death and disability in our country.

IHD derives its importance for a variety of medical and socio-economic reasons, as follows :

- The magnitude of problem in terms of sheer numbers is very high
- The disease has a very high “killing power” - even in developed countries with well established treatment and ambulance services, 25% of those who suffer from Ac. MI would die within one hour and would never reach the hospital; another 8 to 10% would die in the next 24 hours in the hospital and yet another 10% would die in the next one year.
- Even for those who survive, the quality of life in terms of physical capabilities is compromised, alongwith constant apprehension about the future.
- The treatment is quite costly and available at few selected centres.
- Most of the persons affected with clinical disease are in their middle age, and are in the maximal productive phase of their life; they also have the maximum family and social obligations to fulfill at this age. Getting affected by the disease at this age therefore leads to tremendous loss to the organization and much suffering for the family.
- The silver lining is that a large number of factors which place an individual at high risk of getting affected with IHD (called “coronary Risk factors”) are well known to the medical world and potentially amenable to preventive efforts. IHD thus is very much a preventable issue.

The magnitude of problem has been brought out in the earlier chapter on general principles of healthy lifestyle in this section. Some important findings are as follows :

**Global Problem** : Of an estimated 58 million deaths globally from all causes in 2005, cardiovascular disease (CVD) accounted for 30%. This proportion is equal to that due to infectious diseases, nutritional deficiencies, and maternal and perinatal conditions combined (1). It is important to recognize that a substantial proportion of these deaths (46%) were of people under 70 years of age, in the more productive period of life; in addition, 79% of the disease burden attributed to cardiovascular disease is in this age group (2). Between 2006 and 2015, deaths due to non-communicable diseases (half of which will be due to cardiovascular disease) are expected to increase by 17%, while deaths from infectious diseases, nutritional deficiencies, and maternal and perinatal conditions combined are projected to decline by 3% (1). Almost half the disease burden in low- and middle-income countries is already due to non-communicable diseases (3).

**Indian Scenario** : The figures have been extensively summarized by Reddy et al (4) and details have also been presented in the chapter on general principles of healthy lifestyle. Over the past 4 decades, the prevalence of IHD has risen two fold in rural and six fold in urban areas. At present, an estimated 3 to 4% of rural and 8 to 10% of urban adults are likely to be affected by IHD, thus putting the estimated IHD cases in India at 30 million (15 million each in rural and urban areas).

### Special Features of IHD among South Asians / Indians :

As is evident from foregoing discussion, IHD has become a major problem among our countrymen and the issue is likely to worsen unless proactive and intensive preventive measures are initiated now onwards. There is another interesting aspect, in that certain risk factors, epidemiology and presentation of IHD seems to be different among Indians / South Asians as compared to the western world. These special features are summarised in the Box - 1.

<b>Box - 1 : Special Features of IHD among South Asians</b>
IHD tends to occur at an earlier age; mean age of onset almost a decade earlier
Proportion of females to males among IHD cases higher as compared to developed countries
Higher case fatality (may be because of either biological differences or due to poor health services)
IHD occurs even in presence of normal or near-normal levels of “conventional” coronary risk factors as BMI, Total cholesterol and smoking; on the other hand high level of “unconventional” risk factors (increased central obesity in the face of normal BMI and low HDL / high triglycerides in the face of normal total cholesterol levels) as occurs in metabolic syndrome ‘X’, may play an important role.

### The Determinants (Coronary Risk Factors)

With large scale, world-wide research over the past 60 years, both epidemiological as well as clinical, we are now well aware of various coronary risk factors, which place an individual at high risk of getting affected with IHD (5). It needs to be noted that the search for coronary risk factors is an ongoing one and every year a few more are likely to be added to the list. Broadly, these may be classified as “modifiable” and non-modifiable” risk factors.

**Non-Modifiable** : As the name suggests, we can not “change” these factors; only thing is that if a person has any of them, he / she needs to be even more careful as regards modifiable factors. The non-modifiable risk factors are :

**Age** : Age > 45 years for males and > 55 years for females increases the risk.

**Sex** : Male sex is at a higher risk. However, after menopause, the risk for females increases and equalizes that of males by the age of 50 to 55 years.

**Family history** : History of definite MI or sudden death in father or 1st degree male relative before 45 years age or in mother or 1st degree female relative before 55 years age indicates high risk.

**Race** : Some races may be more predisposed. For example, South Asian populations are said to be at higher risk, possibly because of “thrifty gene”; the Finnish population are at a high risk while Japanese are at lower risk. The extent to which these differences are because of genetic factors that differ between races or else due to lifestyle factors peculiar to different races, is still not clear.

**Modifiable Coronary Risk factors** : These are summarized in Table - 1.

<b>Table - 1 : Modifiable Coronary Risk Factors</b>			
<b>Well Established</b>		<b>Emerging / Being Researched</b>	
<i>Lipid</i>	<i>Non-Lipid</i>	<i>Lipid</i>	<i>Non-Lipid</i>
<ul style="list-style-type: none"> <li>• Raised Total Cholesterol (&lt; 200 mg / dl : desirable; 200 - 239 : Borderline high; &gt;= 240 : High)</li> <li>• Raised LDL - C ( &lt; 100 mg/dl : optimal; 100 - 129 : near optimal; 130- 159 : Borderline high; &gt;= 160 : High)</li> <li>• Raised triglycerides (&lt;150 mg/dl : normal; 150 - 199 : Borderline High; &gt;= 200 : High)</li> <li>• Low HDL-C ( &lt; 40 mg/dl in men or &lt; 50 in women)</li> <li>• Metabolic Syndrome (Syndrome 'X') - a clustering of low HDL, raised triglycerides, hypertension, impaired glucose tolerance and obesity</li> </ul>	<ul style="list-style-type: none"> <li>• Tobacco use (even small amount of tobacco use increases risk)</li> <li>• Raised Blood Pressure</li> <li>• Diabetes Mellitus - type 2 or Impaired Glucose Tolerance</li> <li>• Obesity (either generalized or central)</li> <li>• Physical Inactivity</li> <li>• Atherogenic diet (high in total calories, Total fat, saturated fats, cholesterol, salt and refined sugar; low in whole grains, cereals, legumes, fruits, vegetables, antioxidant vitamins, folic acid, fibre, and Omega-3 fatty acids)</li> <li>• Mental stress (depression, low job control, suppressed hostility) and personality (type 'A')</li> </ul>	<ul style="list-style-type: none"> <li>• Raised TC : HDL-C ratio (&gt; 4.5)</li> <li>• "Lipid Triad" (concomitant presence of raised triglycerides, small dense LDL particles and low HDL)</li> <li>• Raised Apolipoprotein - B</li> <li>• Low Apolipoprotein A-1</li> <li>• Small, dense LDL particles</li> <li>• Raised Non-HDL Cholesterol (this is VLDL + LDL and is routinely calculated as TC - HDL)</li> </ul>	<ul style="list-style-type: none"> <li>• Inflammatory markers               <ul style="list-style-type: none"> <li>- Raised Total WBC count</li> <li>- Raised C-reactive Protein</li> </ul> </li> <li>• Prothrombotic factors               <ul style="list-style-type: none"> <li>- Platelet- Hyperaggregability</li> <li>- Raised Fibrinogen</li> </ul> </li> <li>• Raised Plasminogen Activator Inhibitor (PAI - 1)</li> <li>• Tissue Plasminogen Activator (tPa)</li> <li>• Others               <ul style="list-style-type: none"> <li>- Raised serum Homocysteine</li> <li>- Microalbuminuria</li> <li>- Raised Resting Pulse Rate</li> </ul> </li> </ul>

*A discussion on the major risk factors emphasizing on the benefit achieved by controlling them is reviewed in the subsequent paragraphs.*

**Dyslipidaemia** : Over the past two decades, the focus has shifted from "hypercholesterolaemia" to "dyslipidaemia", giving due consideration to various other fractions of lipid profile. Of course, total serum cholesterol (TC) remains the single most important predictor of CHD risk both on individual as well as population level. The incidence of IHD is high among populations with mean serum TC > 200 mg / dl and low in populations with mean TC levels < 150. It is desirable that on individual level, the TC level should be kept below 200, while on population level, we should strive to keep the mean level below 160 mg.

Besides TC, LDL-Cholesterol levels have assumed importance. The Adult Treatment Panel (ATP-3) of USA's National Cholesterol Education Programme recommends that on individual level, the LDL levels should ideally be < 100; since this may be difficult for most people, levels of < 130 are considered as "near optimal". Levels of > 160 indicate high risk while between 130 to 159 indicate moderately increased risk.

HDL has been acknowledged to be the protective component. HDL levels > 40 mg for males and > 50 mg for females should be aimed. In addition to simply going by TC or HDL levels, the ratio of TC : HDL has been increasingly advocated. Ideally, this ratio should be maintained at < 3; ratio of > 4.5 indicates high risk.

Finally, the role of raised triglycerides (TG) as CHD risk factor has been assuming increasing importance, especially in case of South-Asian populations and in the context of metabolic syndrome (see later). Ideally TG levels should be maintained at < 150 mg/dl; levels of 200 and above indicate high risk.

Needless to say, from the preventive action point of view, dyslipidaemia is only an indicator. It results due to a wide variety of other risk factors especially atherogenic diet, smoking, obesity, and physical inactivity and hence, focus should be to control these risk factors for effectively addressing dyslipidaemia.

**Tobacco** : There is a large body of evidence from prospective cohort studies regarding the beneficial effect of smoking cessation on coronary heart disease mortality (6). However, the magnitude of the effect and the time required to achieve beneficial results are unclear. Some studies suggest that, about 10 years after stopping smoking, coronary heart disease mortality risk is reduced to that of people who have never smoked. Other reports suggest that a much longer time is required. It has also been shown that cigarette smokers, who change to a pipe or cigar, and those who continue to smoke but reduce the number of cigarettes, have a greater mortality risk than those who quit smoking. A 50-year follow-up of British doctors demonstrated that, among ex-smokers, the age of quitting has a major impact on survival prospects; those who quit between 35 and 44 years of age had the same survival rates as those who had never smoked. The benefits of giving up

other forms of tobacco use are not clearly established. General recommendations are therefore based on the evidence for cigarette smoking. Recent evidence from the Interheart study (7) has highlighted the adverse effects of use of any tobacco product and, importantly, the harm caused by even very low consumption (1-5 cigarettes a day). The benefits of stopping smoking are evident; however, the most effective strategy to encourage smoking cessation is not clearly established. All patients should be asked about their tobacco use and, where relevant, given advice and counselling on quitting, as well as reinforcement at follow-up. There is evidence that advice and counselling on smoking cessation, delivered by health professionals such as physicians, nurses, psychologists, and health counsellors are beneficial and effective. Several systematic reviews have shown that one-time advice from physicians during routine consultation results in 2% of smokers quitting for at least one year. Data from observational studies suggest that passive cigarette smoking produces a small increase in cardiovascular risk (8-10).

#### **Dietary Risk factors**

**Dietary fat and cholesterol** : The relationship between dietary fat and coronary heart disease has been extensively investigated. Saturated fats as a whole have been shown to raise LDL-cholesterol levels. However, individual fatty acids within the group have different effects, with myristic and palmitic acids having the greatest effect on LDL-cholesterol. Saturated fatty acids are not all equally hypercholesterolaemic. The effects of different saturated fatty acids on the distribution of cholesterol over the various lipoproteins are not well known. When substituted for saturated fatty acids in metabolic studies, n-6 polyunsaturated fatty acids (which are abundant in soybean and sunflower oil) and monounsaturated fatty acids (which are abundant in olive oil) lower total cholesterol, LDL cholesterol and triglyceride concentrations. Trans-fatty acids come from both animal and vegetable sources and are produced by partial hydrogenation of unsaturated oils. Dietary intake of trans-fatty acids increases LDL-cholesterol and, at high intakes, lowers HDL cholesterol. Metabolic and epidemiological studies have indicated that trans-fatty acids increase the risk of coronary heart disease.

A high intake of fat (more than one-third of total calories) generally increases intake of saturated fat and is associated with consumption of excess calories and weight gain. A low intake of fats and oils (less than one-fifth of total calories) increases the risk of inadequate intakes of vitamin E and essential fatty acids, and may contribute to unfavourable changes in HDL-cholesterol and triglycerides. It has also been demonstrated that replacing saturated and trans-unsaturated fats with monounsaturated and polyunsaturated fats is more effective in preventing coronary heart disease events than reducing overall fat intake. Current guidelines recommend a diet that provides less than 30% of calories from dietary fat, less than 10% of calories from saturated fats, up to 10% from polyunsaturated fats, and about 15% from monounsaturated fats. Metabolic studies have shown that dietary cholesterol is a determinant of serum cholesterol concentration.

**Omega-3 fatty acids, fish and cardiovascular risk** : The main dietary sources of omega-3 fatty acids are fish and fish

oils (which contain eicosapentaenoic acid and docosahexaenoic acid), and certain nut and plant oils, such as canola, soybean, flaxseed and walnut (which contain alpha-linoleic acid). Epidemiological studies and clinical trials suggest that people at risk of coronary heart disease benefit from consuming omega-3 fatty acids. The proposed mechanisms for a cardioprotective role include altered lipid profile, reduced thrombotic tendency, and antihypertensive, anti-inflammatory and antiarrhythmic effects. However, further high quality studies are required to confirm suggestions of a protective effect of omega-3 fatty acids on cardiovascular health.

**Dietary salt** : Population studies have demonstrated that high salt intake is associated with an increased risk of high blood pressure (11). Several observational studies have linked baseline sodium intake, estimated from either 24-hour urinary sodium excretion or dietary intake, to morbidity and mortality. The hazard ratios for coronary heart disease, cardiovascular disease, and all-cause mortality, associated with a 100 mmol increase in 24-h urinary sodium excretion in men and women, have been estimated as 1.51 (95% CI; 1.14 to 2.00), 1.45 (95% CI; 1.14 to 1.84), and 1.26 (95% CI; 1.06 to 1.50), respectively. A prospective study in a Japanese cohort also showed that high dietary salt intake increased the risk of death from stroke. The efficacy of reduced sodium intake in lowering blood pressure is well established. An average reduction of 77 mmol/day (1 gram salt = approximately 1 gram dietary sodium), in dietary intake of sodium has been shown to reduce systolic blood pressure by 1.9 mmHg (95% CI, 1.2 to 2.6 mmHg) and diastolic blood pressure by 1.1 mmHg (95% CI, 0.6 to 1.6 mmHg). Phase 2 of the Trials of Hypertension Prevention. Studies has also documented that a reduced sodium intake can prevent hypertension (12). In a meta-analysis of dietary interventions to alter salt intake, a reduction of 100 mmol (6 g) per day in salt intake was associated with a fall in blood pressure of 7.11 mmHg (systolic) and 3.88 mmHg (diastolic). This information strongly supports other evidence that a modest, long-term reduction in population salt intake would immediately reduce stroke deaths by about 14% and coronary deaths by about 9% in people with hypertension, and by approximately 6% and 4% in those with normal blood pressure. It is clear that intensive interventions, in particular the Dietary Approaches to Stop Hypertension (DASH) (13), are capable of reducing salt intake and lowering blood pressure. On the basis of the above, current recommendations on salt intake [< 5 g (90 mmol) per day] are appropriate (14).

**Fruits and vegetables** : Fruits and vegetables may promote cardiovascular health through a variety of micronutrients, antioxidants, phytochemicals, flavinoids, fibre and potassium. The evidence on the role of the individual constituents is so far inconclusive.

A review of ecological, case-control and cohort studies examining the association of dietary fruits and vegetables with cardiovascular disease found a significant protective association with consumption of fruits and vegetables or surrogate nutrients. Overall, the results support a protective effect of fruits and vegetables on stroke and coronary heart disease. Joshipura et al evaluated the association between consumption of fruits and vegetables and risk of coronary heart disease in



the Nurses' Health Study and the Health Professionals' Follow-Up Study. After adjustment for standard cardiovascular risk factors, people with fruit and vegetable intake in the highest quintile had a relative risk for coronary heart disease of 0.80 (95% CI; 0.69 to 0.93) compared with those with intake in the lowest quintile. Each increase of one serving per day in intake of fruits or vegetables was associated with a 4% lower risk of coronary heart disease (relative risk 0.96; 95% CI 0.94 to 0.99;  $P = 0.01$ , test for trend). The relationships between intake of whole grains, refined grains, and fruit and vegetables, and total mortality risk and incidence of coronary artery disease and ischaemic stroke, were also evaluated in the Atherosclerosis Risk in Communities (ARIC) cohort ( $n = 15,792$ ). Over an 11-year follow-up period, whole-grain intake was inversely associated with total mortality and incidence of coronary artery disease. A recent meta-analysis of 10 prospective cohort studies has also shown that the consumption of fibre from cereals and fruits is inversely associated with risk of coronary heart disease. On the basis of the available evidence, a daily intake of at least 400 g of fruit and vegetables is recommended (15).

**Physical inactivity :** It has been estimated that inadequate physical activity is responsible for about one-third of deaths due to coronary heart disease and type 2 diabetes (16). There is evidence from observational studies that leisure-time physical activity is associated with reduced cardiovascular risk and cardiovascular mortality in both men and women and in middle-aged and older individuals. Several meta-analyses have examined the association between physical activity and cardiovascular disease. Berlin & Colditz found a summary relative risk of death from coronary heart disease of 1.9 (95% CI 1.6 to 2.2) for people with sedentary occupations compared with those with active occupations. A meta-analysis of studies in women showed that physical activity was associated with a reduced risk of overall cardiovascular disease, coronary heart disease and stroke, in a dose-response fashion. Physical activity improves endothelial function, which enhances vasodilatation and vasomotor function in the blood vessels. In addition, physical activity contributes to weight loss, glycaemic control, improved blood pressure, lipid profile and insulin sensitivity. The possible beneficial effects of physical activity on cardiovascular risk may be mediated, at least in part, through these effects on intermediate risk factors. Physical inactivity and low physical fitness are independent predictors of mortality in people with type 2 diabetes, which in turn is a strong risk factor for CHD. Overall, the evidence points to the benefit of continued regular moderate physical activity, which does not need to be strenuous or prolonged, and can include daily leisure activities, such as walking or gardening. Taking up regular light or moderate physical activity in middle or older age significantly reduces CVD and all-cause mortality, and improves the quality of life.

**Overweight :** Prospective epidemiological studies have shown a relationship between overweight or obesity and cardiovascular morbidity, CVD mortality and total mortality. Obesity is strongly related to major cardiovascular risk factors, such as raised blood pressure, glucose intolerance, type 2 diabetes, and dyslipidaemia. Meta-analyses of RCTs have shown that a weight-reducing diet, combined with exercise, produces

significant weight loss, reduces total cholesterol and LDL-cholesterol, increases HDL-cholesterol, and improves control of blood pressure and diabetes. A meta-analysis of randomized controlled trials found that a net weight reduction of 5.1 kg (95% CI 4.25 to 6.03 kg), reduced systolic blood pressure by 4.44 mmHg (95% CI 2.95 to 5.93 mmHg) and diastolic blood pressure by 3.57 mmHg (95% CI 2.25 to 4.88 mmHg). The long-term benefit of weight reduction on blood pressure control has been confirmed in several studies, including Phase II of the Trials of Hypertension Prevention Collaborative Research Group.

Evidence also suggests that physical exercise and fitness is equally and independently important. In a review of data from 24 prospective observational studies, Blair & Brodney found that regular physical activity attenuated many of the health risks associated with overweight and obesity. Physically active obese individuals have lower morbidity and mortality than individuals of normal weight who are sedentary; physical inactivity and low cardio-respiratory fitness are as important as overweight and obesity as predictors of mortality.

The appropriate upper limits of measures of overweight and obesity have been recently defined by various expert bodies. For South Asian populations, including Indians, the upper limits are (17 - 19) :

- Waist Circumference - 90 cms for males and 80 cms for females
- Waist : Hip ratio (WHR) - 0.90 for males and 0.80 for females
- Body Mass Index (BMI) - 25 and above as overweight and 30 and above as obese. However, recent WHO recommendations tend to recommend an even lower cut-off for Asian populations as 23 and above as overweight and 27.5 and above as obese.

**Alcohol :** Many studies have shown a U- or J-shaped association between mortality and alcohol consumption, in which people who drink light or moderate amounts have a lower death rate than nondrinkers, while those who drink large amounts have a higher death rate. People who drink heavily have a high mortality from all causes and cardiovascular disease. In addition, they may suffer from psychological, social and other medical problems related to high alcohol consumption. A meta-analysis of 28 cohort studies of alcohol consumption and CHD showed that risk decreased as consumption increased from 0 to 20 g/day ( $RR = 0.80$ ); there was evidence of a protective effect of alcohol up to 72 g/day ( $RR = 0.96$ ), and increased risk at consumptions above 89 g/day ( $RR = 1.05$ ). Smaller protective associations and more harmful effects were found in women. The amount of alcohol associated with the lowest mortality rates was between 10 and 30 g (1-3 units) per day for men and half these quantities for women (1 unit has already been defined in the earlier chapter on general principles of healthy lifestyle). Various mechanisms have been proposed for the protective effect of modest alcohol consumption, including the demonstrated beneficial effects of alcohol on lipid profile, particularly an increase in HDL-cholesterol level, thrombolytic profile, and platelet aggregation (20 - 23). The benefits of alcohol in light to moderate drinkers may be overestimated in observational studies, as a result of confounding because it



is primarily the non-drinking group that causes the U-shaped relationship, and this may contain both life-long abstainers and people who stopped drinking because of ill-health; this could result in a spurious association suggesting that there is a safe level of alcohol intake. A recent meta-analysis of 54 published studies concluded that such lack of precision in the classification of abstainers may invalidate the results of studies showing the benefits of moderate drinking; this would imply that there is no level of alcohol consumption that is beneficial with respect to coronary heart disease; rather, risk increases with increasing consumption in a linear fashion.

Interestingly, earlier, the beneficial effect of hormone replacement therapy (HRT) on HDL-cholesterol convinced many that cohort studies showing a protective effect of HRT on coronary heart disease risk were valid. However, subsequent randomized controlled trials have found either no benefit or a harmful association; the earlier beneficial results were likely to be due to uncontrolled confounding. On the same analogy, it is possible that the protective association between light-to-moderate alcohol consumption and coronary heart disease is also an artefact caused by confounding. Light-to-moderate drinkers may be "light-to-moderate" in other behaviours, such as tobacco use which could be responsible for their lower risk of CHD. It is also important to note that alcohol consumption is associated with a wide range of medical and social problems, including road traffic injuries. Some individuals are also at risk of progression to problem drinking. Other risks associated with moderate drinking include fetal alcohol syndrome, obesity, haemorrhagic stroke, large bowel cancer, and female breast cancer. Consequently, from both the public health and clinical viewpoints, there is no merit in promoting alcohol consumption as a preventive strategy.

**Psychosocial factors** : Observational studies have indicated that some psychosocial factors, such as depression and anxiety, lack of social support, social isolation, and stressful conditions at work, independently influence the occurrence of major risk factors and the course of coronary heart disease, even after adjusting for confounding factors (24 - 26). Other psychosocial factors, such as hostility and type A behaviour patterns, and anxiety or panic disorders, show an inconsistent association (27, 28). Rugulies, in a meta-analysis of studies of depression as a predictor for coronary heart disease, reported an overall relative risk for the development of coronary heart disease in depressed subjects of 1.64. Other studies have also found a strong association between depression and CHD. Depression was shown to be a predictor for risk of myocardial infarction in the Interheart case-control study (odds ratio 1.55). This finding was consistent across regions, in different ethnic groups, and in men and women. More recent trials have cast doubt on the causal nature of the association between depression and CHD. In a large randomized trial of psychological intervention after myocardial infarction, no impact on recurrence or mortality was found. Another large trial that provided social support and treatment for depression also found no impact. Kivimäki et al, in a 25.6-year prospective cohort study in Finland, found that metal industry employees with high job strain (a combination of high demands at work and low job control) had a cardiovascular mortality risk 2.2 times that of their colleagues with low job

strain. This association between stressful conditions at work and CHD is supported by other studies. There is also some evidence that social isolation and lack of quality social support are independent risk factors for CHD onset and prognosis : the risks are increased 2-3-fold and 3-5-fold, respectively, in both men and women. The association has been demonstrated in subjects in different countries, and in various age groups. While these findings provide some support for a causal interpretation of the associations, it is quite possible that they represent confounding or a form of reporting bias. Well planned trials of interventions are required to elucidate whether there is a true cause-effect relationship and, more importantly, whether intervention reduces cardiovascular risk. In the meantime, physicians and health care providers should consider the whole patient. Early detection, treatment and referral of patients with depression and other emotional and behavioural problems are, in any case, important for reducing suffering and improving the quality of life, independent of any effect on cardiovascular disease.

**Raised Blood Pressure** : Raised blood pressure is estimated to cause about 7 million premature deaths throughout the world, and 4.5% of the disease burden (64 million disability-adjusted life years (DALYs)) (1 - 3). It is a major risk factor for cerebrovascular disease, coronary heart disease, and cardiac & renal failure. Treating raised blood pressure has been associated with a 35-40% reduction in the risk of stroke and at least a 16% reduction in the risk of myocardial infarction. Raised blood pressure often coexists with other cardiovascular risk factors, such as tobacco use, overweight or obesity, dyslipidaemia and dysglycaemia, which increase the cardiovascular risk attributable to any level of blood pressure. Worldwide, these coexisting risk factors are often inadequately addressed in patients with raised blood pressure, with the result that, even if their blood pressure is lowered, these people still have high cardiovascular morbidity and mortality rates. Almost all clinical trials have confirmed the benefits of antihypertensive treatment at blood pressure levels of 160 mmHg (systolic) and 100 mmHg (diastolic) and above, regardless of the presence of other cardiovascular risk factors. Observational data support lowering of these systolic and diastolic thresholds. Several trials in patients at high cardiovascular risk have confirmed these observational data, showing reductions in cardiovascular morbidity and mortality in people whose blood pressure is reduced to levels significantly below 160 mmHg systolic and 90 mmHg diastolic. These trials support the view that, in patients at high cardiovascular risk, with blood pressures in the range 140-160 mmHg (systolic) and 90-100 mmHg (diastolic), the treatment for such high-risk patients should begin at the lower blood pressure thresholds of even lesser than 160 mm systolic or 90 mm diastolic.

There is also enough evidence that it is not only the diastolic level but that systolic BP level is also independently related to cardiovascular risk; in fact, as age advances, the level of systolic BP may be more important for CV risk than diastolic level.

*More details regarding the epidemiology, risk factors and prevention of hypertension are addressed in a subsequent chapter.*

**Diabetes and Impaired Glucose Tolerance (IGT) / Impaired Fasting Glucose (IFG) :** Cardiovascular disease accounts for about 60% of all mortality in people with diabetes. The risk of cardiovascular events is 2-3 times higher in people with type 1 or type 2 diabetes (29, 30) and the risk is disproportionately higher in women (29, 31). Patients with diabetes also have a poorer prognosis after cardiovascular events compared with non-diabetics. Epidemiological evidence also suggests that the association between blood glucose and cardiovascular disease begins before diabetes manifests itself. The cardiovascular risk increases as glucose tolerance becomes impaired and then progresses to diabetes. Further, abnormal glucose regulation tends to occur together with other known cardiovascular risk factors, such as central obesity, elevated blood pressure, low HDL-cholesterol and high triglyceride level. The Diabetes Control and Complications Trial (DCCT), which included 1441 young adults with type 1 diabetes, demonstrated that intensive treatment to ensure good glycaemic control substantially reduced the risks of cardiovascular events, neuropathy, nephropathy and retinopathy. The United Kingdom Prospective Diabetes Study (UKPDS) found that glycaemic control in people with type 2 diabetes reduced the frequency of microvascular complications, such as blindness, amputation, and end-stage renal disease. Each 1% increase in HbA1c level was associated with a 14% increase in the incidence of fatal or nonfatal myocardial infarction. A later study suggested that stringent blood sugar control in people with type 2 diabetes, combined with targeted reductions in blood lipids and blood pressure, reduced macrovascular events in diabetic patients with microalbuminuria. Good glycaemic control should be a key goal of treatment of diabetes, to delay the onset and progression of microvascular and macrovascular disease. The first approach to controlling glycaemia should be through diet alone, combined with physical exercise; if this is not sufficient, oral medication should be given, followed by insulin if necessary. Treatment should aim to achieve a fasting blood glucose level of 4-7 mmol/l (72-126 mg/dl); and an HbA1c level of 6.5% or less.

*More details regarding the epidemiology, risk factors and prevention of diabetes type - 2 are addressed in a subsequent chapter.*

**The Metabolic Syndrome (Syndrome 'X') :** In 1988, The noted Diabetologist, Gerald Reaven had postulated that resistance to insulin action would occur mainly due to obesity, central obesity, physical inactivity, and possibly certain genetic reasons. Once insulin resistance develops, the body, in an effort to compensate, releases more and more insulin, resulting into fasting hyperinsulinaemia. Under the influence of this hyperinsulinaemia, there occurs a very unique and specific "clustering" of certain specific cardiovascular risk factors, namely, raised blood pressure, impaired glucose tolerance, and a unique dyslipidaemia manifesting with low HDL and raised triglycerides. This clustering was referred to as "Syndrome X" by Reaven (32) and it was postulated that once such clustering occurs, it is likely to be a major risk factor for development of IHD and Diabetes type -2.

Large number of clinical and epidemiological studies over the past 2 decades have confirmed that the metabolic syndrome is, indeed, a reality. In fact, scientific evidence suggests that

south Asians, especially Indians are likely to be at a high risk of developing this syndrome. There are various defining criteria of this syndrome, of which the WHO criteria and ATP-3 criteria are the most widely used. The **WHO criteria** are (33) : "Diabetes or IFG or IGT or evidence of insulin resistance (either of hyperinsulinaemia or euglycaemic clamp glucose uptake in lowest 25%)" PLUS any two of the following :

- Obesity as defined BMI > 30 or WHR > 0.9 for males or > 0.85 for females (>0.80 for Indian females)
- Hypertension as defined as blood pressure > 140 systolic or > 90 diastolic
- Dyslipidaemia as manifested by triglycerides > 150 mg / dl or HDL < 35 mg / dl for males or < 40 mg / dl for females
- Microalbuminuria defined as albumin excretion > 20 microgram albumin excretion / mt.

**Hormone Replacement Therapy (HRT) :** On the basis of data from observational studies (34), hormone therapy has been used for prevention of cardiovascular disease, osteoporosis and dementia. This practice has been called into question following publication of the results of several randomized clinical trials, which showed no coronary protection, and the Women's Health Initiative (35), which indicated that long-term use of estrogen plus progestin was associated with increased risks of cancer and cardiovascular disease. A Cochrane systematic review (36) of 15 randomized double-blind trials showed that the only statistically significant benefits of hormone therapy were decreased incidences of fractures and colon cancer with long-term use. In relatively healthy women, combined continuous hormone therapy significantly increased the risk of coronary events and venous thromboembolism (after one year's use), stroke (after 3 years), breast cancer (after 5 years) and gallbladder disease. Long-term estrogen-only hormone therapy also significantly increased the risk of stroke and gallbladder disease. In relatively healthy women over 65 years taking continuous combined hormone therapy, there was an increase in the incidence of dementia.

Thus, HRT is not recommended as a preventive step against IHD, from public health point of view.

**The Effect of Multiple Risk Factors :** All the leading CHD risk factors described above tend to act in a multiplicative mode when two or more are present (which, quite often, they are). This means that when multiple risk factors are present, their effect on increasing the coronary risk is not simply additive but rather "multiplicative" (in simple corollary, it is not  $2+2+2=6$  but rather  $2 \times 2 \times 2 = 8$ ). Another aspect which must be kept in mind is that multiple risk factors, even if present in "moderate" quantum, tend to increase the coronary risk quite substantially, compared to when only one factor is present in high quantum. For instance, a person who is marginally obese (e.g. BMI 25.5), smokes 2 or 3 cigarettes a day, has a WHR which is marginally raised (e.g., 0.93), goes for brisk exercise only once a week, and has mild elevation of BP (eg, 150 / 96) would be having much higher overall risk than a person who smokes 10 cigarettes per day but has no other risk factor. This issue is important since we often tend to "condone" who have mild elevations of multiple risk factors thinking that "moderation" is not bad! In fact, as per the widely upheld "continuum of risk theory", if multiple risk factors are present, then IHD risk would start even below

the standard cut-off levels and majority of the events occur at moderate level of risk factors.

## Prevention and Control of IHD

As said earlier, IHD is the prototype example of a serious, lifestyle disease. It needs to be addressed in a very concerted manner, by both, the medical functionaries as well as by Commanders / Administrators. The preventive strategies are summarized in Box - 2.

<b>Box - 2 : Preventive Strategies for IHD</b>
<b>Primordial Prevention</b>
<b>Primary prevention</b>
(a) Population Strategy
- Mass Approach
- Targeted Group approach
(b) Targeted High Risk Individual Strategy
<b>Secondary Prevention</b>
<b>Tertiary Prevention</b>

### Primordial Prevention

The concept may sound “Utopian” to many, but it is a fact that certain countries / communities have been successfully adopting this strategy.

The strategy can be used by those countries / communities where lifestyle has not, as yet, acquired the pattern associated with high CHD incidence and where the average level of critical risk factors is still favourable; however, economic advancements and changing life styles threaten to undermine this favourable situation and in these situations, we could take action to “prevent the very emergence of predisposing conditions, in countries and communities in which they have not yet appeared”. This in essence, is primordial prevention.

### Primary prevention

Primary prevention focuses on measures so that the pathological processes of IHD are either not initiated or else do not progress to develop into the disease. There are two mainstays of this approach : firstly, educating & motivating the individuals and communities with a view to achieve positive life style behaviour changes, and, secondly, supplementing these IEC (Information, Education and Communication) efforts by suitable socio-political, legislative and administrative steps. The ultimate objective is that individuals and communities live a healthy lifestyle, free of coronary risk factors.

Primary preventive steps can be undertaken through two broad strategies, viz. the “population approach” which focuses on large population groups, even the entire states or countries, and the “Targeted. individual, high risk strategy” which focuses on individuals who have a high probability of developing IHD, due to the presence of certain risk factors.

### Population Strategy

**Mass Approach :** This focuses on large sections of populations, may be the entire District, state or even the country; in context of armed forces, IEC methods directed to the entire armed forces or a complete Division or Brigade would be an equivalent

example. The strategy adopts a two pronged approach as follows :

- Education and Motivation by various IEC techniques, with a view to informing the community / population and to secure a healthy lifestyle change. The key issues of IEC are summarized in Box - 3.

<b>Box - 3 : Key Messages For I.E.C. : Primary Prevention of IHD</b>
Eat a diet which gives :
<ul style="list-style-type: none"> <li>• Just sufficient in calories</li> <li>• Total fats provide &lt; 30% of calorie need</li> <li>• Saturated fats provide &lt; 10% of calorie need</li> <li>• Trans-fatty acids to be eliminated from diet</li> <li>• Most dietary fat should be polyunsaturated (up to 10% of calories) or monounsaturated (10-15% of calories).</li> <li>• Refined sugars provide &lt; 10% of calorie need</li> <li>• Salt consumption (all sources) &lt; 5 gm / day</li> <li>• Cholesterol &lt; 200 mg / day</li> <li>• Low in gravied, fried, creamed and sugared food stuffs</li> <li>• Plenty of whole grains, cereals, legumes, beans &amp; pulses</li> <li>• 400 to 500 grams fresh fruits / vegetables</li> <li>• Low fat dairy produce</li> </ul>
Undertake brisk walk every day, covering 2 miles (3.2 Km) in 30 to 35 mts daily; if you can exercise longer or at higher intensity, the better it is
Supplement aerobic exercises (walking, running, cycling, sports) with light weight training and stretching exercises as yoga
NO TOBACCO. If you don't use tobacco, don't start; if you do, stop.
Avoid alcohol. If you must drink, not more than 3 small drinks a day for men (not more than 2 small a day for women); don't drive even after mi,d drinks; try not to drink daily.
Regularly check your body weight and measure your waist and hip circumference; BMI should be kept at < 25 (preferably < 23) and waist < 90 cm or WHR < 0.90 for males (for females, < 80 cm or WHR < 0.80)
Control and manage Mental Stress :
<ul style="list-style-type: none"> <li>• Pray, meditate</li> <li>• Spend Quality time with family</li> <li>• Yoga</li> <li>• Manage your finances well</li> <li>• Exercise regularly</li> <li>• Look after health of yourself and family members</li> </ul>
Undergo periodic / annual medical examinations seriously; take precautions as told by your Doctor
If you have any symptoms of chest pain, fatiguability. Palpitation or breathlessness, seek medical attention.
<i>See further details in the chapter on healthy lifestyle in this section</i>

- Socio-political, administrative and legal actions to supplement the IEC steps, eg., legislation and coercive steps against tobacco and alcohol; provision of Gymnasia,



playgrounds and walkways; encouragement for produce of fruits and vegetables; subsidy on fruits and vegetables; Administrative disincentives for obese persons; and so on.

**Targeted Group Approach :** This strategy focuses the educational and motivational efforts, not on entire population or community, but rather on certain selected groups of persons who, due to certain characteristics, are :

- At high risk of developing the coronary risk factors (e.g., “newly rich” persons, executives, bureaucrats, businessmen; in the context of armed forces, JCOs / senior NCOs are an example), or,
- Can be of help in implementing the preventive programmes (e.g., local leaders, policy makers, influential politicians and bureaucrats; in context of armed forces, senior commanders and senior functionaries of Wives Welfare Associations, Army School-Teachers), or,
- Are in a “formative” stage and may develop healthy lifestyle if properly informed / motivated at this stage (e.g., school & college children; in context of armed forces, Recruits, Cadets and school children of Army schools, Sainik Schools, and KVs).

**Targeted High Risk Individual Strategy :** While population strategy is very effective in gradually bringing down the incidence of IHD in the total population, the process may be slow; secondly it relies on behavioural and lifestyle change by individuals which often may not easily happen, especially permanently. Therefore, the population strategy should be supplemented by the Individual High risk strategy, which aims at identifying those individuals, who have a higher probability of developing IHD, because of presence of certain major risk factors, so that concerted preventive as well as treatment efforts may be directed to these individuals. In the simplest form, when a doctor checks the age, sex, family history of IHD, BP and body weight of each of his adult patient, and educates / treats those who have a few of these risk factors, she is actually practicing the Individual High Risk Strategy.

The recent advancement in this strategy is the development of “Individual Risk Prediction Charts” by the WHO for various regions of the world. (The chart applicable to Indian region is given in Fig. - 1). Use of risk prediction charts to estimate total cardiovascular risk is a major advance on the older practice of identifying and treating individual risk factors, such as raised blood pressure (hypertension) and raised blood cholesterol (hypercholesterolemia). The total risk approach acknowledges that many cardiovascular risk factors tend to appear in clusters; combining risk factors to predict total cardiovascular risk is consequently a logical approach to deciding who should receive treatment. In summary, the great strength of the risk scoring approach is that it provides a rational means of making decisions about intervening in a targeted way, thereby making best use of resources available to reduce cardiovascular risk. Risk scoring moves the focus of treatment from the management of individual risk factors to the best means of reducing an individual's overall risk of disease. It enables the intensity of interventions to be matched to the degree of total risk.

In the chart (Fig. - 1), the subjects are first of all divided into diabetic or non-diabetic. Within each of this category, the

subjects are divided according to tobacco use (users or non users), age and sex. Thereafter, the subject is evaluated as per his / her Systolic BP and Total Cholesterol level, and the level of CHD risk is directly read from the chart. The risk, technically, indicates the probability that the given individual is likely to develop IHD in the next 10 years. In general, < 10% risk is equivalent of low risk (low risk does not mean “NO RISK”); 10 - 20% : moderate risk, 20-30% high risk; and > 30% very high risk.

It may be mentioned that if a person has clear history of having suffered from IHD or has clear family history (as defined in the table of risk factors) then the person is to be taken as “high risk” irrespective of the score obtained in this chart.

Actions to be taken after evaluation of the person on the risk chart are given in Box - 4.

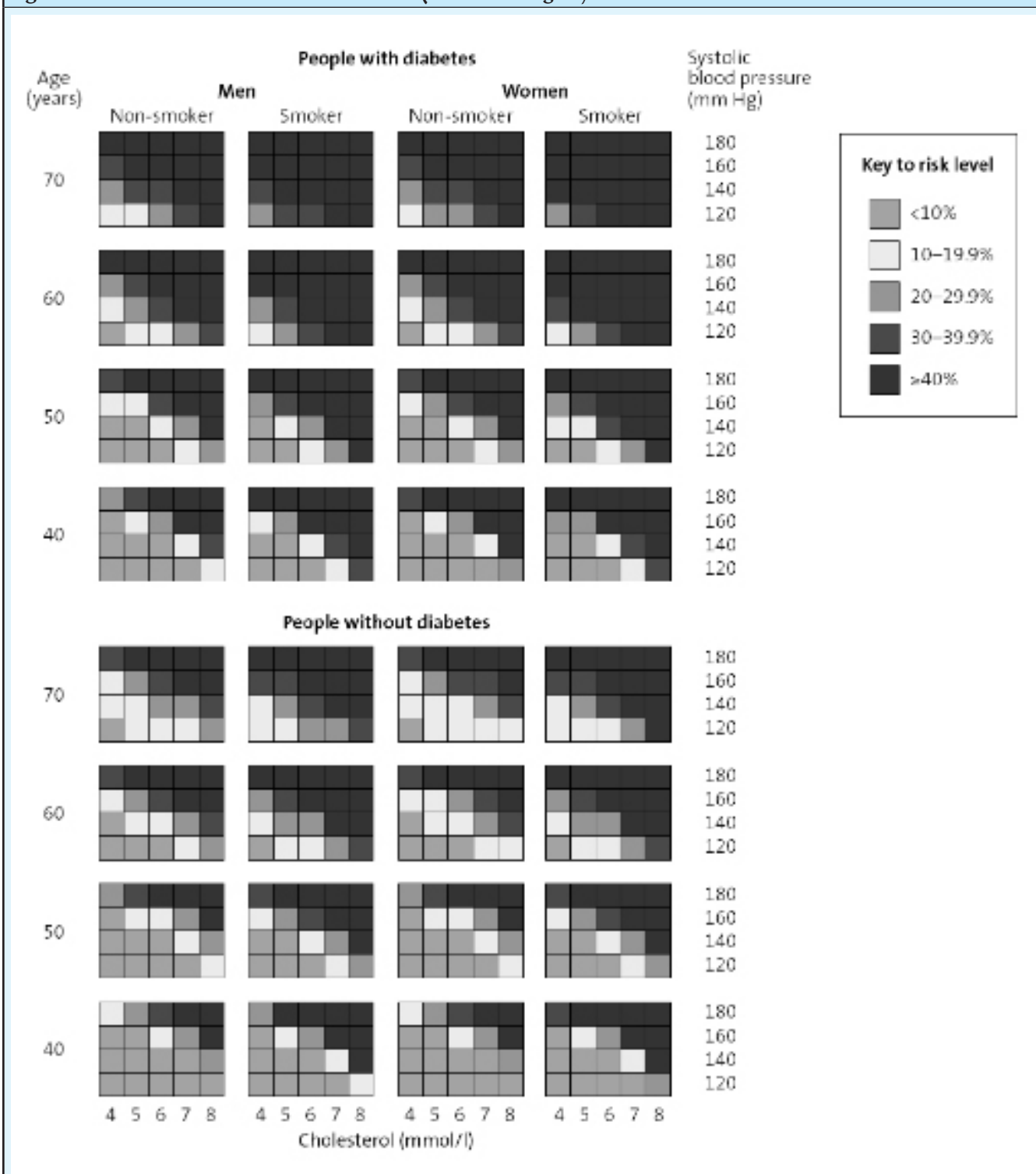
<b>Box - 4 : Actions to be taken after evaluation of the person on the risk chart</b>
All persons, irrespective of risk category should be educated and motivated for healthy lifestyle changes.
<b>Antihypertensive treatment :</b> Individuals with sustained BP readings > 140 / 90 : if risk category 1 or 2, continue lifestyle changes; if category - 3 give lifestyle changes but if despite lifestyle changes for 4 to 6 months BP is > 140 / 90, give treatment starting with a thiazide like diuretic or ACE inhibitor or calcium channel blocker or beta blocker. Indvls in risk category - 4 with BP > 130 / 90 - start drug treatment alongwith lifestyle changes. All individuals with blood pressure at or above 160/100 mm Hg, or lesser degree of raised blood pressure with target organ damage, irrespective of risk category, should definitely have drug treatment and specific lifestyle advice.
<b>Anti-diabetic drugs :</b> Individuals with persistent hypoglycaemia of fasting > 6 mmol / l (110 mg / dl) should be given hypoglycaemic drugs irrespective of risk category
<b>Lipid lowering treatment (use statin) :</b> Risk category 1 and 2, advise healthy lifestyle; category 3 : If despite lipid lowering diet, TC > 200 or LDL > 120 consider a statin alongwith lifestyle advise; category - 4 along with lipid lowering diet, give statin to lower TC to < 200 and LDL to < 120. If TC > 320, give statin irrespective of risk category.
<b>Antiplatelet drugs :</b> consider low dose aspirin only in case of category - 4.

## Secondary Prevention

Early detection of CHD at the incipient stage is quite relevant. The available tools are firstly, resting ECG using Minnesota code criteria for coronary insufficiency, a method which has been used in epidemiological surveys, but has low sensitivity and specificity for individual prediction. Secondly, a combination of Rose questionnaires which taps symptoms of angina on effort and resting ECG can be used. Better predictive values are obtained with exercise ECG, either alone or in conjunction with echocardiography. Exercise ECG however carries some risk and should be undertaken in presence of a physician. All these screening procedures will give better predictive value if



Fig. - 1 : WHO Individual Risk Prediction Chart (For Indian Region)



A person who has diabetes is defined as someone taking insulin or oral hypoglycaemic drugs, or with a fasting plasma glucose concentration above 7.0 mmol/l (126 mg/dl) or a postprandial (approximately 2 hours after a main meal) plasma glucose concentration above 11.0 mmol/l (200 mg/l) on two separate occasions).

Conversion factor for total Cholesterol is 1 mmol / l = 37.5 mg / dl

used in high risk populations, as middle aged, obese, having hypertension or impaired glucose tolerance or dyslipidaemia. The most important practical aspect is to keep a high index of diagnostic suspicion and evaluate any person who presents with coronary risk factors.

### Tertiary Prevention

The patients need to be adequately treated and rehabilitated. Personal discussions with the Doctor would go a long way in this process. The patient should be reassured and apprehensions allayed. Advice should be given regards long term drug therapy, physical exercise, reduction of risk profile and gradually getting back into day to day life activities. Follow up, assessment of status at periodic intervals and appropriate advice should be ensured.

### Summary

The term IHD is a wide spectrum of conditions, which includes asymptomatic coronary insufficiency, typical angina, atypical angina, acute Myocardial Infarction and sudden death, representing increasing severity along the spectrum. IHD is defined as a state of lack of supply of oxygen to the myocardium vis a vis the demands, due to narrowing of the coronary arteries as a result of the atherosclerotic process. The disease has a high "killing power"; even for those who survive, the quality of life in terms of physical capabilities is compromised, along with constant apprehension about the future; the treatment is quite costly and available at few selected centres; most of the persons affected with clinical disease are in their middle age, and are in the maximal productive phase of their life. The silver lining is that "Coronary Risk Factors" are well known to the medical world and potentially amenable to preventive efforts.

In developed countries, half of all deaths are due to CVD and a quarter due to IHD. Of an estimated 58 million deaths globally from all causes in 2005, cardiovascular disease (CVD) accounted for 30%. In India, over the past 4 decades, the prevalence of IHD has risen two fold in rural and six fold in urban areas. At present, an estimated 3 to 4% of rural and 8 to 10% of urban adults are likely to be affected by IHD, thus putting the estimated IHD cases in India at 30 million (15 million each in rural and urban areas).

The risk factors may be grouped as Non Modifiable and Modifiable. Non Modifiable factors are Increasing Age, male sex, Family history and racial factors (South Asian populations are at a high risk). Modifiable factors are classified as lipid and non-Lipid factors. Lipid factors are Raised Total Cholesterol (< 200 mg / dl : desirable; 200 - 239 : Borderline high;  $\geq$  240 : High) Raised LDL - C ( < 100 mg/dl : optimal; 100 - 129 : near optimal; 130- 159 : Borderline high;  $\geq$  160 : High) Raised triglycerides (<150 mg/dl : normal; 150 - 199 : Borderline High;  $\geq$  200 : High) Low HDL-C ( < 40 mg/dl in men or < 50 in women), and Metabolic Syndrome. Non-Lipid factors are Tobacco use, Hypertension, Diabetes Mellitus - type 2 or Impaired Glucose Tolerance, Obesity (either generalized or central), Physical Inactivity, Atherogenic diet and Mental stress. All the leading CHD risk factors tend to act in a multiplicative mode. Multiple risk factors, even if present in "moderate" quantum, tend to increase the coronary risk quite substantially, compared to when only one factor is present in high quantum.

The broad strategy for prevention of IHD includes primordial, primary, secondary and tertiary levels of prevention. The strategy of Primordial Prevention can be used by those countries / communities where lifestyle has not, as yet, acquired the pattern associated with high CHD incidence and where the average level of critical risk factors is still favourable. The primary Prevention would basically utilize the IEC strategy in the form of the population strategy, educating both, the general community (mass approach) and specific groups (group approach) and also in the form of "individual high risk strategy", focusing on individuals with "Risk factors". The recent advancement in this strategy is the development of "Individual Risk Prediction Charts" by the WHO for various regions of the world. These IEC (Information, Education and Communication) efforts are supplemented by suitable socio-political, legislative and administrative steps. Secondary Prevention is through early detection of CHD at the incipient stage by using resting ECG, Minnesota code criteria, Rose questionnaires, exercise ECG, either alone or in conjunction with echocardiography and advice regarding lifestyle changes. Tertiary Prevention includes disability limitation through prompt treatment of the condition and its complications and rehabilitation by Follow up, assessment of status at periodic intervals and appropriate advice regarding lifestyle, treatment and counseling on psycho-emotive aspects.

### Study Exercises

**Long Questions :** (1) Describe the recent advances and concepts regarding 'coronary risk factors" (2) Discuss a draft policy for prevention of IHD in our country.

**Short Notes :** (1) magnitude of problem of IHD in India (2) Special features of IHD among Indians (3) Metabolic syndrome (4) Population versus high risk strategy in IHD prevention.

### MCQs & Exercises

- The estimated deaths due to IHD in industrialized countries is : (a) 25-30% (b) 40-55% (c) 80-90% (d) 10-20%
- It is estimated that number of IHD cases in India is around (a) 55 million (b) 15 million (c) 30 million (d) 1 million
- The Desirable, Borderline high and High values of Total Cholesterol are (a) <200, 200 - 239,  $\geq$  240 (b) <160, 160-180,  $\geq$  180 (c) <200, 200- 249,  $\geq$ 250 (d) <180, 181- 191,  $\geq$ 192
- The desirable value of HDL Cholesterol : (a)  $\leq$  30 (b)  $\leq$  60 (c)  $\leq$  50 (d)  $\leq$  40
- The Optimal, Near Optimal, Borderline high, High, Very high values of LDL Cholesterol are : (a) < 100, 100-129, 130 - 159, 160 - 189,  $\geq$ 190 (b) < 120, 120-129, 130 - 159, 160 - 199,  $\geq$ 200 (c) < 130, 130 - 159, 160 - 199,  $\geq$ 200 (d) < 100, 130 - 159, 160 - 189,  $\geq$ 190
- METABOLIC SYNDROME does not include (a) WHR > 0.9 for males or > 0.85 for females (b) Albumin excretion < 20 microgram (c) Low levels of HDL cholesterol : <40 mg/dL in men, <50 mg/dL in women (d) Elevated blood pressure levels :  $\geq$ 140 mm Hg SBP or  $\geq$ 90 mm Hg DBP
- Atherogenic diet does not include : (a) high in total calories, total fat, saturated fats and cholesterol (b) high in salt and refined sugar (c) low in whole grains, cereals, legumes,

- fruits, vegetables (d) high in antioxidants
8. Not a Coronary Risk Factor : (a) Raised Non-HDL Cholesterol (b) Raised TC : HDL-C ratio ( $> 4.5$ ) (c) Low Apolipoprotein A-1 (d) Low Apolipoprotein B
  9. Upper limit of Waist Circumference is 80 cms for males - T/F
  10. Lower cut-off of BMI for overweight as recommended for Asian populations is : (a)  $>18.5$  (b)  $>20.5$  (c)  $>23$  (d)  $>24.9$
  11. One of the following is a mode of Primary prevention: (a) Individual Risk Prediction Charts (b) resting ECG using Minnesota code criteria (c) Rose questionnaires (d) Exercise ECG
  12. There is a U- or J-shaped association between mortality and alcohol consumption - T/F
  13. Early Diagnosis and Treatment of Hypertension is \_\_\_\_\_ mode of prevention for IHD : (a) Primordial (b) Primary (c) Secondary (d) Tertiary
  14. Early Diagnosis and Treatment of Angina is \_\_\_\_\_ mode of prevention for IHD : (a) Primordial (b) Primary (c) Secondary (d) Tertiary
  15. Early Diagnosis and Treatment of Dyslipidemia is \_\_\_\_\_ mode of prevention for IHD : (a) Primordial (b) Primary (c) Secondary (d) Tertiary
  16. Not a Modifiable Coronary Risk Factor : (a) Raised Non-HDL Cholesterol (b) Raised TC : HDL-C ratio (c) Low Apolipoprotein A-1 (d) MI in father before 45 years age

**Answers :** (1) a; (2) c; (3) a; (4) d; (5) a; (6) b; (7) d; (8) d; (9) F; (10) c; (11) a; (12) T; (13) b; (14) c; (15) b; (16) d

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**Definition / Identification**

Systemic arterial hypertension is defined as a state of chronically elevated arterial blood pressure, as compared to what is normally expected, as per the defined levels given below.

**Levels**

It needs to be noted that blood pressure is a “continuous” variable and hence it may be scientifically difficult to draw a arbitrary cut-off line to delineate normal and raised blood pressure; e.g., blood pressure level of 130 / 86 mm Hg would carry a higher risk for cardiovascular and other morbidity as compared to 120 / 80 mm Hg, though both would fall in the category of “normotensive”. However, for the purpose of epidemiological, clinical and public health needs, the categorization of hypertension, based on systolic and diastolic levels, is shown in Table - 1. This classification is based on the recent guidelines of WHO & ISH and from JNC - VII (1, 2) :

**Table - 1**

Grade	Systolic level (mm Hg)		Diastolic level (mm Hg)
Normal	< 120	AND	< 80
Pre-hypertension	120 to 139	OR	80 to 89
Hypertension Grade - I	140 to 159	OR	90 to 99
Hypertension Grade - II	160 to 179	OR	100 to 109
Hypertension grade - III	≥ 180	OR	≥ 110

The above classification is a clear departure from the earlier WHO classification in which Blood pressure levels of 140 / 90 were taken to qualify as hypertension (3), since in this report, even those with levels between 120 to 139 systolic and 80 to 89 diastolic have also been classified as “prehypertensive” thereby emphasizing the importance of concerted “lifestyle” modification and public education efforts for this group also.

**Classification**

Hypertension can be classified in 3 different ways, as follows :

**According to the level of blood pressure :** This has been described in Table - 1.

**According to identifiable cause, if any :** About 5 to 10% of the cases of hypertension will have some identifiable cause for the raised BP. This is called as “Secondary” hypertension. Important causes of secondary hypertension are given in Box-1a. However, 90 to 95% cases will not have any identifiable cause; these are called as “primary” or “essential” hypertension. Certainly, the word “essential” gives an impression that these persons have to have raised BP, which is not correct; there is nothing like “essential” and most of these cases will also

become normotensive with proper lifestyle changes.

**According to the extent of target organ damage :** The various types of target organ damage that can be caused by raised BP are as per Box - 1b (3, 4).

<b>Box - 1a : Causes of Secondary Hypertension</b>
Induced by exogenous substances or drugs (Hormonal contraceptives, corticosteroids, sympathomimetics, cocaine, Tyramine containing foods & MAO Inhibitors, NSAIDS)
Secondary to Renal Disease (Renal parenchymatous disease, Renovascular hypertension, Renin producing tumours)
Associated with endocrine disorders (Acromegaly, thyroid disease, adrenocortical diseases, carcinoid tumours)
Pregnancy Induced
Coarctation of Aorta
<b>Box - 1b : Target Organ Damage due to Hypertension</b>
Heart : IHD, LVH, Heart Failure
Brain : Stroke, TIC
Chronic kidney disease
Peripheral arterial disease
Retinopathy

**Hypertension as a Risk Factor for Diseases**

For purposes of public health and preventive medicine, hypertension and stroke are considered together since at the large population level, the major cause of stroke is raised blood pressure and efforts to prevent hypertension will pay a rich dividend for prevention of stroke. At the individualized clinical level, of course, there would be other causes of stroke that naturally, would need consideration.

Hypertension, like diabetes, is often referred to as “silent killer”. During most of its course, it produces hardly any signs/symptoms by itself; however, it damages the end organs substantially (cardiovascular system, Kidneys and Retina). Epidemiological estimates from large scale studies indicate that subjects with DBP of 105 have a ten times increased risk of stroke and five times more risk of IHD compared to subjects having DBP < 80. Prolonged reductions in DBP by 5, 7.5 and 10 mm are respectively associated with at least 34%, 46% and 56% reduction in risk of stroke and at least 21%, 29% and 37% reduction in risk of coronary events (5).

It also needs to be clearly noted that both systolic as well as diastolic are important from the morbidity and mortality point of view. In fact, after 55 years age, SBP may become even more important than DBP from preventive point of view. Raised SBP has been shown to be associated with a higher RR of CHD, stroke, CCF, Renal disease and overall mortality. In the follow up of MRFIT trial, as compared to subjects with SBP < 120 and DBP < 80, the RR of coronary events was 3.23 times higher for those with isolated diastolic hypertension (DBP > 100 with normal systolic, i.e., < 140); the RR was 4.19 times for those with isolated systolic hypertension (SBP > 160 with DBP < 90); and 4.57 times among those who had both, i.e., SBP > 160



and DBP > 100 (6).

Besides stroke and IHD, hypertension also substantially increases the risk of Congestive cardiac failure (CCF) by 2 to 4 times, and of end stage renal disease by 1.65 times (6, 7).

Another important aspect to be remembered is that although raised blood pressure is independently associated with an increased risk of cardiovascular events, the risk is substantially increased by the presence of other risk factors namely smoking, dyslipidaemia and diabetes. Thus, equal blood pressure levels would carry different risks when associated with different combinations of risk factors and that too, at different levels. Therefore, raised blood pressure should not be seen in isolation but as a part of the overall, total cardiovascular risk assessment for the individual (8).

### Magnitude of the Problem

**World-wide** : Hypertension affects approximately 50 million individuals in the United States and approximately 1 billion worldwide. As the population ages, the prevalence of hypertension will increase even further unless broad and effective preventive measures are implemented. Recent data from the Framingham Heart Study suggest that individuals who are normotensive at age 55 have a 90 percent lifetime risk for developing hypertension (9). The crux of the issue is that hypertension is now a major public health problem in all parts of the world (10 - 17). When cut-off values of 160 mm SBP and 95 mm DBP are taken, in most of the adult populations in the world, the prevalence comes to 10% to 20% of the adult population. If cut off levels are lowered to the standard values of 140 SBP and 90 DBP, the prevalence would go up further, possibly to 25% to 30% of adult population (3).

**Indian Situation** : In our country, prevalence of hypertension has been estimated to be between 20% to 40% in urban adults and 12% to 17% (even upto 20%) in rural adults. The estimated number of Indians with hypertension was 120 million in year 2000, which is likely to expand to 200 million by 2025, with equal umbers among men and women.

### Determinants (Risk factors)

As for other lifestyle diseases, the risk factors for hypertension can be grouped as modifiable and non-modifiable.

#### Non-Modifiable

**Age** : All studies have demonstrated a positive association between age and blood pressure (18). SBP increases consistently till almost the seventh or eighth decade, while DBP increases till fifth decade, becoming stationary thereafter, leading to an increase of pulse pressure and increased incidence of systolic hypertension in the elderly. However, the age related rise in blood pressure is not an inevitable phenomena of nature since in some isolated populations with very low habitual salt intake, the blood pressure does not increase with age, indicating that with controlled salt intake and physically active lifestyle, the rise of blood pressure can be checked, despite ageing.

**Sex** : In childhood there is no difference between sexes; from adolescence onwards, the average BP is higher in males. However, this difference narrows down after women attain the age of 50 years, and thereafter, may even get reversed (18).

**Heredity** : Family history of elevated blood pressure is a strong

risk factor for future development of hypertension.

**Genetic factors** : The genetic basis of high blood pressure has been well supported by experimental research, and while some monogenic hypertensive disorders in humans have been described (eg, ACE-II and angiotensinogen gene polymorphism), for the most part, hypertension is currently regarded to be a "polygenic" condition.

**Ethnicity** : Black races have been described to be having higher risk of hypertension; whether this is due to racial factors or else due to socio-cultural differences between black and white races is not clear. More recent research indicates that South Asian populations including Indians, may be more predisposed to developing hypertension and metabolic syndrome.

#### Modifiable risk factors

**Dietary salt** : There is substantial and convincing evidence that dietary salt intake over and above the physiological requirements, is a strong risk factor for hypertension. It has been estimated that a 100 mmol per day lower intake of sodium over the lifetime would result in 9 mm smaller rise in SBP between 25 to 55 years of age; this would translate to a reduction in mortality by 16% in IHD, 23% for stroke and 13% deaths from all causes. Well established public health recommendations indicate that dietary salt consumption, from all sources should not exceed 5 to 6 grams a day for an adult (19, 20).

**Dietary Potassium** : In contrast to sodium, dietary potassium is protective; increasing levels of potassium intake are protective. More precisely, it is the ratio of dietary sodium to potassium which is more relevant. Thus, at a given level of dietary salt intake, blood pressure could be lowered by increasing the potassium intake. The case is therefore quite strong to encourage consumption of fresh fruits and vegetables (400 to 500 grams per day for an adult), which are rich sources of potassium (20, 21).

**Other Macro and Micro-nutrients** : The role of saturated fats, dietary cholesterol, fibre (protective), antioxidant vitamins (protective), dietary calcium (increased intakes are protective) have all been postulated, though there is still no convincing evidence. However, keeping in view the fact that these nutrients have been shown to have a role in other lifestyle disease as IHD and diabetes, it would be desirable to adhere to the healthy lifestyle recommendations, in totality.

**Overweight** : There is strong and consistent evidence that overweight / obesity is associated with hypertension, with the RR being 2 to as much as 6 times. The proportion of hypertension attributable to obesity has been estimated to be 30 to 65% in western countries. It is also estimated that for 10 Kg increase in weight (with all other risk factors held constant) the SBP would increase by 2 to 3 mm and DBP by 1 to 3 mm (22). Besides obesity, central obesity due to excessive intra-abdominal (visceral) fat, as measured by waist circumference or WHR has been clearly shown to be a risk factor for hypertension, independent of whether generalized obesity is present or not. Hypertension and obesity / central obesity, in addition, are factors which cluster together in metabolic syndrome.

**Lack of Physical Activity** : It has also been convincingly demonstrated by epidemiological and clinical data that physical inactivity is an important risk factor for hypertension.

Sedentary and unfit normotensive individuals have 20% to 50% increased risk of developing hypertension in the next few years as compared to their fit and more active peers (23). WHO estimates indicate that the RR for developing hypertension due to physical inactivity is between 1.2 to 2.9, in different research studies.

**Alcohol** : Alcohol consumption has been consistently related to blood pressure in different epidemiological studies. The risk effects are independent of obesity, central obesity, physical inactivity, age sex and smoking. The RR of alcohol for causing hypertension has been estimated to be 1.4 to as high as 4.1, depending on the quantity and regularity of alcohol consumption (WHO global estimates). When 2 or more drinks are consumed daily, SBP increases by 1 mm and DBP by 0.5 mm on an average; daily drinkers have SBP and DBP levels which are higher by 6.6 mm and 4.7 mm respectively compared to those who drink only once a week (20, 24).

**Tobacco use** : Tobacco use and hypertension, when present together, interact and greatly increase the cardiovascular risk compared to when either of them would have been alone. The direct risk of tobacco in causing rise in blood pressure is not very clear (some smokers may in fact have lower BP levels, since chronic tobacco use may induce decrease in appetite with consequent low body weight and in turn slight lowering of BP). However, WHO global risk estimates indicate that the RR of hypertension due to tobacco use is 1.17 times higher.

**Psychosocial Stress** : There is evidence that acute mental stress causes an increase in blood pressure. There is, however, not enough evidence to prove that long term stress causes chronic increase in blood pressure. Overall, the available evidence is insufficient to allow for definite conclusions of causality; methodologically sound research is required in this area. Nonetheless, stress management techniques would be of help in controlling acute stress.

**Early Childhood Experiences** : The “Barkers Research Group” has undertaken a large amount of research in various settings and strongly hypothesized that foetal malnutrition (as evidenced in form of low birth weight) and malnutrition during infancy and early childhood may be a strong risk factor for subsequent development of hypertension, diabetes, obesity, dyslipidaemia and metabolic syndrome in later adult life (25). While these observations raise interesting possibilities of “foetal programming”, the findings need to be substantiated by prospective studies.

**Tracking** : The phenomena of “tracking” means that the level of risk factors during childhood and adolescence tends to track into the youth and late adulthood also. Thus, children who have higher levels of body weight, blood pressure, blood glucose and cholesterol, will tend to have the same level of these parameters during adulthood also. For example, in one of the large epidemiological studies, people in their 40's with elevated BP as a group, had higher blood pressure readings than normal when they were aged 7 years (26).

**Other Environmental factors** : Exposure to noise, air pollution and water pollution have all been implicated as a risk factor for hypertension, but no concrete epidemiological evidence is still available. Protection of public against environmental hazards

is, in any case, a worthwhile public health measure.

**Increased Heart Rate** : It has been noted in studies that resting heart rate of hypertensives is higher than normotensives. Whether hypertension leads to raised heart rate, due to haemodynamic adjustments or else, whether increased heart rate is a marker for prediction of hypertension, is not still clear.

**Low Socio-economic Status** : In a number of populations in developed countries, consistently higher levels of BP and a higher prevalence of hypertension have been noted in lower socio-economic groups. Contrarily, in those countries whose economies are improving, higher prevalence is seen in higher socio-economic groups. Thus, in developing countries, the higher prevalence in higher socioeconomic strata probably represents the initial stages of the epidemic of cardiovascular diseases; as the epidemic advances in these countries, there is likely to be a reversal of the social groups affected.

**White Coat Hypertension** : Measurement of BP by a Doctor, may raise the concern and lead to a rise in BP in the subject, a phenomenon called as white coat hypertension. It is therefore important to reassure the subject, and record the blood pressure in a relaxed state. White coat hypertension though, by itself may not be truly a “risk factor” for hypertension.

### Prevention and Control of Hypertension

Prevention and control of hypertension is addressed as per the same strategies, as has been discussed for IHD and diabetes.

**Primary Prevention** : This would be by utilizing the mass approach or the group approach. The strategy utilizes the IEC techniques to educate the community (*mass approach*) of the dangers of hypertension and the fact that it is a silent killer and most of the times the patient may not have any outward symptoms but the disease may progress. Education should be provided as regards the risk factors and adoption of healthy lifestyle to prevent the onset or progress of the disease. Education would also be directed towards specific groups (*group approach*) as outlined for prevention of IHD. Similarly, the primary prevention steps would also include the “*individual high risk strategy*”, focusing on individuals who have strong family history of hypertension, who are changing from active to more leisurely lifestyle (as the newly rich, executives, businessmen, etc), are obese, or are likely to physically inactive as office workers.

**Secondary Prevention** : This would be through early diagnosis and prompt treatment, mainly by way of screening programmes. The strategies could be either “population screening” by screening the entire population or a selected random sample, which is fruitful only if the prevalence of hypertension is very high or else for research or health planning purposes. Secondly, it could be a “selective screening” undertaken in groups of people known to be at high risk, as those with family history, obese persons (BMI > 25), aged more than 40 years in high prevalence populations, or those with diabetes or dyslipidaemia. Thirdly, it could be an “Opportunistic Screening” employed when high risk individuals come in contact with the health care system, e.g. obese persons, diabetics, persons having IHD or risk factors for IHD, those having family history of hypertension, diabetes or IHD, etc, once such a person reports sick. Since

measurement of blood pressure is a very simple, inexpensive and non-invasive procedure, it would be a very fruitful step if all medical persons make it a point to measure the blood pressure of all adult patients who come to them, irrespective of the presenting symptoms.

**Tertiary Prevention** : The role of Doctors as well as paramedical persons assumes importance in context of tertiary prevention - to follow up the patient, to advocate continuous treatment, to educate the patients about importance of treatment and the various precautions to be taken by them.

## Summary

Systemic arterial hypertension is defined as a state of chronically elevated arterial blood pressure, as compared to what is normally expected in context to the age of an individual. Based on the recent guidelines of WHO & ISH and JNC - VII, Hypertension is classified into Pre-Hypertension (Systolic 120-139 or Diastolic 80-89mm Hg), Grade-I (S 140 to 159 or D 90-99), Grade-II (S 160 to 179 or D100 to 109), and Grade III (S  $\geq$  180 or D  $\geq$  110). About 5 to 10% of the cases of hypertension will have some identifiable cause for the raised BP. This is called as "Secondary" hypertension. However, 90 to 95% cases will not have any identifiable cause; these are called as "primary" or "essential" hypertension. The Target organs damaged due to hypertension are Heart (IHD, LVH, Heart Failure), Brain (Stroke, TIC), Chronic kidney disease, Peripheral arterial disease, and Retina (Retinopathy). At the large population level, the major cause of stroke is raised blood pressure and efforts to prevent hypertension will also pay a rich dividend for prevention of stroke. Raised blood pressure should not be seen in isolation but as a part of the overall, total cardiovascular risk assessment for the individual.

Hypertension affects approximately 1 billion worldwide and in our country, it was estimated to affect 120 million in year 2000. In India, the prevalence of hypertension has been estimated to be between 20% to 40% in urban adults and 12% to 17% in rural adults. The risk factors for hypertension can be grouped as modifiable and non-modifiable. Non-Modifiable include increase in Age, Sex (In childhood there is no difference between sexes; from adolescence onwards, the average BP is higher in males. However, this difference narrows down after women attain the age of 50 years, and thereafter, may even get reversed), Positive Family history, Ethnicity (higher among Black races and South Asian populations including Indians). Modifiable risk factors include Diet rich in Sodium (salt exceeding 5 to 6 grams a day for an adult), rich in saturated fats, dietary cholesterol and low in fibre, calcium, potassium and antioxidant vitamins; Obesity especially central obesity; physical inactivity; poor maternal nutrition during pregnancy, and malnutrition during early infancy; psycho-social stress; Alcohol; Tobacco use; Exposure to noise, air pollution and water pollution; and, Low Socio-economic Status. The phenomenon of "tracking" means that the level of risk factors during childhood and adolescence tends to track into the youth and late adulthood also. Thus, children who have higher levels of body weight, blood pressure, blood glucose and cholesterol, will tend to have the same higher level of these parameters during adulthood also.

The broad strategy for prevention and control of hypertension

include primary, secondary and tertiary levels of prevention. The Primary Prevention would basically utilize the IEC strategy in the form of the *population strategy*, educating both, the general community (*mass approach*) and specific groups (*group approach*) and also in the form of "*individual high risk strategy*", focusing on individuals with "Risk factors". Secondary Prevention would be mainly by way of population screening or selective screening or Opportunistic Screening. Tertiary prevention is to follow up the patient, to advocate continuous treatment, and to educate the patient and the family about importance of treatment and the various precautions to be taken by them.

## Study Exercises

**Long Question** : Discuss the epidemiology of hypertension, with special reference to Indian context.

**Short Notes** : (1) Tracking (2) End organ damage in hypertension (3) Dietary approaches to prevention of hypertension

### MCQs & Exercises

- Following is not a Target organ damaged due to hypertension: (a) Brain (b) Retina (c) Kidney (d) Bladder
- The systolic BP range of Grade II Hypertension : (a) 140-149 (b) 150-159 (c) 160-179 (d) 170-179
- The Diastolic BP range of Grade III Hypertension : (a)  $\geq$  100 (b)  $\geq$  150 (c)  $\geq$  110 (d)  $\geq$  120
- The following Diet is a not a risk factor for Hypertension (a) Rich in Sodium salts (b) Rich in saturated fats (c) Low in fibre (d) High in potassium.
- In India, the prevalence of hypertension has been estimated to be between (a) 20% - 40% (b) 40 - 60% (c) 60 - 70% (d)  $<$  10%
- Which mode of prevention does Opportunistic Screening fit in : (a) Primordial (b) Primary (c) Secondary (d) Tertiary.

**Answers** : (1) d; (2) c; (3) c; (4) d; (5) a; (6) c.

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## Diabetes Mellitus

*Rajvir Bhalwar*

### Definition / Identification

Diabetes Mellitus is defined as a metabolic abnormality characterized by hyperglycaemia and disturbances of carbohydrate, fat and protein metabolism that are associated with absolute or relative deficiency in insulin secretion and / or insulin action (1). When fully evolved, it is characterized by fasting hyperglycaemia but it can also be characterized in the less overt stages and before fasting hyperglycaemia appears, most usually by the appearance of glucose intolerance. Most often, it tends to be asymptomatic ("silent killer") in which case the diagnosis depends on biochemical investigations (2).

### Classification

Diabetes mellitus consists of a group of metabolic disorders which have been classified by a WHO expert group as shown in Table - 1 (1).

**IDDM (now called Type - 1 Diabetes or T1D)** : This comprises 5 to 10% of all diabetes. It is due to absolute insulin deficiency as a result of pancreatic beta cell destruction. It is characterized by abrupt onset of severe symptoms, proneness to ketosis, presence of one or more of the classical symptoms (polyuria, polydipsia and polyphagia). The age at clinical onset or diagnosis is usually below 30 years. All patients of this type need exogenous insulin for survival. Blood glucose levels are unequivocally elevated and glucose and ketones are usually present in urine.

**NIDDM (now called Type - 2 Diabetes or T2D)** : NIDDM forms the majority of the problem from lifestyle and non -

communicable diseases point of view, comprising 85 to 90% of all diabetes cases. For the purpose of this chapter, the focus will be on T2D. The disease takes a very silent course and is quite often detected on a routine, screening urine or blood test, with diagnosis being often made after 40 years age. It has a very strong genetic (family history) component. In addition, obesity is frequently associated with T2D, though in developing countries, many of the subjects with T2D may not be obese if we go simply by weight for height standards.

**IGT and IFG** : These are progressive stages of the same disease of which T2D represents the most severe form. Both IGT and IFG are themselves strong risk factors for future development of diabetes. Proper lifestyle management (Diet, Exercise and Weight reduction) prevents progression to the later stage. In the natural course, about one - thirds each of IGT subjects will develop diabetes, or remain as IGT or revert back to normal. The microangiopathic complications (Retinal and Renal) which are characteristic of diabetes are rare in IGT; however, there is increased occurrence of atherosclerosis in IGT as compared to normal people.

**MRD** : In developing countries in the tropics, young people with diabetes may present with a constellation of clinical features including onset usually below 30 years age, average or low body weight (BMI < 30) moderate to severe hyperglycaemia, usually non - proneness to ketoacidosis unless there are precipitating conditions as infections, the requirements of large dose of insulin for metabolic control and frequently a history of malnutrition in infancy and early childhood. The term "MRD" has been assigned to this syndrome.

### Diagnostic Criteria

The diagnostic criteria, as enunciated by the American Diabetic association (ADA) and duly agreed by the WHO are shown in Table - 2 (3, 4).



Table - 1 : Classification of Diabetes Mellitus								
A. Clinical Cases							B. Statistical Risk Classes (Subjects with normal glucose tolerance but substantially increased risk of developing Diabetes)	
I. Diabetes Mellitus				II. Impaired Glucose Tolerance (IGT) and Impaired Fasting Glucose (IFG)		III. Gestational Diabetes Mellitus (GDM)		
Insulin Dependant Diabetes Mellitus (IDDM, Type - 1)	Non Insulin Dependant Diabetes Mellitus (NIDDM, Type - 2)		Malnutrition Related Diabetes (MRD)	Other Types of Diabetes (associated with certain diseases as pancreatic disease, hormonal, drug induced etc.	Non - Obese	Obese	Associated with certain diseases	
	Non - Obese	Obese						
								Previous abnormality of glucose tolerance
								Potential abnormality of glucose tolerance

Table - 2 : Diagnostic criteria of Diabetes Mellitus				
Diabetes Mellitus		IGT	IFG	
Plasma	Whole Blood	Plasma	Plasma	Whole Blood
Fasting $\geq 126$ , <b>OR</b> 2 hrs PP $\geq 200$	Fasting $\geq 110$ , <b>OR</b> 2 hrs PP $\geq 180$	Fasting $< 126$ <b>AND</b> 2 hrs PP $\geq 140$ <b>BUT</b> $< 200$	Fasting $\geq 110$ <b>BUT</b> $< 126$	Fasting $\geq 100$ <b>BUT</b> $< 110$

**Notes :**

- All value shown above are in mg / dl
- 2 hrs PP value are after 2 hrs of 75 gms glucose orally in 250 - 300 ml water
- ADA has recently recommended downgrading the criteria of IFG to 100 mg / dl from above mentioned 110 mg. The WHO is reviewing this recommendation and may enunciate their revised recommendations, if any, in near future.

**Complications of Diabetes**

Diabetes owes its importance to the fact that it is a silent killer. It leads to a large number of serious sequelae which are disabling, besides drastically reducing the quality of life. The complications / sequelae are listed in Table - 3.

It needs to be noted that presence of diabetes carries a very high risk for IHD (RR of 3.5 to 4 times). In addition, diabetes frequently co - exists with other coronary risk factors as hypertension, dyslipidaemia, obesity and metabolic syndrome.

Table - 3 : Sequelae / complications of diabetes	
Acute	
<ul style="list-style-type: none"> <li>• Hypoglycaemia</li> <li>• Hyperglycaemia and Ketoacidosis</li> <li>• Infections (especially fungal infections of skin and mucous membranes, urinary infections, anaerobic infections of deep tissues, mycobacterial infections).</li> </ul>	
Chronic	
<ul style="list-style-type: none"> <li>• Atherosclerosis, manifesting in cerebrovascular and coronary artery disease.</li> <li>• Diabetic eye disease (Retinopathy, cataract)</li> <li>• Diabetic Kidney Disease</li> <li>• Diabetic Neuropathy (peripheral as well as autonomic neuropathies)</li> <li>• Foot ulceration and infections</li> </ul>	

**Magnitude of the Problem**

As per estimates of WHO, the number of people affected worldwide with diabetes were approximately 125 million which are expected to be almost 300 million by 2025. (5). The incidence is peculiarly high among populations living in Nauru islands and among Pima Indians of USA where the prevalence may be as high as 40 to 50%. In developed, industrialized countries, prevalence rates of as high as 10 to 20% may occur (1).

India has the unfortunate privilege of being the "Diabetes capital" of the world, The prevalence rates have been estimated to be 12% in urban areas and 4% in rural areas. More concerning is the fact that diabetes prevalence over the past 4 decades has increased fourfold (6). Another interesting phenomena is that Indians who migrate to affluent countries develop very

high prevalence rates of 10 to 20%, indicating the high racial predisposition that Indians and other South Asian populations have for diabetes, and which gets expressed whenever we get affluent conditions (1).

### Determinants - Risk Factors for Diabetes (T2D)

The two most important determinants of diabetes are firstly, genetic background (family history) and secondly, obesity. It has been very aptly said that for diabetes, “genetics loads the cannon and obesity finally fires it”. As for IHD, the risk factors may be grouped as “*Non Modifiable*” (Age, Sex, Genetic and Racial factors) and “*Modifiable*” (Obesity, physical activity, nutritional factors, stress, drugs, infections and chemical toxins, etc).

**Genetic Factors** : NIDDM shows strong family aggregation. Twin studies and familial studies have provided firm evidence that the role of genetic factors is relatively high. Till now, no specific genetic marker has been identified, though some have been proposed. With the current status of knowledge, it seems that diabetes is a “polygenic” disease and not possibly due to defect in a single gene. History of diabetes among parents, grandparents and first degree relatives predisposes a person to high risk of developing diabetes.

**Age** : Increasing age increases the risk. Most cases are detected during the middle age.

**Sex** : There is no clear difference between sexes as regards the risk of diabetes.

**Race** : Some races are known to be at high risk as Polynesians, Eskimos, Pima Indians, etc. The possibility is also strong that South Asian populations including Indians may be at high risk. One hypothesis is that this may be due to the effect of “*thrifty genes*”. These genes developed as a part of nature’s protective mechanisms, among populations who were for many centuries exposed to starvation, famines and lack of food. The thrifty gene was developed by nature to conserve whatever small amount of energy, which was available to such populations, in the form of body fat stores. However, with economic improvements in such populations, the food supply improves greatly but the protective effect of thrifty gene also continues resulting into excessive levels of obesity and consequent diabetes.

**Obesity** : Obesity has been proven to be a very strong risk factor for diabetes type 2. The estimates of risk vary from RR of 1.8 to 3.2 in different populations. The role of obesity is independent of racial factors. In addition, central distribution of body fat (referred to as central, abdominal, visceral, apple - shaped or android type of fat distribution and measured in terms of Waist Circumference or Waist Hip ratio) is upheld to be an important risk factor, independent of total body weight. The recommended cut - off levels for BMI, waist circumference and Waist Hip Ratio are given in a previous chapter on nutrition and lifestyle.

**Physical inactivity** : It has been clearly demonstrated that physical activity increases insulin sensitivity. The risk of diabetes due to physical inactivity has been estimated to be as high an RR of 4.31 in some large scale studies. The protective effect of physical activity is independent of obesity; this means that an obese person who is physically active and fit would have lower risk of diabetes (as well as lower risk of other life

style diseases) than a normal weight person who is physically inactive and unfit. In addition, physical activity will also assist in keeping the body weight under control.

**Nutritional Factors** : There is increasing evidence from both epidemiological as well as laboratory studies that increased dietary intake of saturated fat and decreased intake of fibre can result in lowered insulin sensitivity and impairment of glucose tolerance. In general, reduction in the overall calories, reduced intake of saturated fats & refined sugars and increased intake of grains, fruits and vegetables would be of utility in preventing diabetes.

**Foetal and Early Childhood Influences** : There has been increasing evidence (*Barker’s Hypothesis*) that poor maternal nutrition during pregnancy, and malnutrition during early infancy may be associated with insulin resistance, obesity, impaired glucose tolerance, raised blood pressure and occurrence of metabolic syndrome in the same person during his / her adult life. This underlines the value of ensuring adequate nutrition during pregnancy and during early childhood.

**Stress** : Several states of physical stress and trauma can lead to glucose intolerance through altered hormonal mechanisms but whether they can permanently lead to diabetes is not established. Similarly, the role of mental and social stress as contributory factor in diabetes mellitus has been suggested but remains unproven.

**Drugs and Hormones** : Phenytoin, diuretics (especially thiazides), beta blockers, corticosteroids and certain contraceptive steroids may, in susceptible persons, induce glucose intolerance or even diabetes, but this usually resolves after withdrawal of the drug.

### Prevention and Control

The broad strategy for prevention and control of diabetes will remain the same as that outlined for IHD earlier, including primary, secondary and tertiary levels of prevention.

**Primary Prevention** : This would basically utilize the Information, education and Communication (IEC) strategy to educate and motivate the community and individuals. The key messages for IEC will remain the same as have been outlined for prevention of IHD in the earlier chapter.

Primary prevention will, as for IHD, include the *population strategy*, educating both, the general community (*mass approach*) and specific groups (*group approach*) as outlined for prevention of IHD. Similarly, the primary prevention steps would also include the “*individual high risk strategy*”, focusing on individuals who have strong family history of diabetes mellitus, who are changing from active to more leisurely lifestyle (as the newly rich), are obese, have evidence of IFG or IGT, have other cardiovascular risk factors as hypertension and dyslipidaemia, and women who have history of Gestational DM or history of giving birth to babies weighing > 4kg. Equally relevant from primary preventive point of view is to create general awareness in the community regarding diabetes, its risk factors and complications and regarding its potential for management, treatment and control. Recent community awareness drives, using prominent personalities, who are themselves diabetics, is a promising trend and should be utilized.

**Secondary Prevention** : This would be through early diagnosis and prompt treatment, mainly by way of screening programmes. The strategies could be either “population screening” by screening the entire population or a selected random sample, which is fruitful only if the prevalence of diabetes is very high or else for research or health planning purposes. Secondly, it could be a “selective screening” undertaken in groups of people known to be at high risk, as those with family history, obese persons (BMI > 25), aged more than 40 years in high prevalence populations, women giving history of GDM, those with history of IGT / IFG, or those with hypertension or dyslipidaemia. Thirdly, it could be an “Opportunistic Screening” employed when high risk individuals come in contact with the Doctor, e.g. obese person, hypertensive, having IHD, having family history, etc. once such a person reports sick. Similarly, in clinical settings, all opportunities should be utilized to undertake screening for known end organs as ophthalmoscopy, urine testing, etc., to detect any evidence of such end organ damages which could have occurred and may have escaped detection till now.

**Tertiary Prevention** : The role of Doctors as well as paramedical personnel assumes importance in context of tertiary prevention - to follow up the patient, to advocate continuous treatment, to educate the patient about importance of treatment and the various precautions to be taken by them. The key issues to be kept in mind are outlined in Table - 4. It should also be noted that presence of diabetes is considered to be a major risk factor for development of IHD and other CVD and hence the need to have a tight control on blood sugar levels for prevention of IHD/ CVD. Moreover, the complications of diabetes particularly CVD are much higher if concomitant hypertension is also present and hence the need of monitoring and adequate control of blood pressure in all diabetics as a part of tertiary prevention.

**Table - 4 : Key Issues for Tertiary Prevention**

Keep a follow up of the patient of diabetes
Reassure about the possibility of leading a near normal life, with proper treatment and precautions
Educate about :
- Do not miss the antidiabetic medicines
- Do not miss the meals
- Diabetic identification card
- Carry some sugar or lozenges for any hypoglycaemic emergency
- Foot care, footwear and daily inspection
- Early identification of complications
- Regular Physical exercise, Diet, No Tobacco, Avoid alcohol

## Summary

Diabetes Mellitus is defined as a metabolic abnormality characterized by hyperglycaemia and disturbances of carbohydrate, fat and protein metabolism that are associated with absolute or relative deficiency in insulin secretion and / or insulin action. It has been classified by a WHO expert group as clinical cases and statistical risk classes. Clinical cases are in turn classified as i) diabetes mellitus (Type - 1, Type - 2,

MRD and others) ii) Impaired glucose tolerance and Impaired fasting glucose and iii) Gestational Diabetes Mellitus. Type - 1 Diabetes is due to absolute insulin deficiency as a result of pancreatic beta cell destruction, characterized by abrupt onset of severe symptoms, proneness to ketosis, with onset below 30 years and it comprises 5 to 10% of all diabetes. Type - 2 Diabetes, comprising 85 to 90% of all diabetes cases, takes a very silent course and is quite often detected on a routine, screening urine or blood test, with diagnosis being often made after 40 years age, with a strong genetic (family history) component and association with obesity. IGT and IFG are progressive stages of the same disease of which T2D represents the most severe form. As per the diagnostic criteria, as enunciated by the American Diabetic association (ADA), a person is said to be diabetic when the Plasma Fasting Glucose is more than or equal to 126 mg/dl or Post - prandial Glucose is more than or equal to 200 mg/dl. The *Acute Complications* of DM are Hypoglycaemia, Hyperglycaemia, Ketoacidosis and Infections while the *chronic complications* are Atherosclerosis (CAD, CVA & PVD), Retinopathy, Nephropathy, Neuropathies, Foot Ulcerations and infections.

As per estimates of WHO, approximately 125 million are affected worldwide. In developed, industrialized countries, prevalence rates are as high as 10 to 20%. In India the prevalence rates have been estimated to be 12% in urban areas and 4% in rural areas. The two most important determinants of diabetes are firstly, genetic background (family history) and secondly, obesity. The risk factors may be grouped as “*Non-Modifiable*” (Increasing Age, Genetic factors and Races like Polynesians, Eskimos, Pima Indians and South Asian populations including Indians) and “*Modifiable*” which include Obesity especially central obesity; physical inactivity leading to decreased insulin sensitivity; increased dietary intake of saturated fat and decreased intake of fibre resulting in lowered insulin sensitivity; poor maternal nutrition during pregnancy, and malnutrition during early infancy; physical, mental and social stress; drugs like Phenytoin, diuretics especially thiazides, beta blockers, corticosteroids and certain contraceptive steroids; infections and chemical toxins.

The broad strategy for prevention and control of diabetes includes primary, secondary and tertiary levels of prevention. The primary Prevention would basically utilize the IEC strategy in the form of the *population strategy*, educating both, the general community (*mass approach*) and specific groups (*group approach*) and also in the form of “*individual high risk strategy*”, focusing on individuals with “Risk factors” Secondary Prevention would be mainly by way of population screening or selective screening or Opportunistic Screening. Tertiary prevention is to follow up the patient, to advocate continuous treatment, to educate the patient and the family about importance of treatment and the various precautions to be taken by them.

## Study Exercises

**Long Question** : Give a classification of diabetes mellitus, including diagnostic cut off criteria and deliberate on the available preventive approaches among populations.

**Short Notes** : (1) Gestational diabetes (2) T2 D as a coronary

risk factor (3) Microvascular and macrovascular complications in NIDDM (4) Rehabilitation of a patient of NIDDM

#### MCQs & Exercises

1. Type - 1 Diabetes is not characterized by (a) Abrupt onset of severe symptoms (b) Proneness to ketosis (c) onset below 30 years (d) it comprises up to 40% of all diabetes.
2. Type - 2 Diabetes is not characterized by (a) comprising 85 to 90% of all diabetes cases (b) quite often detected on a routine screening tests (c) diagnosis being often made after 40 years age (d) very weak genetic (family history) component.
3. As per the American Diabetic association (ADA), a person is said to be diabetic when the Plasma Fasting Glucose is more than or equal to (in mg/dl) (a) 100 (b) 126 (c) 200 (d) 110
4. As per the American Diabetic association (ADA), a person is said to be diabetic when the Plasma Post prandial Glucose is more than or equal to (in mg/dl) (a) 100 (b) 126 (c) 200 (d) 110

5. Drug induced Diabetes is seen in (a) thiazides (b) beta blockers (c) corticosteroids (d) All of the above.
6. Not a risk factor for Diabetes : (a) increased dietary intake of saturated fat and decreased intake of fibre (b) poor maternal nutrition during pregnancy (c) stress (d) High sodium and Low Potassium intake.

**Answers :** (1) d; (2) d; (3) b; (4) c; (5) d; (6) d.

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#### Definition / Identification

The term cancer encompasses a very wide variety of heterogeneous disorders occurring in different parts of the body, with very different clinical manifestations. However, there is a special reason for grouping such diverse diseases under a single heading. The reason is that cancers, as they are defined, are "Group of heterogeneous disorders characterized by *Clonality* (arise from a single stem cell that clones into carcinomatous cells), *Autonomy* (the cell division and growth is uncontrolled), *Anaplasia* (lack of cell differentiation) and *Metastasis* (distant spread)". It is these common features that bind cancers into a single entity for the purpose of description.

Secondly, various cancers, despite their diversity in clinico-pathological manifestations, have some risk factors in common, a phenomenon that again binds them together and can be fruitfully utilized for the purpose of prevention. As we shall see in the course of this chapter, these common risk factors are primarily a reflection of unhealthy lifestyle and hence, the contemporary saying is that cancers are, by and large, diseases of unhealthy lifestyle and are, therefore, potentially preventable.

#### Magnitude of the Problem

Cancers reflect a major load on human health by way of morbidity, mortality and, above all, human suffering.

**Worldwide :** Approximately 10 million new cases and more than 6 million deaths (12% of all deaths) occur due to cancers every year. It is estimated that more than 22 million people would be living with cancers, worldwide at any given point of time (1). These figures represent an increase of around 19% in incidence and 18% in mortality since 1990. In terms of incidence, the most common cancers world-wide are those of lung (12.3% of all cancers), breast (10.4%) and colorectum (9.4%). Lung cancer is the largest single cancer in the world (1.1 million annually). The top three causes of death from cancer are those of the lung (17.8% of all cancer deaths), stomach (10.4%) and liver (8.8%). Developing countries contribute to more than half of the total cancer cases worldwide. By 2020, the new cases are expected to reach at least 15 million a year and deaths 10 million. The projection of new cases of cancer per year, for 2020, is 6 million and 9.3 million respectively from developed and developing countries.

**India :** Approximately 8 lakh new cases of cancers are expected to occur every year. Large majority of these are tobacco related and hence potentially preventable. It has been estimated that 48% of cancers among men and 20% in women are due to tobacco. Cancer incidence in India is estimated to be around 70 - 90 per 100,000 populations with 700,000 - 900,000 new cases of cancer every year. If survival is taken as three years on an average, at any given time there will be about 2,500,000 cancer patients in the country. In the year 2000, five and a half lakh deaths in the country were due to cancer. The commonest cancers in men are those of Lungs, Stomach, Oral cavity and oesophagus, while in women, those of Cervix Uteri, Breast, oral cavity, Ovary, Oesophagus and Stomach are the commonest.



In India, a network of cancer registries was started across the country under the National Cancer Registry Programme (NCRP). There are at present six Population Based Cancer Registries (PBCRs) (five urban and one rural) and five Hospital Based Cancer Registries (HBCRs) generating data on cancer in the country under NCRP. The PBCRs collect information regarding all new cancer cases occurring in a defined population. PBCRs provide data on cancer incidence, survival and mortality. The HBCRs record information on cancer patients attending a specific hospital with focus on clinical care and hospital services. HBCRs provide information on length and quality of survival in relation to site, stage and treatment and help to assess quality of hospital care and cancer services. The details of national cancer registries are given in the section on national health programmes.

### The Major Risk Factors for Cancers

**Tobacco** : Tobacco smoking is the main known cause of human cancer-related deaths, worldwide. An increase in risk of lung cancer (relative to a non-smoker) is consistently evident at the lowest level of daily consumption, and is also proportional to the duration of smoking. In general the relative risk (RR) of lung cancer due to smoking is of the order of 10 to as high as 20 times. Smoking filtered cigarettes probably entails a lower risk for most tobacco-related cancers than unfiltered and high-tar cigarettes. However, it needs to be noted and emphasized that a “safe” cigarette does not exist; all smoking tobacco products entail a carcinogenic risk.

In addition to lung, tobacco also causes cancers of the larynx, oral cavity, pharynx, oesophagus, pancreas, kidney and bladder (2). In non-alcohol drinking male smokers, the risk of developing cancer of the oral cavity is about double that for non-drinking non-smokers. Elevations of ten-fold or more are evident for cancer of the larynx and five-fold or more for oesophageal cancer. A common feature of lung and other smoking-induced cancers is the decreased risk which follows smoking cessation (“quitting”) relative to continuing smoking (2). Despite the clearly established benefit of cessation, the risk for ex-smokers does not decrease to that for “never smokers”.

Other cancer types may be a consequence of smoking. These include cancer of the stomach, liver, nose and myeloid leukemia.

Exposure to environmental smoke (passive smoking) is a definite risk for lung cancer and possibly laryngeal cancer; the relative risk has been estimated at about 1.15-1.20 times.

Smokeless tobacco use (the commonest being tobacco chewing as “quid”) has been associated with increased risk of head and neck cancer, particularly oral cancer. Since chewing of tobacco-containing products is particularly prevalent in southern Asia, especially India, it represents a major carcinogenic hazard in this region.

Alcohol consumption, exposure to asbestos and exposure to ionizing radiations interact with smoking in increasing the risk of cancers. For alcohol drinking and smoking, risk for cancer of the larynx, oesophagus and oral cavity increase multiplicatively in relation to the respective risks generated by either exposure in the absence of the other. For individuals exposed to both asbestos and tobacco smoke (for example,

insulation workers who smoke), risk of lung cancer is also increased multiplicatively.

**Alcohol Drinking** : Causal association of drinking alcohol has been definitely established in respect of oral, oesophageal, liver and other cancers (3). A causal association is also established in the case of breast cancer and is probable for colon and rectal cancer (3, 4). There have been suggestions of a possible carcinogenic effect of alcohol drinking on other organs, such as the lung, but the evidence is still inconclusive (5). For all cancers caused by drinking alcohol, the risk of cancer increases with the level of consumption, up to an intake of about 80 g of ethanol / day (equal to 8 small pegs of hard drinks as Rum or whisky).

The risk of head and neck cancer is 5-10 times higher in heavy drinkers than in abstainers, the carcinogenic effect of alcohol appearing to be more potent in the oral cavity, pharynx and oesophagus and weaker in the larynx. The relative risk of breast cancer in women with a high consumption of alcohol is approximately two-fold. Alcohol drinking and tobacco smoking show a synergistic interaction in the etiology of cancers of the oral cavity, pharynx, larynx and oesophagus.

Alcohol drinking is estimated to be involved in the etiology of 3% of all cancers (that is, 4% in men, 2% in women). In women, approximately half of the neoplasms attributed to alcohol drinking are breast cancers.

**Occupational Exposures** : The first reports of associations between risk of cancer and employment in particular occupations appeared during the 18<sup>th</sup> century (6) and 19<sup>th</sup> century (bladder cancer in workers exposed to dyes) (7). However, the majority of studies establishing a link between an increased risk of cancer and a particular working environment were published between 1950 and 1975 (8).

At present, 25 chemicals or mixtures, for which exposures are mostly occupational, have been established as human carcinogens, the important ones being asbestos, crystalline silica and heavy metals. Aromatic amines have been shown to increase the risk of Bladder cancer; benzene that of Leukemias and that of myelogenous leukaemia in particular (9); Asbestos and other fibres have been associated with Lung cancer and mesothelioma. Cancer of the lung can be caused by exposure to inorganic arsenic in mining and copper smelting and among workers in chromium plants and chromium alloy workers Nickel refining also carries carcinogenic risk.

Coal tar, coal gas production and iron founding are associated with cancers of the skin and of other sites, including the urinary and respiratory systems. Work in iron and steel founding is also associated with an elevated risk of lung cancer. Nasal Adenocarcinomas are caused by exposures in the furniture and cabinet making industry, mainly among people exposed to wood dust. Similarly, among painters, 40% excess risk of lung cancer has been consistently recorded.

**Environmental Pollution** : In the present context, “environmental pollution” refers to a specific subset of cancer-causing environmental factors, namely, contaminants of air, water and soil. The carcinogenic pollutants for which most information is available include asbestos (referring here to non-occupational exposure); toxic agents in urban air; pollutants,

chlorination by-products and other contaminants of drinking water. Various studies suggest that environmental pollution accounts of 1-4% of the total burden of cancer in developed countries (10, 11).

Non-occupational exposure to asbestos may occur domestically and as a consequence of localized pollution. Cohabitants of asbestos workers may be exposed to dust brought home on clothes. Exposure to asbestos under domestic circumstances results in an increased risk of mesothelioma. Likewise, non-occupational exposure to asbestos may cause lung cancer, particularly among smokers (12).

Ambient air pollution has been implicated as a cause of lung cancer. It is possible to attribute some carcinogenic risk to particular atmospheric pollutants, including benzopyrene, benzene, some metals, particulate matter (especially fine particles), and possibly ozone. Vehicular exhaust remains a continuing or even increasing problem. Engine consumption products include volatile organic compounds (benzene, toluene, xylenes and acetylene), oxides of nitrogen (NOx) and fine particulates (carbon, adsorbed organic material and traces of metallic compounds). Some potential carcinogens are also emitted from poorly regulated use of coal, wood and biomass (e.g. animal dung, crop residues) for electricity production and heating.

Drinking water may contain a variety of potentially carcinogenic agents, including chlorination by products and arsenic. Chlorination by products results from the interaction of chlorine with organic chemicals. Among the many halogenated compounds that may be formed, trihalomethanes and chloroform are those commonly found. Studies on bladder cancer have suggested an increased risk associated with consumption of chlorinated drinking water (13). Doubts remain as to whether such associations are causal because of the way in which the studies measured exposure.

Arsenic causes cancer in the skin, lung and other organs. The main source of environmental exposure to arsenic for the general population is through ingestion of contaminated water. High exposure to arsenic from drinking water is found in several areas of Alaska, Argentina, Bangladesh, Chile, India, Mexico, Mongolia, Taiwan and the USA. There is strong evidence of an increased risk of bladder, skin and lung cancers following consumption of water with high arsenic contamination (14, 15).

**Food Contaminants** : Food may be contaminated by mycotoxins. The most studied are *Aflatoxins*, which occur as food contaminants in hot, humid parts of the world, with diets based upon maize and groundnuts (peanuts). Aflatoxins are products of the aspergillus fungi and particularly accumulate during storage of grains. Together, aflatoxin exposure and HBV infection are the main risk factors accounting for the high incidence of hepatocellular carcinoma in some regions of Africa, Asia and South America (16).

Incidence of oesophageal cancer incidence has been related to the occurrence of another fungus, viz., *F. verticillioides* or its toxins in maize. Similarly, Ochratoxin A, also a fungal metabolite, may contaminate grain and pork / pork products and lead to urinary tract tumours.

Certain organochlorines, including DDT and other pesticides, are resistant to degradation and persist in the environment. They are bioconcentrated in the human food chain. DDT in particular has been associated with increased risk of pancreatic cancer, breast cancer, lymphoma and leukaemia in humans.

Certain heterocyclic amines are formed during cooking of meat and fish at high temperature. Heterocyclic amines are carcinogenic in various organs of mice, rats and non-human primates, although their carcinogenic potential in humans has not yet been established (17). Another group of chemicals, the *Polycyclic Aromatic Hydrocarbons* (PAHs) are generated in meat when it is fried, roasted or cooked over an open flame, and many members of this chemical class are carcinogenic. Finally, N-Nitroso compounds are a wide class of chemicals. Nitrosamines may be formed by chemical reactions in foods containing added nitrates and nitrites, such as salt-processed by smoking and direct fire drying. The use of fertilizers may influence the level of nitrites in food.

**Radiation** : Ionizing radiations are one of the most intensively studied carcinogens (18 - 20). Exposure to ionizing radiations from natural as well as from industrial, medical and other sources, can cause a variety of neoplasms, including leukaemia, breast cancer and thyroid cancer.

Sunlight is by far the most significant source of ultraviolet irradiation and causes several types of skin cancer, particularly in highly-exposed populations with fair skin, e.g. Australians of Caucasian origin.

Extremely low frequency electromagnetic fields generated by electrical power transmission have been associated with an increased risk of childhood leukaemia, but the findings are not conclusive. IARC has classified extremely low frequency fields as possibly causing cancer in humans (Group 2B), based on childhood leukaemic findings (21).

Mobile telephones are the greatest source of radio frequency exposure for the general public. The evidence of the carcinogenicity of radio frequency fields is not clear. The experimental evidence is also limited, but suggests that radio frequency fields cannot cause DNA mutations. The lack of reproducibility of findings limits the conclusions that can be drawn.

**Chronic Infections** : Infectious agents are one of the main causes of cancer, accounting for 18% of cases worldwide, and the majority occurring in developing countries. The most frequently affected organ sites are liver (Hepatitis B and C, liver flukes), cervix uteri (Human Papilloma Viruses), lymphoid tissues (Epstein-Barr virus), stomach (*Helicobacter pylori*) and the urinary system (*Schistosoma haematobium*). The mechanism of carcinogenicity by infectious agents may be direct, e.g., mediated by oncogenic proteins produced by the agent (e.g., human papilloma virus) or indirect, through causation of chronic inflammation with tissue necrosis and regeneration. Strategies for prevention include vaccination (Hepatitis B virus), early detection (cervical cancer) and eradication of the infectious agent (*Helicobacter pylori*).

Worldwide, about 2,000 million people have serological evidence of current or past Hepatitis B virus (HBV) infection and about 350 million of them are chronic carriers of the virus.

Chronic carriers of HBV, identified by the presence of relevant antibodies in the sera, have around 20 times higher risk of developing liver cancer than non-carriers (22). It has been estimated that 60% of cases of primary liver cancer worldwide and 67% of cases in developing countries can be attributed to chronic persistent infection with HBV. Hepatitis C virus (HCV) is the major causes of parenterally transmitted hepatitis worldwide. Strong associations with relative risks of as high as 20 have been reported in several case-control studies. About 20% of cases of liver cancer in the world are attributed to HCV.

Dozens of molecular epidemiological studies (23 - 25) have consistently shown relative risks for invasive cervical cancer ranging from 20 to over 100. In fact, HPV DNA is found in virtually all invasive cervical cancers, indicating that HPV is a necessary cause (26). Moreover, about 80% of anal cancers and 30% of cancers of the vulva, vagina, penis and oro-pharynx can be attributed to HPV.

HIV infection enhances the risk of Kaposi sarcoma by approximately 1,000-fold, of non-Hodgkin lymphoma by 100-fold, and of Hodgkin disease by 10-fold. Increased risk of cancer of the anus, cervix and conjunctiva has also been observed. In all these cases, the role of HIV is probably as an immunosuppressive agent and hence indirect.

Infection with *Helicobacter pylori* is one of the most common bacterial infections worldwide. In developing countries, the prevalence of *H. pylori* among adults ranges from 80 to 90% whilst in developed areas it is around 50%. *H. pylori* is the main cause of gastritis and peptic ulcer; infection may be lifelong if not treated with antibiotics (27). It is clear that *H. pylori* plays a role in gastric cancer, but other cofactors (e.g. diet) are also contributory.

**Diet and Nutrition** : A principal environmental factor, now generally recognized as major determinant of cancer incidence, is diet. It is estimated that up to 30% of human cancers are probably related to diet and nutrition. Epidemiological studies suggest that different dietary patterns may be specifically related to higher risk of particular types of cancer. Thus the western diet and lifestyle are generally associated with high incidence of cancers of the colorectum, breast, prostate and endometrium, but with lower incidence of cancers of the stomach, oesophagus, liver and cervix uteri. Based on available evidence, the major factors in diet related to cancers are :

**Vegetables and Fruits** : The most consistent finding on diet as a determinant of cancer risk is the association between high consumption of vegetables and fruits and reduced risk of several cancers. Adequate consumption of vegetables and fruits is associated with reduced risk of cancers of the pharynx, larynx, lung, oesophagus, stomach and cervix uteri, while only vegetables, but not fruits, seem to protect against cancers of the colon and rectum. Large scale studies confirm these observations, suggesting, for example, that a daily consumption of 500g of fruits and vegetables can decrease incidence of cancer of the digestive tract by as much as 25% (28).

**Salt and salt-preserved foods** : Several studies have reported increased relative risks of stomach cancer in relation to the increased consumption of salt and salt-preserved foods. Salted,

smoked, pickled and preserved foods (rich in salt, nitrite and preformed N-nitroso compounds) are associated with increased risk of gastric cancer. Such high salt intake, together with *Helicobacter pylori* infection, may contribute to the development of atrophic gastritis and hence gastric cancer. Consumption of Chinese-style salted fish has been specially associated with increased risk of nasopharyngeal cancer in South-East Asia (29).

**Meat** : Epidemiologic studies on meat consumption and cancer risk support the existence of a specific association with colorectal cancer risk. This association seems to have been found more consistently for consumption of red meat (beef, lamb and pork) and processed meat (ham, salami, bacon etc.) for which consumption of 80 g per day may increase colorectal cancer risk by 25% and 67% respectively (30).

**Refined Sugars** : Increased consumption of simple sugars (mono- and disaccharides) may be associated with increased colorectal cancer risk, while consumption of complex polysaccharides, non-starch polysaccharides and/or fibre is associated with lower risk.

**High Overall fat / Saturated Fat Intake** : The hypothesis that high fat intake is a major cancer risk factor of the Western style diet has been at the centre of most epidemiological and laboratory experimental studies. The results are, however far from clear and definitive. The only moderately consistent result seems to be the positive association between consumption of fats of animal origin (except for fish) and risk of colorectal cancer.

**Food Additives** : Although some animal bioassays have revealed an increased incidence of urinary bladder cancer, there is inadequate evidence for carcinogenicity of saccharin in humans (31). The proportion of dietary-related cancers considered attributable to food additives is very low (32).

**Micronutrients** : Research on vitamin and cancer in humans has focused mainly on carotenoids and vitamin A (retinol), vitamin E, vitamin C and some of the group of B vitamins (folic acid, B6). The biological basis of the interest in these vitamins is their involvement in either of two metabolic mechanisms commonly called the antioxidant effect (carotenoids, vitamins C and E) and methyl donation (folic acid, B6). Studies have shown quite consistently that individuals with lower carotenoid levels have increased lung cancer risk. Less consistent and weaker protective effects of carotenoids have also been reported for cancer of the oesophagus, stomach, colorectum, breast and cervix. Low dietary intake of vitamin C has been found to be associated with increased risk of cancers of the stomach, mouth, pharynx, oesophagus and, less consistently, with cancers of the lung, pancreas and cervix. Although results on vitamin E and cancer are less strong and consistent than those on carotenoids and vitamin C, several studies have suggested that low vitamin E intake is related to increased risk of cancers of the lung, cervix and colorectum.

There is rising interest in the possible cancer-preventive effect of folic acid; some prospective studies have shown that high dietary intakes and higher blood levels may be associated with reduced risk of cancers and adenomatous polyps of the colorectum. Folate deficiency leads to an accumulation of



homocysteine. High homocysteine levels have recently been found to be strongly associated with death from myocardial infarction, total mortality and colon cancer risk (33). Among other micronutrients, Zinc and selenium deficiency may increase cancer risk (34).

**Overweight, Obesity and Reduced Physical Activity :** Western type of diet (characterized by high calorie food rich in animal fat and protein), often combined with a sedentary lifestyle and hence energy imbalance and obesity, increases the risk of colon, breast, prostate, endometrial and other cancers. Epidemiological studies have shown, with varying degrees of consistency, that excess body mass is associated with an increased cancer risk. The strongest and most consistent association with body mass has so far been seen for endometrial cancer, the risk of which is increased two-to six-fold in obese compared to lean women, both before and after menopause. Majority of case control and prospective studies have also found that Obesity (related to various alternations in plasma levels of total and bioavailable sex steroids) is a strong risk factor for endometrial cancer, as well as or breast cancer in postmenopausal women.

**Genetic Susceptibility :** Inherited cancer syndromes (e.g. retinoblastoma, neurofibromatosis etc.), usually involving germline mutation in tumour suppressor or DNA repair genes, may account for up to 4% of all cancers. Inherited mutations of the BRCA 1 gene account for a small proportion of all breast cancers, but affected family members have a greater than 70% lifetime risk of developing breast or ovarian cancer. Environmental factors may modify the cancer risk of individuals affected by inherited cancer syndromes.

**Reproductive Factors and Hormones :** Female sex hormone metabolism, reproductive factors and menopausal status affects the development of endometrial, ovarian and breast cancer. Use of combined oral contraceptives accounts for a slight increase in risk of breast cancer, but is protective against ovarian and endometrial cancers. Hormone replacement therapy is associated with increases in risk of breast and endometrial cancers.

For breast cancer, incidence rates rise more steeply with age before menopause than after, when ovarian synthesis of estrogen production gradually diminishes. Furthermore, breast cancer risk is increased in women who have early menarche, or who have late menopause, whereas an early age at first full-term pregnancy and high parity are associated with reduced risk of cancers of breast, ovary and endometrium (35). Ovarian cancer risk does not show strong relationship with menstrual history, but is clearly and inversely related to parity (36).

### Epidemiology of Common Cancers

**Lung Cancer :** Lung cancer is the most common tumour worldwide, with 900,000 new cases each year in men and 330,000 in women. It is leading causes of death from cancer. In India also, it is the commonest form of cancer among males. In men more than 80% of lung cancer cases are caused by smoking; in women the attributed risk is less (about 70% in Northern Europe; 45% worldwide). Some occupational exposures and air pollution (including passive tobacco smoke) make a minor contribution to incidence. No population-based screening procedures have been established. No effective treatment is

available; the five-year survival rate for lung cancer patients is less than 15%.

**Breast Cancer :** Breast cancer is the most common malignancy affecting women, with more than one million cases occurring worldwide annually. Affluent societies carry the greatest risk, with incidence rates of >80 per 100,000 population per year. In India, it is the second commonest cancer among females. Though it can be detected early and treated with effective measures like self / Clinical Breast examination or mammography, in our country, only 15% patients present in the localized stage; in 75% regional lymph nodes are already involved while 10% have distant spread at the time of reporting.

The worldwide breast cancer epidemic has many etiological factors, including *diet and diet related lifestyle factors* including obesity (for post-menopausal breast cancer), western type of high caloric diet, low intake of dietary fibre, physical inactivity, low intake of fruits and vegetables, alcohol use and, tall stature; *hormone related and reproductive factors* (early menarche, late or no pregnancy, late menopause, use of oral contraceptives, and lack of breast feeding); *previous history* (family history of breast cancer; history of benign breast disease); and, exposure to ionizing radiations at the time of development of breasts.

The positive aspect of breast cancer is that it is possible to detect it at an early stage and treat it effectively. In some regions of the world, including North America, Western Europe and Australia, breast cancer mortality rates have started to decline, mainly due to improvements in early detection and treatment (chemotherapy and tamoxifen). Five-year survival rates are higher than 70% in most developed countries. Breast cancer screening trials of mammography have shown that mortality can be reduced by up to 30%. However, there is limited evidence that this can be achieved in population-based countrywide screening programmes.

**Cancers of the Female Reproductive Tract :** Cervical cancer is the second most common cancer of women worldwide with more than 470,000 new cases per year, of about 230,000 deaths every year. More than 80% occur in developing countries. In India, it is the commonest cancer among females, with more than a lakh new cases being detected and 75000 deaths every year. Sexually transmitted infection with human papilloma virus (HPV) is fundamental to development of carcinoma of the cervix. HPV prevalence increases with multiple sexual partners and poor genital hygiene. Early age at first sexual contact and multiparity are other risk factors.

Population based screening with pap smear has improved early detection and survival. Five-year survival rates are up to 70%. In our country, it is recommended that ideal age at screening should be 35 to 50 years, as chances of detecting pre-cancerous lesions are maximum in this group. Other screening methods being studied for their efficacy in population screening include Unaided Visual inspection (UVI), Visual inspection using 4% acetic acid (VIA) and visual inspection using Lugol's Iodine.

Endometrial cancer mainly affects postmenopausal women in developed countries; worldwide, 188,000 new cases are diagnosed annually and obesity is a major risk factor. About 190,000 cases of ovarian cancer occur each year, predominantly among postmenopausal women in developed countries; five-



year survival rates are about 40%.

**Oral and Other Head & Neck Cancers** : The most common cancer in the head and neck, namely oral cancer, ranks eleventh worldwide (390,000 new cases per year), while cancers of the pharynx (65,000 cases) and larynx (160,000 cases) are less common. In India, oral cancer is the commonest cancer among males. In India, oral cancer is mainly due to smokeless tobacco (tobacco chewing), which is the single most important risk for oral cancer. Other risk factors include alcohol use, betel nut chewing, and chronic trauma to oral mucosa by sharp teeth or ill-fitting dentures. Multiple primary carcinomas are not uncommon. Oral cancer is eminently suited to early detection and treatment by regular inspection of oral cavity for leukoplakia / erythroplakia or ulcers. Early-stage tumours can be surgically resected. However, in developing countries like ours, many patients present late in the disease. Overall, oral cancer patients have a five-year survival rate of less than 50%.

**Stomach Cancer** : Cancer of the stomach is among the most common malignancies worldwide, with some 870,000 new cases every year. Mortality from stomach cancer is second only to lung cancer. In India also it is one of the commonest cancers among males, alongwith cancers of lung and oral cavity. Patients are often diagnosed with advanced disease and five-year survival rates are poor, usually less than 30%. Infection with *Helicobacter pylori* causes chronic atrophic and is considered as an important risk factor in the development of stomach cancer.

Incidence is declining worldwide. In most European countries it has fallen by more than 60% during the past 50 years. This trend is mainly due to markedly decreased consumption of salt-preserved food, increasing avoidance of a high-salt diet and availability, in many countries, of fresh fruits and vegetables throughout the year.

**Oesophageal Cancer** : Cancer of the esophagus is the sixth most common cancer worldwide (more than 400,000 cases per year). Incidence varies markedly, and is highest in western and south-central Asia. Squamous cell carcinoma is the commonest type of oesophageal cancers in developing countries. The major risk factors are tobacco and alcohol abuse. Other risk factors include consumption of very hot beverages and malnutrition. Most cancers of the oesophagus are detected at an advanced stage; five-year survival rates are less than 15%. In developing countries, adenocarcinoma is the commoner variety. Obesity and chronic gastro oesophageal reflux are also known risk factors.

**Colorectal Cancer** : Cancers of the colon and rectum are rare in developing countries, but are the second most frequent malignancy in affluent societies; over 940,000 cases occur annually worldwide. With increasing industrialization and improving economy with consequent changes in lifestyle in many of the developing countries, the incidence may rise. An important etiological factor is unhealthy lifestyle involving a diet rich in fat, refined carbohydrates and animal protein, combined with low physical activity. Studies suggest that risk can be reduced by decreasing meat consumption and increasing intake of vegetables and fruit. Colonoscopy is the most reliable means for early detection. Progressively improved treatment has resulted in a five-year survival rate of about 50%.

**Liver Cancer** : About 5,60,000 new cases of liver cancer, usually hepatocellular carcinoma, occur annually, and contribute significantly to cancer mortality worldwide. More than 80% of cases occur in Asia and Africa. The incidence rate is more than twice as high in men as in women. In Africa and Asia, hepatocellular carcinoma is most frequently caused by hepatitis B virus infection; concomitant dietary exposure to aflatoxin multiplies the risk. In Japan, this cancer is predominantly caused by hepatitis C virus infection. In western countries, liver cirrhosis due to chronic alcohol abuse is the major etiological factor. Hepatocellular carcinoma has very poor prognosis, survival from time of diagnosis often being less than six months; only 10% of patients survive five years or more.

**Cancers of the Male Reproductive Tract** : Prostate cancer accounts for about 200,000 deaths annually worldwide, predominantly afflicting older men in developed countries. Risk factors include high caloric intake and low physical activity. Black men have the highest, white men intermediate and Asian men a lower risk. Recorded incidence is increasing in many countries, partly as a result of screening for elevated serum levels of prostate-specific antigen.

Testicular cancer mainly affects young men, with close to 50,000 new cases each year worldwide. Incidence is increasing in many developed countries; its etiology is largely unknown. The mean five-year survival rate is higher than 95% mainly due to the efficiency of chemotherapy using cisplatin; long-term disease-free survival can even be achieved in cases of metastatic testicular cancer.

**Bladder Cancer** : Bladder cancer is the ninth most common cancer worldwide, with 330,000 new cases and more than 130,000 deaths per year. Bladder cancer is primarily attributable to smoking, which accounts for 65% of male and 30% of female cases in some developed countries. Other important causes include analgesic abuse (phenacetin), some types of cancer chemotherapy and historically, occupational exposure to chemicals such as 2-naphthylamine. In Egypt and some Asian regions, chronic cystitis caused by *Schistosoma haematobium* infection is a major risk factor. Treatment based on endoscopy, surgery, radiotherapy and cytotoxic drugs often permits long-term survival in developed countries, where 65% of patients live for at least five years after diagnosis.

**Leukaemia** : Leukaemia is the eleventh most common cancer worldwide with more than 250,000 new cases each year. It typically results from malignant transformation of white blood cells or their precursors. Subtypes are identified on the basis of the cell of origin (lymphocytic or myeloid etc.) and clinical course (acute or chronic). The etiology of leukemia is largely unknown, although a small proportion of cases are attributed to treatment with anticancer drugs or exposure to ionizing radiations. The genetic characteristics of many leukaemias are being elucidated.

Treatment of acute leukemia has made much progress and helped to establish general principles of cancer chemotherapy and management. Survival varies greatly according to type, with acute lymphoblastic leukemia patients having a five-year survival rate of up to 70%, whilst for those with acute myeloid leukemia it is only 20-30%.

**Lymphoma** : Malignant lymphomas are classified as either Hodgkin's disease or non-Hodgkin's disease or non-Hodgkin lymphoma. Hodgkin's disease affects mainly children and the elderly in developing countries and young adults in developed countries; 62,000 new cases are diagnosed annually. The incidence of malignant Non-Hodgkin lymphomas is increasing worldwide; more than 280,000 new cases occur annually, predominantly in more developed countries. Advances in chemotherapy have led to a five-year survival rate for Hodgkin disease of more than 70% and that for non-Hodgkin lymphomas has increased to 60-70%.

### Prevention and Control of Cancers

The modern knowledge is certain that cancers represent serious maladies which have great potential for prevention, as well as early diagnosis and effective treatment in many instances. Prevention of Cancers should be a totalistic approach, targeting all levels of prevention, viz., primary, secondary as well as tertiary levels.

#### Primary Prevention

**Community Education and Motivation** : As is evident from the foregoing discussions, the commonest (as also serious) cancers, viz. lung, oral cavity, breast, cervix uteri, stomach, upper aerodigestive tract and colorectum, are greatly related to "unhealthy lifestyle" which has been the discussion of this entire section. Education and motivation of the community to adopt simple healthy lifestyle steps, as depicted in Box-1, will go a long way in preventing not only various serious and common cancers but various other serious diseases also.

**Tobacco Control** : Tobacco is the single most important modifiable risk factor for cancer. Tobacco usage was estimated to account for an annual death toll of more than three million in 1990. The latest estimates from WHO put the annual number of deaths today at more than four million. If current smoking patterns continue, the total is predicted to increase to more than eight million. Thus, current cigarette smoking will cause about 450 million deaths worldwide in the next 50 years. Tobacco induced death and diseases are preventable; halving current smoking rates would avoid 20-30 million deaths before 2025 and 150 million by 2050. Smoking cessation is very effective in reducing risk of lung cancer even in later life. The greatest saving of life would result if rates of smoking uptake by children and adolescents were decreased.

Comprehensive tobacco control, including implementation of regulatory measures and encouraging personal commitment, requires coordinated involvement of government, professionals and planners. As has already been described earlier, Tobacco control involves health promotion and education, advocacy, support for cessation, community mobilization, taxation and other fiscal measures, livelihood alternatives, regulation, legislation and enforcement. Policy level interventions would include levy of taxes (to raise cost of tobacco products and act as a disincentive for purchase), regulation of tobacco products (for constituents, emissions, health warnings, and misleading health claims) and measures to reduce supply (ban on sale to youth, curbs on smuggling, and programmes to aid tobacco farmers and workers to switch over to alternative livelihoods).

A tobacco control legislation titled "The Cigarettes and Other

Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act 2003" became an Act of Parliament on 18<sup>th</sup> May 2003. This comprehensive piece of legislation, intended to protect and improve public health, encompasses a wide array of evidence-based strategies to reduce tobacco consumption. This includes provisions for prohibition on direct and indirect advertisements on tobacco products, prohibition on smoking in public places, prohibition on sale of tobacco products to persons less than 18 years age or within 100 yards of an educational institution, and display of statutory health warnings in a conspicuous and legible manner on tobacco products. Each of these provisions is accompanied with corresponding penalties that can be imposed.

<b>Box - 1 : Key Messages - Community Education for Cancer Control</b>
Stop Tobacco in any form today itself; do not start if you are non-user
Stop alcohol; if you cannot stop, drink in moderation
Eat at least half a Kg of fresh, seasonal fruits and vegetables every day
Eat plenty of whole grains, pulses, beans & legumes in diet
Keep salt consumption to < 5 grams a day; avoid food items which are salt-preserved, smoked or cooked in re-heated oils
Exercise briskly : at least 2 miles (3.2 Kms) of brisk walk in 30 minutes every day
Avoid Ghee, butter, deep fried, thick-gravied, creamed and sugary foods
Avoid "Red Meat" (lamb, beef, pork)
Maintain your body weight with proper combination of diet and exercise (BMI at < 25; waist at < 90 for males & < 80 for females)
Avoid sexual promiscuity
Maintain hygiene of genital organs
Take vaccination against hepatitis - B
Do a self examination of oral cavity and breast (females) once a month
Report to the Doctor if you have any "Warning Signs"
Ensure proper protections in occupational settings

**Alcohol** : Hazards of alcohol use in relation to cancers have already been described earlier. Control of alcohol requires actions similar to those for tobacco control. The action should be targeted towards individuals and communities and include taxation, general public education, encouraging highly vulnerable groups like young people to avoid starting consumption, etc.

**Sexual and Reproductive Factors** : Sexual and Reproductive Factors are associated with cancer of the uterine cervix and breast, as explained in foregoing paragraphs. Human Papilloma Virus (HPV) has now been identified as the etiological agent responsible for cervical cancer. HPV prevalence increases

with high risk sexual behaviour and poor sexual hygiene. Education regarding sexual hygiene and safe sexual behaviour should be provided for prevention of cancer cervix. Safe sexual behaviour protects women from the risk of cancer by preventing infection with HPV. Breast cancer is not much amenable to primary prevention, to any large extent. Early detection of cancer is the main strategy for improving survival in breast cancer.

**Diet, Physical Exercise and Avoidance of Obesity :** Proper diet, regular moderate intensity physical exercise and avoidance of obesity are important for prevention of breast, upper aerodigestive tract and intestinal cancers, as has been described in detail earlier. Certain basic measure may help in reducing risk of cancer :

- Avoid being underweight or overweight.
- Engage in regular, brisk physical activity.
- Consumption of alcohol is not recommended.
- Limit consumption of salted, deep fried foods.
- Choose predominantly plant based diets rich in grains, legumes and fruits and vegetables.
- Restrict the intake of red-meat (beef, pork, lamb) and preserved meat.

**Occupation :** Occupational cancers constitute 5 - 10% of all cancers. Limiting exposure to potentially carcinogenic substances through personal protective gear, rotation of workers and mechanized handling of such chemicals may help reduce cancers from occupational exposures.

**Environmental Pollution :** Maintaining proper vehicle emission standards, promoting alternative sources of energy instead of biomass fuel, taking measures to reduce the emissions of CFCs and anti-tobacco measures in home / public places will be of help.

**Radiation Protection :** Personal protective devices and dosimeters by personnel engaged in radiological procedures, avoidance of exposing patients to unnecessary X-rays and adequate safeguards in nuclear facilities should be ensured.

**Infection :** The important infections in relation to cancer prevention, in Indian context, are HBV and HBC, HPV, and *H pylori*. Vaccination against HBV, use of universal precautions in health care settings, proper sterilization of syringes, needles and other medical equipment, blood safety, safe sexual practices, avoidance of sexual promiscuity, maintenance of genital hygiene, and treating the patients with symptomatic infections of *H pylori* are the mainstays in this regards.

**Reduction of Exposure to Ultraviolet Radiation :** Encouragement of sun-protective behaviour is the most effective public health measure to reduce incidence of skin cancer in populations, especially in children. Available options include sun avoidance by using shade, wearing protective clothing and using sunscreens. Efficacy is expressed through the “sunscreen protection factor” (SPF). Most commercial preparations are presented as having SPF values of up to 15-20. Sunscreen formulations typically contain UVA absorbers (examples being cinnamates and derivatives of para-aminobenzoic acid) and UVB absorbers (such as the benzophenones).

**Chemoprevention :** Chemoprevention is defined as reduction of the risk of cancer development through the use of

pharmaceuticals or micronutrients. The breast cancer drug tamoxifen reduces the risk of developing a second cancer in the other breast. A lower risk of colon cancer has been observed following regular use of aspirin and related non-steroidal anti-inflammatory drugs which reduce the risk of recurrence of adenomas. Trials to establish chemo-preventive activity by micronutrients, including carotenoids and retinoids, among people at high risk, have been inconclusive. At present, tamoxifen is the only cancer prophylactic drug being used in medical care, under close supervision of a specialist.

**Secondary Prevention :** Secondary prevention aims at diagnosing the condition at a very early, preferably asymptomatic stage and effectively treating it. In context of cancer prevention, it takes two forms : firstly by educating the community at large regarding “early danger signs” so that they could report to medical facility for further evaluation, should these signs appear. Secondly, secondary prevention uses certain well established screening procedures for early detection.

**Early warning signs :** Community should be educated regarding the following signs / symptoms and report to the medical facility should they occur. Certain symptoms and signs may be early indicators of some cancers. These include -

- Unexplained change in bowel or bladder habit.
- A white patch or ulcer in the mouth that does not heal.
- Obvious change in a mole or wart, like rapid increase in size, bleeding or ulceration.
- Bleeding from body's orifices e.g. - haematuria, bleeding in stools, bleeding PV, haemoptysis, haemetemesis, epistaxis, etc.
- Persistent indigestion / difficulty in swallowing / difficulty in breathing.
- Persistent fever unresponsive to treatment.
- Unexplained loss of weight.
- Chronic cough or hoarseness of voice especially in a smoker.

### Screening for Common & Important Cancers in Indian Context

**Screening For Breast Cancer :** Early diagnosis of breast cancer, by promoting breast awareness among all women and clinical breast examinations for women, preferably in the age group 40-69 years, should be encouraged. Women should be educated and encouraged to inspect and manually examine all quadrants of the breasts with the flat of hand, and the axillae, once a month, ten days after the menstrual period. Every woman should also be made aware of the following signs -

- A change in size
- A nipple that is pulled in or changed in position or shape
- A rash on or around the nipple.
- Discharge from one or both nipples
- Puckering or dimpling of skin
- Lump or thickening in the breast
- Constant pain in the breast or armpit

**Breast Examination by a Health Professional :** With the flat of the hand, both the breasts are palpated in a circular manner starting from the nipple and areolae in a clockwise manner towards the periphery and the axillary tail of the breast in sitting and lying down position. Then the axillae,



supraclavicular regions and liver are also examined.

**Mammography** : The epidemic increase in breast cancer incidence has led to the introduction of population-based mammography screening. The analysis of large randomized trials has shown that in women aged 50 to 69 years, mammography screening can reduce mortality from breast cancer by 25-30%. For women in the age group 40-49 years, the screening efficacy is significantly less.

**Screening for Cervical Cancer** : In most developed countries, cytological screening (Pap test) has led to significant reduction in the incidence of and mortality from cervical cancer in a number of developed countries. Screening should preferably begin at 35 years of age, as at younger ages dysplasia detected through screening rarely progresses to cancer, but adds to programme cost in treatment. Alternative strategies such as visual inspection are being tested for use in low-resource settings where laboratory facilities for cervical cytology are inadequate. There is increasing interest in the use of HPV DNA testing for screening. A very important aspect of cervical cancer screening which should be noted by all medical functionaries is to ensure proper response rates, especially from those who are 'disadvantaged', since they are the ones who are expected to have a higher prevalence. Secondly, it is also equally important to ensure final confirmatory tests and adequate treatment, if required, among those who test positive on screening tests.

**Screening for Oral Cancer** : Oral cancer and its precancerous lesions, including leukoplakia, can be readily detected by visual inspection of the oral cavity not only by trained health workers and doctors, but to a large extent by the subject himself.

**Self Examination of oral cavity** : This is important for detecting oral lesions at an early stage. All habitual tobacco users should do it once a month. The following procedure should be followed :

- Rinse the mouth with water and stand before a mirror in adequate light.
- Look in the mirror for any abnormal white or red patch, ulcer or roughened area, or granular area or swelling in the mouth.
- If any such area is seen, the suspicious area should be felt with the fingers (normal oral mucosal is soft and pink).
- Consult a doctor if any abnormal area is found

**Examination by a Health Professional** : Health care providers should utilize every opportunity to examine the oral cavities of tobacco users. All parts of the oral cavity should be examined; oral cavity includes lip, anterior 2/3 of tongue, floor of mouth, buccal mucosa, gingival mucosa, hard palate and retromolar area.

**Population Screening** : Population screening for oral cancer results in the diagnosis of large numbers of oral pre-cancers and early stage tumours. However, a reduction in incidence of and mortality from oral cancer resulting from such interventions remains to be demonstrated.

#### Screening for Other Cancers

**Prostatic Cancer** : Prostate-specific antigen (PSA) testing is now being widely used in developed countries, for the early detection of prostate cancer. Elevated levels of PSA are closely, but not definitely, associated with prostate cancer.

False positive results may lead to unnecessary treatment. PSA analysis should be combined with a digital rectal examination, the latter providing an assessment of the volume of the gland, since PSA is also released into the bloodstream of patients with benign prostate hyperplasia and other prostatic diseases. The typical cut-off values are : 40-49 years, <2.5 ng/ml; 50-59, <3.5 ng/ml, etc.

**Colorectal Cancer** : Faecal occult blood test (FOBT) is a very cost-effective and quite applicable screening method available, but its specificity and sensitivity are limited. Endoscopy provides the definitive method for detecting colorectal cancer and its precursor lesions, e.g., polyps. However, its application to population-based screening is limited by cost and availability of qualified specialists.

**Tumour Markers** : Certain cancers release biological products into the circulation, which can be measured for increasing the level of diagnostic suspicion. The common ones are :

**Alpha fetal protein ( $\alpha$  - FP)** : This is increased in Liver cancer and certain tumours of testis and ovary. It is also increased in cirrhosis and hepatitis.

**Beta Human Chorionic Gonadotrophin ( $\beta$  - hCG)** : Increased in choriocarcinoma and testicular tumours. Also increased in hypogonadism and hydatiform mole.

**Carcino Embryonic Antigen (CEA)** : Increased in colorectal, breast and stomach cancers and Cholangiocarcinoma. Also raised in liver disease and among smokers.

**CA - 125** : Raised in epithelial ovarian cancers. Also raised during pregnancy, menstruation, endometriosis, ascites and pleural effusion.

**Prostate Specific Antigen (PSA)** : Raised in prostatic cancer as also in prostatitis and BHP.

**Tertiary Prevention** : Tertiary prevention is also quite important in cancers. It consists of proper treatment of disease, especially advanced disease. The available options are Surgery, Radiotherapy and Chemotherapy. It also involves specialized issues as palliative care, terminal care and pain relief and reassurance / advise to the patient and family.

## Summary

Cancers are defined as "Group of heterogeneous disorders characterized by Clonality, Autonomy, Anaplasia and Metastasis". Cancers are, by and large, diseases of unhealthy lifestyle and are, therefore, potentially preventable. Worldwide, approximately 10 million new cases and more than 6 million deaths (12% of all deaths) occur due to cancers every year. In terms of incidence, the most common cancers world-wide are those of lung (12.3% of all cancers), breast (10.4%) and colorectum (9.4%). The top three causes of death from cancer are those of the lung (17.8% of all cancer deaths), stomach (10.4%) and liver (8.8%). Developing countries contribute to more than half of the total cancer cases worldwide. Cancer incidence in India is estimated to be around 70 - 90 per 100,000 populations with 700,000 - 900,000 new cases of cancer every year. The commonest cancers in men are those of Lungs, Stomach, Oral cavity and oesophagus, while in women, those of Cervix Uteri, Breast, oral cavity, Ovary, Oesophagus and Stomach are the commonest. Large majority of these are tobacco related and



hence potentially preventable.

The major risk factors for Cancers are Tobacco use, Alcohol, Occupational hazards, Environmental pollution, Food contaminants, Diet, Obesity & Physical inactivity, radiation, Chronic Infections, Genetic Susceptibility, Reproductive Hormones and many others. Tobacco smoking is the main known cause of human cancer-related deaths, worldwide. Tobacco causes cancers of the Lung (10-20 fold risk), larynx (10-fold), oral cavity (2-fold), oesophagus (5-fold), pancreas, kidney and bladder. Passive smoking is also a definite risk for lung cancer and possibly laryngeal cancer. Causal association of drinking alcohol has been definitely established in respect of oral, oesophageal, liver and breast cancer and is probable for colon and rectal cancer. Occupational exposures like Aromatic amines have been shown to increase the risk of Bladder cancer; benzene that of Leukemias and that of myelogenous leukaemia in particular, Asbestos and other fibres have been associated with Lung cancer and mesothelioma. Cancer of the lung can be caused by exposure to inorganic arsenic in mining and copper smelting and among workers in chromium plants and chromium alloy workers. Nickel refining also carries carcinogenic risk. Coal tar, coal gas production and iron founding are associated with cancers of the skin and of other sites, including the urinary and respiratory systems. Environmental pollution accounts of 1-4% of the total burden of cancer in developed countries. The carcinogenic pollutants include asbestos; Engine consumption products like benzene, toluene, xylenes and acetylene; oxides of nitrogen (NOx) and fine particulates; chlorination by-products and other contaminants of drinking water like Arsenic. Food Contaminants like Aflatoxins cause hepatocellular carcinoma, *F. verticillioides* or its toxins in maize cause oesophageal cancer, Ochratoxin A lead to urinary tract tumors. Bioconcentration of DDT and other pesticides into the food chain; the Polycyclic aromatic hydrocarbons generated in meat when it is fried; Nitrosamines formed by smoking and direct fire drying are all carcinogenic. Exposure to ionizing radiations can cause leukaemia, breast cancer and thyroid cancer. Chronic Infections like Hepatitis B and C, liver flukes, Human papilloma viruses, Epstein-Barr virus, *Helicobacter pylori* and *Schistosoma haematobium*. The western diet and lifestyle are generally associated with high incidence of cancers of the colorectum, breast, prostate and endometrium. A daily consumption of 500g of fruits and vegetables can decrease incidence of cancer of the digestive tract by as much as 25%. Salted, smoked, pickled and preserved foods (rich in salt, nitrite and preformed N-nitroso compounds) are associated with increased risk of gastric cancer. Overweight, Obesity and Reduced Physical Activity increases the risk of colon, breast, prostate, endometrial and other cancers. Cancer syndromes like retinoblastoma, neurofibromatosis etc., breast and ovarian cancers have Genetic Susceptibility. Menopausal status and Hormone replacement therapy are associated with increases in risk of breast and endometrial cancers. Use of combined Oral Contraceptives accounts for a slight increase in risk of breast cancer, but is protective against ovarian and endometrial cancers.

Prevention of Cancers should be a totalistic approach, targeting all levels of prevention, viz. primary, secondary as well as tertiary

levels. Primary prevention includes Education and motivation of the community to adopt healthy lifestyle, Comprehensive tobacco and alcohol control, including implementation of regulatory measures and encouraging personal commitment, requires coordinated involvement of government, professionals and planners. Education regarding sexual hygiene and safe sexual behaviour should be provided for prevention of cancer cervix. Proper diet, regular moderate intensity physical exercise and avoidance of obesity are important for prevention of breast, upper aerodigestive tract and intestinal cancers. Limiting exposure to potentially carcinogenic substances through personal protective gear, rotation of workers and mechanized handling of such chemicals may help reduce cancers from occupational exposures. Maintaining proper vehicle emission standards, promoting alternative sources of energy instead of biomass fuel, taking measures to reduce the emissions of CFCs and anti-tobacco measures in home / public places will be of help. Personal protective devices and dosimeters by personnel engaged in radiological procedures, avoidance of exposing patients to unnecessary X-rays and adequate safeguards in nuclear facilities should be ensured. Vaccination against HBV, use of universal precautions in health care settings, proper sterilization of syringes, needles and other medical equipment, blood safety, safe sexual practices, avoidance of sexual promiscuity, maintenance of genital hygiene, and treating the patients with symptomatic infections of *H. pylori* are important measures. As a part of Chemoprevention, Tamoxifen is the only cancer prophylactic drug being used in medical care, under close supervision of a specialist. Secondary Prevention is firstly by educating the community at large regarding "Early danger signs" and Secondly, by screening procedures for early detection. Screening for Breast Cancer is done by clinical breast examinations for women, preferably in the age group 40-69 years by self or by a health professional or alternatively by Mammography. Screening for Cervical Cancer is by cytological screening (Pap test) or Visual Inspection with Acetic Acid (VIA). Oral cancer and its precancerous lesions, including leukoplakia, can be readily detected by visual inspection of the oral cavity by trained health workers, doctors and by the subject himself. Prostate-specific antigen (PSA) testing is now being widely used in developed countries, for the early detection of Prostate cancer. Colorectal Cancer is screened by Faecal occult blood test (FOBT). Tumour markers like AFP, B - hCG, CEA, CA - 125, PSA are also useful in early detection of some cancers. The options for Tertiary Prevention are Surgery, Radiotherapy and Chemotherapy and it also involves specialized issues as palliative care, terminal care and pain relief and reassurance / advice to the patient and family.

### Study Exercises

**Long Question :** Discuss the epidemiology of common cancers in India and the approach for prevention and control.

**Short Notes :** (1) Early warning signs of cancer (2) Risk factors in cervical cancer (3) Risk factors in oral cancer (4) Secondary prevention in cancers (5) Tobacco use and cancers (6) Alcohol and cancers

## MCQs & Exercises

- Worldwide, the most common cause of death from cancer is that of : (a) Lung (b) Oral cavity (c) Gastric (d) Liver
- Following is not the characteristic of a cancer : (a) clonality (b) metastasis (c) anaplasia (d) all of the above are characteristics
- The most common cancer in Indian women is (a) Breast (b) Cervix (c) Endometrium (d) Oral cavity
- Match the following :

1. Aflatoxin	a. Oesophageal cancer
2. Ochratoxin A	b. Hepatocellular carcinoma
3. <i>F. verticillioides</i> or its toxins	c. Urinary tract cancer
4. Asbestos	d. Lung

- Use of combined Oral Contraceptives accounts for an increase in risk of (a) Breast cancer (b) Ovarian cancer (c) Endometrial cancer (d) None
- Exposure to Benzene causes the following cancer (a) Bladder (b) Lung (c) Prostate (d) Leukemia
- Smoking is NOT a known risk factor for which of the following cancer (a) pancreas (b) kidney (c) bladder (d) prostate
- At present Number of population based cancer registries (PBCRs) in India is : (a) 5 (b) 6 (c) 7 (d) 4
- At present Number of Hospital based cancer registries (HBCRs) in India is : (a) 5 (b) 6 (c) 7 (d) 4
- Match the following cancer with an infection :

1. Cervix uteri	a. <i>Schistosoma haematobium</i>
2. Lymphoid tissues	b. <i>Helicobacter pylori</i>
3. Stomach	c. Epstein-Barr virus
4. Urinary system	d. Human Papilloma virus

- Cancer not having Genetic Susceptibility is (a) Neurofibromatosis (b) Breast (c) Ovarian (d) All of the above have genetic susceptibility
- Visual inspection with Acetic Acid (VIA) is a method of screening for (a) Oral cavity (b) Cervix (c) Gastric (d) Prostate

**Answers :** (1) a ; ( 2) d ; (3) b ; ( 4) 1b,2c,3a,4d ; (5) a ; (6) d ; (7) d ; (8) b ; (9) a ; (10).1-d, 2-c, 3-b, 4-a ; (11) d; (12) b.

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## Part - 1

## Mental Health

Mental health is an important component of the total positive health. Every physical ailment has a mental component and every mental illness has a physical component. The WHO expert committee defines mental health as 'the capacity in an individual to form harmonious relation with others and to participate in or contribute constructively to change in the social environment'. Another definition, forwarded by Ginsburg says "the ability to hold a job, have a family, keep out of trouble with law and enjoy the usual opportunities for pleasure". The comprehensive concept of mental health has thus a four - fold goal before it : to understand and cure the different types of mental disorders and defects; to detect the cases of incipient mental breakdown early; to prevent, or at least to minimize the occurrence of the disorders and defects; and improve the overall mental health of the community (1). A classification of psychiatric disorders is shown in Table - 1. Similarly, the Diagnostic and Statistical Manual for Mental disorders (DSM) has also proved to be of significant value in the diagnosis of mental disorders.

## Magnitude of the problem

**Worldwide** : About 500 million people are believed to be suffering from neurotic, stress related and psychological (somatoform) problems. A further 400 million suffer from anxiety disorders, 340 millions from mood disorders, 60 million from mental retardation and 45 million from schizophrenia. It causes a heavy burden of suffering and economic loss (2). More recent socio - economic estimates by WHO & World Bank, regarding the burden of major psychiatric disorders is presented in Table - 2. Of the entire neuro - psychiatric disease burden, approximately 30 to 40% is comprised of Depression, 6 to 8% is schizophrenia, while Bipolar disorders and panic Disorders comprise 5 to 6% and 2.5 to 3% of all neuropsychiatric disorders, respectively (3).

**India** : Data forwarded by Reddy and Chandrashekhar (4) on mental morbidity in various parts of the country suggest

Table - 1: Classification of Psychiatric Disorders (ICD-10)

<i>Organic (F10) : Acute e.g. delirium and Chronic e.g. dementia</i>
<i>Psychoactive Substance Use (F1)</i>
<i>Schizophrenia and delusional disorders (F2)</i>
<i>Affective (mood) disorders (F3)</i>
- Depression
- Mania
- Recurrent affective disorders
<i>Neurotic, stress related and somatoform disorders (F4) :</i>
- Anxiety disorders incl Generalised anxiety , Phobic anxiety, and Panic disorder
- Obsessive compulsive disorder
- Reaction to severe stress
- Acute stress disorder incl Post - traumatic stress disorder & adjustment disorder
- Dissociative disorder
- Somatoform disorder
- Neurasthenia
<i>Behavioural disturbances (F5) : Eating disorders, Sleeping disorders, Sexual dysfunction and Puerperal mental disorders</i>
<i>Personality &amp; Behaviour disorders (F6) e.g. thumb sucking, bed wetting, juvenile delinquencies.</i>
<i>Mental Retardation (F7) : Mild, Moderate, Severe &amp; profound retardation.</i>
<i>Disorders of Psychological Development (F8) of speech, language &amp; motor function</i>
<i>Behavioural and emotional disorders with onset during childhood or adolescence (F9)</i>

prevalence rate of 58.2 per 1000. The major psychiatric conditions contributing to this morbidity are Neuroses (20.7 per 1000), Affective Disorders (including Mania, Manic Depression and Depression) 12.3 per 1000, Mental retardation and alcohol & drug addiction (6.9 per 1000 each) and Schizophrenia (2.7 per 1000). It is likely that there may be a load of almost 9 million persons in India suffering from severe incapacitating mental disorders and almost 90 million mildly mentally ill

Table - 2 : Burden of Selected Major Psychiatric Disorders, By World bank Region, per year

Disorder	Worldwide			South Asian region		
	<i>Discounted DALYs (in thousand)</i>	<i>DALYs per million population</i>	<i>% of total disease burden</i>	<i>Discounted DALYs (in thousand)</i>	<i>DALYs per million population</i>	<i>% of total disease burden</i>
Schizophrenia	11643	1894	0.76	2896	2087	0.71
Bipolar disorder	9733	1583	0.63	2237	1612	0.55
Depression	51833	8431	3.37	14054	10507	3.57
Panic Disorder	4550	740	0.30	1081	757	0.26



persons in India (5).

### **Epidemiology of Major Psychiatric Disorders**

**Schizophrenia and Non - affective Psychosis** : Schizophrenia is a chronic disorder punctuated by episodes of florid psychotic symptoms, especially hallucinations, delusions, negative symptoms and cognitive symptoms. There is a marked gender effect in the age - specific incidence rates of this disorder, in that the cumulative risk of developing schizophrenia is similar in males and females upto the age of 55 years; the risk after that age is almost zero for both the sexes. However, the mean age of onset is higher in females. Socio - cultural environment has an important role in that while incidence rates are similar across various cultures and countries, the course and outcome seems to be more favourable in subjects from developing as compared to developed countries (6). Many schizophrenics also give history of adverse events during foetal life (as obstetric complications in the mother) or during neonatal life.

There are two main categories of epidemiological determinants - heredity and organic brain damage. The risk is high if one parent is a schizophrenic and is greatly increased if both parents are; identical co - twin of a schizophrenic has 50% risk of being affected. Even if a person is blood related to a schizophrenic, the risk rises. In fact heredity seems to have a stronger risk as compared to the type of upbringing that a child receives. Many schizophrenics also show organic brain damage, as enlargement of lateral ventricles. Schizophrenia can also occur in conjunction with a variety of cerebral and physical diseases, of which epilepsy is the commonest.

**Bipolar Disorders** : These include subjects with history of both depressive and manic episodes (bipolar disorder) and those with only depressive or only manic episodes (unipolar disorder). There is intense emotional drive during an episode, with a tendency to return to pre - morbid functioning as well as a tendency to recur, with multiple episodes during the patient's lifetime. The manic form occurs mainly among the younger age group, while the depressive form is commoner among older age group. Among hospitalized patients, women and those from higher socio - economic status form a higher proportion. Similarly, Bipolar patients are more likely to be married than schizophrenic patients.

**Major Depressive Disorders** : The core symptom is a disturbance of mood. Sadness is most typical but anger, irritability and loss of interest in usual pursuits and decreased energy or "drive" also occurs. Often the affected person is unable to experience pleasure and may feel hopeless. In most of the developing countries, patients may not complain of these symptoms but rather of physical symptoms as fatigue or aches and are often likely to be misdiagnosed at primary care facilities. Illness usually starts in twenties or thirties although new onsets can be observed across the entire lifespan. In community surveys, there is consistent finding of delayed reporting for treatment and to be associated with substantial impairments in both productive as well as social roles. Drugs in the form of tricyclic antidepressants or the newer selective serotonin inhibitors (SSIs), along with psychosocial therapy are effective in taking care of acute episodes as well as increasing the remission period.

**Anxiety Disorders** : These include panic disorders and the generalized anxiety disorders, which also includes the Post Traumatic Stress Disorder (PTSD) and Obsessive - Compulsive Disorder). The central feature is the inability to appropriately regulate fear or worry and occasional panic attack, which is a discrete period of intense fear accompanied by typical symptoms as tachycardia, sweating, etc. There are triggering phobia - precursors as travel, crowded places, elevators, etc. and subjects may try to avoid these triggers. These disorders have been consistently found to be associated with decline in productive as well as social roles. Interventions with Benzodiazepines and psycho - social therapy are effective.

### **Issues of Public Health, Prevention & Control**

**Patterns of mental health care for Populations** : The realization that organizing population based mental health is an achievable goal and that mental health problems can be amenable to primary and secondary prevention (and not only treated when the disease has become apparent and advanced), is a recent one. Many countries, developed as well as developing, are making endeavors to build in mental health care programmes as a part of their public health system, including at the primary level health care level. The general patterns of mental health care services in any country are :

- State supported mental hospitals - This is the oldest pattern. Large hospitals in India include those at Agra, Bareilly and Ranchi and NIMHANS at Bangalore.
- Private Psychiatric Hospitals
- Psychiatric services as a part of general hospitals, as District hospitals.
- Private Practice based psychiatric consultation / treatment
- Mental health services at the primary care level, through trained paramedical workers.
- Preventive & Promotive Mental Health care services as a part of Vertical mental health programs at the national / state level.

### **Organising Mental Health Care as Part of Public Health Services**

**Major Issues to be considered** : In recent times, there has been a shift from focusing on mental health of individuals, usually in the form of organizing psychiatric treatment for sick individuals, to holistic mental health care, preventive, promotive as well as early curative, and that too, not for individuals but for the entire community. Three important issues which need to be addressed while organizing community mental health services are

- Firstly, to have a clear idea of the prevalence and types of mental health problems by deciding clear cut diagnostic criteria (as DSM - IV) and utilizing the available data from hospitals or by undertaking surveys.
- Clearly deciding as to what will be the appropriate indicator criteria of measuring success being achieved in the mental health program, e.g., number of psychiatric cases who voluntarily reported for treatment or the yearly incidence of suicide cases.
- Setting up of realistic targets as regards these selected indicators.



**Needs Assessment** : Having decided on the diagnostic criteria and indicators, the needs of the community as regards mental health care should be undertaken. This will involve obtaining data on the major / common psychiatric conditions prevalent in the community, their distribution according to major person, place and time related variables, and identification of risk groups who are in greater need of mental health services. This should also involve making an assessment of the load of mental health problems as per five levels of care, viz. :

**Level - 5** : patients who are likely to be requiring admission to psychiatry beds at district hospital or specialized centres.

**Level - 4** : patients attending psychiatric services outside the hospitals, as OPD or day care subjects.

**Level - 3** : Patients presenting with conspicuous psychiatric morbidity at the Primary health care / CHC level.

**Level - 2** : patients who report with “hidden” psychiatric morbidity at the primary care / CHC level. They may be having presentations which may be mixed up with other diseases and need good clinical acumen on the part of the medical person to diagnose them.

**Level - 1** : Persons with psychiatric morbidity but who are hidden in the community i.e., have never reported to the health system. Unearthing this load of morbidity will need surveys in the community.

**Developing Political Will and Social Climate** : Mental illness is often associated with stigma and also tends to get a lower priority from political and bureaucratic echelons. It is therefore imperative that before launching any mental health programme, adequate political will is generated through advocacy.

**Reaching out with psychiatric help at grass roots level** : One of the major problems with mental illness is that patients do not present voluntarily to the psychiatric services at an early stage. If care could be provided at an earlier stage than at the point of hospital presentation, better care could be given and unnecessary suffering avoided. Similarly, as far as possible, day care / OPD services / follow up domiciliary care would be a better and more cost effective option than hospitalization for most cases.

**Developing a graded (tier) system of mental health services** : This approach is likely to be of considerable help in establishing community mental health services.

- At the first level, paramedical workers who are in close touch with the community at the village and Health Sub - centre level are adequately trained in recognizing and providing first aid to psychiatric emergencies as well as following up the diagnosed cases in their home environment for ensuring continuity of treatment, for providing basic advice to the patient and family, as well as educating the community members on basic preventive procedures.
- At the second level, the generalist medical officers at the primary health care centre level are adequately trained and equipped to diagnose and treat the common psychiatric illnesses and refer the complicated cases to the next level.
- At the third level, that of the district hospital, a trained psychiatrist deals with the referred cases, as well as provides guidance and training to the persons functioning at the first and second levels. This level also provides

necessary inputs to the district health administration for planning the mental health care services in the district.

- The fourth level is that of super - specialised centres as medical colleges and mental health institutes, to take care to complicated / referred cases as well as to organise epidemiological research and surveys for planning and evaluating the services.

## Prevention

Prevention in mental health scenario is more difficult than other branches of medicine because of relatively vague and multifactorial etiologies, stigmata and misconceptions and the general feeling that available (scarce) resources should be directed towards those already affected by these disorders rather than to preventive strategies.

It is usual to consider the principles of prevention according to the traditional approach of primary, secondary and tertiary levels.

**Primary prevention** : The available strategies are :

- Creating optimum socio - economic environment at the community level, in the form of improved education, improved employment opportunities, optimum nutrition and control of population growth. It needs no emphasis that improved standards of living in a community would reduce the rifts and stresses which often precipitate psychiatric illness.
- Socio - Legal actions in respect of dangerous substances as alcohol and habit - forming drugs / substances.
- Community education regarding common psychiatric illnesses, removing the stigma associated with these diseases and the fact that with the modern armamentarium of drugs, most of the mental illnesses can be stabilized / remission obtained.
- Specific protections as Iodisation of salt to prevent mental handicap associated with cretinism and provision of appropriate diet to children with phenylketonuria; Rubella vaccine before conception to mothers and proper ante - natal care for various vertically transmitted infections; folic acid supplementation for preventing neural tube defects.
- Application of the Science of genetics at the Community level : With advances in clinical genetics, we now know that upto one - third or even more, of the causes of severe mental handicap (Down's syndrome, phenylketonuria, fragile - X syndrome and Tay - sach's disease) are caused by identifiable chromosomal abnormalities and are potentially preventable. As time progresses, these conditions may provide scope for population based screening and identification of carriers in future.
- Community education for adopting measures to reduce personal stress, by stress management techniques (as per details given in the next section of this chapter).

**Secondary Prevention** : As of today, there are more opportunities for secondary prevention as compared to primary prevention, by way of early detection and intervention among those at risk. This would take the following approaches

- High index of suspicion and good diagnostic acumen by the medical and paramedical personnel, especially

those at the primary or grass root levels to identify the earliest symptoms / expressions of stress and mental illness and early intervention with drug / psycho - therapy, as required. These early symptoms include irritability, changes in behavioural pattern which was otherwise being followed for a long time, mood fluctuations, forgetfulness, suicidal thoughts or tendencies, feeling of exhaustion or worthlessness, and symptoms as changes in appetite, aches and pains which are not explained by available physical findings.

- Certain exposed to high pressure jobs groups as industrial workers and defence personnel.
- Inmates of delinquent homes and prisons.
- Certain clinical groups as immediately post - natal women.
- School children showing learning difficulties.

**Tertiary Prevention** : Tertiary prevention aims at the prevention of disability and relapse in those who already have a psychiatric disorder. This needs a complete psychiatric rehabilitation team including psychiatrists, clinical psychologists, medico - social workers and counselors, who would need to work in the community with the patients (and families) of patients who have been discharged from psychiatric care, back into their home environment. Firstly, it needs ensuring that patients take their drugs and other treatment as advised without any loss of compliance. This would also include educating the patient and the family about the side effects of the treatment, which is often prolonged in case of psychiatric illnesses. Thirdly, is the requirement of psycho - emotive and vocational / financial support to the patients and this would need advocacy on part of the health care services to create appropriate social conditions to achieve this.

## Part - 2

### Prevention and Management of Mental Stress

*RajVir Bhalwar & VSSR Ryali*

In contemporary times, any Doctor engaged in health care of the community should be very well aware about various aspects of stress, so as to educate the clientele and be able to prescribe a road map for its management.

#### The Stress Response

The term "Stress" is used as an umbrella term to cover all aspects associated with the phenomena. However, what really concerns us is the "Stress Response". This is the sum total of body reaction, both physiological and psychological, in response to a "stressor" i.e., an event occurring outside the body in the external environment. The stress response leads to various "Stress Symptoms" or "Stress diseases".

**Biology of the stress response** : Nature has built the stress response into our biology and that of all animals for a protective and desirable reason, viz, to gear up the entire body to deal with acute physical emergencies. This quick response is mediated through the autonomic system (ANS), and the endocrine responses mediated through the hypothalamus, pituitary and adrenal glands, consisting of a massive cascade

of instantaneous physiological changes, mainly through hormones like noradrenaline and cortisol. Within milliseconds of their release, they would cause the heart to beat faster and more strongly and the blood pressure to rise (so that more and more blood laden with oxygen and glucose could go to the muscles, to either fight it out or run away). The breathing would become deep and extra glucose would be pumped out into the blood by the liver so that more of sugar and oxygen could be taken by the blood to the active muscles. Kidneys start saving water so that blood volume can increase, digestion reduces and blood from digestive organs is diverted to the active muscles. In addition, the blood clotting mechanism would increase so as to quickly seal off the wounds and minimize blood loss due to bleeding from injuries. All these massive physiological changes occur within the fraction of a second. Their purpose is to prepare us to take instant action against an acute physical stressor, by either fighting it or taking a flight.

However, certainly we don't have to have our body and mind in such a state of alarm, and that too for prolonged periods of hours (may be, weeks or months), to negotiate modern day "stressors" or challenges like having a difficult boss, staying separate from the family, preparing for an important competition, difficulties in career, or lesser difficulties like having a flat tyre while driving on the highway. Unfortunately, even for these small hassles, the body's stress response remains massive or perpetual. The increase in blood pressure and heart rate, increase in blood sugar, increase in blood clotting mechanisms, taut muscles, lowering of the immune defence of the body, reduction in the digestive process continue for long periods and lead to major diseases like hypertension, diabetes, peptic ulcer, infections due to reduced immune defence, muscular and joint pains, just to name a few. It is therefore essential for us to learn ways and means to calm down our reactions to the stressor, and to develop adequate "coping mechanisms" to tackle the stressors of day - to - day living.

**The sequence of stress response** : The process of stress starts when a "demand" is placed on us. Demands are those requirements placed on us, which are potential stressors. A demand can be something as minor as a wrong telephone call in the night, or as major as reporting of embezzlement of funds in your office. At this point, we are not calling a "demand" as a "stressor", because not every demand may end up becoming a stressor.

Once a demand is placed on us, it does not straightaway lead to stress. There are certain intermediary mechanisms that occur, before we experience stress. The awareness of "demand" is followed by our "appraisal" of the problem. This step is more important, since, as described earlier, the impact of a demand (stressor) is a function of, not only the event, but also the appraisal that we make of our own coping abilities to deal with it. The sequence of appraisal is as follows.

- Firstly, the "primary appraisal", which involves evaluation of the significance of the event. In fact, we ask ourselves "Am I in trouble?"
- After the primary appraisal, comes the secondary appraisal. This involves the question "Can I handle it?"
- Following the primary and secondary appraisal, if we feel that, firstly, we are in trouble, and secondly, we

also feel that the demand (potential stressor situation) would outweigh our available coping resources, we are likely to experience the stress response, with many of its consequent “stress symptoms”. On the other hand, if we appraise the demand as not being difficult, or else we see our “resources” as adequate to cope up with the demand, we experience a “challenge” and also the opportunity to increase our capability of ‘coping”.

### The Adverse Effects of Stress

Stress affects our health in a wide variety of ways. The adverse effects are summarized below.

**Psycho - somatic** : These include IHD, Hypertension, Diabetes Mellitus, Peptic Ulcers, predisposition to certain cancers, lowered immune functioning, arthralgias and myalgias, tension - headaches, etc.

**Emotional** : These include suppressed hostility, anger, irritability, “burnout”, fatigue, sleep disorders, anxiety, depression, and, suicide / attempted suicide. Inter - personal problems affecting social relationships also occur.

**Performance problems** : These include difficulties in memory and concentration and impaired ability to take decisions. Physical performance also gets reduced, as evidenced by exhausted feeling and lowered stamina.

**Habit problems** : Quite often (and very wrongly so), persons under chronic stress get into a tendency to treat it by starting up with self medication with antidepressants or anxiolytics and may even take on to tobacco, alcohol and narcotic drugs as means of relieving stress. Consequently, further health problems result.

### Preventing / Pre-empting Stress & Developing “Coping Resources”

This is quite pertinent as the better part of valour is to avoid unnecessary battles. This holds good for potential stressors too. Interestingly, most of these steps are not medical measures but general managerial techniques which are given below.

**Learning and practicing decision making techniques** : Learning and actually using proper decision making skills when faced with critical situations can prevent much of stress later on. Wise decision making incorporates the sequential steps of firstly, defining the problem at hand, secondly, identifying the various alternative options at hand to tackle the problem, thirdly, deciding on the best option and finally, committing oneself to the selected course of action.

**Develop personal financial management skills** : Some of the major stressful situations in our lives result from financial crisis. These are often the result of poor financial management. One should write down, on a paper, ones income and expenditure. Having taken a written stock of the credits and potential expenses, one can sensibly match the resources. Secondly, one must avoid excessive desire that could fall in the category of “greed” (rather than essential or desirable for decent life), since, in our drive to fulfill such desire, we add further stress to our lives.

**Make Conscious and Deliberate Efforts to Maintain Good Health** : Even when one suffers from a disease as minor as common cold, one feels demoralized. Apparently, if one had

to suffer from major diseases like Heart disease, the amount of stress that the person would be subjected to would be tremendous. One should therefore make conscious effort to maintain good health and prevent such diseases. In short, incorporating simple measures for a healthy lifestyle, like regular brisk exercise, giving up tobacco, avoidance of alcohol and eating a healthy diet would go a long way in prevention of some of the most dreaded diseases. One should also deliberately and consciously look after the preventive health care of one's family members; their good health prevents your stress.

**Undertake regular and brisk physical exercise** : By now, it has been clearly demonstrated by medical researchers that regular and brisk exercise is a major “stress - buster”. In addition, the resulting physical fitness tends to shape up the psyche and physiology in such a way that we tend to become resistant to developing stress. With regular exercise, the body and mind get used to cope up with this adverse physiological challenge and the resulting high surge of stress hormones.

**Spend “Quality time” with your family** : Whenever one gets the opportunity, one should make sure that one spends at least a few hours of “QUALITY TIME” with the family members. By quality time we mean that you should get involved with them - play with them, teach them and so on, rather than simply sitting with them and surfing around the TV channels.

**Develop Social Support Systems** : We, human beings, are social animals. At times of need, we should have social support. This is particularly true when we are faced with difficult and stressful situations. Therefore, it would be a very wise investment to put in some effort to develop some close friends towards whom we can look up for support during stressful situations.

**Avoid Ego Struggles** : Many stressful encounters with others are, in fact, unnecessary ego struggles. We often argue with our colleagues, superiors, spouse and even children about trivial issues that really don't matter much. It is best to avoid the tendency to forcefully convince others when it is not so critical to your own health and well - being. Doing so will help you escape a great deal of unnecessary stress.

**Adopt traditional cultures** : As Indians we have the advantage of a rich and ancient culture. Patanjali advocated Yoga as a means of attaining physical and psychological health 5000 years ago. Our culture has elaborated on the virtues of need based living, sharing, acceptance of good with the bad, and renunciation, which if combined with advantages of modern living will improve the quality of life many fold.

**Practice methods to get a good sleep** : Good sleep is very important for de - stressing us, as well as in assisting the repair of the physical and the mental breakdown that occurs during the whole day. Accordingly, practicing methods for getting a good sleep is likely to be of much help in both preventing stress as well as negating it's adverse effects. Some tips for getting good sleep are :

- Associate the bed with sleep only. Don't eat, read or watch TV while in bed.
- Avoid caffeine containing drinks (Tea, Coffee) or tobacco before retiring.
- Don't use alcohol to get sleep. It may make us drowsy



and may initiate sleep, but interferes with the rhythm of normal sleep and causes rebound arousal.

- If you have difficulty in falling asleep or tend to have disturbed sleep in the night, then stop sleeping in the afternoons. This is believed to be a useful adjunct in managing stress.
- Carbohydrates in diet tend promote sleep. So, have high carbohydrate items for dinner (chapatti, rice, vegetables, fruits, pudding, etc.).
- Undertake brisk exercise in the morning.
- Keep a regular sleep schedule - go to bed and get up roughly at the same time.
- If, on some odd occasion, despite all the above measures, you are still not able to get sleep, then do not try to “force” sleep by tossing and turning in the bed. Get up, sit down with a light reading and relax till the time you feel like dozing off.

**Practice “assertiveness” skills** : Assertiveness does not mean being aggressive. The former is a very good quality, while the latter damages the personality and the social support systems. Assertiveness is the honest expression of what you feel and want from others, without trying to force them to give it. Assertive behaviour needs to be developed gradually and carefully. It is particularly useful when dealing with “difficult” people and the consequent stress. So, Speak up for yourself, for your needs and rights, while letting others to speak for themselves; and, protest, maybe politely but definitely, against unfair treatment or unjustified criticism. Also develop the quality of saying “NO”, maybe politely, when you feel that a particular task or favor being asked of you is unjustified or beyond your capabilities.

**Practice “Relaxation Techniques”** : There are certain proven techniques, which, if practiced for just 15 to 20 minutes a day, will help control stress related tension. These include

**Abdominal Breathing (Diaphragmatic breathing)** : To undertake abdominal breathing, sit comfortably, with your back upright. Place your left hand on the chest and right hand on the abdomen. Now, breathe in slowly, through the abdomen, so that the abdomen expands, but the chest should not expand. You can come to know of this by noticing your hands - if you are breathing through your abdomen, your right hand will rise but the left hand will move only very little. Now, gently exhale as much air as you can by slowly contracting your abdomen but not your chest. Once again, your left hand should move very little, while the right hand goes down perceptibly. Practice abdominal breathing for 4 to 5 minutes at any fixed time of the day. In addition, try breathing that way when faced with (or immediately after) a stressful situation.

**Progressive, Deep Muscular Relaxation** : For practicing this technique, you can either lie comfortably on your back, or else, sit in a chair. Begin by taking a slow and deep breath. At the same time, lift your heel a few inches off the ground and extend your legs, pointing your toes towards the knees, thereby tensing your thigh muscles and stretching your calf. Hold in this position for a count of seven. Now inhale deeply. Contract the muscles of your right arm and raise the arm by a few inches. Hold in this raised position for a count of seven, then let it fall down, limp. Relax for a few seconds, then repeat

the same procedure with the left arm. Finally, gently roll your head from side to side and allow your neck to relax. Now inhale and tense up all the muscles of your face, including those of jaws, eyelids, cheeks, lips and forehead. Keep them squeezed for a count of seven, then let them go limp, let the jaw drop down and slowly exhale.

**Spiritual Practice and Meditation** : Engagement in spiritual practice in various forms has been shown to have a strong role in both, preventing the stress response in an exaggerated fashion, as well as for coping up with a deleterious stressful situation. The important methods of spiritual practice relevant to stress management are :

**Praying** : Praying, from the stress management point of view, is like “connecting” us to a higher form. It reinforces our confidence and strengthens us with the feeling that we are not alone and that there is some higher power on which we can bank upon. This hope and confidence leads to release of certain hormones / chemicals in our body which strengthen the physiological functioning of various organ systems. It would be worthwhile devoting at least a few minutes once or twice a day for praying.

**Meditation** : The soothing physiological and psychological benefit of meditation is well known. Meditation essentially means “concentrating or focusing attention on an object and shutting off the mind to all other external thoughts”. Sit down in a comfortable position - in a chair, relaxed, hands on the lap or on the ground, cross - legged. Concentrate on a predecided sound or image and remove any other thought that comes to the mind for the next few minutes that you are practicing meditation.

**Yoga** : There is enough evidence to indicate that Yoga is a powerful strategy for coping up with stress. An ancient Indian practice, Yoga is essentially a way of life. In general, try to practice Yoga daily or at least on 4 to 5 days in a week. It is not necessary to do complicated stretching exercises but even simple ones like a combination of sarpa - asana (Cobra posture), dhanur - asana (Bow pose), Head rotation, shoulder rotation and shava - asana ( Corpse pose) are pretty good.

### Emotion Focussed Coping

Our discussion so far has been directed at preventive measures and on development of coping resources. However, in anyone's life, there are some inevitable difficult situations. Growing old, suffering from chronic diseases, losses in business, etc., are just a few examples of human predicaments that we must learn to live with. These are the situations where it would be wise for us to use the “Emotion Focused Coping” rather than the problem focused approach. The important components of emotion focused approach are listed below.

**Accepting the inevitable** : Once it appears that the problem is there to stay, it is best to accept the same. For those who have developed adequate coping resources, as faith in God, this becomes easier. One must draw lesson, in such times, from the prayer of St Assisi, which says “God, give me the courage to change what I can, the strength to accept what I can't and the wisdom to distinguish between the two”.

**Don't discount the importance of hope** : Hope is a powerful ally in dealing with stress. The hope that things will improve



goes a long way in reducing stress.

**Suppress the distressing thoughts** : If you have done what all can be done, then further mental processing of the problem can only make matters worse. In such situations it is better to suppress our thoughts to control the resultant emotional responses.

**Discharging painful emotions** : We often become unhappy or even sick, due to bottled up emotions. Disclosing our feelings to a near one, or to a Doctor, often provides much relief. Another method is to write a personal diary, often referred to as “therapeutic writing”. Maintaining a stiff upper lip may be a part of the self created “strong personality” for most of us, but it does not seem wise from what we know of the human emotions.

### The Early Signs of Stress

Early recognition of stress is important. The first step is being alert to the signals of stress emanating from our body and mind. Quite often your near and dear ones notice them and it would be worthwhile to occasionally ask them if they have noticed such signs in you. The signs of stress are listed below.

- Headache, pain in neck, backache, aches in muscles and joints, fatigue and exhaustion, vague symptoms of indigestion, sleep problems (either difficulty falling asleep or getting up in between sleep)
- Feeling of being distressed / harassed, decreased interest in life and decline in cheerfulness.
- Deterioration of inter - personal relationships, whether at home, workplace or in social circles, increased “tiffs”, frequent bouts of irritability and social withdrawal.
- Deterioration of performance, difficulty in concentration, forgetfulness, increased errors, reduced efficiency and decreased motivation.
- Initiation or increase of substance abuse (alcohol, tobacco etc.).
- Excessive and frequent eating of food / snacks or avoidance of food and gain or loss of body weight in a short span of time.

Medical Officers should emphasize on the clientele that these warning signs are subtle and may be easily missed, unless one is very observant. For noticing them, one will have to search for these signs and deliberately listen to one’s mind and body. One may have to ask your near ones if they noticed these signs in him. If such signals are noticed, they should not be dismissed lightly. Serious action should be taken by bringing all the coping resources (as discussed earlier) into play. Secondly, the clientele should be assured to consider the Doctor as their best friend; to talk to him about their problem. One must realize that stress can occur to anybody. It is no disease to be shy about. It is just a reaction of one’s body to the adversity in the environment. So, even if there is a slight doubt, one should talk to the family members, friends and with the Doctor.

### Summary

The WHO expert committee defines mental health as ‘the capacity in an individual to form harmonious relation with others and to participate in or contribute constructively to change in the social environment’. Worldwide, the major

psychiatric conditions are neurotic disorders, stress related and psychological (somatoform) problems followed by anxiety disorders, mood disorders, mental retardation and schizophrenia. In India, mental morbidity in various parts of the country suggest prevalence rate of 58.2 per 1000. The major psychiatric conditions contributing to this morbidity are Neuroses, Affective Disorders (including Mania, Manic Depression and Depression), Mental retardation and alcohol & drug addiction and Schizophrenia.

Epidemiological features of Major Psychiatric disorders include Schizophrenia, which is a chronic disorder with episodes of florid psychotic symptoms. Mean age of onset is higher in females; otherwise rates are equal in both males and females. Schizophrenia also shows definite evidence of organic brain damage. In Bipolar disorders history of both depressive and manic episodes is there; manic form occurs mainly among the younger age group, while the depressive form is commoner among older age group, women and those from higher socio-economic status form a higher proportion of bipolar disorder. In Depressive Disorders, core symptom is a disturbance of mood; illness usually starts in twenties or thirties. Drugs in the form of tricyclic antidepressants, selective serotonin inhibitors (SSIs), along with psychosocial therapy, are effective in acute episodes and in increasing the remission period. Anxiety disorders include Post Traumatic Stress Disorder (PTSD) and Obsessive - Compulsive Disorder; triggers are travel, crowded places, elevators, etc. Interventions with Benzodiazepines and psycho-social therapy are effective for treating the condition.

Issues of Public Health, Prevention & Control include organizing Mental Health care as part of Public Health services i.e. a shift to holistic mental health care, preventive, promotive as well as early curative, and that too, not for individuals but for the entire community. Prevention consists of Primary prevention that includes optimum socio-economic environment, Socio-legal actions, Community education, and Specific protections such as Iodisation of salt, Rubella vaccine, administering folic acid and application of the science of genetics at the community level. Secondary Prevention would comprise of identifying the earliest symptoms / expressions of stress and mental illness and early intervention with drug / psycho-therapy in risk groups like high pressure jobs, inmates of delinquent homes and prisons, post natal women and School children showing learning difficulties. Ensuring that patients take their drugs and other treatment, educating the patient and the family about the side effects of the treatment, and requirement of psycho-emotive and vocational / financial support to the patients would form part of Tertiary Prevention.

### Study Exercises

**Long Question** : Discuss the epidemiology of major mental health problems in India, and the possible approach towards their prevention and control.

**Short Notes** : (1) Community based mental health programme (2) Graded (tier) system of mental health services (3) Stress management techniques

### MCQs & Exercises

1. Out of all cases of Depression, what percentage is formed by neuro - psychiatric illnesses ? (a) 20 - 30% (b) 30 - 40%

- (c) 40 - 50% (d) 10 - 20%
- The Prevalence rate of Mental Morbidity in India is :  
(a) 25.8 per 1000 (b) 58.2 per 1000 (c) 107.6 per 1000 (d) None of the above
  - All of the following are major symptoms of Schizophrenia except : (a) Obsessions (b) Hallucinations (c) Delusions (d) Cognitive symptoms
  - Mean onset of age for schizophrenia is higher in which sex: (a) Males (b) Females (c) Equal in both sexes
  - Neurotic, stress related and somatoform disorders includes which one of the following : (a) Depression (b) Obsessive compulsive disorder (c) Eating disorder (d) Mental Retardation
  - Which has a higher risk of developing schizophrenia - Hereditary or Upbringing?

#### Short Questions

- Is Organic damage seen in Schizophrenics?
- Commonest neurological disease that occur in conjunction with schizophrenia?
- Which form of bipolar disorder is more common in younger age group?
- What all interventions can be used in anxiety disorder?
- What are the levels of care for assessment of mental health problem in a community?
- Who forms the first level of graded (tier) system for providing mental health services?
- Ensuring that patients take their drugs and other treatment as advised without any loss of compliance is which level of prevention?

**Answers :** (1) b; (2) b; (3) a ; (4) b; (5) b; (6) Hereditary ; (7) Yes (Enlargement of lateral ventricles); (8) Epilepsy;

(9) Mania; (10) Benzodiazepines and psycho - social therapy; (11) The levels are : Level - 5 : patients who are likely to be requiring admission to psychiatry beds at district hospital or specialized centres; Level - 4 : patients attending psychiatric services outside the hospitals, as OPD or day care subjects; Level - 3 : Patients presenting with conspicuous psychiatric morbidity at the Primary health care / CHC level; Level - 2 : patients who report with "hidden" psychiatric morbidity at the primary care/CHC level; Level - 1 : Persons with psychiatric morbidity but who are hidden in the community; (12) Paramedical Workers; (13) - Tertiary Prevention.

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Injuries have traditionally been defined as damage to a person caused by an acute transfer of energy (Mechanical, Thermal, Electrical, Chemical or Reduction) or by the sudden absence of heat or Oxygen. Unintentional injuries consist of that subset of injuries for which there is no evidence of predetermined intent. The cause-specific intentional injuries for which the World Health Organization routinely analyses & publishes data include road traffic injuries, domestic injuries that include poisonings, falls, burns and drowning (1). Besides these, another major group of injuries, the occupational injuries are not discussed in this chapter. Serious injuries affect more than the individual : They can destroy families and devastate communities as seen in recent earthquakes, hurricanes, and

tsunamis. These events can leave individuals and societies with enormous medical costs, extensive rehabilitation needs, major lifestyle adjustments, and depression losses that cannot easily, if ever, be recouped (2). The WHO Glossary of Health Care Terminology defines accident as - 'An unexpected, unplanned occurrence, which may involve injury'.

#### Burden of Unintentional Injuries

Worldwide, unintentional injuries accounted for more than 3.5 million deaths in 2001, or about 6 percent of all deaths and 66 percent of all injury deaths. More than 90 percent unintentional injury deaths occurred in low-and middle-income countries, accounting for around 7 percent of all deaths in these countries. More than 90 percent of DALYs that were attributed to unintentional injuries occurred in these countries, accounting for about 8 percent of all DALY in these countries (1).

Worldwide, the number of people killed in road traffic crashes each year is estimated at almost 1.2 million or an average of

3242 people every day, while the number injured could be as high as 50 million - the combined population of five of the world's largest cities (3,4). The road traffic death toll represents only the "tip of the iceberg" of the total waste of human and societal resources from road injuries. In 2004 road traffic crashes, which ranked as the 11th leading cause of death and accounted for 2.1% of all deaths globally but on current trends, by 2020, they are likely to become the third leading cause of disability-adjusted life years lost (5).

India has the second largest highway and road networks with an estimated total road length of 24,56,647 Km. As per the Institute of Road Traffic Education, New Delhi, the total number of registered motor vehicles in 2004 were 67million, while the total number of road traffic accidents that year were estimated to be 4.30 million with 0.92 million fatalities and 4.64 million injured. Over 1,275,000 persons are grievously injured each year and by 2050 there will be an estimated 267 million vehicles on Indian roads, accounting for more than 10% of worldwide road traffic accidents. In economic terms, the cost of road crash injuries is estimated at roughly 1% of Gross National Product (GNP) in low-income countries, 1.5% in middle-income countries and 2% in high-income countries. The direct economic costs of global road crashes have been estimated at US \$ 518 billion, with the costs in low-income countries; estimated at US \$ 65 billion. Road crashes not only place a heavy burden on national and regional economies but also on the number of years lost from premature death with the loss of health from disability (5).

### A Causal Model for Injuries

Unintentional injuries and accidents are caused by multiple factors. The traditional epidemiological paradigm of Agent, Host, and Environmental factors that in combination contributes to the incidence of disease best helps to determine & understand the causes of accidents and injuries. This paradigm considers each factor in relation to the time of injury - that is, factors operating before, during, and after the injury or accident (1). While in the traditional epidemiologic causal model for infectious diseases, microbes are the 'agent' of infection and disease; in case of traumatic injury, the '*agent*' of the injury is energy, which could be in many forms including mechanical, electrical, chemical, and thermal. An example of an agent-host interaction in the injury model is a motor vehicle crash in which the energy exerted on the individual is mechanical (2).

The transfer of energy to a host (accident victim) is the necessary and sufficient cause of injury, but this transfer is affected by many other factors. Energy can be transferred to a host through vehicles or 'vectors'. Vectors in this context are animate, such as another human being or an animal. For many injury causes, both vehicles and vectors are involved in energy transfer. For example, when an automobile crash occurs, the vehicles are the automobiles and the vectors are the drivers (2).

The '*environment*' refers to places where energy can be transmitted to a host, and is influenced by many physical, social, economic, demographic, and cultural factors. Modifying the environment can reduce the potential for energy transfer. Characteristics of vehicles and vectors can be modified to reduce the likelihood of causing an injury or to reduce the

amount of energy transmitted. Only energy transmitted beyond the host's tolerance causes an injury, and therefore, not all exposures to energy result in noticeable injury. Humans have natural resistance to energy transfer, which depends on many factors. Intrinsic factors such as age and pre-existing medical conditions can reduce resilience to energy transfer, as can extrinsic factors such as fatigue and alcohol use. Resilience can be increased through the use of protective devices or education to avoid potential injury causing situations; thus the causal model depicts the many potential avenues for intervention (2). The Haddon matrix, which has been discussed later' was initially developed to address the problem of RTIs only but it is also applicable for understanding multitudes of factors that may play role in any causal injury pathway (1).

### Causes of Injuries

As described above in the causal model for Injuries, unintentional injuries and accidents may be caused by multiple factors and the etiological factors causing accidents may be summarized under the following headings :

- Human Factors
- Environmental Factors
- Vehicular Factors

**Human Factors** : Some of the important human factors which may influence road traffic injuries include, age, sex, medical conditions, fatigue, inadequate personal protection and psychological factors. Over 50% of the global mortality due to road traffic injury occurs among young adults aged between 15 and 44 years. In 2002, males accounted for 73% of all road traffic deaths, with an overall rate almost three times that of females. Fatigue, chronic sleepiness of the drivers, long work hours, and exhaustion all contribute to increase the risk (1). Failure to use helmets, use of non-standard helmets or improperly secured helmets is a factor seen in number of Asian countries, including India. This is also a risk factor for increased injury severity among bicyclists, but still there are no stringent laws in most developing countries towards this. Failure to use seat belts is too a significant risk factor associated with increased injury severity among vehicle occupants, still many low-middle income countries do not have such legal requirements (8).

The following psychosocial factors may also play an important role :

- Risk Taking behaviour
- Lack of Experience
- Impulsiveness
- Defective Judgment
- Delay in Decisions
- Aggression
- Poor Perception
- Alcohol intake

**Environmental Factors** : The environmental factors may be vehicle related factors, road related factors, and bad weather. The hallmark of transportation systems seen in many developed countries which are technical aspects of planning, highway design, traffic engineering & traffic management required for a level of heterogeneity in traffic are absent in most of the low middle income countries (1). Road and vehicle-related factors like traffic passing through residential areas, conflict between



pedestrians and vehicle, schools located on busy roads, lack of median barriers are also important risk factors for causing road traffic accidents and injuries. Roadside hazards like trees, poles, and road signs may contribute to between 18 to 42 percent of road crashes and increase the injury severity (1). Some of the road related risk factors are as under :

- Inattention to safety in planning and designing
- Lack of remedial action at high-risk crash sites
- Safety defects in existing roads
- Poor lighting
- Transport, land use and road network planning

**Vehicle Factors :** The increasing volume of traffic is one of the main factors contributing increase in RTIs in low middle-income countries. In some of these countries, this growth has been led by an unprecedented increase in motorized two wheeled vehicles, one of the least safe forms of travel. The rapid growth in motor vehicles in many of these countries has not been accompanied by improvements in facilities for these road users or by facilities that respond to the continued predominance of non-motorized traffic. Important risk factors in relation to vehicles are as under :

**Vehicle Speed :** There is a strong relationship between the increase in vehicle speeds and increased risk of crash and injuries, both for motor vehicle occupants & for vulnerable road users, specially pedestrians, a relationship which is particularly true in low middle income countries, where speed is listed as the leading cause of road traffic crashes, accounting for upto 50 percent of all crashes. Increase in speed of 1 km per hour is associated with 3 percent higher risk of crash. In a crash with an impact speed of 80 km per hour, the likelihood of death is twenty times as compared to a speed of 32 km per hour (6).

**Pedestrians :** They have a 90 percent chance of surviving car crashes at vehicle speeds of 30 km per hour or below and less than 50 per cent at vehicle speed of more than 45 km per hour. The vehicle related factors may be summarized as under :

- Motorized two-wheeled vehicles
- Mixing of Motorized and Non-motorized traffic
- Over Speeding
- Pedestrians and cyclists
- Lack of in-vehicle crash protection
- Non-use of crash helmets by two-wheeled vehicle users
- Non-use of seat belts and child restraints in motor vehicles
- Roadside objects
- Poor maintenance of vehicles
- Increasing vehicle crowd on roads
- Overloaded vehicle
- Rapid motorization

**Precipitating Factors :** Following are some of the important precipitating factors for RTIs :

**Alcohol Consumption :** The role of alcohol consumption by the drivers has been confirmed unequivocally in increasing the risk of road accidents (1). It is an important factor influencing both - the risk of an accident and the severity of injuries due to it.

Data from some of the low-middle income countries has confirmed that drivers had consumed alcohol in 33 to 69 percent of crashes in which drivers were fatally injured and in

8 to 29 percent of crashes in which they sustained non-fatal injuries (7). Alcohol leads to poor judgment, slowed reaction time, loss of concentration and impaired vision.

Blood Alcohol Concentration (BAC) of 80 mg/dl doubles the risk of crash while BAC 100 mg/dl increases the risk of crash to three times. Recent analyses suggest that the risks associated with the blood alcohol levels of 80 mg/dl are higher than that was originally thought. This has led many countries to reduce legal blood alcohol content limits to 50mg/dl (5).

**Hand-Held Mobile Telephones :** Use of hand - held mobiles telephones, and inadequate visibility of vulnerable road users, all of which are equally likely increase the risk of road accidents in both the developed & developing countries (8). Hand-held mobile telephones increase the driver's reaction time by 0.5-1.5 seconds. Drivers who use mobile telephones while driving face a risk of a crash four times higher than those who do not use them (5).

**Social Pressure :** Social pressure like traveling in groups especially among the young who have risk taking behaviours may act as a precipitating factors and use of stolen vehicles are also known risk factors for road crashes (5).

**Demographic factors :** Some of the precipitating risk factors influencing exposure to risk, which may be categorized as demographic factors are enumerated below :

- Increased need for travel
- Choice of less safe forms of travel
- Young drivers and riders
- Alcohol Medicinal and recreational drugs
- Driver fatigue
- Hand-held mobile telephones
- Inadequate visibility
- Pre-hospital factors
- Hospital care factors

## Unintentional Injuries Other Than RTIs

**Fall Related Injuries :** The risk factors for fall-related injuries, in most of the low and middle income countries, especially hip fractures are consistent with the risk factors identified in the developed countries, which include low bone density; poor nutritional status and low body mass index; low calcium intake; co morbid conditions like hypertension and diabetes; low levels of physical activity; poor cognitive function and vision; environmental factors affecting balance or gait; family history of hip fracture and alcohol consumption. Falls usually in and around the home, with significant proportion being associated with fall from heights including rooftops and trees are common in younger people in developing countries. However falls other than from heights predominate, and are frequently related to engagement in vigorous levels of physical activity (1).

**Burn Related Injuries :** Despite focus of most available WHO's data is on burn related injuries to fires, many surveys suggest that scalds from hot water may be equally or even more important causes of burn-related injuries. However in China and particularly India, fire related injuries clearly outweigh scald-related injuries. Overall women are at greater risk of fire related injuries than men. Environmental risk factors that have been identified include lack of water supply, storage of



inflammable substances at home, cooking equipments in kitchen in the reach of children, and housing that is located in slums and congested areas. Protective factors include presence of a living room, better maternal education (1).

**Risk Factors for Drowning :** Most drowning incidents in low middle income countries are associated with every day activities near water bodies, including rivers, wells, and ponds; as against drowning incidents in developing countries being commonly associated with recreation or leisure activities. Men account for a higher proportion of drowning incidents than women, and children aged one to four and young people appear to be at greater risk. Surveys also indicate that those living in rural areas are at a greater risk than their urban counterparts, probably indicating greater exposure to unprotected water surfaces. Most adult drowning incidents also appear to be associated with positive blood alcohol tests. Socio-demographic risk factors & risk factors associated with proximity to water bodies have been seen to cause a higher incidence of drowning in younger children. The risk of drowning in children having a well at their home was seven times higher as against those without one at their homes (1)

## Prevention and Control

### Injuries and the Public Health Approach

Injury prevention is well suited to the public health model, which advocates the following :

- A cycle of surveillance
- Risk factor identification
- Intervention implementation
- Evaluation.

Injury surveillance provides an understanding of the incidence, trends, and magnitude of injuries, identifies specific populations that have a higher incidence of injuries. Surveillance can help identify injuries on which to focus prevention efforts. Priority can be given to the most prevalent injury causes, those that show an increasing incidence, or those that affect a population of special interest, such as children.

The process of risk factor assessment helps identify individual or community factors that increase the risk for injury. Risk factors can be intrinsic, such as age or gender; behavioural, such as drinking and driving; or environmental, such as a poorly maintained roadway. Injury events are usually influenced by many risk factors. An intervention strategy is defined following careful surveillance and risk factor assessment. However, many interventions are implemented in the absence of such information.

An evaluation of the intervention strategy should accompany its implementation. A comprehensive evaluation should identify whether the program was implemented completely (process evaluation), determine if the intervention led to the desired change (impact evaluation), and finally, determine if the injury outcome of interest was achieved (outcome evaluation) (2).

### Approaches to Injury Control

Unlike many chronic diseases, the agent of injury is usually known, and the mechanism of energy transfer from reservoir to host can be described with great detail. With the exception of some poisonings and burns, injuries usually occur immediately

after exposure and have very short 'latent' periods. Within the framework of the public health model (Fig. 1), the primary focus of injury control is to identify sources of energy forces, which cause injury, to define mechanisms of human exposure, and to identify precisely where interventions (countermeasures) may be introduced in the 'natural history' of injury. Public health has defined three levels of prevention.

- Primary prevention
- Secondary prevention
- Tertiary prevention

**Primary prevention** aims to prevent the event, which causes injury by eliminating the mechanisms of energy transfer or exposure. Traffic safety laws, which prevent automobile crashes, fences around swimming pools, which prevent submersion and drowning, locking devices on guns, and safety caps on poisonous substances are all examples of primary prevention, which reduce or eliminate the chance of exposure. The goal of **secondary prevention** is to eliminate injuries or reduce injury severity once a potential injury-producing exposure has occurred. Motorcycle and bicycle helmets, seat belts, life vests, and bulletproof vests are examples of secondary prevention. **Tertiary prevention** acknowledges that an injury has occurred, and aims to reduce the consequences of the injury. These efforts can include emergency response, trauma care, social work, and physical, occupational, and speech therapy.

Specific injury prevention strategies can be divided into following two very broad groups based on need for host actions.

- Passive intervention
- Active intervention

**Passive intervention** requires no input or action by the host and is usually accomplished by modifying the agent, vehicle, vector, or environment. Modifications in car design to improve brakes or increase energy absorption by the vehicle frame are two examples. **Active intervention** requires that the host take some type of action for the intervention to work. Seat belts and helmets are examples of active intervention.

One framework for conceptualizing the many approaches to injury prevention is termed the "4Es," which consist of the following :

- Education
- Environmental modification
- Enforcement
- Engineering

Education refers to efforts using educational messages to increase safe behaviour among the intended audience. Of the four approaches, education is perhaps the most difficult to implement. Successful educational messages must be clear, appropriate for the audience, and must be periodically repeated to maintain behaviour change.

The effectiveness of environmental modification has been demonstrated through reduction in motor vehicle crashes following changes in the driving environment. Examples include skid-free road surfaces, cross slopes on curved roadways in areas with heavy rainfall, and separation barriers on freeways and two-way roads. Environmental modifications as simple as removing trees and adding guardrails can reduce

traffic crashes in some areas by as much as 75%. Another example of successful environmental modification includes the introduction of pool-fencing barriers.

Enforcement refers to legislative regulations and the enforcement of these activities. The introduction of a mandatory helmet use law in California in 1992 led to a decrease in motorcycle fatalities of over 35% and a decrease in severe head injuries among injured motorcycle riders of over 50%. Another example of successful legislation has been the implementation of blood alcohol limits for drivers.

Engineering advancements have been highly successful in reducing injuries. The most notable examples are the seat belt and airbag, which have been attributed with decreasing injuries in frontal collisions by over 50%. Many effective prevention measures have been introduced to motor vehicles without the consumer's knowledge, including improvements in brakes, collapsible steering columns, and stronger head rests.

**The Haddon Matrix** : One of the most successful theoretical approaches to injury prevention is the Haddon Matrix (Table - 1), developed by Dr William Haddon in the 1970s. The Haddon Matrix identifies three phases in an injury event and links approaches to prevent or reduce injury in each phase. This matrix was developed for application to countermeasures for highway safety but continues to be a useful theoretical framework for many types of injuries. The Haddon Matrix divides the timing of the injury event into three phases : pre-injury, injury, and post injury. In the pre-injury phase, the goal is primary prevention to eliminate any energy transfer to the host. Additional examples include fences around swimming pools, which prevent submersion; trigger locks on guns, and safety caps on poisonous substances.

In the injury phase, which represents secondary prevention, the goal is to eliminate or reduce the amount of energy absorbed by the host once an energy transfer has occurred. Post-injury interventions, also called tertiary prevention, reduce the consequences of the injury once an injury producing energy transfer has occurred. The Haddon Matrix categorizes interventions in each injury phase into those that affect the host, the vehicles or vectors in the causal pathway, and the environment. The environment is often separated into physical and socioeconomic components.

The third dimension introduces value criteria to consider when choosing an intervention strategy, and includes such elements as anticipated effectiveness, cost, freedom, equity, stigmatization, preferences, and feasibility. These value criteria can be applied to interventions in each cell of the original

Haddon Matrix to determine which approach is best suited for the specific problem. The principles of injury prevention based on the Haddons Matrix are :

- To reduce exposure to risk
- To prevent road traffic crashes from occurring
- To reduce the severity of injury in the event of crash
- To reduce the consequences of injury through improved post-collision care

### Public Health Issues in Prevention of Road Traffic Injuries

The motto-‘Safer Roads, Safer Vehicles, and Safer Systems’ is popular with many of those who are working to reduce RTIs. A recent augmentation to this motto is ‘appropriate transport and land-use policies in managing exposure to risk of an RTI (8). Managing exposure to risk involves strategies aimed at reducing motor vehicle traffic; making greater use of safer modes of transport; minimizing exposure to high risk situations like giving priority to higher occupancy vehicles or to vulnerable road users, speed restrictions, increasing the legal age for operating motorized two wheeler from 16 to 18 years and use of graduated drivers license system to be strictly enforced (1).

**Safer Roads** : Traffic calming measures are among the strategies recommended for incorporating safety features into road design. Safety awareness in planning road networks, safety features in road design, and remedial action in high risk crash sites like making provision for slow moving traffic and vulnerable road uses, median barriers, street lighting. Speed bumps, use of speed cameras and automated speed enforcements virtually eliminate speeding (1,9).

**Safer Vehicles** : Improving the visibility of vehicles, providing automatic daytime running lights and incorporating crash protective design into vehicles, including installing seat belts help to reduce RTIs (1). Simple strategies like ensuring regular maintenance of older vehicles, removal of vehicles in poor condition from the roads, as well as vehicle licensing and inspection are very cost effective measures (1, 8).

**Safer People** : Intervention strategies aimed at improving road user behaviour focusing on introduction and enforcement of relevant legislations, like increasing fines and suspending driver's license can help to reduce RTIs and deaths (1). Setting and enforcing speed limits reduces RTIs by almost 34 percent. It is also seen that setting and enforcing legal blood alcohol limits and minimum drinking-age laws, using alcohol check points, and running mass media campaigns aimed at reducing drinking and driving also gives very gratifying results.

**Table - 1 : The Haddon Matrix**

Phase	Human	Vector (Vehicles)	Physical Environ	Socioeconomic Environ
Pre-Injury	Alcohol Intoxication	Instability in utility vehicles	Poor visibility of road hazards	Lack of knowledge regarding injury risks
Injury	Low resistance to energy	Sharp or pointed edges/surfaces	Flammable building materials	Lack of enforcement of safety belt legislation
Post-Injury	Conditions affecting energy tolerance	Rapidity of energy reduction	Emergency medical response	Lack of funding for emergency medical Services and rehabilitation services

Mandatory seat belts and child restraint laws reduce vehicle occupant deaths and injuries by almost 25 percent (8). Both bicycle and motorcycle helmet use reduces head injuries among riders by upto 85 percent. Though education may be effective in increasing helmet use, the effect is greater when combined with legislation and enforcement (1).

Exposure to risk can be minimized by reducing the volume of motor vehicle traffic; encouraging use of safer modes of travel; minimizing exposure to high-risk scenarios; and placing restrictions. Salient points, under each heading, are summarized as follows :

***Reducing the volume of motor vehicle traffic may be achieved by :***

- Efficient land use
- Providing shorter & safer routes
- Trip reduction measures
- Providing better public transport facilities
- Pooling of vehicles
- Providing no private vehicle zones.

***Encouraging use of safer modes of travel :***

- Promotion of public transport
- Walking and cycling
- 'PARK & RIDE' facilities
- Higher fuel taxes to discourage private car use
- Financial incentives.

***Minimizing exposure to high-risk scenarios :***

- Restricting access to different parts of the road network
- Priority to higher occupancy vehicles
- Safe crossing facilities to pedestrians like under/ over passes

***Placing Restrictions :***

- Restrictions on speed
- Restrictions on engine capacity
- Increasing legal age
- Graduated driver licensing system

## **Legislations**

The important legislations on the subject in India are as under:

- Motor Vehicles Act, 1988 (59 of 1988)
- Central Motor Vehicles Rules, 1989
- The Carriers Act, 1865 (3 of 1865)

**Motor Vehicles Act, 1988 (59 of 1988)** : This Act governs the regulation of motor vehicular traffic through out the country; however the implementation of various provisions of this Act rests with the State Governments. This Act was last amended in the year 2001. This act includes the definition of the various categories of motor vehicles, tightening of norms for drivers transporting dangerous or hazardous goods, encouraging use of battery, CNG and solar energy as an auto fuel, bars alterations made in transport vehicle without prior approval of the Registering Authority. Vehicle safety standards are specified in Rules 93 to 127, year 2000. This act includes. The amendment made in the year 2001 brought the buses plying on CNG within the purview of State Transport Authority.

**Central Motor Vehicles Rules, 1989** : Central Motor Vehicles Rules, 1989 have been framed so as to have the guidelines for smooth flow of vehicular traffic. It has been frequently

amended keeping in view the changing requirements.

The amendments notified include, norms for construction, updating of specifications for various components of motor vehicles, provision of wearing of seat belts by passengers occupying the rear seats, norms relating to conversion of diesel vehicle to LPG mode.

## **Poisonings**

Suggested interventions to reduce exposure to occupational poisonings include better storage of poisons in terms of both the location and the nature of the storage vessels used. Specific interventions include storing poisons out side the home and above children's head height and reducing the use of secondhand household containers for example soda bottles along with introducing and enforcing legislation to prohibit the sale of poisons in such containers. The efficacy of child-resistant containers in preventing access to poisons has been demonstrated, and free distribution of child resistant containers is a highly effective means of preventing poisoning in children (1).

## **Fall Related Injuries**

Interventions proven effective for preventing falls in older people in developed countries include muscle strengthening and balance retraining that is individually prescribed at home by a trained health professional; home hazard assessment and modification that is professionally prescribed for older people with a history of falling; and multidisciplinary, multi-factorial health and environment risk factor screening and intervention programs, both for community dwelling older people in general and for older people with known risk factors. In relation to fall related injuries among young children, increased supervision of children and the importance of height reductions and appropriate ground surfacing to prevent playground injuries are effective and relevant (1).

## **Burn Related Injuries**

These interventions include separating cooking areas from living areas, including efforts to reduce the use of indoor fires for cooking, ensuring that cooking surfaces are at heights, reducing the storage of flammable substances in households, and supervising young children more effectively. The introduction, monitoring, and enforcement of standards and codes for and the wearing of fire retardant garments have also been proposed. Finally interventions directed at increasing awareness of burn prevention have been proposed, largely because of the success of safe community interventions involving a multitude of strategies (1).

## **Drowning**

Fencing domestic swimming pools, covering wells with grills, fencing nearby lakes or riverbanks, and building flood control embankments might be effective in reducing the risks of drowning.

## **Implementation of Prevention and Control Strategies**

Investments in the health sector to address specific problems are a critical indicator of political commitment, sectoral efforts, and priorities at the national and international levels. In some cases, investments are so low that they provide a useful reference point for assessing the returns on additional investments in the



future. Investments in preventing RTIs, which are responsible for the majority of the burden of unintentional injuries and about which much is known regarding effective interventions, even though such interventions have not been examined in the context of rigorously controlled studies in low -middle income countries, definitely need to be significantly enhanced (1).

Despite the global burden of RTIs, the levels of investment are pitifully small, largely because of a lack of awareness of the scale of the problem and a lack of awareness that interventions can prevent and reduce the levels of harm. As a consequence, the WHO document 'World report on road traffic injury prevention' of 2004, directs a number of recommendations at governments and communities in the hope that they will enable countries, particularly the low and middle-income countries, to begin a sustainable process that will eventually lead to the adaptation and implementation of effective preventive strategies. The recommendations include the following :

- Identify a lead government agency to guide the national road safety effort.
- Assess the problems, policies, and institutional settings relating to RTIs and the capacity or preventing RTIs in each country.
- Prepare a national road safety strategy and plan of action.
- Allocate financial and human resources to address the problem.
- Implement specific actions to prevent crashes, minimize injuries and their consequences, and evaluate the effect of those actions.
- Support the development of national capacity and international cooperation(5).

## Summary

Injuries have traditionally been defined as damage to a person caused by an acute transfer of energy (Mechanical, thermal, electrical, Chemical or reduction) or by the sudden absence of heat or Oxygen. Unintentional injuries consist of that subset of injuries for which there is no evidence of predetermined intent. The cause-specific intentional injuries for which the World Health Organization routinely analyses & publishes data include road traffic injuries, domestic injuries that include poisonings, falls, burns and drowning. The WHO Glossary of Health Care Terminology defines accident as - 'An unexpected, unplanned occurrence, which may involve injury'.

Worldwide, unintentional injuries accounted for more than 3.5 million deaths in 2001, or about 6 percent of all deaths and 66 percent of all injury deaths. Worldwide, the number of people killed in road traffic crashes each year is estimated at almost 1.2 million, or an average of 3242 people every day, while the number injured could be as high as 50 million. In 2004 road traffic crashes, which ranked as the 11th leading cause of death and accounted for 2.1% of all deaths globally but on current trends, by 2020, they are likely to become the third leading cause of disability-adjusted life years lost. In India in 2004, the total number of road traffic accidents that were estimated were 4.30 million with 0.92 million fatalities.

Unintentional injuries and accidents are caused by multiple factors. The 'agent' factor of the injury is energy, which could be in many forms including mechanical, electrical, chemical,

and thermal. Human factors include Fatigue, Chronic sleepiness of the drivers, long work hours and exhaustion, failure to use helmets, use of non-standard helmets or improperly secured helmets and psychosocial factors like risk taking behaviour, lack of experience, impulsiveness, defective judgment, delay in decisions, aggression, poor perception, alcohol intake etc. The environmental factors may be vehicle related factors, road related factors, and bad weather. The precipitating factors are alcohol consumption, hand-held mobile telephones, social pressure, and demographic factors like increased need for travel, choice of less safe forms of travel, young drivers and riders etc.

Injury prevention includes a cycle of surveillance, Risk factor identification, Intervention implementation and Evaluation. Injury surveillance provides an understanding of the incidence, trends, and magnitude of injuries, identifies specific populations that have a higher incidence of injuries. Surveillance can help identify injuries on which to focus prevention efforts. The process of risk factor assessment helps identify individual or community factors that increase the risk for injury. An intervention strategy is defined following careful surveillance and risk factor assessment. However, many interventions are implemented in the absence of such information. An evaluation of the intervention strategy should accompany its implementation. A comprehensive evaluation should identify whether the program was implemented completely (process evaluation), determine if the intervention led to the desired change (impact evaluation), and finally, determine if the injury outcome of interest was achieved (outcome evaluation).

Primary prevention includes Traffic safety laws, which prevent automobile crashes, fences around swimming pools, which prevent submersion and drowning, locking devices on guns, and safety caps on poisonous substances. The secondary prevention includes Motorcycle and bicycle helmets, seat belts, life vests, and bulletproof vests. Tertiary prevention includes emergency response, trauma care, social work, and physical, occupational, and speech therapy. Specific injury prevention strategies can be divided into Passive and Active interventions. Passive intervention requires no input or action by the host and is usually accomplished by modifying the agent, vehicle, vector, or environment. Modifications in car design to improve brakes or increase energy absorption by the vehicle frame are two examples. Active intervention requires that the host take some type of action for the intervention to work. Seat belts and helmets are examples of active intervention. One framework for conceptualizing the many approaches to injury prevention is termed the "4Es," Education, Environmental modification, Enforcement and Engineering.

The Haddon matrix was initially developed to address the problem of RTIs only but it is also applicable for understanding multitudes of factors that may play role in any causal injury pathway. It identifies three phases in an injury event and links approaches to prevent or reduce injury in each phase.

## Study Exercises

**Long Question :** Describe the various epidemiological factors causing Injuries and Accidents, and discuss the strategies for



Prevention and control of RTAs.

**Short Notes :** (1) Human factors causing Accident (2) Environmental factors causing Accident (3) Primary prevention for RTAs (4) Haddon Matrix

**MCQs :**

1. Worldwide, the number of people killed in road traffic crashes each year is estimated at almost (a) 0.2 million (b) 1.2 million (c) 2.2 million (d) 4.2 million
2. In India in 2004, the total number of fatalities in road traffic accidents were estimated to be (In million) (a) 0.02 (b) 0.92 (c) 2.92 (d) 4
3. The following is not a Precipitating Factor for causing RTAs (a) Alcohol Consumption (b) Hand-Held Mobile telephones (c) Social Pressure (d) none of the above
4. The legal blood alcohol content limit while driving is (a) 50mg/dl (b) 75mg/dl (c) 100mg/dl (d) 150mg/dl
5. The important legislation related to Accidents in India are (a) Motor Vehicles Act, 1988 (b) Central Motor Vehicles Rules, 1989 (c) The Carriers Act, 1865 (d) all of the above

**Answers :** (1) b; (2) b; (3) d; (4) a; (5) d.

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## Intentional Injuries (Including Inter-Personal and Domestic Violence)

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Injuries, with their resultant mortality, morbidity, disability and reduced quality of life are a major public health issue the world over. Very broadly, injuries can be classified into two broad groups, viz. "un-intentional" (accidental) injuries, in which there is no premeditation of the act causing the injury; these have been covered in detail in an earlier chapter in this section. The second group is "intentional" injuries which are due to pre-meditated and intended acts. Such intentional injuries, which are the subject for this chapter, can be further divided into the following categories (1) :

- Self directed violence in which the perpetrator is the victim (as, suicide).
- Inter-personal violence, which means violence inflicted on a person by another person or by a small group of individuals.
- Domestic (family) violence is a special type of inter-personal violence in which the perpetrators as well as the victim are members of the same family. Family violence

can be further subdivided into 3 groups, namely child violence, intimate partner violence (synonymous with couple violence) and elderly directed violence. The serious and extreme forms of couple violence are also referred to as "intimate terrorism" by some workers. In general, especially in context of developing countries, it is the female partner who is subjected to violence.

- Collective violence which is committed by larger groups as terrorists, militia groups, local political groups and communal frenzies.
- War related in which the defense personnel are subjected to violence due to declared war between states.

Violence has been defined by the WHO as "*The intentional use of physical force or power, threatened or actual, against oneself, another person or against a group or community that either results in or has a high likelihood of resulting in injury, death, psychological harm, mal-development or deprivation.*" (The word "intentional" as italicized in the definition discriminates violence from unintended injuries and accidents).

### Sources of Information Regarding Inter-personal Violence

It is important to obtain data which is complete as well as accurate, when addressing the public health concerns directed towards violence. This is quite a difficult proposition as compared to other disease conditions as IHD, TB or AIDS. One

would need to resort to multiple sources of information when addressing the public health issues related to violence.

The most widely used sources are from the health and criminal justice sectors. Coroner and mortuary reports, police records, death certificates and vital statistics records may be useful in this field of epidemiology. Health sector records may provide data regarding medical details of injuries, and the circumstances surrounding the attack. In developing countries, population based surveys, though costly and logistically difficult, may provide more comprehensive information regarding the epidemiology of violence, especially those cases which may not be reported to the health, police or legal sector.

Estimates based for the year 2001 indicate that approximately 1.65 million died globally due to violence. These included 1.5 million from developing and 0.15 million from developed countries. Out of these 1.65 million, 53.3% were due to suicide, 34% due to homicide and 12.7% were war related fatalities.

Risk factors for becoming a Victim or Perpetrator of Violence : Violence is an outcome of complex interactions among many factors. To explain this complex relationship of risk factors, Dahlberg and Krug (1) have proposed a model which classifies risk factors for violence at four levels : individual level, intimate relationship level, community, and societal levels, as follows :

**Individual Level** : (Biological and personal history factors that influence as how individuals behave). These include :

- Early psychosocial developmental experiences
- Demographic factors (young age, male sex, poor education, poor socio-economic status, and large family)
- Being a victim of childhood abuse and neglect
- Personality disorders / psychological problems
- Ill health / physical disabilities
- Alcohol or substance abuse problems
- Ownership of a weapon (legal or illegal)

**Relationship Level** : Relationship Level (among family members, intimate partners, friends and peers) - These include marital conflicts, association with friends who engage in violent or delinquent behaviour, poor parenting practices, conflicts among parents, and poverty in the household.

**Community Level** : Community Level (among neighborhood, schools and workplaces) - These include factors as high residential mobility, high unemployment levels, high population density, proximity to drug and substance trade, and inadequate victim care services.

**Societal Level** : These include broad factors that reduce inhibitions against violence, viz. rapid social changes, economic inequality, gender inequality, norms that encourage male dominance over females or of parents over children, poor

**Table - 1 : Preventive Steps at Individual Level**

Developmental stage			
<i>Age upto 3 years</i>	<i>Age 4 to 11 years</i>	<i>Age 12 to 19 years (Adolescence)</i>	<i>Adulthood (Age 20 years and above)</i>
<ul style="list-style-type: none"> <li>• Reduction in unintended pregnancies</li> <li>• Access to prenatal and post natal services</li> <li>• Treatment programmes for child witnesses of violence and victims of maltreatment</li> </ul>	<ul style="list-style-type: none"> <li>• Programmes against drug abuse</li> <li>• School based programs to prevent child maltreatment</li> <li>• Community based prevention of child sexual abuse</li> <li>• Training in safe handling of firearms / weapons</li> </ul>	<ul style="list-style-type: none"> <li>• Programmes against drug abuse</li> <li>• Educational incentives for at risk, disadvantaged students</li> <li>• Individual counseling</li> <li>• Academic enrichment programs</li> <li>• Residential programs in psychiatric or correctional institutions</li> <li>• School / college based violence prevention programs</li> </ul>	<ul style="list-style-type: none"> <li>• Incentives for post-secondary or vocational training</li> <li>• Services for adults abused during their childhood</li> <li>• Strict scrutiny and waiting period for weapon licensing / purchases</li> <li>• Treatment for child and intimate partner abuse offenders</li> </ul>

**Table - 2 : Preventive Steps at "Relationships' Level**

Developmental stage			
<i>Age upto 3 years</i>	<i>Age 4 to 11 years</i>	<i>Age 12 to 19 years (Adolescence)</i>	<i>Adulthood (Age 20 years and above)</i>
<ul style="list-style-type: none"> <li>• Home visit services</li> <li>• Therapeutic foster care</li> </ul>	<ul style="list-style-type: none"> <li>• Partnership programs between homes and schools to promote parental involvement</li> </ul>	<ul style="list-style-type: none"> <li>• Peer mediation and counseling</li> <li>• Temporary foster care programs for serious and chronic delinquents</li> <li>• Psychosocial counseling at familial level</li> </ul>	<ul style="list-style-type: none"> <li>• Programs to strengthen ties within families</li> <li>• Programs to strengthen ties to job</li> <li>• Relationship education and therapy</li> </ul>

**Table - 3 : Preventive Steps at Community Level**

Developmental stage	
<i>Children aged &lt; 11 years</i>	<i>Adolescents and adults aged 12 years and above</i>
<ul style="list-style-type: none"><li>• Community policing</li><li>• Emergency responses and trauma care improvements</li><li>• Health care providers trained in detection and reporting of child maltreatment</li><li>• Secure means of transportation of children to and from schools</li><li>• Child protection service programs</li><li>• Educational campaigns to increase awareness of child maltreatment</li></ul>	<ul style="list-style-type: none"><li>• Health care professionals trained in identification and referral of high risk youth and victims of sexual violence</li><li>• Improvements in emergency response, trauma care and access to health services</li><li>• Shelters and crisis centres for battered women and victims of elder abuse</li><li>• Mandatory arrest policies and strict laws for people indulging in intimate partner violence, child abuse and elder abuse; possibly public shaming of such persons</li><li>• Community policing</li><li>• Disruption of illegal weapons trade</li><li>• Coordinated community interventions and educational campaigns against interpersonal violence</li></ul>

**Table - 4 : Preventive Steps at Societal Level**

Developmental stage	
<i>Children aged &lt; 11 years</i>	<i>Adolescents and adults aged 12 years and above</i>
<ul style="list-style-type: none"><li>• Reduce violent content of movies, televisions, video games and internet sites</li><li>• Launch public information campaigns to promote pro-social norms</li><li>• Strengthen police and judicial system</li><li>• De-concentrate poverty</li></ul>	<ul style="list-style-type: none"><li>• Enforce strict weapons licencing policies to inhibit easy acquiring of weapons by people</li><li>• Reduce violent content of movies, televisions, video games and internet sites</li><li>• Create job opportunities for youth</li><li>• Reduce violent content of movies, televisions, video games and internet sites</li><li>• Launch public information campaigns to promote pro-social norms</li><li>• Strengthen police and judicial system</li><li>• De-concentrate poverty</li></ul>

law and order situations and poor governance, societal norms that support the use of excessive violence by police personnel against civilian citizens, socio-religio-cultural norms that support violence, availability of weapons among civilian population, and conflict-like situations.

### Preventive Strategies

Based on the ecological model of risk factors at four levels, as explained above, a model has been developed for violence prevention, which recommends preventive steps at the above mentioned four levels and according to the stage of developmental of individuals (1, 2) are shown in Table - 1, 2, 3 and 4 :

### Summary

Violence has been defined by the WHO as “The intentional use of physical force or power, threatened or actual, against oneself, another person or against a group or community that either results in or has a high likelihood of resulting in injury, death, psychological harm, mal-development or deprivation.” Injuries can be classified into two broad groups, viz., “un-intentional” (accidental) injuries and “intentional” injuries. Intentional injuries can be further divided into Self directed

violence, Inter-personal violence, Domestic (family) violence, Collective violence and War- related violence. The most widely used sources of information when addressing the public health issues related to violence are from the health and criminal justice sectors. Estimates based for the year 2001 indicate that approximately 1.65 million died globally due to violence. To explain the complex relationship of risk factors for becoming a Victim or Perpetrator of Violence, Dahlberg and Krug have proposed a model which classifies risk factors for violence at four levels : individual level, intimate relationship level, community, and societal levels. Based on the ecological model of risk factors at four levels, a model has been developed for violence prevention.

Preventive Steps at Individual Level includes Access to prenatal and post natal services, Community based prevention of child sexual abuse, Individual counseling and Treatment for child and intimate partner abuse offenders. Preventive Steps at “Relationships’ Level includes Therapeutic foster care and Relationship education and therapy. Preventive Steps at Community Level Community policing and Child protection service programs. Preventive Steps at Societal Level include reduction violent content of movies, televisions, video games and internet sites and steps to De-concentrate poverty.

## Study Exercises

### MCQs

1. A model which classifies risk factors for violence at four levels has been proposed by : (a) Watson & Crick (b) McMohan & Pugh (c) Ramazzini (d) Dahlberg and Krug
2. All of the following are preventive steps that can be taken to prevent violence at Societal Level, except (a) De-concentrate poverty (b) Create job opportunities for youth (c) Therapeutic foster care (d) Reduce violent content of movies, televisions, video games and internet sites
3. Violence which is committed by larger groups as terrorists, militia groups, local political groups is known as (a) Collective violence (b) Domestic violence (c) Inter-personal violence (d) Self-inflicted violence

4. High residential mobility, high unemployment levels, high population density, proximity to drug and substance trade are a few risk factors leading to violence on a (a) Individual level (b) Community level (c) Societal level (d) Relationship level

**Answers :** (1) d; (2) c; (3) a; (4) b.

### References

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## Chronic Obstructive Pulmonary Diseases

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Chronic Obstructive Pulmonary Disease (COPD) is a major cause of chronic morbidity and mortality throughout the world. Many people suffer from this disease for years and die prematurely from it or its complications (1). COPD is the fourth leading cause of death in the world, and further increases in its prevalence and mortality has been predicted in the coming decades (2,3). Furthermore, although COPD has received increasing attention from the medical community in recent years, it is still relatively unknown or ignored by the public as well as public health and government officials (4). COPD and asthma are the two chronic diseases with very different diagnoses and causes. However the treatments for these two different chronic respiratory diseases share similarities (1).

### Definition

Chronic Obstructive Pulmonary Disease (COPD) is the internationally preferred term encompassing chronic bronchitis and emphysema. By definition, COPD is a chronic, slowly progressive disorder characterized by airflow obstruction, which is often assessed by reduced pulmonary function as measured by simple spirometry and the presence of reduced ratio of the forced expiratory volume in one second (FEV1) divided by the vital capacity (VC). FEV1 less than 80% of the predicted value and FEV1/VC ratio below 70%, which does not change markedly over several months, is the recommended objective criteria for the same. Historically, the term 'Chronic bronchitis' was used to define any patient who coughed sputum on most days of at least 3 consecutive months for more than

2 successive years, provided other causes of cough have been excluded; while 'Emphysema' refers to the pathological process of a permanent destructive enlargement of airspaces distal to the terminal bronchioles. Although pure forms of these two conditions do exist, there is a considerable overlap in the vast majority of patients (5). Based on the current knowledge, a working definition of COPD is : 'Chronic Obstructive Pulmonary Disease (COPD) is a preventable and treatable disease with some significant *extra pulmonary* effects that may contribute to the severity in individual patients. Its pulmonary component is characterized by *airflow limitation that is not fully reversible*. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases' (4).

Asthma is characterized by chronic airway inflammation and increased airway responsiveness resulting in symptoms of wheeze, cough, chest tightness & dyspnoea. It is characterized functionally by the presence of airflow obstruction, which is variable over short periods of time or is reversible with treatment. It is not a uniform disease but rather a dynamic clinical syndrome, which has a number of clinical patterns. Patients with well-controlled asthma, who are asymptomatic, may have normal lung function tests between exacerbations but may have evidence of chronic airway inflammation and hyper responsiveness. By contrast, in some patients with chronic asthma, the asthma progresses, leading to irreversible obstruction of airways (5).

### Spiro Metric Classification of Severity

Spirometry is essential for diagnosis and provides a useful description of the severity of pathological changes in COPD. Specific spirometric cut-points are used for purposes of simplicity. A simple spirometric classification of disease severity into four stages is given below (4).



**Stage I** : Mild COPD- Characterized by mild airflow limitation ( $FEV_1/FVC < 0.70$ ;  $FEV_1 > 80\%$  predicted). Symptoms of chronic cough and sputum production may be present, but not always. At this stage, the individual is usually unaware that his or her lung function is abnormal.

**Stage II** : Moderate COPD- Characterized by worsening airflow limitation ( $FEV_1/FVC < 0.70$ ;  $FEV_1 < 80\%$  predicted), with shortness of breath typically developing on exertion and cough and sputum production sometimes also present. This is the stage at which patients typically seek medical attention because of chronic respiratory symptoms or an exacerbation of their disease.

**Stage III** : Severe COPD- Characterized by further worsening of airflow limitation ( $FEV_1/FVC < 0.70$ ;  $FEV_1 < 50\%$  predicted), greater shortness of breath, reduced exercise capacity, fatigue, and repeated exacerbations that almost always have an impact on patient's quality of life.

**Stage IV** : Very Severe COPD- Characterized by severe airflow limitation ( $FEV_1/FVC < 0.70$ ;  $FEV_1 < 30\%$  predicted or  $FEV_1 < 50\%$  predicted plus the presence of chronic respiratory failure).

(**Note** :  $FEV_1$  : Forced Expiratory Volume in one second;  $FVC$ : Forced Vital Capacity; respiratory failure : arterial Partial pressure of Oxygen ( $PaO_2$ ) less than 8.0 kPa (60 mm Hg) with or without arterial Partial pressure of  $CO_2$  ( $PaCO_2$ ) greater than 6.7 kPa (50 mm Hg) while breathing air at sea level).

### Natural History

COPD has a variable natural history and not all individuals follow the same course. However, COPD is generally a progressive disease, especially if a patient's exposure to noxious agents continues. Stopping exposure to these agents, even when significant airflow limitation is present, may result in some improvement in lung function and slow or even halt progression of the disease. However, once developed, COPD and its co morbidities cannot be cured and thus must be treated continuously. COPD treatment can reduce symptoms, improve quality of life, reduce exacerbations, and possibly reduce mortality (4).

### Magnitude of the Problem

COPD is a leading cause of morbidity and mortality worldwide and results in an economic and social burden that is both substantial and increasing. COPD prevalence, morbidity, and mortality vary across countries and across different groups within countries but, in general, are directly related to the identified COPD risk factors like prevalence of tobacco smoking, air pollution resulting from the burning of wood and other biomass fuels. Existing COPD prevalence data show remarkable variation due to differences in survey methods, diagnostic criteria, and analytic approaches.

The lowest estimates of prevalence are usually those based on self-reporting of a doctor's diagnosis of COPD or equivalent condition. Most national data show that less than 6% of the population has been told that they have COPD which reflects the widespread under recognition and under diagnosis of COPD as well as the fact that those with Mild COPD may have no symptoms, or else symptoms that are not perceived by individuals or their health care providers as abnormal

and possibly indicative of early COPD. By contrast, data from prevalence surveys carried out using standardized methods and including spirometry, it is estimated that up to about one-quarter of adults aged 40 years and older may have airflow limitation classified as mild to moderate COPD. The incidence of COPD in India is high. Over 13 million people are estimated to be suffering from it out of which 62 percent are estimated to be males (6).

The prevalence and burden of COPD are projected to increase in the coming decades due to continued exposure to COPD risk factors and the changing age structure of the world's population, with more people living longer, and thus reaching the age at which COPD normally develops (4). Despite the problems with the accuracy of the COPD mortality data, it is clear that COPD is one of the most important causes of death in most countries. The Global Burden of Disease Study has projected that COPD, which ranked sixth as the cause of death in 1990, will become the third leading cause of death worldwide by 2020. This increased mortality is driven by the expanding epidemic of smoking and the changing demographics in most countries, with more of the population living longer (7,8).

### Economic and Social Burden of COPD

COPD is a costly disease with both direct costs and indirect costs. The presence of COPD greatly increases the total cost of care for patients, especially when inpatient costs and professional medical care in their homes are considered. Since human capital is often the most important national asset for developing countries, the indirect costs of COPD may represent a serious threat to their economies (4).

In 1990, COPD was the twelfth leading cause of DALYs lost in the world, responsible for 2.1% of the total. Presently on a worldwide basis COPD dominates all other chronic respiratory diseases in adults accounting for 2 percent to more than 10 percent of lost disability adjusted life years (DALYs). According to the projections, COPD will be the fifth leading cause of DALYs lost worldwide in 2020, behind ischemic heart disease, major depression, traffic accidents, and cerebro-vascular disease. This substantial increase in the global burden of COPD projected over the next twenty years reflects, in large part, the continued high use of tobacco in many countries and the changing age structure of populations in developing countries (1,7,8).

As compared to the developing world, data from the developing countries is much scarcer. It is estimated that the burden of respiratory diseases in India that is attributable to indoor air pollution is between 1.6 million to 2 billion sick days per year(1).

### Risk Factors

As the understanding of the importance of risk factors for COPD has grown, so has the recognition that essentially all risk for COPD results from a gene- environment interaction. The salient risk factors of COPD are discussed as under (4).

**Tobacco Smoke** : Worldwide, cigarette smoking is the most commonly encountered risk factor for COPD. Cigarette smokers have a higher prevalence of respiratory symptoms and lung function abnormalities, and a greater COPD mortality rate than nonsmokers. The risk for COPD in smokers is dose-related. Age

at starting to smoke, total pack-years smoked, and current smoking status are predictive of COPD mortality. Passive exposure to cigarette smoke (also known as environmental tobacco smoke or ETS) may also contribute to respiratory symptoms (4). Smoking cessation has been associated with reduced morbidity from COPD. Within a few years of stopping smoking, the smoker's rate of decline of pulmonary function (FEV1) returns to the rate found in non-smokers, although little of the lost pulmonary function is regained (1). Some recent studies have also emphasized the strong familial risks associated with the development of COPD, with the incidence of disease in an individual who smokes and also has an affected sibling, being 4.7 times than that of the matched control (1,5).

**Indoor Air Pollution** : Wood, animal dung, crop residues, and coal, typically burnt in open fires or poorly functioning stoves, lead to very high levels of indoor air pollution. Almost 3 billion people worldwide use biomass and coal as their main source of energy for cooking, heating, and other household needs. Biomass fuels used by women for cooking account for the high prevalence of COPD among nonsmoking women in developing countries in parts of Asia, the Middle East and Africa. Indoor air pollution resulting from the burning of wood and other biomass fuels is estimated to kill two million women and children each year (1,4,5).

**Gender** : Most of the earlier studies showed that COPD prevalence and mortality were greater among men than women. Studies from developed countries show that the prevalence of the disease is now almost equal in men and women, which probably reflects changing patterns of tobacco smoking (4).

**Genetic Factors** : COPD is a polygenic disease and a classic example of gene-environment interaction. The genetic risk factor that is best documented is a severe hereditary deficiency of alpha-1 antitrypsin- 4 (4).

**Inhalational Exposures** : An individual may be exposed to a variety of different types of inhaled particles over their lifetime, which may contribute to the risk of COPD; but only tobacco smoke and occupational dusts and chemicals (vapours, irritants, and fumes) are known to cause COPD on their own. Tobacco smoke and occupational exposures also appear to act additively to increase the risk of developing COPD (4).

**Occupational Dusts and Chemicals** : Occupational exposures are an under appreciated risk factor for COPD. These exposures include organic and inorganic dusts and chemical agents and fumes (4).

**Outdoor Air Pollution** : The role of outdoor air pollution in causing COPD appears to be small when compared with that of cigarette smoking. However, air pollution from fossil fuel combustion, primarily from motor vehicle emissions in cities, is associated with decrements of respiratory function (4).

**Infections** : Repeated infections, viral and bacterial, may contribute to the pathogenesis and progression of COPD, and may also play a significant role in acute exacerbations. Newer infections as HIV infection has been shown to accelerate the onset of smoking-related emphysema (4).

**Nutrition** : Malnutrition and weight loss can reduce respiratory muscle strength and endurance, apparently by reducing both respiratory muscle mass and the strength of the remaining

muscle fibers. But the role of nutrition as an independent risk factor for the development of COPD is unclear (4).

## Prevention and Control

### 1. Primary Prevention

- Population education on causes and risk factors, and symptomatology, with particular focus on tobacco smoking and indoor/outdoor air-pollution, using all possible media.
- Comprehensive public health actions focused on reducing tobacco use including health education, legislative and legal measures, fiscal measures and social action. These would also include measures to protect against passive smoking.
- Legislative, legal as well as social measures to reduce outdoor air pollution especially from automobiles and industries.
- Educational, fiscal and promotive measures to reduce the use of biomass as fuel in domestic settings and converting to environmental friendly fuel as LPG.
- Specific protective measures in occupational settings as discussed in detail in the section on occupational health.
- General improvements in nutrition at the population level, particularly disadvantaged groups as the elderly, children, women and the low socio economic groups.

### 2. Secondary Prevention

- Training and retraining of health care workers especially at the primary care level for keeping a high diagnostic suspicion and diagnosing the disease at the earliest.
- Provision of diagnostic (especially spirometry) facilities at the PHC/CHC level and definitely at District Hospital Level.
- Equipping the primary health care level with required drugs and equipment, namely bronchodilators for long term management and inhaled bronchodilators, corticosteroids, antibiotics and oxygen for acute exacerbations.
- Surveys to find out magnitude of the problem.
- Periodic health examination especially among the individual worker and the elderly.
- Early diagnosis and Management of COPD** : Management of Mild to Moderate COPD involves the avoidance of risk factors to prevent disease progression and pharmacotherapy as needed to control symptoms. Severe and Very Severe COPD often require the integration of several different disciplines, a variety of treatment approaches, and a commitment of the clinician to the continued support of the patient as the illness progresses. In addition to patient education, health advice, and pharmacotherapy, COPD patients may require specific counseling about smoking cessation, instruction in physical exercise, nutritional advice, and continued nursing support. An effective COPD management plan includes four components; (1) Assess and Monitor Disease (2) Reduce Risk Factors (3) Manage Stable COPD and (4) Manage Exacerbations.

**Assess and Monitor Disease** : The Key Points in assessment and monitoring of COPD in a patient are :

- A clinical diagnosis of COPD should be considered in any patient who has dyspnoea, chronic cough or sputum production, and/or a history of exposure to risk factors

for the disease. The diagnosis should be confirmed by spirometry.

- For the diagnosis and assessment of COPD, spirometry is the gold standard as it is the most reproducible, standardized, and objective way of measuring airflow limitation. The presence of a post-bronchodilator  $FEV_1/FVC < 0.70$  and  $FEV_1 < 80\%$  predicted confirms the presence of airflow limitation that is not fully reversible.
- COPD is usually a progressive disease and lung function can be expected to worsen over time, even with the best available care. Symptoms and objective measures of airflow limitation should be monitored to determine when to modify therapy and to identify any complications that may develop.
- Co-morbidities are common in COPD and should be actively identified. Co-morbidities often complicate the management of COPD, and vice versa.

**Reduce Risk Factors :** The Key Points in to achieve reduction of risk factors are as under :

- Reduction of total personal exposure to tobacco smoke, occupational dusts and chemicals, and indoor and outdoor air pollutants are important goals to prevent the onset and progression of COPD.
- Smoking cessation is the single most effective-and cost effective-intervention in most people to reduce the risk of developing COPD and stop its progression. Comprehensive tobacco control policies and programs with clear, consistent, and repeated nonsmoking messages should be delivered through every feasible channel. Efforts to reduce smoking through public health initiatives should also focus on passive smoking to minimize risks for nonsmokers.
- Many occupationally induced respiratory disorders can be reduced or controlled through a variety of strategies aimed at reducing the burden of inhaled particles and gases.
- Reducing the risk from indoor and outdoor air pollution is feasible and requires a combination of public policy and protective steps taken by individual patients.

#### **Managing Stable COPD and Acute Exacerbations of COPD**

- For patients with COPD, health education plays an important role in smoking cessation and can also play a role in improving skills, ability to cope with illness and health status.
- None of the existing medications for COPD have been shown to modify the long-term decline in lung function that is the hallmark of this disease. Therefore, pharmacotherapy for COPD is used to decrease symptoms and/or complications.
- Bronchodilator medications are central to the symptomatic management of COPD. They are given on an as-needed basis or on a regular basis to prevent or reduce symptoms and exacerbations.
- Regular treatment with long-acting bronchodilators is more effective and convenient than treatment with short-acting bronchodilators.
- All COPD patients benefit from exercise training programs, improving with respect to both exercise tolerance and symptoms of dyspnoea and fatigue.
- An exacerbation of COPD is defined as an event in the natural course of the disease characterized by a change

in the patient's baseline dyspnoea, cough, and/or sputum that is beyond normal day-to-day variations, is acute in onset, and may warrant a change in regular medication in a patient with underlying COPD. The most common causes of an exacerbation are infection of the tracheo-bronchial tree and air pollution, but the cause of about one-third of severe exacerbations cannot be identified. Inhaled bronchodilators (particularly inhaled Beta-2- agonists with or without anticholinergics) and oral gluco-corticosteroids are effective treatments for exacerbations of COPD.

- Patients experiencing COPD exacerbations with clinical signs of airway infection (e.g. increased sputum purulence) may benefit from antibiotic treatment.
- Medications and education to help prevent future exacerbations should be considered as part of follow-up, as exacerbations affect the quality of life and prognosis of patients with COPD.

#### **3. Tertiary Intervention**

- (a) Establishment of referral centers at each district level.
- (b) Establishment of apex institute for chest diseases in each region preferably one in each state.
- (c) Training of patients in self management programmes.

#### **Summary**

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of chronic morbidity and mortality throughout the world and it is the fourth leading cause of death in the world. It is the internationally preferred term encompassing chronic bronchitis and emphysema and by definition, COPD is a chronic, slowly progressive disorder characterized by airflow obstruction, which is often assessed by reduced pulmonary function as measured by simple spirometry ( $FEV_1$  less than 80% of the predicted value and  $FEV_1/VC$  ratio below 70%). Asthma is characterized by chronic airway inflammation and increased airway responsiveness resulting in symptoms of wheeze, cough, chest tightness & dyspnoea and it is characterized functionally by the presence of airflow obstruction, which is variable over short periods of time or is reversible with treatment.

Based on Spirometry, Stage I : Mild COPD- ( $FEV_1/FVC < 0.70$ ;  $FEV_1 > 80\%$  predicted), Symptoms of chronic cough and sputum production may be present, but not always. Stage II: Moderate COPD- ( $FEV_1/FVC < 0.70$ ;  $FEV_1 < 80\%$  predicted), with shortness of breath typically developing on exertion and cough and sputum production sometimes also present. Stage III : Severe COPD- ( $FEV_1/FVC < 0.70$ ;  $FEV_1 < 50\%$  predicted), greater shortness of breath, reduced exercise capacity, fatigue, and repeated exacerbations that almost always have an impact on patient's quality of life. Stage IV : Very Severe COPD- ( $FEV_1/FVC < 0.70$ ;  $FEV_1 < 30\%$  predicted or  $FEV_1 < 50\%$  predicted plus the presence of chronic respiratory failure).

The prevalence, morbidity, and mortality of COPD vary across countries and within countries mostly as a result of differences in survey methods, diagnostic criteria, and analytic approaches. It is estimated that about one-quarter of adults aged 40 years and older may have airflow limitation. The incidence of COPD in India is high and over 13 million people are estimated to be suffering from it out of which 62 percent are estimated to be males. The cost of management of patients with COPD is high,



hence it adds to the economic burden of a country in addition to causing loss of DALY's.

The salient risk factors of COPD are tobacco smoke, indoor air pollution, genetic factors, inhalational exposures of which tobacco smoke and occupational dusts and chemicals (vapors, irritants, and fumes), outdoor air pollution, repeated viral and bacterial infections, malnutrition and weight loss.

COPD management includes assessment and monitoring of the disease, reducing the associated risk factors mainly exposure to tobacco smoke, occupational dusts and chemicals, and indoor and outdoor air pollutants, pharmacological management of stable patients and exacerbations if any. Spirometry is the gold standard for diagnosis and monitoring of COPD. Regular monitoring is essential in order to determine when to modify therapy and to identify any complications and other comorbidities. Since none of the medications modify the long term reduction in lung functions, *primary preventive* strategies like health education of the patient and general population, legislative measures to keep check on tobacco smoking and indoor/outdoor air-pollution play a very vital role in improving the quality of life of the patient. *Secondary prevention* strategies include regular treatment with long-acting bronchodilators and inhaled bronchodilators and oral gluco-corticosteroids, antibiotics and oxygen for treating exacerbations of COPD, training of staff at periphery to recognize symptoms of COPD as well as provision of diagnostic facilities and drugs and equipments for the long term management of symptomatic cases as also to prevent exacerbations. *Tertiary intervention* requires establishment of referral centers at each district level and working out the feasibility of establishing an apex institute for chest diseases preferably in every state as well as training of patients in self management programmes.

## Study Exercises

**Long Question :** Discuss the risk factors involved in the development of COPD and the strategies for prevention and control of the same.

**Short Notes :** (1) Risk factors of COPD (2) Diagnosis and classification of COPD (3) Preventive strategies for COPD

## MCQs

1. Which of the following is a diagnostic criteria for COPD: (a) FEV1 less than 80% of the predicted value (b) FEV1 less than 90% of the predicted value (c) FEV1 less than 85% of the predicted value (d) FEV1 less than 94% of the predicted value
2. Mild COPD is characterized by : (a) FEV1 less than 80% predicted (b) FEV1 more than 80% predicted (c) FEV1 less than 50 % predicted (d) FEV1 less than 60% predicted
3. Very severe COPD is characterized by : (a) FEV1 less than 80% predicted (b) FEV1 more than 80% predicted (c) FEV1 less than 30 % predicted (d) FEV1 less than 60% predicted
4. The gold standard for diagnosis and assessment of COPD is (a) Chest X Ray (b) Spirometry (c) Clinical examination (d) none of the above
5. Most important pharmacotherapy for the management of COPD is (a) Bronchodilators (b) Glucocorticosteroids (c) Anticholinergics (d) None of the above
6. The most cost effective-intervention to reduce the risk of developing COPD and stop its progression is (a) Pharmacotherapy (b) Better nutrition (c) Reducing indoor air pollution (d) Cessation of smoking

**Answers :** (1) a; (2) b; (3) c; (4) b; (5) a; (6) d.

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## 219 Visual Impairment & Blindness

RajVir Bhalwar

Impairment or loss of vision leads to a substantial reduction in the quality of life, besides being an important cause of comorbidities among the affected persons. It also contributes to early death. The importance of this condition, from the public health point of view is further increased keeping in view the considerable size of the problem in terms of disease frequency particularly in the developing world, as well as the fact that 80% of these conditions are potentially amenable to either primary prevention (trachoma, Vitamin A deficiency, injuries, glaucoma, diabetic retinopathy) or by early diagnosis and specific treatment (cataract, glaucoma, refractive errors).

### Definitions

*The defining criteria for visual impairment and blindness as per WHO (ICD - 10) (4)*

Degree of Impairment	Definition	Visual impairment category
Low Vision	Visual acuity of less than 6 / 18 (Snellen 20 / 70) in worse eye but equal to or better than 3 / 60 (Snellen 20 / 400) in the better eye with best possible correction.	1 & 2
Blindness	Visual acuity of less than 3 / 60 (Snellen 20 / 400) or corresponding visual field loss of less than 10 degrees in the better eye with best possible correction	3, 4 & 5
Visual impairment	Blindness as well as low vision	1 to 5

### Magnitude of the problem

It is estimated that 35 - 45 million people are blind and an additional 110 - 135 million suffer from low vision conditions. The total number of "visually impaired" worldwide is thus estimated to be approximately at least 161 million. The estimated number of blind persons in the world, as per the conditions causing blindness are : cataract (17.6 million), glaucoma (4.5 m), age related macular degeneration (3.2m), corneal opacity (1.9m), diabetic retinopathy (1.8m), childhood blindness (1.4m), Trachoma (1.3m), Onchocerciasis (0.3 m) and other causes (4.8m) (2, 3). Worldwide, in percentages, the major contributors are cataract (47.8%), glaucoma (12.3%), macular degeneration (8.3%), diabetic retinopathy (4.8%) and trachoma (3.6%). These conditions together account for more than 75% of the blindness.

The socioeconomic impact of these conditions is tremendous. According to World Bank estimates, the DALYs (in thousands), worldwide were 23,898 for cataract, 3,493 for glaucoma and

2,211 for trachoma; the corresponding DALYs for South Asia for these 3 conditions were 10259, 566, and 226 respectively.

As per the global statistics on Blindness 1998, India has approximately 10 million blind persons requiring services. The estimated incidence of blindness in India is 2.13 million per year (1). The common causes of blindness and visual impairment in India are : Cataract, Glaucoma, Corneal ulcer, Xerophthalmia and other forms of vitamin A deficiency, Conjunctivitis, Retinal detachment, Albinism, Astigmatism, Nystagmus, Optic atrophy, Retinitis pigmentosa, Trachoma. The percentage wise distribution of causes of visual impairment in India is cataract (81%), refractive errors (7%), corneal opacity (3%), glaucoma (2%), trachoma (0.2%), malnutrition related blindness (0.04%) and other causes put together (6.76%). The magnitude of blindness in India has multifarious dimensions with most of them having preventable background.

### Risk factors

**1. Age :** It is estimated that almost 82% of the blind people are aged above 50 years, mainly because the major contributors to blindness are cataract, glaucoma and diabetes which are all advanced age - related. However, childhood visual impairment though representing only about 4 to 5 % of all visual impairment, is also quite important since it contributes to a very large number of DALYs and also since it has defined and preventable reasons as Vit A deficiency and injuries.

**2. Gender :** The number of women with visual impairment is higher than men, even after adjustment for age. The female to male ratio of visually impaired, worldwide, has been estimated as 1.5 to 2.2 women for 1 male. The main reason is probably the reduced access of women to eye care services.

**3. Diabetes :** Diabetics have much higher risk of developing retinopathy as well as higher risk of cataract.

**4. Tobacco smoking :** The risk of macular degeneration and possibly of cataract is higher among tobacco users.

**5. Occupation :** Various occupations, especially if proper personal protective measures are not used, are prone to eye injuries, as welders, agriculturists, soldiers.

**6. Cultural factors :** Festivals during which use of crackers is widespread pose a risk for eye injuries, especially among children.

**7. Poor Socio-Economic Status :** Poor socio - economic status plays an important role in many ways. Major pathways are poor nutritional status (Vitamin A deficiency blindness), inadequate water supply and poor general hygiene (trachoma), poor personal protection especially in occupational settings (eye injuries) and poor access to general health care and eye care services (cataract, glaucoma, diabetic retinopathy).

**8. Genetic factors :** Retinitis Pigmentosa is an example of genetically determined (X linked recessive) disease.

**9. HIV Infection and the eye :** The frequency of HIV / AIDS has reached epidemic proportions. 40 to 70% of all AIDS patients show evidence of some ocular disease. AIDS may involve the eye directly by causing a microangiopathy, or anterior segmental manifestations as molluscum contagiosum and kaposi's sarcoma; or, posterior segmental opportunistic

infections, mainly by Cytomegalovirus causing CMV retinitis.

### **Prevention, Control and Public Health Issues**

Prevention and control of visual impairment needs a coordinated approach and actions at all levels of prevention - primary, secondary and tertiary, as follows :

**Primary Prevention** : The steps will include the following :

- Health Education of the community regarding eye care, hygiene and sanitation and frequent washing of eyes in trachoma endemic areas, regarding proper nutrition especially in context of vitamin A rich foods, and regarding availability of eye care services.
- Upliftment of socio - economic status, general standards of living and general education.
- Nutritional supplementation programmes, especially with vitamin A. The details are dealt with in the chapter on national programme for prevention of visual impairment and blindness.
- Immunization of children against common diseases, particularly measles, since measles aggravates the effects of an existing vitamin A deficiency state.
- Provision of eye care services as a part of general health services. The approach in our country is to provide ophthalmic services as a part of the primary health care system.
- Personal protection : personal protection using goggles / eye shields in high risk occupations should be ensured. Details are discussed in the section on occupational health.
- Social actions during fairs and festivals by keeping children at a safe distance from places where crackers are being burst.

**Secondary Prevention** : Secondary prevention, by way of early diagnosis and treatment is the mainstay of programmes for prevention and control of blindness. As said earlier, eye care services should be provided as a part of general health services at the grass root level, through the medical officers at PHC, assisted by ophthalmic assistants and optometrists. The major conditions which would be resolved by this approach are cataract, glaucoma, trachoma, refractive errors and diabetic eye complications, besides providing early emergency treatment for injuries.

**Cataract** : Surgical removal of the opacified lens followed by either intraocular lens implantation or else provision of spectacles is the only way of tackling cataract. Early diagnosis at PHCs or using the community outreach approach and provision of surgery using eye camp approach is the cornerstone. The details are discussed in the chapter on national programme for visual impairment and blindness.

**Trachoma** : The “SAFE” strategy (Surgery, Antibiotics to control infection, Facial cleanliness and Environmental improvements) has been recommended by the WHO. The details are discussed in an exclusive chapter on trachoma in the section on infectious diseases.

**Glaucoma** : Early diagnosis and treatment should be addressed at the PHC level and referral to the District ophthalmologist / apex ophthalmic institutes if required.

**Diabetic Eye Complications** : Early detection of diabetes, including detailed ophthalmologic assessment of diabetics

should be aimed at the PHC level. All diabetics as well as their family members should be educated regarding eye care, control of blood sugar levels and warning signs of diabetic eye complications.

**Refractive Errors** : Medical officers / optometrists working at the primary health care level should be equipped to undertake refraction and provide glasses to those who need them. This should ideally be a part of the general health services, with facilities for refraction being made available at PHC level.

**Health Examinations** : Health examinations should be utilized for ophthalmologic assessment and vision / refraction. The potential groups include school children and occupational workers. Proper corrective glasses and advise should be provided to those requiring glasses.

**Special Screening Examinations** : Retinopathy of Prematurity (ROP) and Retinitis Pigmentosa (RP) are important conditions in which screening during early childhood may be helpful. However, at present the scope of such screening, at public health level in developing countries may be limited.

**Tertiary Prevention** : The community should cater for specialized treatment of complicated cases and research as well as cater to social action and security for rehabilitation of visually impaired.

**Disability Limitation** : At the District level, there should be an ophthalmologist along with the ophthalmic team to cater to any referred cases. Similarly the medical colleges and apex ophthalmic institutions need to be developed for management of difficult cases as well as for research purposes.

**Rehabilitation** : Social security and rehabilitation programmes should be developed as a part of community action to ensure that visually impaired persons lead a fulfilling life and become productive members of the society. Details of social security and rehabilitation facilities in our country are discussed in detail in the chapter on “rehabilitation process in India”.

### **Summary**

Impairment or loss of vision leads to a substantial reduction in the quality of life, besides being an important cause of co - morbidities among the affected persons. It also contributes to early death as the fact that 80% of these conditions are potentially amenable to either primary prevention (trachoma, Vitamin A deficiency, injuries, glaucoma, diabetic retinopathy) or by early diagnosis and specific treatment (cataract, glaucoma, refractive errors). The total number of visually impaired world wide are estimated to be approximately at least 161 million, of which the major contributors are cataract (17.6 million), glaucoma (4.5 m), age related macular degeneration (3.2m). India has approximately 10 million blind persons requiring services. The estimated incidence of blindness in India is 2.13 million per year. Age above 50 years, female gender, co - morbidities like Diabetes, Tobacco smoking, poor Socio - economic Status and HIV Infection are some of the risk factors. Primary Prevention consists mainly of Health Education of the community, upliftment of socio - economic status, Nutritional supplementation programmes (especially Vitamin A), and Immunization and Personal protection. Provision of eye care as part of general health services should be the aim.

Secondary prevention, by way of early diagnosis and treatment is the mainstay of programmes aimed at prevention/ control of cataract, Trachoma, Glaucoma, Diabetic eye complications and Refractive errors. Health examinations and Special Screening Examinations form part of this strategy. Tertiary prevention consists of Disability Limitation, wherein, at the District level, there should be an ophthalmologist along with the ophthalmic team; and Rehabilitation as a part of community action to ensure that visually impaired persons lead a fulfilling life and become productive member of society.

## Study Exercise

### MCQs

1. Diabetics have much higher risk of developing retinopathy as well as higher risk of cataract. Yes/ No
2. What percentage of of all AIDS patients show evidence of some ocular disease (a) 10 - 20% (b) 30 - 40% (c) 40 - 70% (d) 80 - 100%

3. Visual impairment category 3, 4 & 5 is termed as (a) Low vision (b) Blindness (c) Both (d) Neither
4. Immunization against which particular disease is part of specific protection measures aimed at preventing Blindness (a) Mumps (b) Measles (c) Rubella (d) Chickenpox

**Answers :** (1) Yes; (2) c; (3) b; (4) b.

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## Hearing Impairment & Deafness

*RajVir Bhalwar*

Hearing loss is a chronic and often lifelong disability that causes profound damage to the development of speech, language and cognitive skills in children, especially if commencing pre - lingually. Such damage greatly affects the child's progress in school and later his or her ability to obtain and execute an occupation. Besides, it causes, for all ages and both genders, difficulties in inter - personal communication and leads to significant individual social problems, especially isolation and stigmatization. All these difficulties are much magnified in developing countries which have limited services, little equipment, facilities and trained personnel, and little awareness about how to deal with these difficulties.

### General Definitions

Normal human being hears at an intensity of 20 decibels (dB). The term "hearing loss" is used to denote any of the following four levels of hearing difficulty, viz., mild ( 26 to 40 decibel hearing level, dBHL), moderate ( 41 to 60 dBHL), severe (61 to 80 dBHL) and profound (81 dBHL or above). Out of these four levels, profound hearing impairment (81 dBHL and above) is taken to be equivalent of "deafness" (1, 2). *Disabling hearing impairment* in adults is defined as "permanent unaided hearing threshold level for the better ear of 41 dB or greater; for this purpose, the hearing threshold level is to be taken as the better ear average hearing threshold level for the four frequencies, viz., 0.5, 1, 2, and 4 kHz.

From the disease classification point of view, hearing loss is

divided into three categories in ICD - 10, viz. conductive hearing loss, sensori - neural hearing loss and other hearing losses.

### Magnitude of the Problem

It has been estimated that worldwide, in 2002, almost 255 million people had disabling hearing loss (as per above definition of moderate or worse hearing loss i.e. 41 dB or above, in the better ear). This represents more than 4% of the world population. These 255 m include 192 million with adult onset loss (age 20 years and above) and 62 m with childhood onset loss (3). Estimates also indicate that another one and a half times more persons, i.e. another approximately 400 m would be there with mild hearing loss.

In our country, the NSSO estimated in 1991, that there are 3 million persons with hearing impairment in India. The age wise distribution per 1000 persons with hearing impairment was :

Age Group (years)	Hearing Impairment	
	Rural	Urban
0 - 4	NA	NA
5 - 14	85	80
15 - 59	387	377
60 & above	526	541

WHO in 1980 summarised the main causes of hearing impairment in India as infections, neglect and ignorance.

### Causes and Risk Factors

The main causes of hearing loss according to the proportion that these contribute to the total burden of hearing loss are as follows (5) :



**Causes contributing to high proportion of hearing loss :** Genetic causes, Otitis Media, Presbycusis.

**Causes contributing to moderate proportion of hearing loss:** Excessive noise, Ototoxic drugs and chemicals, Prenatal and Perinatal problems, Infectious causes, wax and foreign bodies.

**Causes contributing to low proportion of hearing loss:** Nutritionally related (as iodine deficiency disorders and cretinism), Trauma related, Meniere's disease, Tumours and Cerebrovascular disease.

#### **The Important Risk Factors Include**

**Age and Sex :** The prevalence of hearing loss increases with increasing age groups apparently due to age-related hearing loss (presbycusis). The incidence is higher among males possibly because of occupational related hearing loss.

**Genetic Risk Factors :** A large proportion of childhood deafness is likely to be congenital and having genetic background. Consanguinity, and history of congenital deafness among blood relatives are important risk factors and need to be addressed from genetic counselling / testing point of view.

**Intranatal Risk Factors :** Transplacentally transmitted infections as TORCHES, especially Rubella, are well known risk factors for congenital hearing loss.

**Environmental Noise :** Noise induced hearing loss (NIHL) is a well documented entity. The adverse effects of noise can be in occupational settings (occupational hearing loss), which has been discussed in detail in the section on occupational diseases. In the citizen life settings too, noise can play a hazardous role, as loud speakers used during fairs and festivals, personal stereos, music systems, firecrackers and noisy toys. High noise traffic on highways can affect residents staying in houses besides these streets.

**Infections :** Exposure to conditions facilitating the transmission of bacterial and viral infections causing Upper respiratory tract infections / otitis media is an important risk factor. In addition, measles and meningococcal infections are also documented.

**Trauma :** Inserting sharp or even blunt objects into the ear, as is quite common practice in developing world, for cleaning the ear, is a definite risk factor for otitis media.

**Poor Socio - Economic Conditions :** Poverty, poor environmental and domestic hygiene, overcrowding and poor access to health care services are all risk factors that lead to upper respiratory infections, otitis media and other infections that can lead to hearing loss (as measles and meningitis).

**Nutrition :** Cretinism and even mild varieties of Iodine Deficiency disorders may present with hearing loss.

**Other Risk Factors :** Ototoxic medications, low birth weight and low apgar score have been cited by certain workers as risk factors.

#### **Prevention, Control and Public Health Issues**

It has been estimated that at least 50% of the burden of hearing loss, worldwide, can be prevented by primary, secondary and tertiary preventive measures (1, 4).

#### **Primary Prevention**

**Improvement in socioeconomic and living conditions :** Improved general hygiene and sanitation, housing standards and prevention of domestic overcrowding will go a long way in preventing infections which cause URTI, otitis media and other infections that may lead to hearing loss as measles and meningitis.

**Improvements in health care services :** Health care services would need to be improved in respect of the following aspects:

**Improvements in facilities :** this would include availability of drugs and equipment for early detection and treatment of URTI and otitis media, as well as providing specialized equipment as facilities for audiometry for early detection, at places as near to the community as possible.

**Improvements in trained manpower :** At present, developing countries have a definite shortage of ENT trained doctors as well as paramedical staff trained in ENT issues, as audiologists and speech therapists. The need is to increase the availability of such trained manpower and position them at places as near to the community as possible, after adequately equipping them with required equipment and drugs.

**Improvements in accessibility and affordability :** Even if trained manpower and facilities are available, they are clustered in larger cities, far away from the majority of the population. The need would be to make these services as accessible as possible as well as to ensure that the community can afford these services.

**Promotive & Preventive Genetics :** A substantial proportion of hearing loss is due to genetic background. All efforts should be made towards genetic counselling and, if required, genetic intervention in the form of prenatal diagnostics, in this regards, as already detailed in the chapter on genetic aspects of public health. The target individuals and communities include those where consanguineous marriages are common and family history of childhood hearing loss among blood relatives.

**Prevention of noise pollution :** Noise pollution would need to be addressed at two echelons. Firstly, in the occupational settings, as has been discussed in detail in the section on occupational health. Secondly, at the societal level, by individual and community education, backed up by legal provisions to prevent noise pollution at public places.

**Immunization :** Against measles, meningitis, and various other diseases as provided under the national immunization programme and of potential mothers against Rubella, will be of definite help in reducing the problem.

**Nutrition :** Implementation of various steps for control of iodine deficiency diseases as enumerated in the sections on nutrition and on national health programmes should be undertaken.

#### **Secondary Prevention**

##### **Early detection and prompt management**

- **Community Education regarding the importance of early detection :** This is a very important issue, particularly in developing countries, especially in context of congenital/ childhood hearing loss. The fact is that if a child with hearing loss can be detected as early as 6 months of age and provided with audiometric assistance, most of these



children can live a normal or near normal life. If this detection and provision of hearing aids is delayed to even 3 years of age, much preventable loss would occur. However, in developing countries, most parents keep waiting till about 3 to 5 years of age, thinking that their child may be one who is probably developing delayed speech or may be having “tongue - tie”. It must be remembered by all medical personnel, and conveyed to the community that any child who is not speaking is most probably the one who is not hearing and hence needs to be evaluated. Therefore, any child who has delayed socio - developmental milestones as delayed social smile, delay in speaking 2 or 3 syllables, or any child who has history of childhood hearing loss among another member of the family should be subjected to special evaluation.

- Early detection of Upper respiratory tract infections, otitis media (both acute and chronic) and other infections that can cause hearing loss, by organizing adequately staffed, equipped and accessible health care services, as described above.
- Early detection of hearing loss : This is a very important, as has been already outlined above. The children / adults falling under these criteria of suspicion should be subjected to an evaluation by an ENT surgeon / trained audiologist. The most commonly used screening technique is audiometry. Childhood audiometry is possible for children even as young as 3 to 4 months of age. More advanced techniques as Brainstem Evoked Response Audiometry (BERA) are available at specialized centers only.

**Among Adults :** The groups which need to be subjected to preventive audiometry include Occupational workers exposed to high noise and old people.

**Among Children :** Detailed risk factors and indicators have been developed for neonates and infants who should be subjected to hearing evaluation. These include children who suffered from conditions which should have required admission to neonatal ICU, stigmata of syndromes causing hearing loss, positive family history of hearing loss, craniofacial anomalies, certain in - utero and post-natal infections (TORCHES and meningitis), hyper - bilirubinaemia, conditions requiring prolonged mechanical ventilation, or effusion, persistent discharge for ear, and infants who do not achieve developmental milestones in time.

- **Adequate Treatment :** Prompt treatment of infections by suitable antibiotics and supportive measures; and, surgical intervention including tympanoplasty for relevant cases of chronic otitis media. For hearing impairment, the correct hearing aid / cochlear implant should be provide after detailed audiometric and clinical evaluation by an ENT surgeon. It must be remembered that parents / patients should be advised that for a given patient, the correct hearing aid has to be worked out and not that they should go to the market and buy any hearing aid, as is often done. Secondly, hearing aids, once given should be followed up with proper evaluation by the ENT surgeon as well as speech and educational rehabilitation programmes.

**Tertiary Prevention :** Tertiary prevention would include the following :

**Speech Therapy :** A number of patients provided hearing aid, especially childhood cases will need assistance for developing proper speech. In community and public health context, it needs to be noted that the best speech therapists are the motivated parents and every opportunity should be taken to educate the parents in bringing about speech rehabilitation of their affected child.

**Vocational and Educational Training :** Very large proportion of children with childhood hearing loss if detected and treated early with appropriate hearing aids, will live a near normal life. Children should be sent to normal schools as far as possible unless there are indications that the child has to be sent to special school for hearing challenged. For adults, those who are not able to cope up with the fine requirements of occupation even after provision of hearing aids, the employers should consider alternative areas of work.

**Follow up :** Cases who have been provided hearing aid, or have undergone surgical correction for otitis media should be followed up as prescribed.

**Social Actions :** Suitable facilities need to be created for education and vocation of the hearing challenged. Various provisions including reservations in education and jobs, travel facilities and economic relaxations are available in our country for this group, the details of which have already been provided in the chapter on rehabilitation process in India.

**Specialized Training, Research and Referral :** Efforts should be made to develop apex centres for undertaking training of ENT surgeons in specialized hearing problems and of support manpower as audiologists. These institutions should also cater to research and referral support for specialized cases. In our country, such specialized centers are available at Mysore and Mumbai.

## Summary

Hearing loss is a chronic and often lifelong disability that causes profound damage to the development of speech, language and cognitive skills in children. The term “hearing loss” is used to denote any of the following four levels of hearing difficulty, viz., mild ( 26 to 40 decibel hearing level, dBHL), moderate ( 41 to 60 dBHL), severe (61 to 80 dBHL) and profound (81 dBHL or above). It has been estimated that worldwide, in 2002, almost 255 million people had disabling hearing loss. The NSSO estimated in 1991, that there are 3 million persons with hearing impairment in India. Among the main causes of hearing loss are Genetic causes, Excessive noise and Trauma related. The important risk factors include increasing age, Genetic factors, trans - placentally transmitted infections as TORCHES, Noise - induced hearing loss, Infections, Trauma, Ototoxic medications and Poor Socio - economic conditions. Important among the measures of Primary Prevention include improvement in socioeconomic and living conditions, improvements in health care services, genetic counseling, prevention of noise pollution, Immunization towards specific diseases and Nutrition. Secondary Prevention measures include Community Education regarding the importance of early detection, particularly in

developing countries, early detection of Upper respiratory tract infections that can cause hearing loss, early detection of hearing loss using tests like Brainstem Evoked Response Audiometry (BERA) and Adequate Treatment. Speech therapy, Vocational and Educational training, Follow up, Social Actions, Specialized training, Research and Referral all form part of Tertiary Prevention.

## Study Exercises

### MCQs

1. Childhood audiometry is possible for children even as young as (a) From birth (b) 1 - 2 months of age (c) 3 - 4 months of age (d) 01 year of age
2. Age related hearing loss is known as (a) Presbycusis (b) Presbyopia (c) Otitis Media (d) NIHL
3. All of the following are measures of tertiary prevention of hearing loss, except (a) Speech therapy (b) Using tests like Brainstem Evoked Response Audiometry (BERA) (c) Specialized training (d) Follow up

4. Moderate hearing difficulty refers to that which includes the range of (a) 41 - 60 dB (b) 61 - 80 dB (c) 81 - 100 dB (d) 101 - 120 dB
5. It has been estimated that at least what percentage of the burden of hearing loss, worldwide, can be prevented by primary, secondary and tertiary preventive measures (a) 20% (b) 30% (c) 40% (d) 50%

**Answers :** (1) c; (2) a; (3) b; (4) a; (5) d.

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## Dental and Oral Health

*Ramen Sinha*

During the past few decades, oral health authorities in the fields of epidemiology, education, services, health education and disease prevention have given special attention to the highly prevalent oral health problems like dental caries and periodontal diseases. With these approaches, dramatic improvement in scientific knowledge and technology has taken place in the field of oral health.

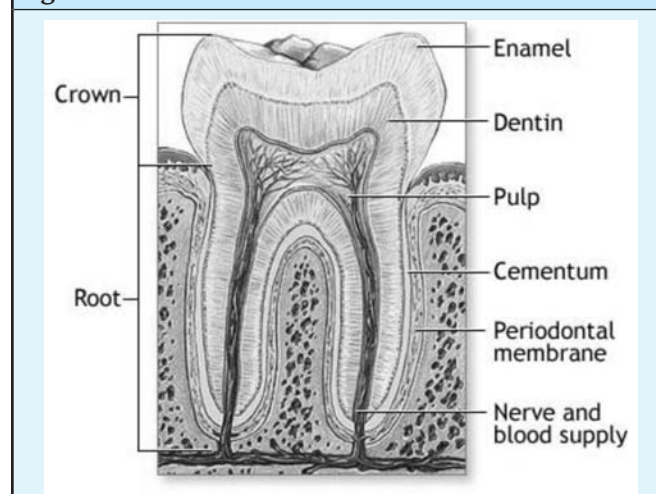
### Structure of the Tooth

The teeth are hard-calcified structures set firmly in bone sockets in the maxilla and mandible by means of a root or roots. The part visible in the oral cavity is the crown, which is separated from the roots by a narrow portion called the neck or cervical portion of the tooth. The crown is covered with hard shiny enamel. The tissue covering the root is the cementum. The ivory-like structure that forms the bulk of the tooth is the dentine. Enamel lacks the capacity for self-repair since it contains no cells. It resists wear only through its extreme degree of hardness. Dentine is capable of repair, but it is less hard and resistant than enamel. Investing between the roots of teeth and socket wall formed by alveolar bone is the thin periodontal ligament, the fibre-bundles of which help to suspend and anchor the teeth in place. Its cushioning effect also helps in

protecting periapical tissues from likely compression during mastication. The dental pulp occupies hollow pulp chambers and pulp canals in the crown and roots of teeth. It contains a plexus formed by connective tissue fibers, nerve endings, blood vessels, tissue cells and lymphatics which communicate with their major source of supply through apical foramina in the roots ends (Fig. - 1).

The gingival, periodontal ligament, alveolar bone and cementum which support the teeth are collectively termed as periodontium.

**Fig. 1 : Structure of Tooth**



## Dentition

The first dentition brings forth the deciduous or “Milk teeth”. There are twenty teeth in this set; ten in each jaw. The tooth buds begin to form about the sixth week of prenatal life and calcification starts about the sixteenth week of prenatal life. The position of the first permanent molar determine to a great extent, the position of the other teeth. Therefore, early examination and care will help to ensure their retention throughout life. Deciduous teeth are shed about the 7th year onwards, when the permanent teeth follow. There are 32 teeth in the permanent set; 16 in each jaw. Calcification of permanent teeth begins in the jaws about the time of birth. The last four teeth to erupt are the third permanent molars, or “wisdom teeth”. They do not erupt until about the age of 18 years or later and may even never erupt. Sometimes they become “impacted” below the gum surface necessitating extraction to preserve the health of the adjacent teeth. Dentition schedule is shown in Table-1.

## Tooth Numbering

The system which is recommended for use is as per Federation Dentaire International system is Modified Palmer System. In this two-digit system, the first digit indicates the quadrant and the second digit a particular tooth in that quadrant. Quadrants are allotted the digit 1 to 4 for the permanent and 5 to 8 for the deciduous teeth in a clockwise sequence, starting at the upper right side; permanent teeth within the same quadrant are allotted the digits 1 to 8 whereas deciduous teeth (1 to 5) from the mid-line backwards. The digits should be pronounced separately : thus the permanent canines are teeth one-three, two three, three-three and four three. Numbering system is as follows :

<i>Permanent teeth</i>	
(Upper right)	(Upper left)
18 17 16 15 14 13 12 11 48 47 46 45 44 43 42 41	21 22 23 24 25 26 27 28 31 32 33 34 35 36 37 38
(Lower right)	(Lower left)
<i>Deciduous teeth</i>	
(Upper right)	(Upper left)
55 54 53 52 51 85 84 83 82 81	61 62 63 64 65 71 72 73 74 75
(Lower right)	(Lower left)

## Functions of Teeth

Besides mastication, the teeth help in phonetics and also contribute towards aesthetics. The process of mastication involves incision and grinding of food. The incisors serve to incise the food and the premolars and molars do the grinding. The food is broken into smaller portions and is thoroughly mixed with saliva before it is swallowed. For efficient performance of their function the teeth must be correctly aligned in arches and meet in normal occlusion. Occlusion means a contact relationship of the teeth when the jaws are closed. Normally mastication is done at one side only at a time. Chewing ability depends upon the soundness of teeth, firmness of their embedment, hardness of enamel, uniformity of occlusion and strength of the jaws. Chewing the fibrous foods such as meat, radish, celery, carrots, and apples and so on develops the jaws and at the same time keeps the gums in proper tone by stimulating blood circulation through them. Children should be taught to chew their food thoroughly, but not to crack nuts or very hard items, less it may damage the

**Table - 1 : Dentition Schedule**

	Maxillary			Mandibular		
	<i>Formation Begins</i>	<i>Eruption</i>	<i>Shedding</i>	<i>Formation Begins</i>	<i>Eruption</i>	<i>Shedding</i>
<b>(A) Deciduous Teeth</b>	Intra Uterine	Postnatal				
Central incisors	4 months	7 months	7 years	4 months	6 months	7 years
Lateral incisors	4½ months	9 months	8 years	4 months	7 months	7-8 years
Canines	5 months	18 months	11-12 years	5 months	16 months	10-12 years
First molar	5 months	14 months	9 - 10 years	5 months	12 months	8-9 years
Second molar	6 months	24 months	11-12 years	6 months	20 months	10-11 years
<b>(B) Permanent Teeth</b>	Postnatal					
Central incisors	3-4 months	7-8 years	No definite schedule	3-4 years	6-7 years	No definite schedule
Lateral incisors	10-12 months	8-9 years		3-4 years	7-8 years	
Canine	4-5 months	11-12 years		4-5 years	9-10 years	
First pre molar	1½ years	10-11 years		1½-2 years	10-12 years	
Second pre molar	2-3 years	10-12 years		2 - 2½ years	11-12 years	
First molar	At birth	6-7 years		At birth	6-7 years	
Second molar	2½ -3 years	12-13 years		2½ - 3 years	11-13 years	
Third molar	7-9 years	17-21 years		8-10 years	17-21 years	



enamel, so that the teeth and the supporting structures develop properly as a well functioning organ. Teeth that are properly aligned and occlude normally help in proper pronunciation of words. Facial appearance, beauty, and symmetry depend upon well-developed jaws and a full compliment of teeth developed in proper alignment. If the teeth are mal-aligned or have spaces between them or a few teeth are missing, the speech becomes faulty and lacks clarity. The unpleasing expression due to irregular or missing teeth may cause self-consciousness, which leads to inferiority complex that may ultimately, result in social maladjustment. Teeth and their supporting structures thus considerably influence and affect the personality.

It has always been commonly believed that with the advancing age the loss of teeth should be considered a natural and inevitable occurrence. However, it is now recognised to be a direct result of pathological process. It was earlier inferred, although rather incorrectly, that below the age of 35, the tooth loss was the result of dental caries, where as beyond the age of 35 it results from 'pyorrhoea'. However, from the epidemiological studies world over, it has been established that diseases of four different supporting structures of the teeth (termed collectively as 'periodontium') can have their origin even amongst the school going children. Such global surveys therefore indicate, that although drastic and damaging results might be discernable in a majority of population, beyond the age of 35 or more, the damaging influences on the periodontal tissues can be traced to have commenced even as early as 12-15 years of age. The universal axiom that "prevention is better than cure" still holds true, and to be more effective, this too must therefore commence during the school-going age.

### Dental Plaque

Dental plaque is thin, tenacious, firmly adherent and well organized biofilm adhering to the tooth surface, restorations and dentures. It is different from other deposits on the tooth surface such as materia alba and calculus. Materia alba refers to soft accumulations of bacteria and tissue cells that lack organized structure of dental plaque and are easily displaced with water spray. Calculus is a hard deposit that forms by mineralization of dental plaque and is always covered by a layer of unmineralized plaque. Dental plaque is composed primarily of more than 325 different bacterial species and one gram of plaque contains approximately  $2 \times 10^{11}$  bacteria (14). The dental plaque may be cariogenic, causing dental caries or calcuogenic, causing periodontal diseases.

### Dental Caries

Dental caries (commonly referred as "tooth decay" in layman's language) is a public health problem worldwide. As per official reports, it is the single most common chronic childhood disease in the USA. Epidemiological data for large number of countries is available on the Who site <http://www.whocollab.od.mah.se/index.html> and interested readers are advised to refer to the same.

Dental caries is found not only in children and young adults but also in other age groups. The elderly, particularly those with exposed tooth root surfaces constitute a special risk population. There is evidence that persons aged 50 years and above are also a caries active group, experiencing new caries at

a rate comparable to that of adolescents.

**Epidemiological Measurements of the Load of Dental Caries:** Caries prevalence of permanent teeth in a community is generally assessed by an index known as "Decayed Missing and Filled teeth (DMFT)". It is calculated by counting the number of DMFT of each individual and then calculating the mean for the group examined. A very common age group used for international comparisons of DMFT is the 12-year age group. The WHO also recommends this age group, and the WHO goal was to achieve "3 or less DMFT" among 12 year old children" by the year 2000. According to estimates, 70% of the countries, representing 85% of the world population had achieved this goal by 2001; however, several developing countries have reported a trend towards higher level of dental caries.

Another parameter for measuring the load of caries is "Significant caries (SiC)" index. This is calculated by calculating the mean DMFT of the one-third of the group having the highest DMFT in that population (i.e., in the upper teeth). This is because the distribution of DMFT among children in a population often tends to be skewed, with a proportion of children showing high or very high number of DMFT while the remaining showing low number or none. Expressing caries prevalence as mean DMFT may therefore not accurately describe the disease level in populations with such skewed distributions.

**Pathophysiology and Clinical Features :** Dental Caries develops due to localized dissolution of hard tissues of the tooth, caused by acids that are produced by the bacteria (mainly streptococci), in the "biofilms" (dental plaque) which form on the teeth and eventually lead to "cavities". The destructive acids are produced when fermentable carbohydrates come in contact with these biofilms, each episode resulting in tooth damage, which manifests clinically as an 'episode'. If this process does not occur frequently, then the natural capacity of the body (through saliva) to remineralize will prevent formation of a cavity. Thus the main risk factors are presence of "carioenic" biofilm, frequent consumption of fermentable carbohydrates and conditions in which saliva production is decreased. The protective factors against caries include exposure to fluorides in optimum concentration (as through drinking water or fluoridated toothpastes) and normal saliva flow.

Untreated caries can give rise to infection of tooth pulp, causing pain and destruction of the tooth. The infection can spread to the supporting tissues and the jaws, culminating in advanced disease conditions.

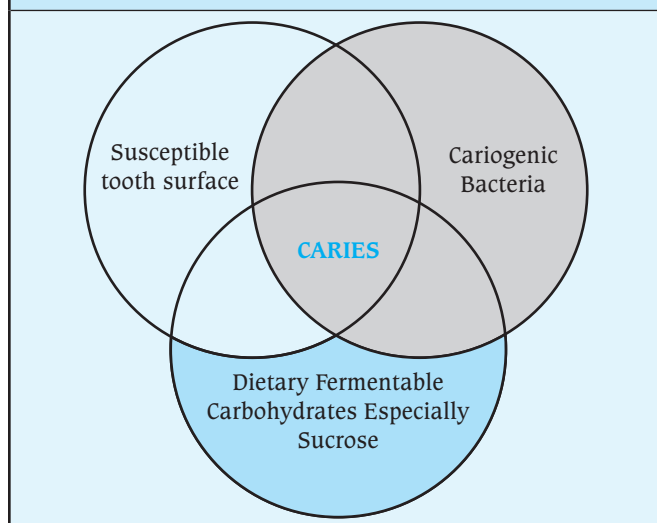
**Diagnosis :** Although bacteria on the teeth are the direct cause of dental caries, a large number of microbiological, environmental and host factors interact to determine whether or not an individual will be affected and if affected, how and to what extent. Dental caries is therefore a multifactorial disease (Fig. - 2).

In the past, diagnosis of dental caries involved the use of a mouth mirror, an explorer and perhaps bites wing radiographs. "Tug back" or a feeling of resistance when the explorer was moved on the tooth surface led to an almost confirmed diagnosis of caries. Treatment of dental caries as per Black's "Extension for prevention" necessitated considerable loss of tooth substance beyond the actual carious lesion. The modern



approach to diagnosis and treatment based on a series of important advances differs from Black's rules in almost all respects. The diagnostic process does not focus only on the presence of lesions but is expanded to include identification of factors that lead to the formation of lesions.

**Fig. - 2 : Dental Caries is a Multifactorial Infectious Disease**

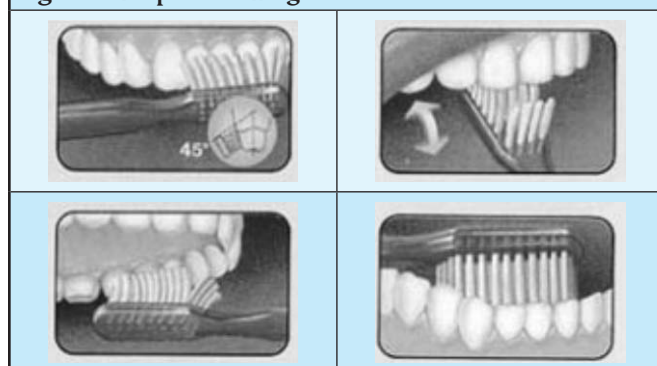


### Prevention

The multi-factorial nature of caries allows scope for a number of different approaches for prevention of this disease. It should also be recognized that certain etiological factors have vastly different consequences, depending on the total mix of factors. For example, the consequence of a diet rich in sucrose is quite different for a person who is frequently exposed to fluorides than for one who has very little exposure.

#### (a) Proper Brushing

**Fig. - 3 : Proper Brushing**



1. Place the brush at an angle against the tooth, making certain that the bristles are at the gumline. Gently brush the surface of each tooth using a short, gentle vibrating motion.
2. Brush the outer surface of each tooth, upper and lower, keeping the bristles angled against the gumline. Repeat the same method on the inner surface of the teeth as well.

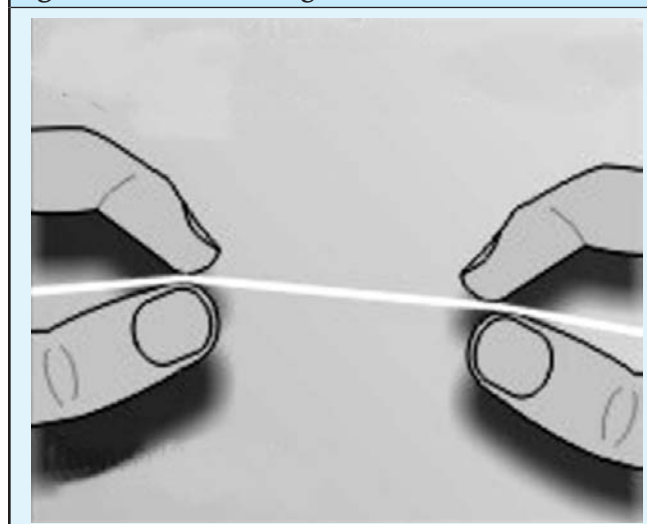
3. To clean the inside surfaces of the front teeth, tilt the brush vertically and make the several gentle up and down strokes using the front half of the brush.
4. Scrub the chewing surface of the teeth using a short back and forth movement. Brushing the tongue will remove bacteria and freshen your breath.

**(b) Diet** : The contribution of sucrose to implantation, colonization and metabolic activities of cariogenic bacteria has been clearly established and has led to search of sucrose substitutes.

#### (c) Dental Flossing

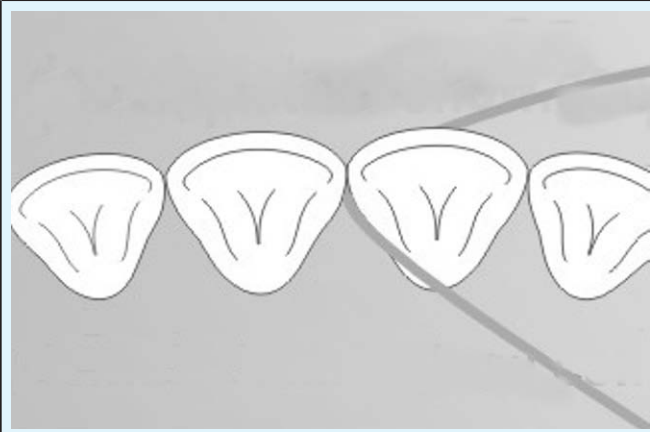
- When flossing your teeth, start off by breaking about 18 inches of dental floss from your floss dispenser. Take each end of the floss and begin to wrap it around the middle two fingers of each of your hands. Wrap most of the floss on the fingers of one hand while wrapping just enough on the other hand that the dental floss is easily held. Continue to wrap the floss until just a small length (3 to 4 inches) is left stretching between your hands (Fig. - 4a).

**Fig. - 4a : Dental Flossing**



- The floss will be held by the middle fingers while some combination of each hand's index finger and thumb will be used to manipulate the dental floss between your teeth. There should be about 1/2 to 1 1/2 inches of dental floss stretched between your pinch hold on the floss. This is the section of the dental floss that will be worked between your teeth and used to clean away the accumulated food debris and dental plaque.
- To floss a particular location you will need to work the dental floss past the contact point where the two teeth touch. If the contact between the teeth is very tight you may need to use a slight back and forth sawing motion to get the floss to go. You might also need to use a small amount of pressure to help to guide the floss through the contact point. But don't use so much force that the dental floss snaps past the contact and traumatizes your gums. *Work the dental floss up and down the side of each tooth. Always keep the pressure of the dental floss against the tooth's surface* (Fig. - 4b).

**Fig. - 4b : Dental Flossing**



- Once you have finished cleaning the side of this first tooth you will need to bring the floss back above the gum line, pull it up against the side of the other tooth, and then clean this second tooth just like you did the first one.
- Don't forget to floss the back side of the last teeth in your mouth and the sides of any teeth that face spaces where teeth have been removed.
- Using dental floss once a day should be often enough to keep you in good oral health.
- You should floss your teeth first and then brush afterwards.

**(c) Fluoride** : Recent reports from Australia and United States have confirmed the safety and efficacy of fluoride in preventing dental caries. The United States has set a limit of 4 mg / litre as the maximum allowable level in drinking water and recommends a level of 0.7 to 1.2 mg / litre. During decreases in the pH of the dental plaque free fluoride is available and helps in remineralization process. Moreover fluoride used on a regular basis becomes concentrated in dental plaque and appears to interfere with enzymes used by the bacteria in metabolizing sugars. Fluoridated toothpaste, rinses, gels and tablets are important delivery system. Water, salt and milk are highly cost effective vehicles and should be implemented wherever technically feasible.

Fluorides supplements are available as

**(i) Systemic fluorides** : e.g. Water fluoridation, various food products

**(ii) Topical fluorides** : Available in the form of gels, mouthwashes, solutions and toothpastes

**(d) Sealant** : The use of dental sealant is an effective way to prevent pit and fissure caries. One of the barriers to increased use, however is the fact that successful placement and retention of sealant are highly dependent on technique and the availability of appropriate equipment.

**(e) Antimicrobials** : Infants acquire the bacteria that colonize the oral cavity and digestive tract usually through normal handling by their mothers or other care givers. Investigators have found that it is possible to interfere with the process of transmission of mutans streptococci by treating mothers and other close family members with antimicrobials like

chlorhexidine gluconate 0.2 or 0.12%.

### Immunization

An improved understanding of genetics of oral bacteria is also leading to new approaches to development of safe and effective oral vaccines. The possibility of creating a polyvalent vaccine effective against caries, as well as measles, poliomyelitis and other serious infections is under consideration. With successful programme to reduce the effects of etiological agents & increase host resistance, a new approach to treatment of the caries lesion can therefore be outlined as follows :

#### **(a) Incipient Lesion**

- (i) Remineralization using topical fluoride therapy.
- (ii) Counselling on dietary and other risk factors.

#### **(b) Initial Cavitation**

- (i) Application of a sealant.
- (ii) Restoration with preventive materials after minimal excavation and preparation with hand or rotating instruments if necessary.

**(c) Moderately Sized Lesion** : Restoration conserving maximum amount of tooth substance

#### **(d) Deep Lesion**

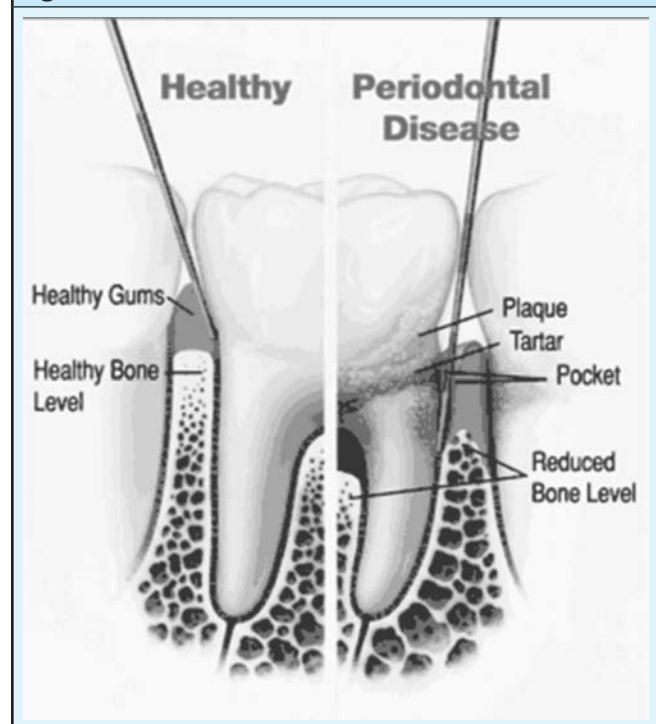
- (i) Restoration, conserving maximum amount of tooth substance.
- (ii) Endodontic therapy, if necessary.

This new approach can also be applied to retreatment using same steps and repairing physical defects only if symptoms are evident in the teeth or supporting tissues.

### Periodontal Diseases

The inflammatory diseases, viz., gingivitis and periodontitis are quite common (Fig. - 5).

**Fig. 5 : Periodontal Diseases**



**Gingivitis** : While caries has been linked strongly with only a few organisms, the development of gingivitis appears to be caused by nonspecific bacterial plaque flora, which changes over time from predominantly gram positive to more gram negative. In gingivitis the gums become spongy, red, swollen, bleed when brushed or touched, stand away from teeth, often causing little pain and discomfort. Gingivitis therefore is often neglected until it has reached an advanced stage. Gingivitis does not necessarily develop into periodontitis. However, periodontitis is always preceded by gingivitis. The disease can spread to involve deeper supporting tissues viz. periodontal ligament, cementum and alveolar bone. Due to apical migration of junctional epithelium there is formation of a gap between teeth and gums known as the periodontal pocket. Such pockets harbour dental plaque and calculus which, if untreated, ultimately leads to alveolar bone resorption, mobility of teeth and exfoliation.

**Diagnosis** : Traditional approaches to periodontal diagnosis include assessment of gingival health and measure of pocket depth, alveolar bone height and loss of periodontal attachment. In addition, the presence or absence of dental plaque and supra and sub gingival calculus is recorded. Assessment of gingival health continues to rely on visual evaluation of the tissues and the extent to which gingival gentle probing can provoke bleeding. The height of alveolar bone is assessed from radiographs. A complete assessment of the periodontal situation should include quantification of the loss of attachment around the teeth (pocket depth and gingival recession as measured from the cemento - enamel junction or some fixed points). It is important to note that pocket depth, bone height and periodontal attachment, represents only the cumulative results of past pathological events and do not reflect the rate of progression of lesions unless measurements of radiographic assessments are made at short time intervals. Many diagnostic tests aimed at detecting early events in the disease process such as bacterial cultures, DNA probes, immunofluorescent assays, specific antibody determinations and the measurements of hydrolytic enzymes, break down products and cytokines are currently being studied. Markers of host defence mechanisms, such as chemotactic responses and phagocytic capability of polymorphonuclear leucocytes have also been investigated.

There is no single organism that is pathognomonic of a change from gingivitis to adult periodontitis. Several species like *Porphyromonas gingivalis*, *Prevotella intermedia*, *Eikenella corrodens*, *Wolinella recta*, *Treponema denticola* and *Capnocytophaga* are present in various combinations in patients with adult periodontitis. The association between a gram-negative anaerobic microflora and periodontitis has been extensively demonstrated and elimination / control of this flora will reduce risk of periodontitis.

**Treatment** : Epidemiological studies from many countries show that severe periodontal destruction is less prevalent than it was thought to be 10 to 15 years ago. Improvements in oral hygiene are believed to be the primary factor in this change. Due to increased life expectancy, periodontal care will also be needed by many elderly people who are medically compromised, have physical and mental handicaps, or take medications with potentially harmful side effects.

At present, the prevention of periodontitis is based on mechanical removal of plaque, plus antimicrobial and antiseptic mouthwashes, if necessary. Where Oral hygiene levels are generally high, fewer than 10% of adult population develops advanced periodontal destruction. However, treatment of gingival inflammation (gingivitis) and maintenance of gingival health depend on adequate plaque control through self-care. Instruction in good oral hygiene and constant practice early in life may lead to good habits, which will help to prevent the formation of calculus. Regular examinations and frequent removal of calculus are also beneficial. Regular brushing of teeth, using proper brush and correct technique needs no emphasis. Rubbing and cleaning with finger and rinsing the mouth vigorously with water, after eating, also help.

Moderate or advanced periodontitis can be treated by elimination of bacterial infection and establishment of effective plaque control. It has been conclusively demonstrated that the large majority of periodontal problems can be treated using non-surgical, conservative approaches. With a better understanding of the biology of connective tissue and of the regenerative potential of periodontal tissues, guided tissue regenerative procedures have been shown to enhance formation of new alveolar bone. This approach has great potential value for individual teeth but can not be applied as a general public health measure.

A rare condition, Juvenile periodontitis, seems to be familial and is characterized clinically by inflammation and rapid progression of periodontal lesion. Presence of *Actinobacillus actinomycetemcomitans* may be an early marker of this disease.

### Dental Implants

In the recent past, dental implants have been successfully used for replacing missing teeth without unnecessarily damaging adjacent tissues or compromising function. The principle of osseointegration of dental implants using high biocompatible materials and appropriate prosthetic concepts has provided the oral health profession with opportunities that transcend the original concept of tissue restitution. During the past decade, implementation of this principle in the treatment of total and partial edentulousness has contributed to a rapid increase in replacing removable dental prosthesis with fixed restorations.

### Other Oral Lesions

#### Oral Sub Mucous Fibrosis (OSMF)

It was initially described in 1966 by Pindborg and Sirsat as an insidious, precancerous, chronic disease that may affect the entire oral cavity and that sometimes extends to the pharynx. Although it is occasionally preceded by the formation of vesicles, OSF is always associated with a subepithelial inflammatory reaction followed by fibroelastic changes of the lamina propria, accompanied by epithelial atrophy. Various factors have been implicated in the development of OSF, the most common of which is chewing areca nut. Associations with tobacco use and vitamin deficiency have also been reported. Symptoms of OSF include the following : Trismus due to oral fibrosis and scarring, pain and a burning sensation upon consumption of spicy food stuffs, increased salivation, change of gustatory sensation, hearing loss due to stenosis of the eustachian tubes, dryness of the mouth, nasal tonality to the voice, dysphagia



to solids, impaired mouth movements (e.g. eating, whistling, blowing, sucking).

Group classification system for the surgical management of trismus.

**Group I** : earliest stage, interincisal distance of greater than 35 mm.

**Group II** : interincisal distance of 26-35 mm.

**Group III** : Moderately advanced cases, interincisal distance of 15-26 mm Fibrotic bands are visible at the soft palate, and pterygomandibular raphe and anterior pillars of fauces are present.

**Group IVA** : Trismus is severe, with an interincisal distance of less than 15 mm and extensive fibrosis of all the oral mucosa.

**Group IVB** : Disease is most advanced, with premalignant and malignant changes throughout the mucosa.

*The medical management in moderate cases involves* : Cessation of the habit followed by use of Steroids, Placental extracts, Hyaluronidase. Surgical management in severe cases : excision of the fibrous bands, buccal pad of fat grafting or Split-thickness skin grafting following bilateral coronoidectomy..

#### Aphthous Stomatitis

This most common oral condition has been usually associated with stress, nutritional deficiencies and malabsorption syndrome. Various symptomatic treatment options have been proposed but improvements seen are considered to be due to placebo effect.

#### Lichen Planus

It is a common oral mucosal disease of unknown etiology, which often occurs without simultaneous skin lesions. In the ulcerated form, the disease often presents significant therapeutic problems. Occasionally, patients may present with lesions called lichenoid reactions, which are sometimes related to drugs and / or graft versus host reactions.

#### Oral Manifestations of HIV Infections and AIDS

In most of the countries, HIV epidemic is spreading with alarming speed. The WHO prediction for the year 2001 is 10 million AIDS cases and 40 million HIV seropositive individuals. In many cases, oral lesions are the first signs of HIV infection and members of the oral health profession should therefore be well trained in recognizing these lesions. The common oral conditions reported to occur in HIV infected patients are Candidiasis; Erythematous, hyperplastic, pseudomembranous hairy leukoplakia; HIV - gingivitis; HIV - Necrotizing gingivitis; HIV - Periodontitis; Kaposi's sarcoma; and, Non Hodgkin's Lymphomas.

In patients with AIDS, treatment of oral Candidiasis should follow general recommended guidelines; use of a triazol drug or Fluconazole may be required. Necrotizing gingivitis and Stomatitis are also frequently encountered. Good oral hygiene is essential, supplemented with antibiotic treatment if necessary. The drug of choice is often Metronidazole. For Kaposi's sarcoma various treatments are used including radiotherapy, surgery and intralesional cytotoxic drugs such as Vinblastine, Vincristine and Bleomycin. Like Candidiasis, hairy leukoplakia is a strong predictor of AIDS.

#### Impacted Tooth

The definition of an impacted tooth is "tooth that can not, or will not, erupt into its normal functioning position, and is, therefore, pathologic and requires treatment.

Mandibular and maxillary third molars, followed by maxillary canine are the teeth most commonly impacted. Failure of teeth to erupt into their normal position in the arch may result in problems that include pericoronitis, pericoronal abscess, periodontal disease, caries, and root resorption of adjacent teeth, dentigerous cysts or odontogenic tumors.

Clinical features include : redness, swelling and tenderness of the gingiva around the impacted tooth, unpleasant taste when biting down on or near the area, halitosis, pain radiating to ear, trismus, and palpable lymph nodes of submandibular region.

Treatment of mandibular third molars involves surgical extraction of the teeth by the dental surgeon under local anesthesia

#### Take home message

- Brush your teeth after every meal, at least twice daily.
- Stop deleterious habits like chewing tobacco, *pan masala*, etc. and smoking
- Visit your dentist at least after every six months for regular check ups.
- Visit the nearest dental centre, immediately without any delay if you experience severe pain or any discomfort rather than taking any indigenous domestic remedies.

#### Summary

During the past few decades, oral health authorities in the fields of epidemiology, education, services, health education and disease prevention have given special attention to the highly prevalent oral health problems like dental caries and periodontal diseases.

Dental plaque is thin, tenacious, firmly adherent and well organized biofilm adhering to the tooth surface, restorations and dentures. The dental plaque may be cariogenic, causing dental caries or calculogenic, causing periodontal diseases. Dental caries (commonly referred as "tooth decay" in layman's language) is a public health problem worldwide. Caries prevalence of permanent teeth in a community is generally assessed by an index known as "Decayed Missing and Filled teeth (DMFT)". The WHO goal was to achieve "3 or less DMFT" among 12 year old children" by the year 2000. According to estimates, 70% of the countries, representing 85% of the world population had achieved this goal by 2001; however, several developing countries have reported a trend towards higher level of dental caries. Another parameter for measuring the load of caries is "Significant caries (SiC)" index. Dental caries is a multifactorial disease. "Tug back" or a feeling of resistance when the explorer was moved on the tooth surface led to an almost confirmed diagnosis of caries. Treatment of dental caries as per Black's "Extension for prevention" necessitated considerable loss of tooth substance beyond the actual carious lesion. It can be prevented by proper brushing, Diet, Flossing, fluorides (Systemic or topical), sealant, antimicrobials like chlorhexidine gluconate 0.2 or 0.12%. The possibility of creating a polyvalent vaccine effective against caries, as well



as measles, poliomyelitis and other serious infections is under consideration.

Periodontal Diseases are the inflammatory diseases, viz., gingivitis and periodontitis and are quite common. While caries has been linked strongly with only a few organisms, the development of gingivitis appears to be caused by nonspecific bacterial plaque flora, which changes over time from predominantly gram positive to more gram negative. In gingivitis the gums become spongy, red, swollen, bleed when brushed or touched, stand away from teeth, often causing little pain and discomfort. Gingivitis therefore is often neglected until it has reached an advanced stage. Gingivitis does not necessarily develop into periodontitis. However, periodontitis is always preceded by gingivitis. The disease can spread to involve deeper supporting tissues viz. periodontal ligament, cementum and alveolar bone. At present, the prevention of periodontitis is based on mechanical removal of plaque, plus antimicrobial and antiseptic mouthwashes, if necessary. Moderate or advanced periodontitis can be treated by elimination of bacterial infection and establishment of effective plaque control. It has been conclusively demonstrated that the large majority of periodontal problems can be treated using non-surgical, conservative approaches. In the recent past, dental implants have been successfully used for replacing missing teeth without unnecessarily damaging adjacent tissues or compromising function.

Oral submucous fibrosis (OSMF) is always associated with a subepithelial inflammatory reaction followed by fibroelastic changes of the lamina propria, accompanied by epithelial atrophy. Various factors have been implicated in the development of OSF, the most common of which is chewing areca nut. Associations with tobacco use and vitamin deficiency have also been reported. Symptoms of OSF include Trismus, pain and a burning sensation upon consumption of spicy food stuffs, increased salivation, change of gustatory sensation, hearing loss, dryness of the mouth, nasal tonality to the voice, dysphagia to solids, impaired mouth movements. The medical management in moderate cases involves Cessation of the habit followed by use of Steroids, Placental extracts, Hyaluronidase. Surgical management in severe cases include excision of the fibrous bands, buccal pad of fat grafting or Split-thickness skin grafting following bilateral coronoidectomy.

Aphthous Stomatitis is associated with stress, nutritional deficiencies and malabsorption syndrome. Lichen Planus is a common oral mucosal disease of unknown etiology, which often occurs without simultaneous skin lesions. In the ulcerated form, the disease often presents significant therapeutic problems. The common oral conditions reported to occur in HIV infected patients are Candidiasis; Erythematous, hyperplastic, pseudomembranous hairy leukoplakia; HIV - gingivitis; HIV - Necrotizing gingivitis; HIV - Periodontitis; Kaposi's sarcoma; and, Non Hodgkin's Lymphomas.

Brushing teeth after every meal, at least twice daily, Stopping deleterious habits like chewing tobacco, pan masala, etc. and smoking, Visiting dentist at least after every six months for regular check ups are the most important preventive measures for Oral and Dental Diseases.

### Study Exercises

**Short Notes :** (1) Prevention of Dental Caries (2) Dental Examination in School Health Surveys (3) Prevention of Periodontal diseases (4) Epidemiology of Dental caries

#### MCQs :

1. As per WHO goal How many "Decayed Missing and Filled teeth (DMFT)" was to achieve among 12 year old children" by the year 2000 (a) 3 or less (b) 2 or less (c) 4 or less (d) 6
2. Dental caries can be prevented by (a) Proper brushing (b) Flossing (c) Fluorides (d) All of the above
3. Aphthous Stomatitis is associated with the following : (a) Stress (b) Nutritional deficiencies (c) Malabsorption syndrome (d) All of the above
4. All of the following are common oral conditions reported to occur in HIV infected patients except (a) Candidiasis (b) Pseudomembranous hairy leukoplakia (c) Gingivitis (d) Caries

**Answers:** (1) a; (2) d; (3) d; (4) d.

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Ashok K Verma

Rheumatic fever is a febrile disease affecting connective tissues particularly in the heart and joints initiated by infection of the throat by group A beta haemolytic streptococci. Rheumatic fever often leads to Rheumatic Heart Disease (RHD), which is a crippling disease.

RF and RHD remain significant causes of cardiovascular diseases in the world today. Despite a documented decrease in the incidence of acute RF and a similar documented decrease in the prevalence of RHD in industrialized countries during the past five decades, nonsuppurative cardiovascular sequel of group A streptococcal pharyngitis remain medical and public health problems in both developed and developing countries even at the beginning of the 21st century. The most devastating effects are on children and young adults in their most productive years (1-6).

### Magnitude of the Problem

The reported prevalence rates among school-age children in various parts of the world range from very low of about 0.2 per 1000 in Havana to as high as 77.8 cases per 1000 in Samoa (7). It has been estimated that RF is the most common cause of heart disease in the 5-30 year age group throughout the world. Based on hospital data, RHD accounts for 12-65 percent of hospital admissions related to cardiovascular disease.

### Epidemiological Factors

**Agent Factors** : Rheumatic Fever (RF) and Rheumatic Heart Disease (RHD) are nonsuppurative complications of Group A streptococcal pharyngitis due to a delayed immune response (8,9). All strains of Group A streptococci are not implicated in causation of Rheumatic Fever but the serotype which has attracted the most attention in M type 5(10).

Carriers of Group A streptococci are responsible for the subclinical infections in the community. These carriers can be convalescent, transient and chronic. The carrier stages make the disease difficult for eradication (11).

**Host Factors** : The host factors are as follows :

- Age- Rheumatic Fever is commonly a disease of childhood and adolescent age group (5-15 years).
- Sex-Affects both sexes equally.

**Environmental Factors** : Rheumatic fever is more commonly seen among individuals of low socio-economic status. Poverty, overcrowding and poor ventilation/housing conditions are important precipitating factors.

### Clinical Features

Fever and polyarthrititis are the cardinal features of Rheumatic Fever. Fever is normally acute in onset lasting for 12 weeks or longer. Large joints like ankles, knees, elbows and wrists are more commonly involved than smaller joints. Carditis occurs in 60-70% of cases, which manifests clinically in the form of cardiac murmurs, pericarditis, myocarditis, endocarditis, heart enlargement and heart failure. First degree AV block is the most common ECG finding.

Appearance of small, painless and non tender subcutaneous nodules 4 weeks after onset of Rheumatic Fever may also be seen. These are self limiting and disappear with no residual damage. Other clinical features could be skin rashes and chorea.

### Diagnosis

The 2002-2003 WHO criteria (Table - 1) (7) for the diagnosis of RF and RHD are based on revised Jones criteria and facilitate the diagnosis of :

- A primary episode of RF.
- Recurrent attacks of RF in patients without RHD.
- Recurrent attacks of RF in patients with RHD.

Table - 1 : The diagnostic criteria	
Primary episode of RF	Two major* or one major and two minor** manifestations <i>plus</i> evidence of a preceding group A streptococcal infection***
Recurrent attack of RF in a patient without established rheumatic heart disease	Two major or one major and two minor manifestations <i>plus</i> evidence of a preceding group A streptococcal infection.
Recurrent attack of RF in a patient with established rheumatic heart disease	Two minor manifestations <i>plus</i> evidence of a preceding group A. Streptococcal infection. c
*Major manifestations	Carditis
	Polyarthrititis
	Chorea
	Erythema marginatum
**Minor manifestations	Subcutaneous nodules
	Fever, polyarthralgia
***Supporting evidence of a preceding streptococcal infection within the last 45 days	Laboratory; elevated acute phase reactants (erythrocyte sedimentation rate or leukocyte count).
	Prolonged P-R interval
	Elevated or rising antistreptolysin-O or other streptococcal antibody OR
	A positive throat culture OR
	Rapid antigen test for group A streptococci OR
	Recent scarlet fever.

### Prevention of Rheumatic Fever and Rheumatic Heart Disease

**Primary Prevention** : The primary prevention of Rheumatic Fever (RF) is defined as the adequate antibiotic therapy of group A streptococcal Upper Respiratory Tract (URT) infections to prevent an initial attack of acute RF (12, 13, 14, 15). Primary prevention is administered only when there is group A streptococcal URT infection while approach is theoretically

simple, but it may not be practically feasible. In order to prevent a single case of RHD, several thousand cases of streptococcal throat infection will need to be identified and treated.

A more practical and viable approach is to concentrate on “high risk” group such as school children and to treat a sore throat with penicillin empirically even without the throat swab culture. The recommended treatment regimes for streptococcal pharyngitis for primary prevention of Rheumatic Fever are as given in Table - 2.

**Secondary Prevention** : Secondary prevention of Rheumatic Fever (RF) is defined as the continuous administration of specific antibiotics to patients with a previous attack of RF, or a well-documented Rheumatic Heart Disease (RHD). The purpose is to prevent colonization or infection of the Upper Respiratory Tract (URT) with group A beta-hemolytic streptococci and the development of recurrent attacks of RF. Secondary prophylaxis is mandatory for all patients, who have had an attack of RF, whether or not they have residual rheumatic valvular heart disease.

The antibiotics used in secondary prophylaxis of Rheumatic

Fever are as given in Table - 3.

**Other Preventive Measures** : Non-medical measures for the prevention/control of RF are related to improving living conditions, and breaking the poverty-disease-poverty cycle. Improvements in socio-economic conditions (particularly better housing) will in the long term reduce the incidence of RF.

### Planning and Implementation of National Programme for the Prevention and Control of Rheumatic Fever and RHD

The establishment of a national prevention programme is essential in countries where Rheumatic Fever (RF) and Rheumatic Heart Disease (RHD) remain significant health problems. Both primary and secondary prevention of RF and RHD have been proven to be safe, feasible and effective in both developed and developing countries. The overall goal of a national programme should be to reduce morbidity, disabilities and mortality from RF and RHD.

The main components of a national programme would be :

- (a) Secondary prevention activities aimed at preventing the

**Table - 2 : Treatment regimes for streptococcal pharyngitis for primary prevention of Rheumatic Fever**

Antibiotic	Administration	Dose	Comments
Benzathine Benzylpenicillin	Single intramuscular injection	1200 000 units intramuscularly; 600000 units for children weighing <27kg.	Preferable to oral penicillin G because of patient adherence problems.
Phenoxymethyl penicillin			
(Penicillin V)	Orally 2-4times/day for 10 full days	Children: 250mg bid or tid. Adolescents or adults:250mg tid or qid, or 500mg bid	Penicillin G resistance by group A streptococci has never been reported.
Amoxicillin	Orally 2-3 times/day for 10 full days	25-50mg/kg/day in three doses. Total adult dose is 750-1500mg/day.	Acceptable alternative to oral penicillin G because of the taste.
First-generation Cephalosporins	Orally 2-3 times/day for 10 full days	Varies with agent	Acceptable alternative for oral penicillin.
Erythromycin Ethylsuccinate	Orally 4 times/day for 10 full days	Varies with formulation. Available as the stearate, ethylsuccinate, estolate or base.	Alternative drug for patients allergic to penicillin. Should not be used in areas where group A streptococci have high rates of macrolide resistance.

**Table - 3 : Antibiotics used in secondary prophylaxis of Rheumatic Fever**

Antibiotic	Mode of administration	Dose
Benzathine Benzylpenicillin	Single intramuscular Injection every 3-4 weeks	For adults and children >30kg in weight: 1200000 units. For children<30kg in weight: 600 000 units.
Penicillin V	Oral	250mg twice daily. For adults and children >30kg in weight
Sulfonamide (e.g. sulfadiazine sulfadoxine, sulfisoazole)	Oral	1 gram daily
Erythromycin	Oral	For children <30kg in weight: 500mg daily. 250mg twice daily

- recurrence of acute RF and severe RHD;
- (b) Primary prevention activities aimed at preventing the first attack of acute RF;
  - (c) Health education activities;
  - (d) Training of health-care providers;
  - (e) Epidemiological surveillance;
  - (f) Community involvement.

Although proven inexpensive cost-effective strategies for the prevention and control of streptococcal infections and their non-suppurative sequelae, acute Rheumatic Fever and Rheumatic Heart Disease, are available, these diseases remain significant public health problems in the world today, particularly in developing countries.

Primary prevention of Rheumatic Fever consists of the effective treatment of group A beta-hemolytic streptococcal pharyngitis, with the goal of preventing the first attack of Rheumatic Fever. While it is not always feasible to implement broad-based primary prevention programs in most developing countries, a provision for the prompt diagnosis and effective therapy of streptococcal pharyngitis should be integrated into the existing healthcare facilities.

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# 11

## Occupational Health



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### Definition

'Occupational health' should aim at the promotion and maintenance of the highest degree of physical, mental and social well being of workers in all occupations; the prevention amongst workers of departures from health caused by their working conditions; the protection of workers in their employment from risks resulting from factors adverse to health; placing and maintenance of the worker in an occupational environment adapted to his physiological and psychological equipment and to summarize : the adaptation of work to man and of each man to his job'.

*- Joint Committee of WHO and ILO, 1950*

### Health Hazards in Industry

Hazards in the industry can be due to physical, chemical, biological, mechanical and psychosocial causes. Table - 1 gives

the physical hazards and their adverse health effects due to them.

**Chemical Hazards** : Almost all the occupations in industry have scope of exposure to some chemical substance or the other. These substances may be solids, liquids or gases, vapours, fumes, dusts, smoke, mist, fog or smogs.

**Biological Hazards** : Viruses, rickettsiae, bacteria, fungi, protozoa and helminthes may be transmitted in certain occupations.

**Mechanical Hazards** : Mechanical factors of importance in illness and injury in industry are defective design of machinery, defective procedures, unguarded machinery, protruding and moving parts, falling heavy objects and poor ergonomics.

**Psychosocial Hazards** : Factors responsible for psychosocial illness are frustration due to type of work, risks involved in work, monotony, long working hours, lack of recognition, lack of job satisfaction, poor remuneration, poor man management, lack of welfare activities and tensions at home and place of work. The indicators for psychosocial group of are chronic absenteeism, mass leave lock outs, strikes and unexplained reduction in production.

**Table - 1 : Physical Hazards in an industry**

Hazard	Occupation	Health Effects
Heat	Foundry, glass, heavy metal industries, underground mines, vulcanization of rubber, spinning room of textile industry	Heat stroke, heat hyperpyrexia, heat exhaustion, heat syncope, heat cramps
Cold	Armed forces, food processing and preservation industry	Chill blains, frost bite, trench foot, erythrocyanosis
Light	Mines, driving	Eye strain, eye fatigue, nystagmus, headache
Noise	Machinery in factories producing loud noise	<i>Auditory</i> : Auditory fatigue, permanent hearing loss; <i>Non auditory</i> : Nervousness, fatigue, decreased efficacy, annoyance, raised blood pressure, loss of sleep
Vibration	Pneumatic drill users	Vibration induced white fingers due to Raynaud's phenomenon, osteoarthritis of wrists, elbows, shoulders.
UV radiation	Arc welding	Glare and dazzle, pain and gritty feeling in the eyes
Ionizing radiation	Radiography, radioisotope use, processing of plastics, food preservation, industrial radiography, industrial hydrology, chemical industry and medical research	Cancer, leukemia, aplastic anemia, pancytopenia

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### Health Hazards in Foundry Work

Founding consists of pouring molten metal into a mould which is made to the outside shape of a pattern of the article required and contains, in some case a core which will determine the dimensions of any internal cavity. The basic principles of foundry work have hardly changed over the years though a lot of modernization has come, making plants more mechanized and automatic. Molten metal is introduced into the mould. After cooling occurs, the mould is subjected to a 'shakeout' procedure, which releases the casting and removes the core. The casting is then cleaned and any extraneous metal is removed from it.

#### Process

The various processes involved in foundries include Moulding & pattern making, Core making, Melting & pouring, Shakeout (Knockout) and Dressing & cleaning.

The various process outlined in the preceding section give rise to heat, molten metal splashes, dusts, noise, gases and vapours in the foundry environment. If these hazards are not controlled or contained, serious health effects in exposed workers can result. Foundry work also involves various manual operations which carry a risk of physical injury. The occupational health and safety issues are encountered during foundry activities include Physical hazards, Radiation hazards, Respiratory hazards, Electrical hazards, Noise exposure, Burial hazards, and Fire & explosions. The common and important ones are as follows :

**Silicosis** : Silica dust presents a prominent hazard of silicosis. This dust is generated during mixing, moulding, shakeout and dressing operations, and during sand conditioning for re-use. The dust arises from quartz in the sand, and the concentration of free silica in the air varies with the handling process, the efficiency of dust control, the chemical composition of the sand and the physical state of the sand, that is, whether the sand is screened or un-screened, wet or dry and is either dumped or re-milled, with water and binder added before it is re-used. The amount of respirable dust is increased by such re-use. Sand is dry at the mixing or 'mulling stage prior to mould making', and at the shakeout stage; this dry sand is potentially more hazardous than wet sand. Screened sand does not produce as much silica dust as unscreened sand and pure quartz sand is more hazardous than olivine sand. Abrasive blasting processes may involve the use of sand containing high concentrations of free silica.

#### **Irritation, Allergy, Asthma, Metal Fume Fever, Malignancy:**

In addition to dusts, the air in foundries may contain the potential irritants like formaldehyde, various amines and phenol. These contaminants are generated primarily by the core making and moulding processes, and may irritate the eyes and the respiratory tract. Some hardwoods used in

pattern making can release products which may cause asthma in exposed workers. Vapours from various resins can initiate severe allergic reactions. Carbon monoxide gas is produced in substantial amounts by a variety of furnaces. Exposure to concentrations of 500 to 1000 ppm for approximately 30 minutes may precipitate headache, accelerated breathing, nausea, dizziness and mental confusion. Thus a possible secondary effect of exposure is an increased risk of accident and injury to the worker. Various metal fumes may be generated during founding processes, especially during melting and pouring operations. Lead, magnesium, zinc, copper, aluminum, cadmium, antimony, tin and beryllium fumes are commonly present in non-ferrous foundries. Iron oxide is the major fume generated in iron and steel operations. 'Metal fume fever' may result from exposure to these contaminants. This is an acute illness of short duration which commences some hours after inhalation of the metallic fumes. The initial symptoms are flu-like; nausea, headache, dry throat and coughing, and muscular pains, chills and sweating may occur later. Recovery is usual within 24 hours after removal from exposure. The lead hazard in furnace cleaning, dross disposal and the fettling of lead alloys deserves particular attention. Besides dusts & fumes in foundries are known to have carcinogenic properties.

**Occupational Dermatitis** : Formaldehyde, isocyanates, various resin products associated with pattern making and core making processes can irritate the skin and may precipitate allergic skin reactions.

**Noise Induced Hearing Loss and Related Effects** : The foundry process generates noise from various sources, including scrap handling, furnace charging and EAF melting, fuel burners, shakeout and mould / core shooting, and transportation and ventilation systems. Some fettling workers have been shown to be exposed to levels of noise over 100 db; shakeout and knockout processes are typically associated with readings of 90 - 110 db. Mechanical sand mixing processes and forced draught furnaces may produce noise levels of 90 - 100 db. Extraction fans, die-casting machines, core-making and shell-making equipment may also be sources of excessive noise.

**Vibration** : Pneumatic grinding and chipping tools used in dressing the cooled castings may cause vibration induced health effects in operators. Hazardous vibration equipment may also be utilized in shakeout and core removal operations.

**Heat and Heat Stress** : Radiant heat is the major contributor to the heat load imposed on the worker by the environment. Convective heat transfer adds to this radiant heat. Protective clothing is worn for protection against the heat radiating from the heat sources and against contact with molten metals. Such clothing greatly restricts the potential for body heat loss via evaporation. The effects of heat range from decreased concentration to painful cramps, fainting, heat exhaustion and heatstroke. Heat stress can also aggravate the effects of exposure to other agents such as noise and carbon monoxide.

**Accidents & Injuries** : Serious burns may result from splashes of molten metal in the melting and pouring areas of foundries. Frequent, unprotected viewing of white-hot metals in furnaces and pouring areas may cause eye cataracts. Eye injuries from molten metal or fragments of metal may occur in pouring and



dressings areas, during continuous casting processes, non - ferrous molten metals, such as copper and aluminum, may explode violently if they contact water. Injuries related to the manual handling of materials, and injuries due to falls, may occur. Grinding wheels used for dressing small articles may result in hand injuries.

### Preventive Measures

**Monitoring & Evaluation of Exposure** : Monitoring of the work environment, personal monitoring and biological monitoring should be undertaken, In some cases, biological monitoring may be required to supplement static or personal monitoring. When developing a monitoring programme in foundries, due consideration should be given to the hazards in the foundry. In the control of health hazards due to specific contaminant, where it has been demonstrated that the exposure of the employee to the contaminant is approaching the relevant exposure standard, or where biological monitoring indicates that an unacceptable exposure is occurring, immediate action must be taken to reduce the health hazard and intensive monitoring should continue. Worker exposure to dusts, gases and vapours should be kept as low as workable. Exposures should be well below the exposure standards recommended in the Factories Act 1948.

### Engineering Control Measures

- (a) **Elimination/substitution and process modification** viz. quartz sand can be substituted by olivine sand in 'sand blasting' as it is less hazardous. Silica - based polishing pastes should not be used in metal cleaning operations.
- (b) **Engineering controls** like local exhaust ventilation should be provided at the mixing or mulling stage as the sand is dry. It is a means of controlling carbon monoxide emissions at their source. Total enclosure of abrasive and cleaning operations should be provided. Potentially irritant vapours or fumes generated in core making or moulding processes should be collected by exhaust ventilation at the point of emission.
- (c) The **reduction of noise at the source** or in the transmission path should be achieved wherever workable.

### Preventing Physical Injuries

- (a) **Mechanically propelled vehicles or machinery** should be inspected regularly. Contact between molten metal and water must be avoided. All ladles and other equipment used for handling metal should be completely dry before contacting molten metal.
- (b) **Good house keeping practices** are to be followed.
- (c) **Floors around furnaces** should be of slip - resistant, non - combustible material, kept free of obstructions and cleaned regularly.
- (d) Persons would be prohibited from **entering furnace areas** when the temperature exceeds 50°C.
- (e) Foundries should be **equipped with safety blankets, automatic emergency showers or hoses** to extinguish burning clothing.
- (f) **Self - contained breathing apparatus** must be used in emergencies when high carbon monoxide concentrations are suspected.

**Minimizing the Risk of Heat Illness** : People who have any history of heat intolerance or a circulatory disorder, anyone

recovering from a fever, and any dehydrated worker must be regarded as being in a high - risk category for heat illness. Unacclimatised persons must be given time to acclimatize to work in the heat. Planned job rotation can assist in reducing exposure to heat. Cool water should always be available in close proximity to hot working areas and encouragement be given for the use of these facilities. The exposure of workers to radiant heat can be reduced by the strategic positioning of shields between workstations and heat sources. Clothing should be carefully selected so that a balance between protection and facilitation of heat loss through evaporation is achieved.

**Personal Protective Equipment** : Personal protective equipment such as goggles, padded gloves, ear muffs must be used by the workers. If the mechanical ventilation in the foundry is not adequate in removing the dust at all points of contamination, the wearing of personal respiratory protective equipment, such as a face mask/respirator, is a complementary preventive measure together with local exhaust ventilation. If operators are required to work inside the enclosure, a continuous - flow, air - line respirator must be worn.

**Education and Training** : All employees working with foundry hazards must be informed of the hazards and the precautions necessary to prevent damage to their health. Employees exposed to contamination hazards should be educated in the need for, and proper use of, facilities, clothing and equipment and thereby maintain a high standard of personal cleanliness.

**Health Assessment** : Pre - placement examination and periodic medical examination of all worker should be done annually for early identification of health effects and for documentation for compensation claims.

### Noise Management Techniques :

- Enclose the process buildings and / or insulate them
- Cover and enclose scrap storage and handling areas, as well as shake out and fettling processes
- Enclose fans, insulate ventilation pipes and use dampers
- Implement management controls, including limitation of scrap handling and transport during night time. Noise abatement measures should achieve the ambient noise levels

### Health Problems of Agricultural Workers

Agriculture is art/practice of cultivating land. WHO defines it as an industry comprising of all forms of activities connected with growing, harvesting and primary processing of all types of crops. It also includes activities related to breeding, raising caring for animals in the farms and tending gardens and nurseries. Any person engaged either temporarily/ permanent in activities related to agriculture is called as agricultural labour. Agricultural sector occupies a key position in our country. It provides employment to about 65 per cent of the working population of India (5). It is the major source of income for about three - fourths of India's populations who live in villages. Agricultural workers constitute by far the largest segment in the unorganized sector. Most of them are listed as cultivators (large, medium and small) of whom approximately 50% belong to the category of small and marginal farmers. A significant number of them are engaged in livestock, forestry, fishing, orchards and allied activities. Agricultural workers constitute

the most neglected class in Indian rural structure. Their income is low and irregular. They do not possess any skill or training and have no alternative employment opportunities. Socially, a large number of agricultural workers belong to scheduled castes and scheduled tribes. Therefore, they are a suppressed class. They are not organized and they cannot fight for their rights (6). Occupational hazards of agriculture sector are given in Table - 1 (7).

The various types of respiratory diseases in agriculture are highlighted in Table - 2.

Table - 2 : Respiratory diseases in agriculture	
Agent	Disease
Saw dust	Carcinoma nasal septum
Sugar cane dust	Bagassosis
Cotton, flax, sisal or hemp	Byssinosis
Husk with thermophilic actinomycis ( <i>Micropolyspora faeni</i> )	Farmer's lung
Tobacco dust	Tobaccosis
Dusts of grains, rice, coconut fibres, tea	Asthma, COPD
Cocoa bean handling	Respiratory allergy

**Others :** Agriculture being labour intensive activity musculo - skeletal disorders are the leading cause of the occupational ill health (8). This risk of musculo - skeletal disorders is higher in agricultural workers because of the longer working hours, practice of lifting heavy weights and inconvenient work posture. There is poor application of ergonomics principle to agricultural tools. There are no legislations related to health, safety and welfare of agricultural workers. There is no social security for agricultural workers other than crop insurance. There is no act to provide welfare to the workers. Living condition of these people, low educational status, lack of medical facilities in rural areas aggravate there problems. Being in close proximity to animals agricultural labour also faces hazards of zoonosis.

### Women in Agriculture

Women in India are the major work force in agriculture and perform almost all the agricultural activities. Since agriculture by its nature is an unorganized sector and in case of women, their contribution is generally unrecognized. In fact some economist have use the term 'Labour for Love' while describing the status of Indian women who is married with farmer'. A significant proportion of women work force in rural areas is dependent for their livelihood (8). The lives of these women are plagued by high levels of occupational, poverty - induced diseases and reproductive health problems. Abortions, premature delivery, and still birth are outcomes of their deprived socio - economic,

Table - 1 : Occupational Health Hazards of Agriculture		
Exposure	Health Effect	Remarks
Weather, Climate	Dehydration, heat cramps, heat exhaustion, heat stroke, skin cancer	Most agriculture occupations are performed outdoors
Snakes, insects	Fatal or injurious bites and stings	Close proximity in high incidence
Sharp tools, farm equipment	Injuries ranging from cuts to fatalities, hearing impairment from loud machinery	Most farm operations require variety of skills for which workers have little formal training and there are few hazard controls on tool equipment
Physical labour carrying loads	Numerous types of (largely unreported) musculoskeletal disorders, particularly soft - tissue disorders, e.g. back pain	Agricultural work involves awkward and uncomfortable conditions and sustained carrying of excessive loads
Pesticides	Acute poisonings, chronic effects such as neurotoxicity, reproductive effects and cancer	More hazardous products are used in developing countries with minimal Personal Protective Equipment (PPE)
Dusts, fumes, gases, particulates	Irritation of the eyes and respiratory tract, allergic reactions, respiratory diseases such as Byssinosis, bagassosis, asthma, chronic obstructive pulmonary disease and hypersensitivity pneumonitis	Agricultural workers are exposed to a wide range of dusts and gases from decomposition of organic materials in environments with few exposure controls and limited use of PPE use in hot climates.
Biological agents and vectors of disease	Skin diseases such as fungal infections, allergic reactions and dermatoses	Workers are in direct contact with environmental pathogens, fungi, infected animals and allergenic plants
	Parasitic diseases such as schistosomiasis, malaria, sleeping sickness, leishmaniasis, ascariasis and hookworm	Workers are in direct contact with environmental pathogens, fungi, infected animals and allergenic plants
	Animal - related diseases or zoonoses such as anthrax, bovine tuberculosis and rabies (at least 40 of the 250 zoonoses are occupational diseases in agriculture)	Workers have ongoing, close contact with animals through raising, sheltering, and slaughtering exposed to a mix of biological agents, pesticides, and diesel fumes, all linked with cancer

cultural, and political conditions and gender inequities (9). The socio - cultural norms and practices that endanger the women's health are reflected in their low age at marriage and low age at first childbirth. Women working in fields shoulder the double burden of work - within home and outside home - and stretch themselves beyond their physical capabilities to procure adequate economic security for their families. They bear the brunt of the deprivation due to the gender inequities. The low nourishment and the resultant general under - nourishment lead to illnesses, which prevent them from translating their labour endowments into economic resources. In short, the poverty of the women agricultural workers encompasses a wide range of unmet needs and gender - specific inequities including lack of adequate access to education, employment, resources as well a range of violence, relative powerlessness, and feelings of hurt, low self - esteem and denial of identity.

### Legislations

Though agriculture is the major occupation in India and gives not only employment but is also responsible for providing food security to the nation but unfortunately only lip service has been paid in providing social security for the welfare of the workers engaged in this class. As a result they can go into penury due to floods, droughts, extensive loans under taken

from money lenders to buy costly fertilizers and pesticides. The general public health system of the country is also in a poor state and has very little to offer as preventive, promotive and curative care to this class. This is evident from the large number of suicides that have taken place among farmers. There is a definite need to take case for social security for this sector. In this connection government has come out with National Policy for Farmers 2007(10). The objective of the policy is to improve the economic viability of farming through substantially improving net income of farmers. The policy emphasis on increased productivity, profitability, institutional support, and improvement of land, water and support services apart from provisions of appropriate price policy, risk mitigation measures and so on. Government of India has recently taken several initiatives such as the National Horticulture Mission, the National Bamboo Mission, reforms in agricultural marketing, the revitalization of cooperative credit structure and setting up of the National Fisheries Development Board and the National Rainfed Area Authority. More recently, the National Food Security Mission and the *Rashtriya Krishi Vikas Yojana* (Additional Central Assistance Scheme) have been approved to substantially enhance investment in agriculture and increase production and productivity.

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## Organ / System Diseases Peculiar to Occupational Settings

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### Occupational Lung Disease

An occupational lung disease is a lung condition that develops as a result of a person inhaling harmful substances at his or her place of work. Occupational lung diseases are the most common work - related illness but fortunately many are preventable or controllable with proper treatment. Occupational lung diseases are classified into two major groups : pneumoconiosis, caused by dust that gets into the lungs, and hypersensitivity diseases, such as asthma, that are caused by the lungs' overreaction to airborne pollutants. Table - 1 depicts important features of various lung diseases.

#### Pneumoconiosis

By ILO definition it is the accumulation of dust in the lung and tissue reaction to its presence. The concept of using the term pneumoconiosis has undergone a change. Earlier this term was used to describe all lung related problems caused by any kind of dust (17). However the term should be used

for all dust damage to the alveolar part of lung including the airways which do not have mucociliary lining (18). Therefore the term does not include bronchitis, asthma or cancers. In other words the inorganic dusts like silica, asbestos and coal cause pneumoconiosis where as organic dust like cotton and cane sugar cause bronchitic changes and do not qualify to be called pneumoconiosis.

**Body Defence Mechanism** : Dust is an aerosol consisting of finely divided particulate matter, size  $1\mu$ -  $150\mu$ , organic or inorganic, generally inanimate and produced by attrition of solid matter by processes such as cutting, sawing, crushing, grinding, blasting etc. Dust particles  $10\mu$  or more in size are released in size settle down on the floor due to effect of gravity. The dust particles of such larger size which are inhaled are mostly arrested by the upper airway filter of hairs in the nostrils and by the folds of mucosa over the turbinates and carried down in the mucus and swallowed over airway filter, carried in the mucus back to the larynx and swallowed. Irritant particles are thrown out by reflex acts of coughing and sneezing. Of smaller particles those are inhaled in size of  $3$  -  $10\mu$  are tackled by the mucociliary lining of lower airway, filter, carried in the mucus back to the larynx and are swallowed. Particles  $0.5\mu$  -  $3\mu$  in size reaches the alveoli and get deposited causing damage to the lungs, producing various types of pneumoconiosis. Particles less than  $0.5\mu$  in size have a slim chance of settling down in

Table - 1 : Comparison of Different Types of Lung Diseases							
	Silicosis	Anthracosis	Asbestosis	Byssinosis	Bagassosis	Farmers' lung	Siderosis
Type	Major	Major	Major	Major	Major	Major	Major
Occupational exposure	Silica dust mines, tunnels : quarries, foundries; potteries and soap	Coal miners and handlers : carbon electrode manufacturing	Asbestos industry; brake and fire resistant product manufacturing	Exposure to cotton dust released during cording, spinning and weaving	Fibrous residue of sugar cane in cardboard and paper industry	Agricultural workers	Foundry workers, grinders and welders
Initiating stimulus	Chemical	Unknown	Mechanical	Allergy	Infection	Infection	Absent
Pathogenesis	Fibrosis initiated by silicic acid leading to nodular fibrosis, emphysema and right heart failure. Pulmonary TB in 50% cases	Two distinct stages - simple CWP and PMF. Average time taken is 12 years	Asbestos fibres initiate fibrosis of pulmonary tissue, emphysema and its associated complication	Cotton dust inhalation produces allergic reaction leading to broncho - spasm, emphysema and its complications	Fungal infection leading to acute bronchitis and broncho - pneumonia	Fungal infection leading to bronchitis and broncho - pneumonia	No tissue reaction or functional impairment though lungs are loaded with iron dust.

the lungs and are mostly breathed out in the expiratory air.

**Silicosis** : Silicosis is a disease caused by breathing air containing silica in its free state, as quartz ( $\text{SiO}_2$ ). The pathological result is a generalized fibrotic change and development of miliary nodules of variable sizes in both lungs. The clinical manifestations are shortness of breath, decreased chest expansion, a lessened capacity for work and chronic bronchitis with the absence of fever and characteristic X - ray findings. There is an increased susceptibility to tuberculosis. The diagnosis of the disease mainly depends upon occupational history symptom complex and the radiological findings. The pathological process starts only when the dust particles, which contain silica in a free state such as quartz ( $\text{SiO}_2$ ), reach the alveoli. Most of the dust inhaled is expelled by the ciliated epithelium and some part is eliminated by phagocytosis, which brings up the particles and discharges them to the ciliated epithelium and the cough mechanism expels them. However, when the fine particles are present in the atmosphere in a large quantity, some find way to the finer air passages. They first cause the inflammation of the ciliated epithelial cells with their subsequent destruction, reducing the first line of defense. Epithelial cells crowded with silica dust get aggregated into definite clumps around which fibrosis occurs. This damage produced in the lung is permanent. It is liable to activate the preexisting tubercular focus and develop tuberculosis. The disease finally produces emphysema and corpulmonale.

Very little can be done once the disease has set in and therefore, prevention is most important, pre - placement & periodic health examinations of the worker are important. Chest X Ray is to

be taken to see if the individual has pulmonary tuberculosis or any other lung disease. Basic lung function tests should be carried out, including measurement of the Vital Capacity & Forced Expiratory Volume in one second. Dust control is the most important engineering procedure to reduce risk. If a significant number of workers develop silicosis within 20 - 25 years of first employment, the dust control measures should be suitably revised.

**Asbestosis** : Asbestos is a fibrous material. These are silicates; silica combined with bases like magnesium, iron, calcium, sodium and aluminum. These are of two types - serpentine and amphibole. However, 90% of production is of serpentine variety. Asbestos used in the manufacture of asbestos cement, fireproof textiles, roof tiling, brake lining, gaskets, and such other items. Asbestos fibres are inhaled and fine dust gets deposited in the alveoli. These are insoluble and cause chronic irritation resulting in pulmonary fibrosis of lungs. It can also cause carcinoma of bronchus and mesothelioma of pleura and peritoneum (more due to amphibole variety). These possibilities are more when exposure is coupled with smoking. The disease appears after an exposure of 5 to 10 years. The fibrosis is peribronchial, diffuse and more near the bases in contrast to fibrosis due to silicosis. Clinically, patient gets cough, pain in chest and dyspnoea disproportionate to the clinical signs in lungs. In advanced cases, there may be clubbing of fingers, cardiac failure and cyanosis. Sputum show asbestos fibres coated with fibrin called "asbestos bodies". X - ray chest shows a ground glass appearance in lower parts of lungs. Disease is progressive even after removal from exposure. Preventive



measures include :

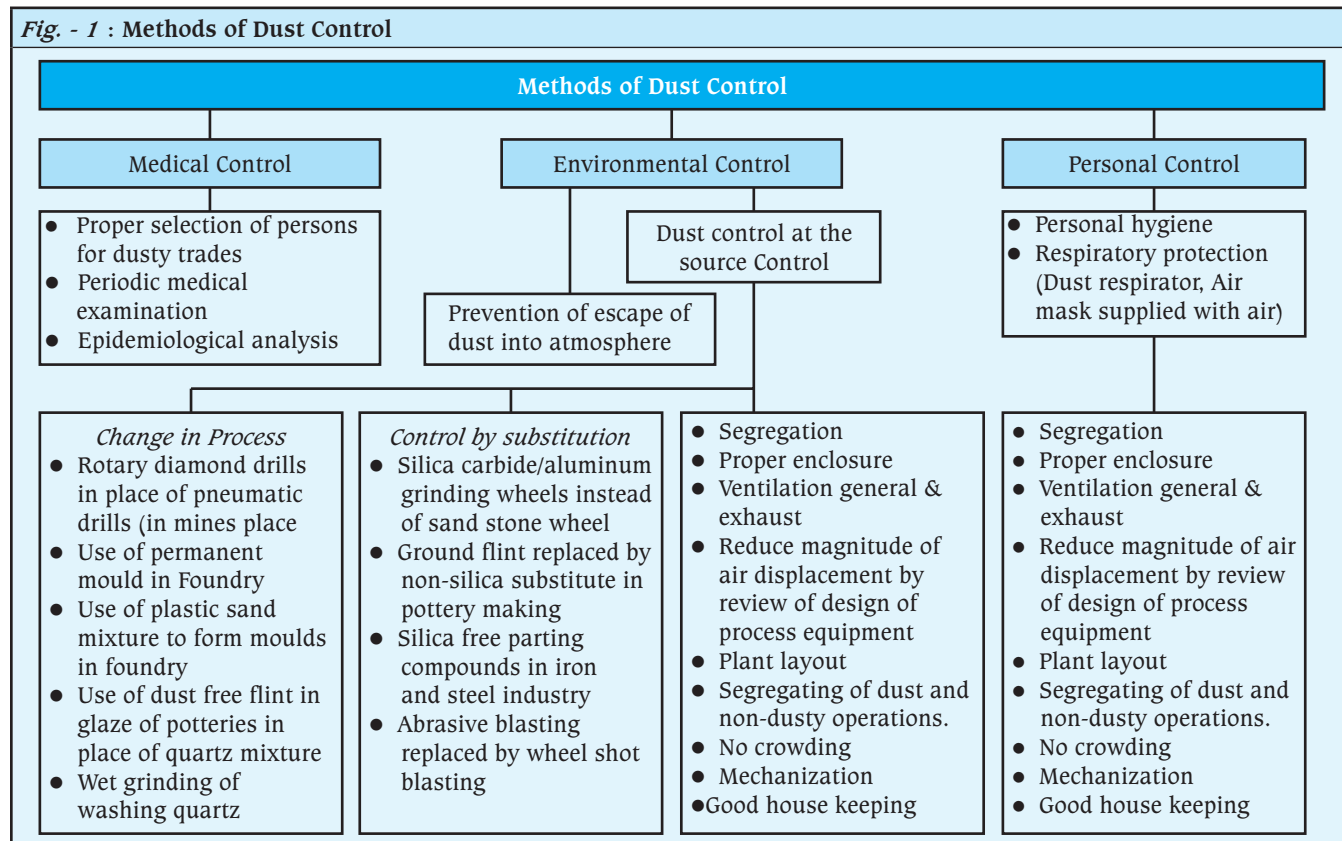
- Adopt all measures for dust control. The legal exposure limit in India is 23 fibres/ml of air. Fig.-1 shows various methods of dust control.
- Substitute it with safer materials like glass fibres, calcium silicate, plastic foam etc. where feasible.
- Use safer varieties of asbestos (chrysotile and amosite).
- Periodic medical examination of workers and elimination of susceptible from workforce.
- Use of personal protective measures.
- Good housekeeping & the use of vacuum cleaners.
- Use of respirators & protective clothing is to be encouraged.
- Health education of the workers.
- Continuing research to find out safer substitutes (19-24).

**Anthracosis or Coal Worker's Pneumoconiosis** : (Synonyms: Anthracosis, Coalminer's consumption, phthisis melanotica, black spit). The diseases due to inhalation of dust in coal mines are simple coal - worker's pneumoconiosis (CWP) and complicated coal - worker's pneumoconiosis. Simple CWP is due to chronic exposure to coal dust with a low level of other mineral dust contamination. In this condition, the progression of small rounded opacities may be associated with only a slight loss of ventilation, which is insufficient to produce any disability. It can be very difficult to differentiate these effects from those of aging and cigarette smoking. Complicated CWP is one in which CWP is complicated by the additional pathology of large masses of solid tissue within the lung parenchyma. The condition usually occurs after 20 - 30 years in the occupation.

It is associated with breathlessness, clubbing, bronchitis, emphysema and right heart failure. This condition may be due to quartz, coal mine dust plus rheumatoid arthritis (as seen by Dr. A Caplan in 1953 in New South Wales Coal mines). Progressive massive fibrosis is characterized by formation of a mass 3 - 10 cm or more in length in the lung tissue and lying parallel to the pleura : this may cavitate after many years releasing large quantities of black necrotic tissue and dust which is coughed out as an expectorant resembling black ink (melanoptysis). Control measures centre on dust control and early detection of the disease.

In X - rays, 3 stages are seen in simple CWP **First stage** - Generalized mottling of the lung through which exaggerated lung markings are seen. **Second stage** - Mottling becomes very dense and exaggerated lung marking cannot be seen through them. **Third stage** - Very dense reticulated opacities seen all over the lung. The reticular markings indicate coal dust foci around the tips of the bronchioles. A person suffering from silicosis is both breathless and ill but a person with CWP is breathless but does not look ill. It has been seen that there is a negligible risk of developing CWP over a working lifetime with a dust level below 2mg/cu.m. The basic lesion of CWP is the local macule. Air spaces adjacent to the macule get enlarged, consistent with focal emphysema. A small percentage of miners develop complicated CWP or PMF diagnosed radiologically by the appearance of a density 1 cm or greater. Recent studies suggest that superoxide anion generation by alveolar macrophages may play a role in the lung injury of CWP. The introduction of improved ventilation, water spraying

**Fig. - 1 : Methods of Dust Control**



and mechanized equipment has greatly reduced dust levels in the mines. Medical surveillance is the second most important measure to prevent disabling CWP.

### Other Lung Diseases

**Byssinosis** : Bronchopulmonary diseases caused by exposure to airborne dust of cotton, flax & soft hemp leads to Byssinosis. It is a chronic respiratory disease characterized by tightness of the chest & breathlessness at work after the weekend or other absence. It is also called 'Monday Fever'. This is probably due to a histamine releasing substance. In addition to histamine release, exposure to cotton dust causes irritation in the upper respiratory tracts & bronchi, which after prolonged exposures slowly progresses to chronic obstructive pulmonary disease. In early stages there may be decline in FEV1, which may be symptomless in some workers. Within, one or two days, most symptoms tend to disappear except for irritation in the upper respiratory tract. As the disease progresses, the chest tightness is accompanied by breathlessness, the symptoms becoming worse & persisting for a longer time. In its late stages the disease resembles chronic bronchitis & emphysema, except for the history of chest tightness & decline in ventilatory capacity, characteristically worse at the beginning of the work week. Chest X - rays do not show any specific changes. Prevention includes Pre - placement examination, which should include Chest X ray, VC and FEV1. Periodic medical examination is recommended every year. In groups of workers, a drop of more than 10% in FEV1 during the work shift on the day after the weekend holiday may provide advance warning that workers are liable to develop Byssinosis.

**Occupational Asthma** : Occupational asthma is a form of lung disease in which the breathing passages shrink, swell, or become inflamed or congested as a result of exposure to irritants in the workplace. Occupational asthma is a lung disorder characterized by attacks of breathing difficulty, wheezing, prolonged exhalation, and cough, which is caused by various agents found in the work place.

**Hypersensitivity Pneumonitis** : Hypersensitivity pneumonitis is an inflammation of the lung (usually of the very small airways) caused by the body's immune reaction to small air - borne particles. These particles can be bacteria, mould, fungi, or even inorganic. Hypersensitivity pneumonitis is usually an occupational disease in which exposure to organic dusts, fungus, or moulds leads to acute and over time, chronic lung disease.

**Berylliosis** : Berylliosis (or beryllium disease) is caused by the inhalation of beryllium particles, dust or fumes. Its symptoms include coughing, shortness of breath, fatigue, weight loss or loss of appetite, fever and sweating. Medical tests may reveal abnormal lung sounds, lung scars, decreased pulmonary function, granulomas (a nodular form of chronic inflammation) and an allergy to beryllium.

### Occupational Cancers

Occupational cancer is any malignancy wholly or partly caused by exposures at the workplace or in occupation. Such exposure may be to a particular chemical (such as  $\beta$  - naphthylamine), a physical agent (such as ionising radiation or a fibre like

asbestos), a biological agent (such as hepatitis B virus), or an industrial process in which the specific carcinogen may elude precise definition (such as coke production) (13). Common occupational carcinogens include Benzidine, 2 - naphthylamine, Arsenic, Beryllium, Cadmium, Chromium, Nickel, Asbestos, Silica, Talc containing asbestiform fibres, Wood dust, Benzene, Trichloroethylene (TCE), Polychlorinated Biphenyls (PCBs) and Ethylene oxide.

### Prevention

Occupational cancers have two characteristic features namely they are preventable (14) and most occupational carcinogens have first been recognized by clinicians (15).

#### Primary Prevention

- Recognising presence of hazards and risks
- Educating management and workforce
- Eliminating exposure by substitution and automation
- Reducing exposure by engineering controls (such as local exhaust ventilation and enclosure), changes in handling, and altering physical form in processing
- Monitoring exposure and maintaining plant
- Protecting workers by means of personal protective equipment
- Limiting access
- Providing adequate facilities for showering, washing, and changing
- Legislative provisions

**Secondary Prevention** : A secondary approach to prevention consists of detection at an early stage to prevent the further progression of diseases and increased survival by institution of treatment. Screening tests and medical surveillance - for example, exfoliative urinary cytology and skin inspections.

### Occupational Dermatoses

An occupational dermatitis is one where the inflammatory reaction is caused entirely by occupational contact factors or where such agents are partly responsible by contributing to the reaction on compromised skin. The commonest site is hands followed by forearms. In case of airborne contact dermatitis face may be the prime site on inflammation. Contact dermatitis accounts for at least 60% of occupational skin disease, which, in turn, account for 40 - 70 % of occupationally acquired illness.

### Causes

**1. Physical agents** : Heat, Low Humidity, High Humidity, Cold, Pressure, Vibrations, Friction (Coal Mines, Construction Workers) and Occlusion, Presence of Sharp Particles (Fibre Glass), Damage from Minor Lacerations of the Skin, Solar Radiation, Ultraviolet Radiation, Ionizing Radiation.

**2. Biological Agents** : Bacteria, Viruses, Fungi (Confectioners - Monilia, Sewage Workers, Doctors), Parasites (Miners and Workers in tea gardens - Ankylostomiasis).

**3. Chemical Agents** : These account for 70% of all occupational dermatoses and include :

- **Acids** : HCl,  $\text{HNO}_3$ ,  $\text{H}_2\text{SO}_4$
- **Alkalis** : Hydroxides, Carbonates of Sodium, Potassium and Ammonium
- **Chlorides** : Sulphuryl Chloride, Arsenic Chloride, Stannous Chloride

*Some examples of substances causing occupational dermatitis are :*

- Rubber accelerating chemicals, such as Thiurams and Carbamates
- Biocides - such as Formaldehyde
- Hairdressing chemicals - such as Thioglycolates, Phenylenediamine
- Epoxy resin monomers
- Chromates
- Plant allergens - such as Sesquiterpene Lactones found in Chrysanthemum

#### **Diagnostic Criteria**

1. Disease appears during a period of occupational exposure or within a reasonable period of time after the exposure ceases
2. Occurs first on the exposed part
3. Disease has not been present previously
4. Disease improves after the termination of exposure
5. Disease recurs after exposure
6. Morphology of the disease is similar to the well known cases resulting from similar exposure and other fellows with similar exposure similarly affected.

#### **Types**

Occupational dermatitis is commonly of two types Irritant contact or Allergic contact Dermatitis. Others are contact urticaria, rubber latex protein sensitivity and photo contact dermatitis.

#### **Management**

1. Detailed occupational history
2. Evaluation of contact factors
3. Patch test followed by recommendation on reducing or stopping exposure to the offending agent and similar ones.
4. Chemical analysis of environmental materials to determine whether they contain a substance to which the patient is patch test positive.

#### **Prevention**

1. Primary prevention is aimed at providing appropriate information and protection.

2. Employer and employee should be aware of the potential risks of exposure
3. Education of need for good occupational hygiene
4. Adequate provision of suitable and effective means of reducing exposure
5. Awareness of limitations of personal protection devices
6. Engineering or environmental control. Few examples are given below :
  - Substitution of mineral oil by vegetable oils
  - Segregation and mechanical handling of radioactive substances
  - Local exhaust ventilation - chromium plating
  - Good general ventilation
  - Good housekeeping - mercury and its compounds
  - Safe design of the plants
  - Provision of adequate bathing and washing facilities
  - Provision of protective clothing
  - Periodic environmental survey to ascertain TLV
  - Wet methods

#### **7. Medical methods**

**(i) Pre - placement medical examination :** careful and detailed history to exclude allergic tendencies such as eczema/ asthma. Such people may not be employed in occupations with sensitizers.

#### **(ii) Standardized Patch Test**

- a) Test substances appropriately diluted. Standardized kits available.
- b) Apply the patch to the upper or mid back.
- c) Leave the patch in place and keep dry for 2 days before removing.
- d) Read tests :
  - The same day that patches are removed
  - One additional reading 3, 4, or 7 days after test initially applied
- e) Grade test reactions according to intensity : 0 = no reaction to 3+ = small blisters

Relate relevance of positive reactions to clinical dermatitis cautiously. Careful history and review of skin exposures must establish significance.

**(iii) Treatment :** Treatment with barrier / moisturizing creams, topical steroids, oral steroids and antibiotics if required.

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The most important industrial hazard due to machinery is the accidental injury. A detailed account of the prevention of industrial accidents is outside the scope of this book. Box - 1 depicts epidemiology of industrial accidents, while Fig. - 1 shows methods of accident prevention.

The first step in any accident prevention programme is elimination of various hazards whilst designing the process. If this is not possible, the next best step would be to control the physical, mechanical and chemical hazards in work environment by suitable engineering design. But when this also is not possible or is not able to give full protection to workers the third line of defence has to be resorted i.e., the personal protective equipments. These protective equipments cannot eliminate hazard or stop an accident taking place. These equipments merely set up a barrier against the hazards thereby preventing or minimizing an injury.

In selection of these equipments, the following points are to be borne in mind :

- (a) Type of hazard to be faced
- (b) Selection of right type of personal protective equipment
- (c) Availability of correct equipment in good condition at the work spot
- (d) Training of workers to use the equipment
- (e) Convincing the workers that the equipment is used will protect them from hazard
- (f) Making it a habit with the worker to use the equipment,
- (g) Degree of protection needed

- (h) Ease and comfort with which it can be used and freedom of movement with equipment which should not hamper performance of the worker
- (i) Maintenance of these equipment
- (j) Periodical check up
- (k) Good earthing

## Safety Audit

### Objectives

- (i) Critically evaluate the safety programme
- (ii) Evaluate the systems to identify and control hazards
- (iii) Check that the above system meets the statutory standards and codes of practice

### Benefits

- (i) Strengthening of the Organization safety standard and programme.
- (ii) Improve the skill and performance of employee and managers.
- (iii) Helps to create group and self awareness and provides motivation.
- (iv) Identifies specific deficiencies in the safety programme.
- (v) Provides timely information before any injury producing incident occurs.

### Mechanism

Safety audit shall be carried out at three levels

**(i) Level - I :** Internal Audit inspection by Safety Officers from within the factory once in every three months.

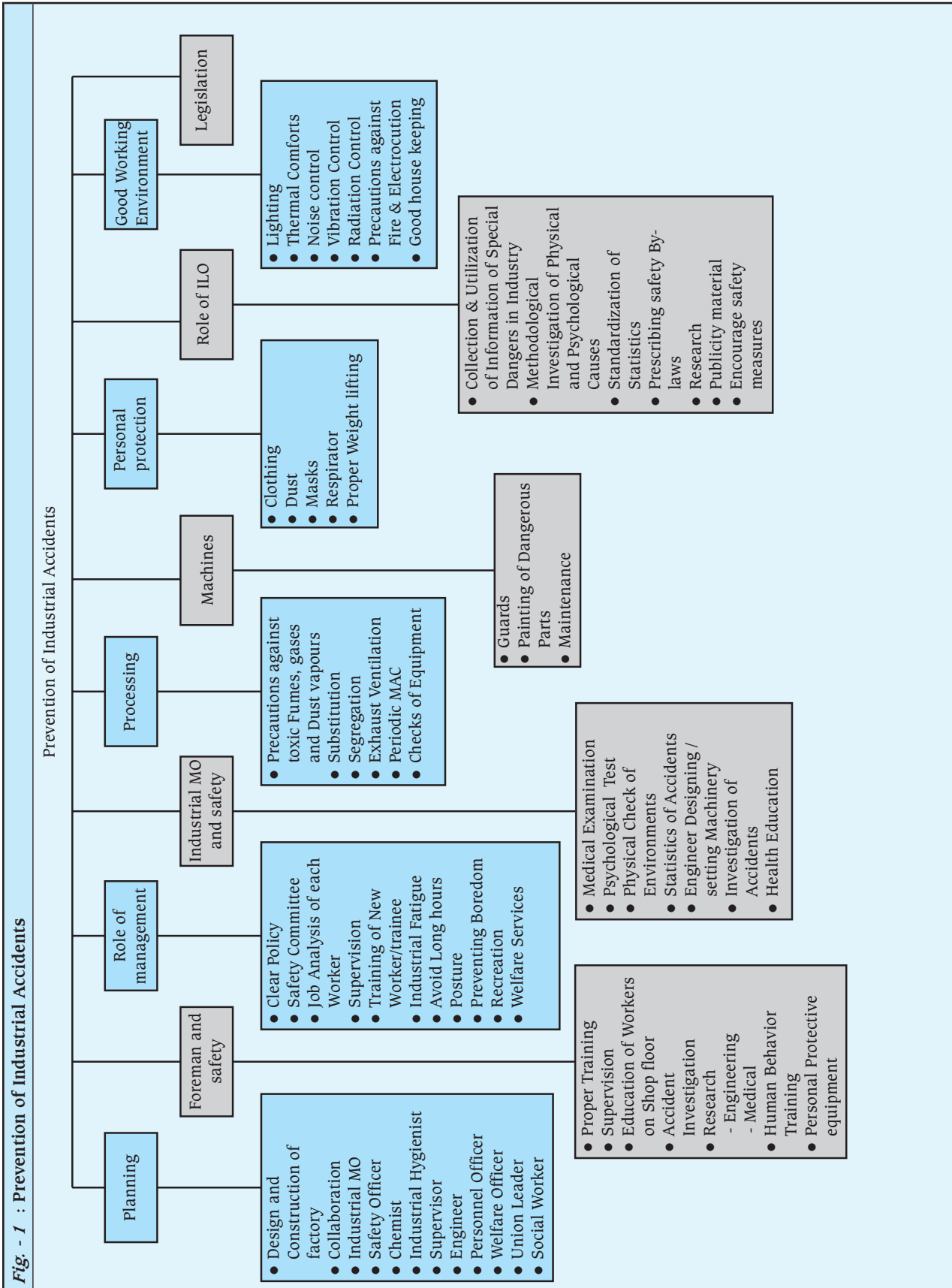
**(ii) Level - II :** Audit inspection by a group comprising of 3 officers of the factories in the concerned group, once in a period of six months.

**(iii) Level - III :** Annual Audit inspection by the Regional Controller of Safety / O.F. Board.

**Box - 1 : Epidemiology of Industrial Accidents**

Host factors	Agent factors	Environment factors
<ul style="list-style-type: none"> <li>Age</li> <li>Sex</li> <li>Experience and education</li> <li>Concomitant disease</li> <li>Psychological factors</li> <li>Personality Traits/Emotional stability</li> <li>Wearing unsuitable shoes</li> <li>Carrying improper loads</li> <li>Faulty stepping</li> <li>Not using personal Protective measures</li> <li>Physical defects</li> </ul>	<ul style="list-style-type: none"> <li>Improper planning and construction of factories</li> <li>Machines</li> <li>Faulty design</li> <li>Lack of maintenance</li> <li>Entanglement of loose clothes and hair</li> <li>Transmission of Machinery</li> <li>Speed of Work Processes</li> <li>Faulty planning</li> <li>Boiler explosion</li> <li>Dust explosion</li> <li>Corrosive materials</li> <li>Molten metal and Hot liquids</li> <li>Flying solid particles</li> <li>Metal grinding</li> <li>Stone dressing</li> <li>Riveting</li> <li>Chipping metal</li> <li>Electricity</li> <li>Gassing</li> </ul>	<p><b>Physical</b></p> <ul style="list-style-type: none"> <li>Overcrowding</li> <li>Defective lighting</li> <li>Temperature</li> <li>Ventilation</li> <li>Humidity</li> <li>Radiations from surroundings</li> <li>Pressure</li> <li>Noise</li> <li>Vibrations</li> <li>Ionizing Radiation</li> <li>Slippery Floors</li> <li>Uncovered drains</li> </ul> <p><b>Social</b></p> <ul style="list-style-type: none"> <li>At work place</li> <li>Domestic</li> <li>Relationship between workers and management</li> <li>Lack of Safety Policy</li> </ul>





## Scope

The Audit is necessarily very wide ranging in scope and covers all aspects of a company's operations. Some of the broad areas to be covered for Safety Audit are to study, in detail, the Safety Policy, Process Safety, Fire Safety, Hazards in the processes and their control, Pollution control, Machine guarding, Housekeeping, Material Handling system, Training of workers/supervisory staff and Management personnel, Accident reporting, investigation & analysis, Emergency preparedness and availability of Health, First Aid, Periodical Medical examination.

**Accident Investigation** : All accidents should be investigated by the concerned Heads of Sections and an unambiguous report sent in Form No. 14. Safety section shall investigate selected accidents involving plants/machineries/chemicals

where accidents are due to unsafe conditions. In case of all serious accidents, a Board of Enquiry to investigate in to the accident shall start investigation immediately on receipt of intimation by visiting the accident spot so that the evidence is not tampered. Photographs may be taken if necessary. The investigations should be towards fact finding and not fault finding. The concerned sections shall not disturb the site until it is cleared by the board of Enquiry of Safety Officer.

**Accident Returns & Analysis** : The accident statistics indicating details of accidents, man days lost, man hours worked are compiled quarterly. A monthly report on the accidents taking place during the preceding month is also compiled. Any accident taking place in the factory shall be analyzed by Safety Section.

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Industry uses and manufactures wide variety of substances, which are either known or suspected to cause toxic effects in the persons working with them. Industrial toxicology is concerned with the study of various substances used in industry either as media for processing some other materials or as raw materials or the finished product. The *Permissible Exposure Limit* (PEL) to a substance is defined as exposure to a maximum time weighed average (TWA) of concentration of a toxicant for an 8 - hour work. The *Threshold Limit Value* (TLV) is that limit in an environment of a toxic agent or the substance or the deleterious material which when inhaled by a worker for a duration of 8 hours per day for indefinite periods will not cause any harmful effects.

Details of industrial toxicology in respect of common and important toxic substances are being described in this chapter. The general measures of prevention and control are dealt with subsequently.

## Lead

Lead is ubiquitous in industry and poisoning due to absorption of lead and its compounds is still common. Lead is the most commonly used metal in industries because of anticorrosive property. Hazardous process are lead smelting, burning and making paint, painting, welding riveting, battery manufacture, and lead baths connected with heat treatment of metals, specially when carried out in confined spaces. Inhalation of lead dust and fumes is the chief route of poisoning, the next common route is ingestion, cutaneous absorption is rare. It is rapidly absorbed into general circulation when inhaled

and produces ill effects much more rapidly and probably in a more severe form than when ingested. Young persons are more prone to lead poisoning than adult. Lead concentration in the working atmosphere should be kept below 2.0 mg per 10 cu m of air ( 25 - 31).

**Symptoms** : The commonest manifestations of lead poisoning are blood changes and lead palsy. Lead makes the RBC fragile and causes haemolysis, which results in anaemia with compensatory stimulation of the bone marrow. So immature RBC or reticulocytes appear in the blood. The RBC count is generally below 3 million with haemoglobin under 70 percent (Sahli). In 'Lead palsy' there is a typical degenerative neuritis and subsequent fibrosis. In acute lead encephalopathy, there is involvement of the meninges with oedema and increased intracranial pressure. There may be some capillary damage as well. The lead line showing blue discoloration of the margins of the gums is a classical sign. A diagnosis of lead poisoning should be based on clinical finding, biochemical evidence of excessive lead absorption and by evidence of unusual exposure (See Table - 1 and 2).

**Prevention** : It depends on good housekeeping, personal protection and education of workers and medical supervision for the detection of hazards the occurrence of poisoning followed by its rectification.

- (i) Exhaust ventilation measures so arranged that whatsoever position the worker assumes the lead dust and fumes are drawn away from his face.
- (ii) Strict periodical inspection of the exhaust system : All ducts and their angles should be cleaned periodically.
- (iii) Avoidance of crowding in the workrooms where metallic lead is heated.
- (iv) The floor should be impervious to water, and smooth so that no lead dust can accumulate.
- (v) The floor should be constantly kept wet & swept before

<b>Table - 1 : Manifestations of Lead Poisoning</b>			
<b>System</b>	<b>Evidence of absorption</b>	<b>Evidence of incipient poisoning</b>	<b>Evidence of definite poisoning</b>
<b>General appearance</b>	Restive, moody, easily excited, emotional, lead line	Pallor, Leadline, Jaundice	Anemia, Leadline, Jaundice, Emaciation, "Premature ageing"
<b>Digestive System</b>	Persistent Metallic taste, slight anorexia slight constipation	Metallic taste, definite anorexia, slight colic, constipation	Metallic taste, increasing anorexia, nausea and vomiting, marked colic, rigid abdomen marked constipation, blood in stool
<b>Nervous System</b>	Irritability, uncooperativeness	Slight headache, insomnia, slight dizziness, palpitation, increased irritability, increased reflex	Severe headache, increased insomnia, increased dizziness ataxia, confusion, marked reflex changes, tremor, fibrillary twitching, neuritis, visual disturbances, encephalopathy hallucinations, convulsions, coma paralysis.
<b>Miscellaneous</b>	-	Muscle soreness, easily fatigued	General weakness, arthralgia, hypertension
<b>Urine examination</b>	Abnormal lead content	Abnormal lead content, Albumin, Casts	Abnormal lead content, Albumin, Casts, Porphyrinuria, Haematuria
<b>Blood changes</b>	Polycythemia, polychromatophilia, increase platelets, reticulocytosis, abnormal blood lead	Normal red cell count and haemoglobin, reticulocytosis 50 - 100 stippled cells per 100,000 RBC, abnormal blood lead	Decrease in haemoglobin, decrease in RBC, increase in cells showing basophilia, anisocytosis and poikilocytosis, decreased platelets, increase in blood lead

<b>Table - 2 : List of Bio-Chemical Tests</b>			
<b>Test</b>	<b>Normal Population</b>	<b>Acceptable absorption in occupation</b>	<b>Excessive absorption occupation with signs &amp; symptoms</b>
Blood lead	10µg/dl	75 µg/dl	> 80µg/dl
Urinary lead	10-65µg/g Cr	Upto-150 µg/g Cr	> 150 µg/g Cr
Zinc protoporphyrin	16-35 µg/dl	Upto 100µg/dl	> 100 µg/dl
Urinary delta aminolaevulinic acid	5 mg/g Cr	6-20 mg/g Cr	> 20mg/g cr

and after the day's work with a vacuum cleaner.

- (vi) Workers should wear special work clothes which should be removed before leaving the factory and deposited in specially provided lockers in order to ensure the prevention of contamination of private clothes.
- (vii) Suitable respirators against lead dust and fumes should be use and inspected regularly.
- (viii) No food, drink and tobacco should be taken in a place where there is a risk of lead poisoning - special rooms should be provided for this in factories.
- (ix) Personal cleanliness should be ensured by providing bathing and washing facilities.
- (x) Health education to avoid dusts and fumes of lead being inhaled or ingested.
- (xi) **Medical surveillance** : Pre-employment medical scrutiny of the prospective workers in the hazardous process should include the history of previous exposure to lead and elimination of those with a positive history of symptoms of lead poisoning. Quarterly medical examination during employment with attention paid to the loss of weight, gastrointestinal symptoms, weakness of wrist muscles and blood picture, removal from exposure should be followed

by active treatment.

**Treatment** : When lead poisoning is diagnosed, the further exposure should be discontinued, the use of penicillamine and Ca - EDTA, chelating agents, help in bringing down the blood lead levels by promoting lead excretion in urine. A saline purge will help to remove unabsorbed lead from the gut and also will relieve constipation.

#### **Tetraethyl Lead**

Exposure to high concentrations of vapour of leaded petrol, especially in hot weather, is responsible for an acute form of lead poisoning (lead encephalopathy). In industry this hazard occurs by spillage in petrol filling sheds/holds/barges with inadequate ventilation, inhalation from clothing saturated with petrol from spillage and splashing and absorption through the skin, which is relatively sight. In some cases a chronic form of lead poisoning occurs. Proper ventilation of the shed is important. The operation of filling should be carried out in the open air. Exhausted fans may be necessary. Special precautions must be adopted when containers are loaded in the holds of the barges. Only containers in sound condition should be accepted for loading and care should be taken in the

storage of the containers. The holds of the barges /tanks should be provided with adequate ventilation. Short shifts at frequent intervals during the work and overall turnover of the labour, so that each man is employed for one week in four on this work, are essential preventive measures. Other precautions are the same as have been described under lead poisoning with the current trend on use of unleaded petrol; it is presumed that toxicity due to this cause will be on the decline.

## Phosphorous

### White Phosphorus (WP)

White phosphorus (WP) is being used in smoke producing ammunition. After white phosphorus exposure burnt skin is washed with 5 % sodium bicarbonate and 3 % copper sulphate in 1 % hydroxy ethyl cellulose. Phosphorus particulars become coated with black cupric phosphide allowing easy identification. Copper sulphate also decreases rate of underlying tissue. Since blackened particles continue to elicit tissue injury, they can be removed. Of late, copper sulphate is found to be toxic and systemic copper poisoning can manifest as vomiting, diarrhea, oliguria, haematuria, hepatic necrosis and cardio - pulmonary collapse.

## Mercury

### Mercury Fulminate

It is a brownish yellow, heavy, crystalline solid prepared by the action of alcohol on mercuric nitrate. The chief hazard is dermatitis affecting those who are employed in filling operations where a fine dust is raised, which comes in contact with the naked skin. The susceptibility of some individuals may not enable them to withstand exposure even for a day. The exposed parts of the body become erythematous accompanied by violent itching, swelling and oedema of the face, eye - lids, ears, neck and forearms. Teeth become black owing to the formation of mercuric sulphide. Cleanliness of the plant is important. All precautions as for a lead factory should be taken. Exhaust ventilation with fitting overalls, aprons, rubber gloves, and if necessary respirators as well. Additional hand washing facilities should be provided (26 - 31).

## Chromium

Chromic Acid and bichromates of sodium and potassium are used in chromium plating of metals, manufacture of explosives and for tanning of leather, characteristic chrome ulcers occur on nail beds and the nasal septum. They are small, deep ulcers varying in size from the head of a matchstick to the end of a lead pencil. The tissues around the ulcers are heaped up and are covered by crusts. They may cause perforation of the nasal septum. The ulcers are as rule not painful but heal very slowly (25 - 31).

### Prevention

Mechanical lateral exhaust ventilation should be provided for the removal of the vapour and spray at the point of origin. The floor of rooms containing chrome baths should be impervious, maintained in good condition and flushed out daily. Suitable rubber gloves, aprons and other protective clothing should be provided and maintained properly. Water taps should be installed in workplaces, to enable the workers to wash hands

frequently. Shower bath and a change of clothing should follow the day's work. All cuts, abrasions and other injuries on hand and forearm should be protected by adhesive strapping before starting work. The forearm should be inspected twice a week and any breach of continuity of the skin should be immediately reported to the factory doctor. A protective ointment should be applied in the nostrils.

### Metal Fume Fever

It is an transient illness and is commonly known as 'Brass Founders Ague' 'Zinc Fever' or 'Metal Chill'. It follows the inhalation of high concentrations of finely dispersed zinc or brass fumes, usually in the form of oxides. After heavy exposure, the nose and throat feel dry and sore giving rise to a dry cough. In a few hours, the symptoms appear. There is shivering which may last for some time and this is followed by profuse perspiration, the picture simulating that of an attack of malaria. Considerable prostration follows the attack, but by the next morning recovery is almost complete. Some degree of insusceptibility is produced by low - grade inhalation but is lost in 48 hours. Workers therefore, are likely to suffer more on Monday morning; Metal fumes should be eliminated by proper exhaust ventilation. When conducting replacement or transfer medical examinations, cases with a history of chronic bronchitis, asthma or any other respiratory trouble should be withheld.

## Mineral Oils

Mineral oils are insoluble and soluble. The insoluble ones are used mainly as lubricants for cutting tools and the soluble ones are used as cooling agents. Cutting oils have the property of defatting the skin. They also plug the pores of the skin and form comedones. After some days of use they may contain steel slivers, which may injure the skin and thus start dermatitis affecting the forearm and thigh, small blackheads due to blocking of the sebaceous glands appear in these areas.

### Prevention

Cleanliness of persons, their clothes and machines should be ensured by the provision of adequate washing and shower bath facilities. suitable industrial cleaners should be placed at convenient location in the washroom. Clean rags or cotton waste free from silver should be provided. Time should be allowed for workers to carry out thorough cleansing, change of clothes and dressing. Those who give a previous history of dermatitis should be excluded by pre placement examination. Persons suffering from seborrhea, acne and excessive sweating should be prohibited from employment appear, the person should be temporarily withdrawn from the process and re - employed when the skin condition clears up.

### Treatment

The treatment is usually by soothing lotions or cream like calamine. Barrier creams may help in getting the skin of the beginners slowly conditioned to the contact with cutting oils but cannot serve as a permanent protective measure for persons whose skins are excessively sensitive.

## Benzene

This is colourless aromatic hydrocarbon with a characteristic



pleasant smell. It is extensively used as a solvent and a starting material in the synthesis of numerous chemicals (25, 26, 32 - 36).

### **Acute Poisoning**

Clinically, acute poisoning is of three general types, depending upon the severity of its anaesthetic effects on brain centers. Very high concentrations of benzene inhalation may result in unconsciousness, followed by death from respiratory failure. With somewhat lower concentrations, there may be dizziness, weakness, apprehension, collapse and unconsciousness. Death may occur from respiratory failure.

### **Chronic Poisoning**

The haemopoietic system is mostly affected but degenerative changes are also observed in the kidneys and heart. There is weakness, dizziness, rapid pulse, persistent headache, malaise, loss of appetite, shortness of breath, undue fatigue, decreased resistance to infections, and ulcers in the throat. Due to decrease in platelets, there is bleeding from the mucous membrane and haemorrhage in tissues. Macrocytic anaemia gives more reliable indication of the poisoning than leucopenia, especially in the early part of the disease.

### **Prevention**

The ventilation of the workroom should be improved by mechanical exhaust ventilation. A monthly examination of the employees should be carried out including a complete blood count, and findings recorded in a special register. There should be a rotation in duties of the personnel. Worker's showing an altered blood picture should be removed from exposure. They should report for medical examination, if bleeding from the nose, gums or other mucous membranes is noticed. Toluene, Xylene, Cyclohexane or trichloroethylene can be used as comparatively safer and satisfactory substitutes for benzene.

### **Trichloroethylene (Trilene)**

It is colourless liquid with chloroform like odour. It is largely used in the metal industry as a degreaser. When the exposure is sudden, the worker may die and the post - mortem examination may reveal oedema of the lungs and petechial haemorrhages. Fatty degeneration of the liver, kidneys and heart is present if death is delayed. Repeated exposure affects the central nervous system leading to paralysis of the hypoglossal nerve, sensory fibres of the fifth nerve, second cranial nerve and polyneuritis in the limbs. Mild poisoning may cause various grades of unconsciousness as occurred in the past in laundry workers. Trichloroethylene should be used only in closed systems or in rooms with a downward exhaust ventilation system. Workmen with dry and fissured skin should not be permitted to handle the chemical. Inhalation of a mixture of 95 percent carbon dioxide is of great value in the treatment of poisoning. Artificial respiration may be necessary ( 25,26,31,32).

### **Carbon - Monoxide**

It is a colorless and odourless gas formed from the incomplete combustion of materials containing carbon. It is encountered in various industries such as foundries, gasworks, ovens, blast furnaces and in automobile garages. It is a chemical asphyxiant. It forms a relatively stable compound, carboxyhaemoglobin

when it combines with haemoglobin, as its affinity for the haemoglobin is about 300 times that of oxygen ( 25,26 ).

### **Symptoms**

Acute poisoning causes a sudden onset of unconsciousness, rapidly developing cyanosis and death. Initial symptoms of sub acute carbon monoxide poisoning, which are more likely to be encountered in industry than the acute poisoning are shortness of breath palpitation on exertion accompanied by slight headaches which tend to increase in severity. With the increased concentration of this gas in the blood, judgment becomes fogged and the affected individual may not realise his own danger. If the exposure continues, mental aberration is followed by unconsciousness resulting in death from respiratory failure. Chronic poisoning shows all these symptoms coming on gradually and then continuing for longer periods.

### **Prevention**

Minimising its leakage by ensuring efficient ventilation, and finally by observing the rules of personal protection can prevent carbon monoxide poisoning. No person should be allowed to work single handed in a place where there is a danger of production of this deadly gas. No workman should enter or approach a place until the gas has been flushed out by fresh air and a suitable breathing apparatus issued. Safety posters in common languages should be displayed at strategic points explaining the deadly nature of symptoms of poisoning and means of rescue and first aid. Workmen should be given practice drill in rescue operation, artificial respiration and resuscitation. A cylinder containing a mixture of 95 percent oxygen and 5 percent carbon dioxide with a close fitting mask, should be available at all times for immediate use.

### **Treatment**

The victim should be removed immediately into fresh air and should not be made to walk even if he is conscious. The oxygen and carbon dioxide mixture should be administered or oxygen should be administered under positive pressure if available. If the breathing has stopped or is shallow, artificial respiration must be started and continued until normal breathing returns. If the heart has stopped beating, cardiac massage and stimulants should be given. Absolute rest in bed and warmth are essential. A close vigil should be maintained because of the tendency to relapse. Artificial respiration, administration of oxygen - CO<sub>2</sub> mixture and cardiac massage should not be stopped until it is quite certain that heartbeat can not be revived.

### **Hydrogen Cyanide**

It is colourless gas with a penetrating bitter almond odour, Sodium and potassium cyanide baths used in the heat treatment of steel and iron are potential health hazards (25, 26).

### **Symptoms**

Hydrogen cyanide like carbon monoxide is a chemical asphyxiant and prevents the tissue from using the oxygen carried in the blood. When inhaled in high concentration it caused sudden collapse and almost immediate death. In lower concentration symptoms are delayed; the patient complains of headache, dizziness, vomiting, general weakness; slow and irregular respiration and pulse is almost imperceptible. There

is a smell of bitter almonds in the breath, and if inhalation continues for some time coma supervenes, followed by death from respiratory failure.

### Prevention

Efficient plenum and exhaust ventilation, respiratory devices, protective hood and respirators ensure safety.

### Treatment

Immediate first aid measure comprises of removing the patient to fresh air, keeping the patient warm and at rest and removing contaminated clothing. Contaminated skin is washed well with water. Treatment consists of inhalation of amyl nitrite for 15 - 20 secs every 2 - 3 mins along with oxygen inhalation and artificial respiration. If patient is comatose or becomes drowsy then Dicobalt edetate ( 300 mg in 20 ml glucose sol) should be given by slow IV injection over 3 - 4 mins. If there is no return to consciousness then give sodium thiosulphate (12.5 gm in 25 ml of 50 % sol) IV over 5 - 6 mins. If the symptoms reappear or persist, half the dose of the antidotes should be repeated one hour later. If cyanide has been swallowed, gastric lavage is essential.

### Nitrous Fumes

The chief constituent of nitrous fumes are nitrous oxide, nitric acid and two forms of nitrogen dioxide,  $\text{NO}_2$ ,  $\text{N}_2\text{O}_4$ ; the last two lend a brown colour to the fumes. Nitrous fumes are present in industries where sulphuric & nitric acids and explosives are manufactured. The fumes are also a hazard in certain operations e.g. welding, metal cleaning and electroplating. Toxicologically nitrogen dioxide  $\text{NO}_2$  is the most important of the oxides of nitrogen (25, 26).

### Symptoms

The fumes should be controlled at the point of origin by efficient general ventilation and by local exhaust ventilation. Isolation of the offending operation is helpful where the process does not yield readily to the above measure of control. Respiration protective devices such as chemical filter respirator are justified as a last resort when all other measures of control have proved ineffective. These masks need periodical examination and proper maintenance. The education of the worker in the use of the respirator is of utmost importance.

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### Alkalies

The alkalies used in industry are chiefly ammonia, potassium and sodium hydrates. The industrial hazard from ammonia is invariably due to the accidental escape of the liquid or gas. It is very irritating to the upper respiratory passages and

may give rise to pulmonary edema. Burns may follow the splashing of ammonia and other alkalies, especially in the eyes. Prevention is achieved by taking precautions to obviate the except of ammonia and the use of goggles or eye shields. If splashing occurs, frequent irrigation of eyes by a 4 percent solution of ammonium chloride should be ensured to reduce the fixed alkalies. Penicillin droops or ointment should follow irrigation.

### Acids

The common acids used in industry are sulphuric, nitric and hydrochloric acids. When splashed into the eyes they cause severe burns of the cornea and conjunctiva. Prevention of splashing by protective devices, training of workers in work methods and personal protection are important precautions. Tubs full of water 'plunge baths' should be kept in the sections which involve the risk of chemical burns so that the affected individual can immediately plunge into it for washing the chemical without vigorous rubbing. In cold weather, the water bath should be kept at  $38^\circ\text{C}$  (about the body temperature) during working hours. A number of ointments containing 3 percent boric acid solution should be placed in strategic places and workmen should be taught how to irrigate the eyes immediately. Splashing clean water into the eyes is also helpful. Arrangements should be made for the mechanical transport of carboys containing acids covered with baskets and handled as little as possible.

### General Measures for Prevention / Reduction of Hazards : Industrial Toxicology

#### Engineering Measures

General rules for prevention/reduction of hazards from dangerous and obnoxious substances are as under :

(a) **Substitution** : Wherever practicable the use of offending substances should be prohibited. Failing that, a harmless substance should be substituted for the harmful one e.g. the use of yellow phosphorus substituted by phosphorus sesquisulphide in the match industry, sand - blasting may be substituted by shot blasting, and acetone may be issued in place of benzol as solvent.

(b) **Total enclosure** : Through airtight enclosure, personal contact with harmful substances such as dusts, fibres, fumes, gases, mists or vapours can be prevented.

(c) **Local exhaust Ventilation** : Where an airtight apparatus cannot be used, the harmful products should be removed at or near their point of origin by means of fume chambers or suction hoods properly connected to efficient exhaust systems.

(d) **Dust Suppression** : Where practicable the material should be used in a moist or wet state to prevent the evolution of dust e.g. lead

(e) **Duration of Exposure** : Limitation of the duration of exposure or employment should be compulsory in certain trades e.g. in radioactive processes.

(f) **Segregation** : Segregation of process involving toxic agents i.e. radioactive material is segregated. Segregation is also coupled with mechanical handling.

(g) **Use of wet methods** : Dry processes lead to cloud of dust. Wet methods can prevent this.

i. **Wetting basic material** : when painters scrap the lead paint, repeatedly wetting sand paper in water.

ii. **Periodic environmental sprays** : for humidification in mines and mills

iii. **Use of hydraulic mills in mines**

(h) **Good housekeeping** : The golden rule is that there is a place for everything and everything has a place.

(j) **Good general ventilation** : It dilutes the substance in work environment.

(k) **Provisioning of control equipment** : Equipment like continuous carbon monoxide detectors and carbon monoxide detection tubes.

(l) **Periodic environmental surveys** : These will help in detection of any leak at an early stage. Threshold limit value of a substance should not be exceeded.

(m) **Safe plant design** : Safety engineers should be involved in the construction of the plant.

#### Personal control measures

(a) **Protective clothing** : It includes the following -

- i. Helmets
- ii. Goggles
- iii. Earplugs
- iv. Gowns and aprons
- v. Shoes
- vi. Personal monitoring equipment like dosimeter
- vii. Respirators

#### Medical control measures

(a) **Medical examination**

- i. Pre placement medical examination - before one is employed in a particular job.
- ii. Periodical medical examination.
- iii. Medical examination of susceptible groups - young people, old age, people with anaemia, malnutrition, females.
- iv. Medical examination before leaving the job or work.
- v. Medical examination of persons joining after a periods of sickness.
- vi. Medical examination for early detection of cases and treatment.

(b) **Good record keeping** : It helps both in early detection and research.

(c) **Periodic environmental surveys** : Done by medical and safety personnel.

(d) **Health education** : By far the most important safety factor is the cooperation of the worker in obeying the given safety orders and instructions. Too often the safety notices / posters are couched in purely negative terms; the worker is exhorted not to perform one or other action and is left in doubt as to the reason for prohibition. A positive approach has been found to be more effective. If the notices give an indication of the hazard to which the workman would be exposing himself, there could be less temptation for disobeying the restrictions.

#### Legislative Measures

(a) **Restriction of Employment** : Children below 14 years are not permitted to work in any industry. Women and young persons between 15 - 18 years are prohibited from working in hazardous industries. Women are prohibited from working underground in a mine.

(b) **The Factories act, 1948** modified in 1987 lists diseases which are notifiable.

Measures of Prevention and Control of occupational diseases are shown in Fig. - 1.

#### Engineering measures

General rules for prevention/reduction of hazards from dangerous and obnoxious substances have been discussed under the heading of safe design of building. However other

methods for prevention of occupational hazards are given as under :

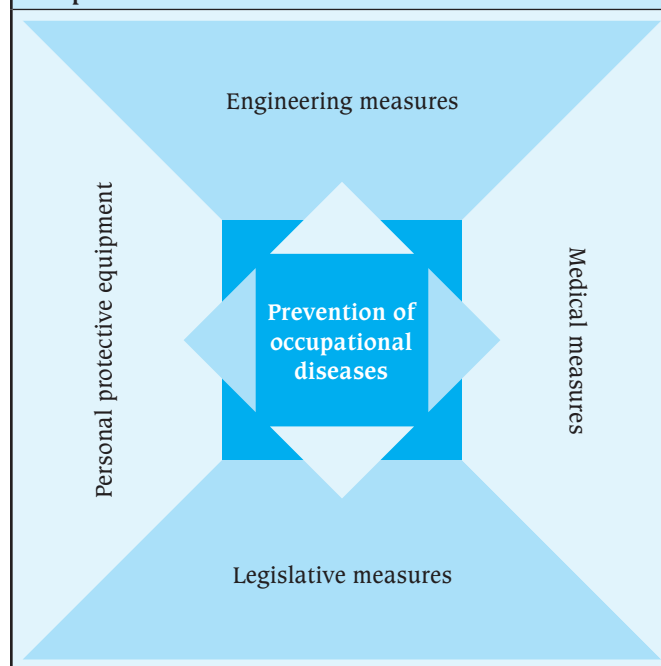
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**Total enclosure** : Through airtight enclosure, personal contact with harmful substances such as dusts, fibres, fumes, gases, mists or vapours can be prevented.

**Local exhaust Ventilation** : Where an airtight apparatus cannot be used, the harmful products should be removed at or

near their point of origin by means of fume chambers or suction hoods properly connected to efficient exhaust systems.

**Fig. - 1 : Measures of Prevention and Control of occupational diseases**



**Dust Suppression** : Where practicable the material should be used in a moist or wet state to prevent the evolution of dust e.g. lead.

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**Segregation** : Segregation of process involving toxic agents i.e. radioactive material is segregated. Segregation is also coupled with mechanical handling.

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- Wetting basic material : when painters scrap the lead paint, repeatedly wetting sand paper in water.
- Periodic environmental sprays : for humidification in mines and mills.
- Use of hydraulic mills in mines.

**Good housekeeping** : The golden rule is that there is a place for everything and everything has a place.

**Good general ventilation** : It dilutes the substance in work environment.

**Provisioning of control equipment** : e.g. continuous carbon monoxide detectors and carbon-monoxide detection tubes.

**Periodic environmental surveys** : These will help in detection of any leak at an early stage. Threshold limit value of a substance should not be exceeded.

**Safe plant design** : Safety engineers should be involved in the construction of the plant. A positive approach has been found to be more effective. If the notices give an indication of the

hazard to which the workman would be exposing himself, there could be less temptation for disobeying the restrictions.

## Medical Control Measures

### Medical examination

**Pre placement medical examination** : It is done before one is employed in a particular job i.e. at the time of entry into an employment and includes a detailed history followed by complete physical examination and laboratory/ radiological investigations of the individual. It helps in rejecting the individuals who are unfit and also helps in placement of the worker to the right job so that there is maximum productivity and at the same time it is less detriment to worker's health. It also gives a baseline for various parameters which can be used for future comparisons.

**Periodical medical examination** : This involve checkup of workers at periodic intervals for early detection and treatment of cases. The frequency and content of this examination depends upon the occupational exposure. Ordinarily the workers are examined once a year. However, monthly examination is recommended in case workers are exposed to toxic substances as lead, radium etc.

- *Medical examination of susceptible groups - young people, old age, people with anemia, malnutrition, females.*
- *Medical examination before leaving the job or work.*
- *Medical examination of persons joining after a period of sickness.*
- *Medical examination for early detection of cases and treatment.*

**Good Record Keeping** : It helps both in early detection and research. Records also play an important role in planning, development and efficient operation of an occupational health service. It also helps in planning of preventive services in an industry.

**Periodic Environmental Surveys** : This includes survey of the working environment in form of temperature, lighting, ventilation, humidity, noise, cubic space, air pollution and sanitation which have an important role in the health of the worker. It is done by medical and safety personnel. These surveys also include study of raw materials, the process and manufactured products.

**Health Education** : Health education about the process, handling of raw material, correct use of protective devices has a lot of impact in prevention of occupational diseases. The aim is to assist the worker in his process of adjustment to the working, home and community environment. It also includes guiding the worker about various legislations available and social security schemes existing for the benefit of workers.

### Personal Protective Equipment (PPE)

Personal protective equipment is designed to protect the worker from health and safety hazards that cannot practically be removed from work area. Personal protective equipment protects many parts of body including eyes, face, head, hands, feet, and ears.

**Head Protection** : Helmets /Hard hats protect from impact and penetration caused by objects hitting head. They also give you



limited protection from electrical shock or burns.

**Eye Protection** : Goggles give eye protection when working with : molten metals, liquid chemicals, hazardous gases or flying particles.

**Ear Protection** : Ear protection consists of earplugs and earmuffs. These should be used when the sounds in work area are irritating, sound levels reach 85 decibels or higher for an 8 - hour time period or there are short bursts of sound that can cause hearing damage.

**Hand Protection** : Gloves give protection against severe cuts or lacerations, severe abrasions, punctures, chemical burns, thermal burns, and harmful temperature extremes.

**Foot Protection** : Foot protection is important to prevent injuries in case a heavy or sharp object falls on foot or when the worker can step on an object that could pierce his shoe.

**Respiratory Protection** : Masks (filter/gas/ air purifying respirator) should be used to prevent inhalation of toxic gases into the lungs.

## Legislative Measures

Labour protection for the working people in India is available under various laws enacted by the Parliament as well as the State Legislatures. The Preamble of the Constitution of India guarantees its citizens justice - social, economic and political; liberty of thought, expression, belief, faith and worship; equality of status and opportunities and fraternity, dignity of individual and dignity of nation. The organized sector workers which constitute about 7% of the total workforce of about 400 million in the country are covered under various legislations providing social security to these workers. The major legislations providing social security to these workers are : the Employees' State Insurance Act, 1948 and the Employees' Provident Fund & Miscellaneous Provisions Act, 1952 etc. These two legislations provide for medical and health insurance and provident fund & pension to the workers respectively. The Factories act and ESI act have been dealt in detail under social security.

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## Ergonomics

Leo S Vaz

'Ergonomics' is derived from two Greek words 'Ergon' meaning work and 'Nomos' meaning principles or laws. *Ergonomics is the Science of Work*. Ergonomics is essentially fitting the workplace to the worker. The better the fit the higher the level of safety and worker efficiency. It takes account of the worker's capabilities and limitations in seeking to ensure that tasks, equipment, information and the environment suit each worker. The anticipated benefits of good Ergonomics are :

- Improved health and safety by reducing work - related injuries and disorders;
- Improved comfort, morale and job satisfaction;
- Improved productivity and reduced workers' compensation costs and employee turnover.

### Basic Ergonomic Principles

To assess the fit between a person and their work, ergonomists consider :

- The job being done and the demands on the worker;
- The equipment used (its size, shape, and how appropriate it is for the task);
- The information used (how it is presented, accessed, and changed).

Currently, the focus of ergonomics is to minimize work stressors, both physical and environmental to reduce the potential for bodily harm. The basic work stressors that promote repetitive

or cumulative injuries include excessive repetition, forceful movements, and awkward movements and postures. General ergonomic principles help us to control these work stressors.

- a) **Repetitive tasks** may not require much muscular effort, but the velocity and range of the movements can cause muscles to fatigue quickly as the muscle never completely relaxes and never completely contracts. With insufficient rest time, recovery of micro - trauma to the muscles, tendons and joints is not complete. Gradually, injury builds until swelling and pain begin to limit activity.
- b) **Forceful movements** require excessive tension or pressure on the tissues of the body, increasing muscular effort, reducing circulation to the body's tissues, and causing muscles to rapidly fatigue.
- c) **Awkward movements and postures** place biomechanical stresses on the joints, muscles and tendons, causing friction and inflammation at the stressed sites, reducing the body's ability to perform work efficiently and comfortably.

### Work - Related Musculoskeletal Disorders (WMSDs)

These are MSDs that are caused or made worse by work methods and environment. They occur when the physical capabilities of the worker do not match the physical requirements of the job. Common MSDs are Tendonitis, Epicondylitis (Tennis or Golfer's Elbow), Bursitis, Trigger Finger, Carpal Tunnel Syndrome, and Back Strain. Work - related MSDs are also known as Repetitive Strain or Stress Injury (RSI) Repetitive Motion Injury (RMI), Cumulative Trauma Disorder (CTD), Overuse Syndrome or Activity - related Pain Syndrome.

**Causes of MSDs** : The characteristics of a job which put a worker at risk for MSDs are :

(a) **Repetition** : Performing the same motion or group of motions excessively.

(b) **Awkward Postures or Postures outside of neutral** : Neutral is the optimal position of each joint that provides the most strength and control.

(c) **Static Postures** : Holding the same position or using the same muscles for extended periods of time.

(d) **Cold Temperatures** : Working in environments below 68°F can cause nerve damage.

(e) **Forceful exertions** : A strong physical exertion produces tension by muscles and is transmitted through tendons.

(f) **Vibration** : Single Point Hand and Arm exposure results from vibrating objects such as power tools.

Whole Body exposure to vibration results from vehicles such as forklifts, cranes, trucks, buses subways and aircraft.

(g) **Compression** : Soft tissue is compressed between the bone and a hard or sharp object.

(h) **Poor work-Station design** : It is a risk factor for the development of upper limb disorders. The computer mouse is one of several input devices used with today's IT, usually with a standard keyboard. Several reports have appeared in the literature of upper limb disorders such as tenosynovitis, lateral epicondylitis and myofascial syndrome resulting from mouse use. The use of mouse results in abduction and flexion at the shoulder, flexion of the elbow and resting of the wrist on the mat along with ulnar deviation for standard tasks. The prevention of problems involves ensuring that the user handles the mouse within his or her normal zone of comfort.

**Signs and Symptoms of MSDs** : Common Signs and Symptoms of MSDs are Painful aching joints, muscles, tingling or numbness, fingers or toes turning white, Shooting or stabbing pains, Swelling or inflammation, Stiffness or difficulty moving, Burning sensation or Pain during the night.

**Carpal Tunnel Syndrome** : Carpal tunnel syndrome is associated with exposure to some workplace hazards. Clinically diagnosed carpal tunnel syndrome has been reported to occur in textile and other industrial workers. Pressure on the median nerve as it passes under the flexor retinaculum may lead to the development of a clinical picture compromising pain and paraesthesiae in the thumb, index and middle fingers, which is often worse at night. Wasting of the small muscles of the hand supplied by the median nerve may occur if the condition remains untreated for some time. Nerve conduction studies are often used to assist the diagnosis. Probably the main occupational hazard is repetitive movements of the wrist, although exposure to hand - arm vibration is also thought to be important. Surgery to decompress the median nerve may be required to relieve symptoms or preserve function in the hand.

**Pre - Patellar Bursitis** : Occupational disorders due to repetitive strain are not new. Coal miners, for example, suffered from 'beat' conditions. Repeated kneeling and crawling could lead to the development of inflamed pre - patellar and pre - tibial bursae. Beat knee is a combination of haemorrhagic bursitis and pyogenic infection. This condition arises as a result of manual labour causing excessive pressure or friction in the area of the knee. Workers who have to kneel repeatedly in their

jobs may suffer from bursitis at the knee.

**Back Pain and Work** : Low back pain is common in the general population, and is a common symptom in workers whose jobs involve manual handling. Although the aetiology of back pain is complex, studies have shown that repetitive overuse and postural factors resulting from systems of work are associated with increased prevalence rates. It is not merely a requirement to lift heavy loads in jobs that leads to an increased risk of back pain; the prolonged maintenance of abnormal postures also causes marked increases in pressures on the spine because of the protective responses of the supporting muscles. Consequently, guidelines on manual handling should not merely focus on weights to be lifted, but should also include an assessment of the associated ergonomics.

The handling of load may involve pushing and pulling as well as lifting. Risks of injury to the back or upper limbs are dependent not only on the weight lifted, but also on the posture needed for the lift. Lifting with the back outside of its normal range of movement places stresses on the soft and bony tissues of the spine. The majority of injuries to the back are due to damage to the soft tissues rather than the intervertebral discs, but the symptoms of pain, restriction of movement and disability are the same. Prevention of injury involves eliminating or modifying tasks, and providing lifting aids and training in safe lifting techniques.

Employers should minimize the risks to workers by avoiding lifting and handling manoeuvres except where they are unavoidable. The use of lifting aids and the provision of training are both important risk - reducing measures. There is increasing evidence that psychological risk factors are also important with respect to both the development of low back pain and the occurrence of chronic low back pain. The identification of these risk factors is a necessary component of a holistic risk assessment.

**Pregnancy and Ergonomics** : A number of studies have looked at the risk to the mother and foetus from physically tiring work and strenuous exercise. The former has a reported association with amenorrhoea, and the latter may lead to an increased risk of abortion, stillbirth and foetal growth retardation. The ergonomic aspects of the developing pregnancy and the resulting reduced flexibility and movement also need to be taken into account when assessing the job, and different recommendations may be appropriate at different stages of the pregnancy.

**Prevention of MSDs** : The principles involved in prevention of MSDs lies in good Ergonomics and the motto '*Work Smarter, Not Harder!*' This can be achieved by the following principles :

- Work in neutral postures
- Reduce excessive force & repetition
- Keep everything in easy reach and at proper heights
- Keep warm
- Minimize static unsupported postures and pressure points

Methods of Reducing Repetition are :

- a) Break up the repetitive components of a job.
- b) Switch frequently between tasks.
- c) Find a different tool that makes the job easier.
- d) Let the tool or automation do the work instead of the

body.

- e) Introduce leisure activities that have different physical demands than work activities.

**Methods of Reducing Force :** To reduce the force or exertion required to perform specific activities, use the appropriate tool for the job and maintain tools in good working order. For example, blades should be kept sharp; use longer handles for better leverage; use clamps to hold parts instead of holding with the other hand. A slippery surface requires extra grip strength to hold the object; Avoid sudden impact, jerking, or sudden start - stop movements; when lifting or moving objects, keep them close to your body; push rather than pull.

**Methods of Reducing Awkward Positioning & Improving Posture :** Proper posture ensures that one keeps reaching to a minimum. This can be done by assuring proper fit of the chair. There should be support for the lower back. Height should be adjustable in relationship to the work surface so that the shoulders are relaxed and the elbows are positioned at the side of the body (in - line with the shoulders). The work should be positioned at a height that allows the elbows to be open slightly greater than 90 degrees. A foot - rest should be used when necessary. The work should be positioned directly in front of the body to avoid excessive reaching or turning. Frequently used items should be within an easy reach. Tools that fit the hand well and/or are shaped to help maintain the neutral wrist position should be used. One of the best ways to prevent injuries is to keep a relaxed and neutral posture while working. For those who work at a desk or on a computer, the forward head and rounded shoulder posture is prevalent. However the following are recommended :

- The head should be upright with the neck relaxed.
- The monitor should be at a height that allows you to view it directly in front of you, not looking up or looking down or to one side or the other.

- Use a copy holder if you work input information from hard copies.
- The ears, shoulders and elbows should be in vertical alignment.
- The shoulders should be relaxed, not elevated.
- Arm rests are optional. If you do use arm rests, position them at a height that does not push your shoulders towards your ears.
- The keyboard and most work should be positioned at a level just slightly below elbow level. However, depending on the type of work, this may need to be adjusted.
- The wrists should be in the neutral position flat and straight. They should not be bent forward or back, or angled to one side or the other.
- The fingers should be relaxed. Do not pound on the keyboard. Use the lightest touch possible to activate the keys or any tool control.

**Seating in the Workplace :** Ideally, seats should be personal to the individual worker and move with him or her where necessary, but where this is not possible, adjustable seating should be provided at every workstation. The lumbar region needs to be supported to decrease disc pressure. Providing both a seat back that inclines backwards and has a lumbar support is critical to prevent excessive low back pressures. The combination which minimizes pressure on the lower back is having a backrest inclination of 120 degrees and a lumbar support of 5 cm. The 120 degrees inclination means the angle between the seat and the backrest should be 120 degrees. The lumbar support of 5 cm means the chair backrest supports the lumbar by sticking out 5 cm in the lower back area. Another key to reducing lumbar disc pressure is the use of armrests. They help by putting the force of your body not entirely on the seat and back rest, but putting some of this pressure on the armrests. Armrest needs to be adjustable in height to assure shoulders are not overstressed.

## Noise

High levels of occupational noise remain a problem in all regions of the world. Although noise is associated with almost every work activity, some activities are associated with particularly high levels of noise, the most important of which are working with impact processes, handling certain types of materials, and flying commercial jets. Occupations at highest risk for NIHL include those in manufacturing, transportation, mining,

construction, agriculture and the military. The review of the literature indicates that noise has a series of health effects, in addition to hearing impairment. Some of these, such as sleep deprivation, are important in the context of environmental noise, but are less likely to be associated with noise in the workplace. Other consequences of workplace noise, such as annoyance, hypertension, disturbance of psychosocial well - being, and psychiatric disorders have also been described. For occupational noise, the best characterized health outcome is hearing impairment.

### Effects of Noise

The first effects of exposure to excess noise are typically an increase in the threshold of hearing (threshold shift), as assessed by audiometry. This is defined as a change in hearing



thresholds of an average 10 dB or more at 2000, 3000 and 4000 Hz in either ear (poorer hearing). NIHL is measured by comparing the threshold of hearing at a specified frequency with a specified standard of normal hearing, and is reported in units of decibel hearing loss (dBHL). Threshold shift is the precursor of NIHL, the main outcome of occupational noise. It corresponds to a permanent increase in the threshold of hearing that may be accompanied by tinnitus. Because hearing impairment is usually gradual, the affected worker will not notice changes in hearing ability until a large threshold shift has occurred. Noise - induced hearing impairment occurs predominantly at higher frequencies (3000–6000 Hz), with the largest effect at 4000 Hz. It is irreversible and increases in severity with continued exposure.

The consequences of NIHL include :

- a) Social isolation
- b) Impaired communication with coworkers and family
- c) Decreased ability to monitor the work environment (warning signals, equipment sounds)
- d) Increased injuries from impaired communication and isolation
- e) Anxiety, irritability, decreased self - esteem
- f) Lost productivity
- g) Expenses for workers' compensation and hearing aids.

*For a detailed account on noise pollution and control kindly refer to chapter on environmental pollution.*

## Vibration

Increased mechanization and industrialization has introduced a number of tools which produce variable quantities of vibration. In today's world, vibration induced illness is common in Foundry workers, Shipyard workers including workers in the ship breaking industry, Chain saw operators, Grinders and drivers of various vehicles which vibrate. What has been observed is that the number of affected people increases as the intensity and duration of vibration exposure increases. This type of exposure - response relationship indicates a possible link between health effects and the total amount of vibration energy entering the hands or body. Depending on the intensity of exposure, the symptoms may appear months or years after the start of the exposure.

Three important factors affect the health effects that can result from exposure to vibration :

- *The threshold value* or the amount of vibration exposure that results in no adverse health effects In other words, it is the maximum intensity of vibration to which workers can be exposed every workday for their entire full - time employment without developing numbness, paleness or chill of fingers.
- *The dose - response relationship* (how the severity of the ill health effects is related to the amount of exposure): What has been observed is that the number of affected people increases as the intensity and duration of vibration exposure increases.
- *Latent period* (time from first exposure to appearance of symptoms) : The higher the intensity, the shorter the latent period.

## Effects of Vibration

**Hand - Arm Vibration Syndrome (HAVS) & Vibration - induced white finger (VWF)** : It is the most common condition among the operators of hand - held vibrating tools. Vibration can cause changes in tendons, muscles, bones and joints, and can affect the nervous system. Collectively, these effects are known as *Hand - Arm Vibration Syndrome* (HAVS). The symptoms of VWF are aggravated when the hands are exposed to cold.

Hand-arm vibration syndrome is also known as Raynaud's phenomenon of occupational origin. Vibration is just one cause of Raynaud's phenomenon. Other causes are connective tissue diseases, tissue injury, diseases of the blood vessels in the fingers, exposure to vinyl chloride, and the use of certain drugs. The resulting reduced blood flow can produce white fingers in cold environments.

Workers affected by HAVS commonly report :

- Attacks of whitening (blanching) of one or more fingers when exposed to cold
- Tingling and loss of sensation in the fingers
- Loss of light touch
- Pain and cold sensations between periodic white finger attacks
- Loss of grip strength
- Bone cysts in fingers and wrists

The development of HAVS is gradual and increases in severity over time. It may take a few months to several years for the symptoms of HAVS to become noticeable. Hand - arm vibration exposure affects the blood flow (vascular effect) and causes loss of touch sensation (neurological effect) in fingers.

The severity of hand - arm vibration syndrome depends on several other factors, such as Protective practices and equipment including gloves, boots, work - rest periods, duration of exposure each workday, Years of employment involving vibration exposure, State of tool maintenance, acceleration of vibration, frequency of vibration, the characteristics of vibration exposure, work practice, personal history and habits.

**Whole - Body Vibration** : Whole - body vibration can cause fatigue, insomnia, headache and "shakiness" shortly after or during exposure. The symptoms are similar to those that many people experience after a long car or boat trip. After daily exposure over a number of years, whole - body vibration can affect the entire body and result in a number of health disorders. Sea, air or land vehicles cause motion sickness when the vibration exposure occurs in the 0.1 to 0.6 Hz frequency range. Studies of bus and truck drivers found that occupational exposure to whole - body vibration could have contributed to a number of circulatory, bowel, respiratory, muscular and back disorders. The combined effects of body posture, postural fatigue, dietary habits and whole - body vibration are the possible causes for these disorders.

Studies show that whole - body vibration can increase heart rate, oxygen uptake and respiratory rate, and can produce changes in blood and urine. Researchers have noted that exposure to whole - body vibration can produce an overall ill feeling which they call "*vibration sickness*." Many studies have reported decreased performance in workers exposed to whole



- body vibration. As in all occupational exposures, individual sensitivity to vibration varies from person to person.

**Vibration and Noise** : Since most vibrating machines and tools produce noise, a vibration - exposed worker is likely to be exposed to noise at the same time. Studies of hearing loss among lumberjacks revealed that, for equal noise exposure, those with Vibration-induced White Finger (VWF) had greater hearing loss than those without VWF. The reason for this effect is not clear. Studies of the effect of separate and simultaneous exposure to noise and whole - body vibration have concluded that whole - body vibration alone does not cause hearing loss. However, simultaneous exposure to noise and vibration produces greater temporary hearing loss than noise alone.

## Prevention & Control of hazards Due to Physical Environment

### Personal Protective Equipment

The main danger for employees working in hazardous industries lie in working with chemicals, machinery and tools, noise and vibrations. Therefore, health and safety measurements focus on chemical handling, dust formation, safety of machines and tools and noise and vibrations. An employer must meet specific requirements concerning "personal protective equipment" (PPE), such as gloves, goggles, hard hats, face shields and ear muffs.

**Responsibilities of an Employer** : It is the responsibility of an employer to :

- a) Survey the workplace to identify hazards, (this survey must be in writing and must be available to workers or their representatives upon request),
- b) Determine whether any hazard requires PPE,
- c) Pay special attention to working conditions or processes that can produce the following hazards :
  - Falling objects
  - Objects that could puncture the skin
  - Objects that could roll over workers' feet
  - Toxic chemicals
  - Heat
  - Harmful dust
  - Radiation

In order to avoid accidents and unhealthy environments, managers give high priority to :

- Reducing the frequency of accidents by good plant design and good operational control; Good - housekeeping measures are general measures within the company organising issues as occupational health and safety and also environment. These measures often are not very complex, but rather basic and therefore important. Good - housekeeping is about reducing and preventing accidents and injuries by organising the company, especially the work floor. Measures will vary from training employees on possible hazards associated with the materials they work with, handling machines, using adequate protective gear, reducing spillages by putting down working procedures to keeping the work floor clean and tidy.
- Minimising the consequences if they occur by appropriate

plant design and procedures, but in addition a predetermined set of emergency plans for personnel.

- Be aware of the possible origin of accidents.

Reassess hazards whenever necessary, especially when new equipment is installed or following accidents. The employer must ensure that all PPE used is the right kind of equipment for the job, and that it is maintained properly, even when workers are using their own equipment. Every employer must ensure that :

- a) PPE provides a level of protection above the minimum required to protect the worker,
- b) All PPE fits properly,
- c) No defective or damaged PPE is used,
- d) All PPE is properly cleaned and maintained on a regular basis.

Employers must train all workers who use personal protective equipment. Training must cover : when and which PPE is necessary, how to know if it fits properly, how to put on, remove, adjust and wear PPE, how to dispose of PPE and the limitations of using PPE. Training must be given whenever working conditions change, or when new or different PPE is used, or if a worker does not understand or remember any topic in the training. Employers must certify in writing that each worker has received and has understood the training. Workers should know how to inspect all PPE to make sure that it is not damaged. Defective PPE should be replaced as soon as the defect occurs.

It is always preferable for the employer to remove or minimize hazards. The provision of PPEs does not enable an individual to take liberties against the hazard, as it is not foolproof. Hence, emphasis should be directed at prevention of hazards by making the system foolproof. Wearing PPE can be uncomfortable (especially in hot weather) or awkward, and many people complain that it gets in the way of doing the job. Although PPE cannot usually completely protect the wearer, people often get a false sense of security when they use it. Also, PPE protects only the person wearing it and many people may not be able to wear PPE due to certain types of medical conditions. Problems such as incorrect fit, use of the wrong PPE for the job, use of damaged or poorly maintained PPE or inconsistent PPE use can all result in less than adequate protection.

The material and shape of special protective overalls should vary with the substances involved e.g. liquid proof or gas proof against corrosive and irritant liquids / gases; asbestos suits complete with a helmet, gloves and boots against risks of excessive heat and fire; against radio - active substances, washable material so designed as to cover other clothing at the neck and wrists. Washing of working clothing is necessary at least once a week as prevention against contamination of other clothing.

### Types of Personal Protective Equipment

**Eye and face protection** : Goggles and face protection must be used when workers are at risk from flying particles, liquid chemicals, acids or caustic liquids, chemical gases or vapours. Workers must also be protected from radiation during welding, torching, soldering, and brazing, or other operations that emit light. Goggles and face protection must meet certain design

criteria for safety. Workers with errors of refraction should have the error corrected. Glasses or transparent plastic materials for goggles and windows of protectors should be free from striae and air bubbles. All goggles intended for mechanical protection should be splinter proof. Goggles and shields for workers engaged in welding, furnace work or any other operation where their eyes are exposed to glare should have filter lenses or windows of standard absorption value against ultraviolet and heat rays. Nonflammable, transparent visors, free of scratches should be provided for protection against glare and sparks. Goggles, when not in use should be kept in special closed containers protecting them from mechanical damage and should be inspected at regular intervals once a month and all defective parts should be replaced immediately.

**Head protection :** Hard hats/Helmets must be worn where there is a danger of falling objects. Specialized hard hats are required to reduce electrical shock hazards. Well fitting helmets made of aluminium; fibreglass or steel should be worn as a protection against falling or flying objects and blow on the head. For protection of hair from overhead moving belt, well fitting caps of washable and non - inflammable material should be used.

**Foot protection :** Safety shoes with impact protection are required in work areas where heavy objects or tools could be accidentally dropped on the feet. Safety shoes with compression protection must be worn where objects could roll over workers' feet, and in operations involving skid trucks, hand trucks, dollies, etc. Safety shoes with puncture protection are required when working around nails, wire, tacks, scrap metal, and other objects that could pierce the feet. Leggings for workers handling molten metals should be made of asbestos or other suitable heat resisting material, extending to the knee. At the lower end they should also cover eyelets of footwear. Metal toe guards or safety boots or shoes should be worn in operations where heavy objects are handled. Footwear for workers handling corrosive liquids should be of rubber, specially treated leather, wood or other suitable corrosion resisting material. Footwear for electrical workers should have nonconductive soles.

**Hand Protection :** Gloves are required to protect workers from cuts, scrapes, punctures, burns, chemical absorption, or temperature extremes. It is crucial that the type of glove being used is the right one for the job since incorrect gloves may provide no protection. This is a particular problem with chemical absorption where incorrect gloves may allow certain chemicals to reach the skin. Gloves for workers handling sharp edged or abrasive objects should be made of tough material and where necessary provided with special reinforcements of leather pieces or even a metal piece over the palm. Gloves should also be made of steel mesh for use in cutting process. Gloves and sleeves for workers handling hot metals could be made of asbestos or other heat - resisting material. Gloves with sleeves made of rubber capable of withstanding voltage of 10000 or more should be used for electrical workers. Gauntlets made of natural synthetic rubber or pliable plastic material should be used when handling corrosive liquids. Close fitting gloves should be used for avoiding exposure to toxic fumes and infectious agents. Barrier creams prevents penetration of irritant substance into the skin. Ideally a barrier cream should be non - irritating, nonsensitising, insoluble in substance

against which being used, easily removable and cosmetically agreeable.

**Hearing Protection :** Appropriate ear muffs or ear plugs must be made available as a last resort if it is not possible to make the workplace less noisy. Employers must ensure that workers are exposed to less than 90 decibels of noise over an 8 - hour day. If noise levels reach 85 decibels over an 8 - hour day, the employer must develop a hearing conservation program. If no other method of eliminating or reducing the noise exposure is found, the employer must supply PPE. These reduce the sound level exposure by about 20 dB each.

**Respirators :** Appropriate respirators must be worn as a last resort, if it is not possible to ventilate the work area properly. The following are a few types of respirators used in various industrial processes and environments. These should all be inspected and tested at regular intervals by responsible trained persons.

A mechanical filter respirator can only filter the suspended atmospheric impurities. A wide variety of impressive patterns and designs are available. None afford protection against solvent vapours, injurious gases or in atmospheres deficient in oxygen, and are essentially dust and fume filters in an otherwise healthy atmosphere. The simplest example of such type of respirator is the common surgical gauze mask. By introducing a thin layer of wet cotton wool in between the layers of gauze, it may be worn as a protection against coarse particles, such as fibres or sawdust. Their efficiency against fine particulate, such as those of silica dust, will depend upon the quality of the filtering medium. In course of time, these filters become clogged and there is increased resistance to breathing. The filters should then be washed or changed. Everybody should be supplied with a personal mask.

Chemical cartridge respirators and canister masks ensure the purification of air, which passes through the canisters containing specific neutralisers against specific toxic gases. The canisters have a particular coloured design painted on them indicating the specific toxic gases against which they afford protection; e.g. an orange coloured canister indicates that it is meant to be used against nitrous fumes. The user has to depend upon the oxygen content of the atmosphere, therefore, such respirators should not be worn in confined or poorly ventilated places or where the concentration of the offending gases is high.

The term 'supplied - air - respirators' means a respirator equipped with a hose line, through which fresh air is supplied under positive pressure whereas through hose masks the wearer can inhale air at atmospheric pressure. These are also used when the canister for cartridge respirator cannot be used due to high concentration of dangerous gases or fumes.

A self-generated oxygen mask is an oxygen breathing apparatus consists of a face piece with a corrugated tube connecting it to an oxygen tank or cylinder. This is used by workers engaged in fire fighting, rescue or repair work in atmospheres containing high concentrations of gases or which is deficient in oxygen or sufficient pure air supply. A self - generated oxygen mask is a new type of oxygen breathing apparatus fitted with a small canister containing a chemical. Moisture from the inhaled air starts a chemical reaction, which liberates oxygen.

## Safe Work Environment

**Design of Building** : All buildings, permanent or temporary should be structurally safe and sound to withstand the stress and strain of machinery. Single storey construction is the usual rule as it allows flexibility of layout. Any intensity of natural light can be obtained in it by a combination of wall and roof lighting and it is easier to manage natural ventilation. By careful orientation, direct exposure to the tropical sun can be avoided. Protection from conducted heat can be achieved by a choice of suitable material. Asbestos lining of the walls and ceilings will reduce the noise of machines by controlling the reverberation, resonance and sympathetic vibrations. This will also make the building fireproof.

**Space Requirement** : A floor area of 3.8 sq.m and 14.2 cu.m of space per worker should be provided. The height of the work rooms should not be less than 3 m. In calculating the space, no deduction need be made for furniture, machines and material, but a height above 4.2 meters should be excluded. The floor should, however, not be crowded with machinery. Individual machines or process units should have sufficient space around them to permit safe operation.

**Lighting** : Workrooms should be adequately provided with natural and /or artificial lighting. Any special type of work should have special, extra or sport lighting suitable for the operations. In all places where persons work or pass through, enough diffuse background lighting should be ensured. Natural lighting is ensured by the provision of skylights and windows located and spaced with devices to avoid glare. Artificial lighting should be provided where the daylight illumination is insufficient. It should be uniform and free from sharp and contrast shadows and direct or reflected glare. Supplementary lighting specifically designed for particular visual task should be so arranged as to avoid glare, flicker or after - image. Emergency lighting should be provided in all important stairway exits and passages, to and from work places and windowless buildings. The fluorescent tube in strip lighting is being increasingly used. Their efficiency is high and running costs are low. They give uniform illumination and there is low heat formation with absence of shadows. However, in course of time when the tube gets exhausted it develops a flicker, which is irksome to the eyes and also produces a stroboscopic effect.

**Ventilation** : Modern concept of ventilation requires replacement of vitiated air by supply of fresh outdoor air, the quality of the incoming air should be such that its temperature, humidity and purity are conducive for healthful working. Clean fresh air should be supplied to enclosed work places and it is recommended that in work rooms and assemblies there should be 4 to 6 air changes in one hour. If the air is changed more frequently, i.e. more than 6 times in one hour, it is likely to produce a draught which should be avoided. Where an adequate supply of fresh air cannot be obtained by natural ventilation, mechanical ventilation should be provided. All dust, fumes, gases, vapours or mists generated and released in industrial processes should be removed by local exhaust ventilation at their point of origin.

**Thermal Comfort** : Temperature and humidity should be maintained in enclosed work places suitable to the kind or

work performed. In localities subject to high or low seasonal temperatures appropriate means such as heat insulation of roofs, walls and floors, and even of doors and windows should be adopted. All employees should be protected against radiant heat and excessive temperature from heated machines or hot processes by heat insulation of the equipment and / or by suitable protective clothing. In industries involving exposure of workers to high or low temperatures, 'transition rooms' should be provided so that the workers can gradually adjust themselves to the external climatic environments. Roof - shelters and windbreakers should be provided for yard - workers where necessary.

**Working Comfort** : Seats and Workbenches of suitable shape and height should be provided for workers. The seats should be so placed that working material can be reached easily without strain or having to bend forward unduly. Seats should also be provided for all workers who have to work in a standing position, for rest during occasional short interruptions in their work.

**Sanitary Conveniences** : These should be conveniently located.

(a) **Latrines** : Scales of latrine accommodation is 4 for the first 100 workers and 2 for subsequent 100 workers or part thereof.

(b) **Urinals** : Two urinals for every 100 workers upto 500 and there after one for 100 workers are to be provided. For female workers separates sanitary conveniences are to be provided.

(c) **Wash Basins** : Adequate hand washing facilities should be provided for persons whose work involves contact with any injurious substances, there should be at least one tap for every 15 workers.

(d) **Bath - rooms** : Adequate number of bathrooms for bathing and washing of clothes should be provided.

(e) **Spittoons** : Sufficient number of spittoons should be placed at convenient places.

(f) **Cloak Rooms** : Well - ventilated rooms with individual lockers should be provided for dressing purposes and storage of personal clothing.

**Drinking Water** : An adequate supply of cool and safe drinking water should be provided in a readily accessible place. Water coolers are ideal and most hygienic. Proper precautions to prevent contamination of water in tanks, pails and other containers must be enforced, section 18 of the factories Act lays down that every factory having more than 250 workers will provide cool drinking water during hot weather.

**House-Keeping** : It implies general cleanliness and orderliness of the plants, the tools and the products. Cleaning and sweeping should be done during non - working hours; vacuum cleaning or wet mopping should be adopted. Effective drainage should be maintained where wet processing is carried out. False floors, platforms, mats or other dry standing places along with suitable footwear should be provided in oily and greasy places. However, 'house - keeping' means much more than merely keeping the working places clean. "*There is a place for everything and everything in its right place*" is a tried and true axiom of industrial safety. Stumbling and tripping



due to improper house - keeping is another potential cause of accidents.

#### Miscellaneous Requirements

Infestation with rodents, insects and vermin should be eliminated by suitable measures. Workrooms and work places should not be used as living or sleeping quarters. No food, drink, betel nut or leaves or tobacco should be consumed or

brought by any worker into any workroom in which dangerous and obnoxious materials, particularly lead and radioactive substances, are in use. Any one suffering from communicable diseases should be at once isolated and preventive and control measures instituted.

## 231 Social Security and Labour Laws

*Ashok K. Jindal, Puja Dudeja*

Rapid industrialisation of the country has led to a sharp increase in the Labour force in the twentieth century. The expansion of the workforce has taken place more in the unorganised sector. Today a staggering 92.5% of the Indian Labour is employed in this sector. It comprises largely the needy small and marginal farmers, the contract labourers and the agricultural workers. The organised sector, considered better off, employs 280 lacs employees. Out of these, 195 lacs are in the public sector and 85 lacs in private sector.

The earliest legislation in the field of Social Security in India was the "Fatal Accident Act" of 1855 that provided compensation to workers who died as a result of an industrial accident. However, the law remained merely on paper, as it was left to the heirs of the deceased to prove that the accident occurred due to the personal negligence of the factory owner, which was a Herculean task. The powerful Indian Bourgeoisie had thus ensured by getting this clause inserted, that Social Security for the working class remained a non starter. The easy availability of cheap labour and the capital might of the Indian industrialist ensured that it took a long time for the Indian labour force to get organized and fight for their rights. History has shown that legislation and Social Security in industry has come about not due to growth in knowledge or due to a philanthropic attitude of the employers or Government but due to a continuous struggle by the working class. The constant pressure from the workers, trade unions and the ILO forced the Indian Government to enact legislations in the realm of Social Security and Labour Welfare. These were the Workmen's Compensation Act 1923, the ESI Act 1948 and the Factories Act 1948. While the first two dealt with primarily compensation of occupational diseases and injuries, the Factories Act provided for enforcing Safety and Health measures on the factory floor.

The Workmen's Compensation Act 1923 was based on the principle of employer's liability to compensate the worker. This legislation provided for compensation of a personal injury from an industrial accident or an occupational disease and also led

to the setting up of special machinery to deal with claims of compensation under the Act. The Workmen's Compensation Act became an important means in the system of social security for labour in India till independence. It provided for compensation in case of death, total disability, permanent partial disability and temporary disability. However, this Act was criticized as being inadequate to provide compensation to workers in case of Employment Injury or Occupational Disease as the worker had to undergo protracted litigation against the employer to get his legitimate dues. In the name of collective responsibility and functioning of the state, the employer and the employee; and with the assistance of liberal intellectuals and administrators, a compulsory contributory Health Insurance Scheme for Industrial workers was framed giving birth to the ESI Act 1948, which replaced the Workmen's Compensation Act in respect of employees covered by the former.

Under the Constitution of India, Labour is a subject in the Concurrent List where both the Central & State Governments are competent to enact legislation subject to certain matters being reserved for the Centre. Table - 1 gives the responsibilities under union and concurrent list.

Table -1: Responsibilities under union and concurrent list	
Union List	Concurrent List
Regulation of labour & safety in mines and oil fields	Trade Unions; industrial and labour disputes
Industrial disputes concerning Union employees	Social Security and insurance, employment and unemployment
Union agencies & institutions for "Vocational training"	Welfare of labour including conditions of work, provident funds, employers 'invalidity and old age pension and maternity benefit

#### List of Acts Related to Labour

- The Child Labour (Prohibition and Regulation) Act 1986
- The E.P.F. and Miscellaneous Provisions Act, 1952
- Industrial Disputes Act, 1947
- The Maternity Benefit Act, 1961



- Minimum Wages Act, 1948
- Payment of Bonus Act, 1965
- Payment of Gratuity Act, 1972
- Payment of Wages Act, 1936
- Payment of wages (Amendment) Act 2005
- Public Provident Fund Act, 1968
- Workmen's Compensation Act, 1923
- Factories Act, 1948
- ESI Act, 1948 (Employees State Insurance Act, 1948)

### The Child Labour Act 1986

The problem of child labour is a big challenge before the nation. Government has been taking various pro-active measures to tackle this issue (33). This quandry will require concerted efforts from all sections of the society. This problem is intimately related to poverty. Based on the recommendations of Gurupadaswamy Committee, the *Child Labour (Prohibition & Regulation) Act* was enacted in 1986. The Act prohibits employment of children in certain specified hazardous occupations and processes and regulates the working conditions in others. The list of hazardous occupations and processes is progressively being expanded on the recommendation of Child Labour Technical Advisory Committee constituted under the Act. *National Policy on Child Labour* was formulated in 1987. The Policy seeks to adopt a gradual & sequential approach with a focus on rehabilitation of children working in hazardous occupations & processes in the first instance. The Action Plan in the Policy for tackling this problem is as follows :

- Legislative Action Plan for strict enforcement of *Child Labour Act* and other labour laws to ensure that children are not employed in hazardous employments, and that the working conditions of children working in non-hazardous areas are regulated in accordance with the provisions of the Child Labour Act.
- Focusing of General Developmental Programmes for Benefiting Child Labour.
- Project Based Plan of Action envisages starting of projects in areas of high concentration of child labour. Pursuant to this, in 1988, the *National Child Labour Project (NCLP)* Scheme was launched in 9 districts of high child labour endemicity in the country.

### The Factories Act 1948

The factories Act was enacted by the parliament of India in 1948, and since then it has been revised and amended from time to time (34), the latest being the factories (Amendment) Act, 1987. The amendment in 1987 was elaborated following the Bhopal Gas Tragedy. This landmark amendment of 1987, in the factories Act - 1948, in effect means that the affair of the Company cannot be entrusted to a managing agent, and the owners or directors of the factories will be deemed to be the 'occupier' of the factory. This makes the factory owners directly responsible for ensuring Safe and Healthy working conditions in their factory.

**Scope of the Act :** The Act defines "factory" as an establishment employing 10 or more workers where power is used, and 20 or more workers where power is not used. The term 'worker' includes within its meaning contract labour employed in the manufacturing process. The Act applies to the whole of India except the State of Jammu & Kashmir, under the provisions

of the Act, the State Governments are authorized to appoint besides the Chief Inspector or Factories as many Additional Chief Inspector of Factories, joint Chief Inspectors, Deputy Chief Inspectors and Inspectors as they think fit to enforce the provisions of the law. The system of enforcement of Factories Act, 1948 is established on two tier basis. At the Central level, the Director General Factory Advisory Services & Labour Institutes (DGFASLI) has an advisory role. It coordinates the activities of the factory Inspectorates and provides training and advisory services to the inspectors. In addition it also assists the Ministry in drafting amendments to the Act and the Model Rules. The latter are recommended to the State Governments for adaptation with necessary modifications to suit local conditions. The Factory Inspectorates under the State Government and Union Territories carry out the enforcement functions (35).

**General Duties of Employer :** The Act specifically directs the employer to ensure the Health, Safety and Welfare of all workers while they are at work in the factory. His duties include ensuring Proper maintenance of plant and systems of work in the factory; Ensuring safety in connection with the use, handling, storage and transport of articles and substances; Provision of information, instruction, training and supervision necessary to ensure the health and safety of all workers at work; Provision and maintenance of risk free and safe means of access, and egress from, all places in the factory; and, Provision, maintenance and monitoring of working environment in the factory so that the same is risk free and safe.

**The Inspecting Staff :** The state government is empowered to appoint inspectors/Additional Chief Inspector of Factories and as many officers, it thinks fit to ensure that provisions of the Act are complied with (36), these inspectors are empowered to enter any factory or any place which he believes is being used as a factory and undertake inspections.

**Certifying Surgeons :** The State Government is empowered to appoint qualified medical practitioner to be certifying surgeons for the purposes of the Factories Act.

**Health and Safety :** Elaborate provisions have been made in the Act under chapter III, IV and IV A, with regard to health and safety of workers, These chapters deal with laws pertaining to such matters as cleanliness, lighting, ventilation, treatment of workers, effluents and their disposal, elimination of dusts and fumes in the workplace, provision of spittoons, control of temperature, supply of cool drinking water and for the employment of cleaner to keep the water closets clean. A minimum of 350 cu feet of space for each worker for factories installed before 1948 and 500 cu feet for factories installed after 1948 has been prescribed by the govt not taking into account space more than 14 feet above ground level. The Act also prescribes in detail provisions relating to the safety of workers. Section 40B provides for the appointment of "Safety Officers" in every factory wherein 1000 or more workers are ordinarily employed. The state Government is empowered to prescribe maximum weights, which may be lifted or carried by men, women and children. Some of the other safety provisions relate to caring of machinery, devices for cutting off power, hoists and lifts, protection of eyes and precautions against dangerous fumes, explosives and inflammable materials.

**Welfare** : Chapter V of the Act relates to welfare measure for the worker. The Act specified that wherein more than 250 workers are ordinarily employed, a canteen shall be provided. In every factory, wherein 30 or more women workers are ordinarily employed, a crèche should be provided. Provisions have been made under the Act to ensure adequate washing facilities, appliances, shelters, rest rooms and lunchrooms. There should be a welfare officer for every factory employing more than 500 workers.

**Employment in Hazardous Processes** : Chapter IV A, incorporate by the Factories (Amendment) Act, 1987, relates to hazardous processes. A site appraisal Committee is to be constituted to submit recommendations on the siting of factories using hazardous processes. Provisions have been made for workers, participation in safety management in industries involving hazardous processes.

**Hours of Work** : The Act has prescribed a maximum of 56 hrs of work (60 hrs including overtime) per week with maximum spread over of work upto 12 hrs per day (including rest interval of ½ hr after every 5 hrs of work). For adolescents, the maximum hours of work per day have been restricted 4 ½ hours.

**Employment of Young Persons and Women** : The Act prohibits employment of children below 14 years of age. Persons between the ages of 15 and 18 years are to be duly certified as adolescents by “Certifying Surgeons” and also deemed thus fit to work. Adolescent employees and Women are restricted from employment in certain dangerous occupations and hazardous processes and are allowed to work between 6 A.M and 7 P.M.

**Leave with Wages** : The Act lays down that besides weekly holidays, every worker will be entitled to leave with wages after 12 months of continuous work at the rate of one day for every 20 days of work for adults and one day for every 15 days of work for adolescents.

**Notifiable Occupational Diseases** : The Act gives a schedule of Notifiable disease (see 3rd schedule of the Act). It is obligatory on the part of the factory management to give information regarding specified accidents, which cause death or serious bodily injury and regarding occupational diseases. Provisions have also been made for safety and occupational health surveys in the factories.

## Social Security Schemes

Social Security is a wide term and it is difficult to have a standard uniform definition of the term. The international Labour organization (ILO) defines it as “the Security that society furnishes through appropriate organization against certain risk to which its members are exposed. It is social because it represents a collective effort by society. The security is provided in an organized form and therefore is not haphazard. Examples of Social security schemes in India are :

1. Employees Provident Fund Organization
2. Central Government Health Scheme (CGHS)
3. Central Maternity Benefit Act 1961
4. Workmen's Compensation Act 1923
5. Employees State insurance Act 1948
6. The Family Pension Scheme 1971
7. Various insurance Schemes of LIC, private insurers

## The Employees State Insurance Act 1948

The ESI scheme is hailed as the largest Social Security Scheme of its kind in Asia. The ESI Act 1948 was enacted to “provide for certain benefits to employees in case of sickness and employment injury and to make provision for certain other matters in relation thereto. It has undergone amendments several times. The ESI Act, at present, applies in the first instance to non - seasonal factories using power in the manufacturing process and employing 10 or more persons and non power using factories employing 20 or more persons for wages. A factory or an establishment to which this Act applies shall continue to be governed by this Act, notwithstanding that the number of persons employed there at any time falls below the limit specified by or under this Act or the manufacturing process therein ceases to be carried on with the aid of power.

The Act contains an enabling provision under which the ‘appropriate government’ is empowered to extend the provisions of the Act to other classes of establishment. Under these provisions most of the state governments have extended provisions of the Act to certain additional establishments, viz., Shops, hotels, restaurants, cinemas including preview theatres, road motor transport agencies, newspaper establishments, employing 20 or more persons; Beedi manufacturing establishments employing 10 or more persons in the implemented area; and, State pencil manufacturing establishments employing one or more persons (37).

All factories or establishment to which the Act applies are required to register themselves in the Local office of the ESI Corporation. The Act empowers the Central Government, the State Government and the Corporation to frame rules for the running of the scheme. For carrying out its functions a statutory body called the ESI Corporation has been set up with the Minister of Labour as its Chairman, It has representatives of the Central and State Governments, Employers, employees, medical professionals and members of Parliament. The Chief Executive of the Corporation is the director General ESI who is assisted by an insurance Commissioner, a Medical Commissioner, a Finance Commissioner and an Actuary. The DGESI and the Finance Commissioner are appointed by the Central government. The other executives get promoted through ESI departmental channels. The Corporation has one Regional office each, in all the States who have local offices under them in all areas covered by the Act. There is a Medical Benefit Council, which decides medical care policies, headed by the DGHS who is assisted by the Medical Commissioner. The other members of the Medical Benefit Council include Dy DGHS, State ESI medical heads, and representatives of employers, employees and medical professionals. The latter are nominated by the Indian Medical Association.

The medical care component called the Kingpin of the scheme is to provide full preventive, curative and occupational health services to its beneficiaries (38, 39, 40). Through it the Scheme provides Out - patient treatment, Domiciliary treatment, Specialist Consultation, In - patient treatment, Free supply of drugs, dressing, artificial limbs, aids and appliances, X - ray and laboratory investigations, Vaccination and preventive inoculations, Antenatal care, confinement and postnatal care, Ambulance service or conveyance charges for

going to hospitals, diagnostic centres, etc. where admissible, Family welfare services and other national health programme services, Medical certification, Special provisions including super - specialist services, and, early detection and diagnosis of occupational diseases.

Initially the medical care was provided only to workers in active employment. It has subsequently been extended to families of workers. In 1989, the Act was amended to include provision of medical care to an IP who ceases to be in insurable employment on account of permanent disablement, subject to payment of contribution, till the date on which he would have been superannuated had he not sustained such permanent disablement. It also brought under the 'medical care umbrella' retired workers and their spouses subject to payment of nominal contribution of Rs 10 only by a subsequent amendment. This Scheme is run by the State Governments under the guidance of the Corporation except in Delhi and NOIDA where it is run directly by the Corporation. The State Government bears 1/8th of the cost of medical care and the balance is met by the Corporation. For budgetary calculations the ceiling for the total cost on medical care benefit has been fixed at Rs 500 per IP annually. These benefits are provided free of cost including hospitalization in case of sickness, employment injury and maternity related causes. Medical care is provided either directly through the exclusive ESI hospitals and Dispensaries or indirectly through a panel of private medical practitioners (Panel System). All industrial Centres having large concentration of insured persons have the direct pattern of medical care, and the indirect pattern if restricted to areas having less concentration of insured persons where providing exclusive ESI services is not considered cost effective. It has its own referral chain and patients requiring super specialty treatment can be referred to the zone level ESI hospitals cum occupational Centres. In addition patients can be sent to specialized non ESI hospitals also at the expense of the ESI Corporation. Besides, the ESI Scheme provides the following major benefits :

**Sickness Benefit** : This consists of periodical cash payment to an insured person if his sickness is duly certified by an ESI/ insurance Medical Practitioner. The benefit is payable for a variable period of time depending on the type of illness and subject to the individual remaining under medical treatment provided under the Act. The insured person is protected from dismissal or discharge from service by the employer during the period of sickness.

**Maternity Benefit** : The benefit is payable in cash for an insured Woman for confinement/miscarriage or sickness arising out of pregnancy/confinement or premature birth of child or miscarriage. For confinement the duration of benefit is 12 weeks, for miscarriage 6 weeks and for sickness arising out of confinement 30 days. The benefit is allowed at about full wages.

**Disablement Benefit** : The Act provides for periodic cash payment, besides free medical treatment, in the event of a temporary or permanent disablement as a result of employment injury as well as occupational disease.

**Dependent Benefit** : In case of death, as a result of employment injury, the dependents of an insured person are eligible for periodical payments.

**Funeral Benefit** : Funeral expenses are in the nature of lump sum payment up to a maximum of Rs 1500 made to defray the expenditure on the funeral of a deceased insured person. This payment is to be made to the eldest surviving member of the family of the deceased.

**Unemployment Allowance** : This benefit has been introduced from 10 Apr 2005 & provides for an unemployment allowance to an individual for a maximum period of 6 months on account of closure of factory or establishment, retrenchment or permanent invalidity arising out of non employment injury, after being in insurable employment for five or more years.

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Keeping in view the problems likely to be encountered by workers in various industries it is essential that the Occupational health physician put in place a detailed surveillance system which would be effective and provide predictive guidelines for prevention of diseases due to occupation. These evaluations explore the physical demands and environmental hazards of a worker's position. The Occupational Medical Services health care provider reviews the individual's personal medical and

immunization history to determine whether the worker can assume/continue the duties. The staff provides work - related health and safety advice, administers appropriate vaccines, and enrolls the individual in applicable surveillance programs.

#### **Preassignment (Pre-placement)**

Some companies require pre - placement testing as a means to determine if the applicant has the capacities to accomplish the specific duties of the job, based upon the physical, environmental and psychological demands of the position. Pre - placement medical evaluations are recommended for individuals whose work involves:

- Hazardous industries
- Strenuous activity



- Animal contact
- Patient contact,
- Possible exposure to human body fluids
- Potential contact with human pathogens, or
- Work in an area that is used for clinical care.

As per factories Act, all workers should undergo a medical examination before entering industrial employment for the first time (engagement or preplacement examination) or within 15 days of employment. The focus of these exams is to avoid potential work - related accidents by detecting medical conditions early. Diagnosis made on these medical examinations should be strictly confidential. Persons suffering from unsafe traits, such as, 'accident - proneness' should not be employed near hazardous jobs.

### Periodic Medical Surveillance

Medical surveillance is a valuable tool for assuring and maintaining a healthful workplace environment. Medical surveillance is the periodic testing of employees exposed to potentially hazardous materials or other risks in the workplace. The purpose of medical surveillance is to detect early signs of work - related illness so that appropriate action can be taken to eliminate the underlying exposures. The Factories Act requires companies to conduct Periodical medical examination at regular intervals (monthly, quarterly, yearly) depending upon the hazard to which a worker is exposed. For instance, medical surveillance is required to detect illnesses caused by materials such as asbestos, lead, formaldehyde, benzene, and hazardous waste. The clinical examination should be supplemented by special investigations where indicated. Date and results of such examination should be recorded in special registers maintained for this purpose.

### Post - Illness or Injury (return - to - work)

An employee's health status may be reevaluated following prolonged absence from work due to illness or injury. This exam is conducted to ensure that an employee has sufficiently recovered from an illness or injury to perform the job without harm to himself/herself or to others. In addition medical examination of workers should be carried out on their returning from sick leave and those seeking change of employment.

### Pre Retirement / Change of Job

An employee's status requires to be evaluated prior to his retirement or change of job so that it can be assessed as to whether he has suffered from disability/ disease due to the job. This is also beneficial to the employer as the employee cannot make subsequent claims.

### Components of Tests

Physical testing is composed of several distinct tests. Exam components may vary based upon the protocols required by

your company. In general, an occupational health test may include:

- Physical exam
- Vision
- Audiometry Tests
- Pulmonary Function (PFT)
- ECG
- Blood tests
- Chest X - ray

**(a) Physical Exam** : The physical exam is conducted by an occupational health physician, and is designed to provide an assessment of health as it relates to the specific occupation. The evaluation usually consists of a thorough physical exam: review of systems (head/neck, heart/lungs, gastrointestinal, genitourinary, skin and soft tissue, musculoskeletal, neurological). A physician will usually inquire further on any positive responses in the medical history questionnaire to help determine physical ability to work.

**(b) Vision Screening** : This test screens for visual acuity (both near and far visual fields, depth perception) or colour (if required on job). A glaucoma screen may also be performed under certain circumstances.

**(c) Audiometric Tests** : This testing is part designed to protect workers with significant occupational noise exposure from suffering material hearing impairment.

**(d) Pulmonary Function Test** : Pulmonary function testing (PFT), or lung function testing, is carried out in workers working in industries which are likely to have adverse affects in pulmonary function.

**(e) ECG**

**(f) Blood Tests** : as considered essential by the physician.

**(g) Chest X-Ray** : A chest X-ray is usually done for the evaluation of lungs, heart and surrounding anatomy.

### Report

The physician must send his report to the third party/employer who requested the assessment. He may discharge the mandate entrusted to him by giving his opinion in the report. This opinion may take any of the following forms:

- Unconditional acceptance of the applicant;
- Acceptance despite the presence of limitations not entirely incompatible with the job, accompanied by a description of these limitations;
- Acceptance conditional upon accommodations made to the job because of incompatible limitations;
- Refusal because of impairments resulting in total incompatibility.



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### **Burden of Occupational Disease and Injuries**

There are 100 million occupational injuries causing 0.1 million deaths in the world according to WHO. It is also estimated that in India, 17 million occupational non-fatal injuries (17% of the world) and 45,000 fatal injuries (45% of the total deaths due to occupational injuries in the world) occur each year. Out of 11 million cases of occupational diseases in the world 1.9 million cases (17%) are contributed by India and out of 0.7 million deaths in the world 0.12 (17%) is contributed by India. National Institute of Occupational Safety & Health (NIOSH) has developed a priority list of 10 leading work-related illnesses and injuries. Three criteria were used to develop the list: (a) The frequency of occurrence of the illness or injury (b) Its severity in individual cases and (c) Its potential for prevention. Occupational lung disease is first on the list. Silicosis, asbestosis and byssinosis are still prevalent in many parts of the world. The prevalence of Occupational Asthma varies from 10% to nearly all of the workers in certain high-risk occupations. NIOSH considers occupational cancer to be the second leading work-related disease, followed by cardio-vascular diseases; disorder of reproduction, neurotoxicity, noise induced hearing loss, dermatological conditions, and psychological disorders.

### **Global Strategy for Occupational Health**

The first WHO programme on occupational health was designed in 1950, just two years after the Organization was established. WHO joined with ILO to form the Joint ILO/WHO Committee on Industrial Hygiene. In the 1960s and most of the 1970s, the WHO occupational health strategy focused on the scientific and technical aspects of occupational health services, including the early diagnosis of occupational diseases, and training and education in occupational health. A new strategy for the further development of occupational health services was adopted in 1979, with the World Health Assembly Resolution WHA32.14 on the proposed comprehensive workers' health programme, stressing the need to organize primary health care services "as close as possible to where people live and work". To mitigate the adverse health impact of work-related risk factors, the WHO Programme on Occupational Health set up a new agenda in the 1990s with the adoption of a new resolution in 1996 (WHA 49.12) which led to the development of the WHO Global Strategy for Occupational Health for All.

The global strategy for achieving occupational health for all (WHO-SEARO 1999) includes the following ten major areas for action (41):

1. Strengthening of international and national policies for health at work and developing the necessary policy tools.
2. Development of healthy work environment.
3. Development of healthy work practices and promotion of health at work.
4. Strengthening of occupational health services (OHS).
5. Establishment of support services for occupational health.
6. Development of occupational health standards based on scientific risk assessment.
7. Development of human resources for occupational health.
8. Establishment of registration and data systems, development of information services for experts, effective transmission of data and raising of public awareness through public information.
9. Strengthening of research.
10. Development of collaboration in occupational health and with other activities and services.

### **National Programme**

Occupational health was one of the components of the National Health Policy 1983 and now also included in National Health Policy 2002, but very little attention has been paid to mitigate the effect of occupational disease through proper programme. Ministry of Health & Family Welfare, Govt. of India has launched a scheme entitled "National Programme for Control & Treatment of Occupational Diseases" in 1998-99. The National Institute of Occupational Health, Ahmedabad (ICMR) has been identified as the nodal agency for the same (42).

Following research projects has been proposed to be initiated by the Government :

1. Prevention, control and treatment of silicosis and silico-tuberculosis in Agate Industry.
2. Occupational health problems of tobacco harvesters and their prevention.
3. Hazardous process and chemicals, database generation, documentation, and information dissemination.
4. Capacity building to promote research, education, training at National Institute of Occupational Disease.
5. Health Risk Assessment and development of intervention programme in cottage industries with high risk of silicosis.
6. Prevention and control of Occupational Health Hazards among salt workers in the remote desert areas of Gujarat and Western Rajasthan.

## Study Exercises (For Section 11)

### MCQs

- Father of occupational medicine is (a) Bernardino Ramazzini (b) Karl Marx (c) Donald Hunter (d) John Simon
- First Industrial Health nurse (a) Philippa Howerday (b) Mother Teresa (c) None of the above
- Which of the following is not an agricultural hazard (a) Musculoskeletal disorders (b) Bagassosis (c) Byssinosis (d) Silicosis
- Which is not true of occupational cancer (a) History of exposure to carcinogen is present (b) Danger of getting cancer even after exposure has ceased (c) Location and histological pattern are quite common in most occupations (d) Short latent period
- Exposure to vinyl chloride leads to (a) Angiosarcoma of the liver (b) Laryngeal tumour (c) Nasal cancer (d) None of the above
- Aromatic amines lead to carcinoma of (a) Bladder (b) Lung (c) Nasal Septum (d) All of above
- By ILO definition, Pneumoconiosis is \_\_\_\_\_ (a) accumulation of dust in the lung (b) Tissue reaction to its presence. (c) a & b (d) Any damage to lung
- Which is not true of silicosis (a) Clinical manifestations are shortness of breath (b) The dust must contain silica in a free state as quartz ( $\text{SiO}_2$ ) and the particles must be of respirable size. (c) No X ray changes (d) Wet processes carry less risk or none at all but dry processes are definitely dangerous
- "Asbestos bodies" are seen in (a) Sputum (b) X-ray (c) Clinical examination (d) None of the above
- Ground glass appearance on X ray is seen in (a) Asbestosis (b) Silicosis (c) Anthracosis (d) Berylliosis
- Caplan's syndrome is seen in (a) Asbestosis (b) Silicosis (c) Anthracosis (d) Berylliosis
- Byssinosis is caused by exposure to (a) Cotton dust (b) Sugarcane dust (c) Tobacco (d) All of above
- Level I safety audit is done (a) Once in a month (b) Once in two months (c) Once in three months (d) Fortnightly
- Asbestosis causes all except (a) Mesothelioma (b) Calcified pleural plaque (c) Pneumoconiosis (d) Farmer's lung
- Farmer's lung results from exposure to :- (a) Sugarcane dust (b) Cotton fibre dust (c) Grain dust (d) Tobacco
- Micropolyspora faeni* is the main cause for (a) Byssinosis (b) Bagassosis (c) Anthracosis (d) Farmer's lung
- Lead is the most used metal commonly in the industries because of : (a) Low boiling point (b) Anticorrosive (c) Least toxic (d) Easily mixes with other metals
- Acceptable blood lead levels are: (a) 25  $\mu\text{g}/100\text{ml}$  (b) 50  $\mu\text{g}/100\text{ml}$  (c) 75  $\mu\text{g}/100\text{ml}$  (d) 100  $\mu\text{g}/100\text{ml}$
- Lead poisoning in industries commonly occurs by: (a) Inhalation (b) Ingestion (c) Skin absorption (d) Conjunctival route
- Size of respirable dust is below (a) 0.1 micron (b) 1 micron (c) 5 micron (d) 10 micron
- Toxic effects of inorganic lead exposure include all except: (a) Abdominal colic (b) Blue line on gums (c) Wrist drop (d) Mental confusion (e) Stippling of RBC
- Safer Alternatives for benzene are (a) Toluene (b) Xylene (c) Trichloroethylene (d) Cyclohexane (e) All the above
- Smell of 'Bitter Almonds' in the breath is seen in poisoning of (a) Hydrogen cyanide (b) Nitrous Fumes (c) Carbon – Monoxide (d) Trichloroethylene (Trilene)
- Which one of the following is not the direct effect of heat exposure in an industry : (a) Heat exhaustion (b) Heat stroke (c) Erythrocytosis (d) Burns
- Canteen for workers as a welfare measure under Factories Act is a must when the strength of the workers is more than (a) 200 (b) 100 (c) 250 (d) 500
- Which of the following statement is Not true for ESI (a) Funeral benefit up to a maximum of Rs 2500 (b) In result of employment injury, the dependents of an insured person are eligible for periodical payments (c) Disablement benefit @ 80% of wages (d) Maternity benefit for 12 weeks for confinement.
- Which of the following is not a benefit to the employer in ESIC (a) No responsibility for the employee's health (b) Exemption from applicability of Workmen's Compensation Act 1923 (c) Healthy work force (d) Rebate under Income tax act
- All of the following are notified under Factories act except (a) Asbestos (b) Nickel (c) Coal tar (d) Silica
- Which of the following disease may be encountered as occupational hazard (a) Leptospirosis (b) Brucellosis (c) Anthrax (d) All of the above
- All the following are pneumoconiosis except : (a) Siderosis (b) Bagoasosis (c) Farmers's lung (d) Psittacosis
- Pneumoconiosis is caused by all except (a) Coal dust (b) Silica (c) Chromium (d) Asbestos
- The ESI Act came into being in : (a) 1948 (b) 1952 (c) 1962 (d) 1975
- ESI corporation works under:- (a) Ministry of Labour (b) Ministry of Health (c) As autonomous body (d) Respective state government.

**Answers :** (1) a; (2) a; (3) d; (4) d; (5) a; (6) a; (7) c; (8) c; (9) a; (10) a; (11) c; (12) a; (13) c; (14) d; (15) c; (16) d; (17) b; (18) c; (19) a; (20) c; (21) d; (22) e; (23) a; (24) a; (25) c; (26) b; (27) a; (28) b; (29) d; (30) d; (31) c; (32) c; (33) c.

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Keywords	Reference
Accident - Industrial	31, 389, 1271, 1279
Accident and Emergency Services	400
Accommodation	392, 393, 569, 697
Accounting	326
Accreditation	424, 425
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Acute Viral Gastroenteritis	1121, 1124
<i>Aedes</i>	520, 909, 932
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Affective (Mood) Disorders	1232
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Alcohol Control	1185, 1230
Amoebiasis	186, 1148
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# Text Book of Public Health and Community Medicine

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